" A Critical Overview of the Global Arthroplasty Practices from Patient's Point-of-View".

A thesis submitted towards partial fulfilment of requirements for the award of degree of

MASTER OF ENGINEERING

in

BIOMEDICAL ENGINEERING

Submitted by

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ACKNOWLEDGEMENT

I would like to take this opportunity to express my sincere appreciation and indebtedness to persons whose help, support, and wishes have been a source of inspiration and strength during this entire thesis work.

No words are sufficient to describe, the sense of gratitude and sincerest regards to my Thesis Supervisor, Guide and Advisor, Prof. (Dr.) Abhijit Chanda, for everything that he has helped me with, throughout my course in this esteemed university, and especially during the period of my thesis work.

For every chance I was bestowed with, the trust and faith my guide has rewarded me with during the development of this work, and to always encourage me to extract the best results out of those chances and scopes, would definitely require no less than an entire lifetime of gratitude, to express how deeply am I indebted for it.

During the darkest of days and in the glory of the completion of this work, Prof. (Dr.). Abhijit Chanda, was always the glaring North Star, that always supported and help me reach this destination, cruising all the waves of turbulence, throughout this journey of mine.

I would also take this opportunity to express my sincerest regards and gratitude to Prof. (Dr.) Piyali Basak, Director, School of Bio-Science and Engineering, Jadavpur University, for not just enlightening my ever-inquisitive mind with the valuable teachings and lessons, but also for the undiluted and resolving guidance, she has guided me with through out my journey, and showing me the beacon of light, to pursue fresh and higher heights of excellence.

I would also like to thank Dr. Niloy Das & Dr. Anamika Basu for their valuable guidance and teachings on human anatomy, that was critically crucial to the formulation of this work. Their collective wisdom and encouragement have been instrumental in the successful completion of this research work.

I would like to express my gratitude to my Seniors in the department, Mr. Pratik Das and Mr. Tathagata Adhikary from Biomaterials and Cell Culture Laboratory, Ms. Sagun Murmu from Biomechanics Laboratory, School of Bio-science and Engineering, Jadavpur University for their general help and support at various points of this journey.

I would also express my sincerest thankfulness for the valuable guidance and knowledge, my B.Tech professors, Prof.(Dr.) Sandip Bag and Prof. (Dr.) Karabi Ganguly for instilling the basic foundations of biomedical principles in me, that formulated as the pillars of my engineering skills and knowledge, that I tried to utilize to the best of my capabilities for the development of this thesis work.

Last but certainly not the least, I am always and ever be indebted to my constant support system – my family and my parents, who sacrificed their glory of day, to make my evenings brighter, and for all the appreciations and wishes they have bestowed me with in the days of my successes and for all the support they have given me during the darkest of hours, and never allowed to lose hope and determination to fulfil my dreams and targets, which was always their one and only aspiration.

Last but not the least, I my deepest regards to all the Divine powers in this world, for providing me and helping me with the strength to carry out this work and to be worthy of all the faith and trust I'm bestowed with.

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MODULE – I

"Introduction."

INTRODUCTION

- Hip and Knee are two most vital joints of the human anatomy as far as locomotive, weight bearing and ability to perform physically demanding tasks are concerned. However, these are the two joint modules that often become the victim of a disease, often arising out of a repeated loading action on these joint modules of human skeletal structure, i.e., osteoarthritis.

- However, there may be other inherent or underlying acquired reasons for osteoarthritic damage of the hip and knee joints, these joints are the commonly artificially replaced joint in the human anatomy, unless there's an incidence of a major accident or injury, that damages other important joint structures of the human anatomy.

- The most widely practiced method of resolving the afore-mentioned conditions is through a hip or knee arthroplasty of the diseased and troubled hip/knee joint.

- From a biomedical engineer's point-of-view, there are several aspects that is relevant to be discussed from a biomedical rationale, which are – biomaterial usage scenario for the artificial hip and knee prostheses that implanted, the general biomechanics involved behind the designing, selection and final patient requirement specific implementation, the implant designing and innovation in the bearing surfaces that improve or limit the patient's post-op mobility, and finally the intricate policies of medical device usage and regulation, that encircles around the scenario of a hip/knee arthroplasty procedure.

- Therefore, this thesis work is essentially an amalgamized application of many biomedical principles that are crucial to manifest in the best way plausible, in order to qualify this round of academic pursuit.

- This research therefore collected, evaluated, cross-verified and inferred the general global arthroplasty practices, concerning hip and knee joints, and it's related outcome scenarios in connection with the quality and margin of improvement assessed multi-parametrically of the patient's respective health standard, functional capabilities and the overall QoL, post-operatively.

- Various arthroplasty related approaches that are potentially empowered to influence the end-results and the short-term vis-à-vis long-term outcome scenarios, whether good or bad, are assessed as per patient reported outcome measures or PROMs, a globally acknowledged tool to capture qualitative and quantitative responses of the recipient patient to adjudge the general margin of improvement or degradation in the post-operative period.

- The prevailing revision rate scenarios, their respective causes and the overall leading cause, and the global practice of answering a failing hip/knee replacement, is a critically important parameter in this entire work, since to undergo a revision surgery, is what this research infers as the worst plausible scenario, he/she can attain, in connection to a hip/knee arthroplasty.

- Lastly, various governmental regulatory body, implant manufacturer/supplier firm and arthroplasty monitoring bodies respective responses to an undesirous implant failure scenario, compared vis-à-vis respective nations and how their patient cohorts respond to them is also critically important to consider, before finally commend the efforts of all the involving stakeholders to make hip and knee arthroplasty a truly benevolent intervention, to alleviate the quality of lives of the patients in dire need of them.

MODULE – II

"Literature Review."

Literature Review

- With the arrival of the 21st century, orthopedic surgeries of various kinds, have made their all-glorious place in the modern healthcare setup, with arthroplasty being the majorly dominated procedure, among all of the orthopedic procedures combined.

- Various reasons have been widely attributed to the steady rise in global arthroplasty numbers, a major of them being due to osteoarthritis, as sedentary lifestyles and other lifestyle changes have touched the modern-day population.

- Beyond osteoarthritis, arthroplasties have seen preferences from both clinicians and patients, for sports injuries, fall accidents, and other critical issues that have disturbed the skeleton-muscular harmony of the patient. This preference and wide usage, have grown from a steady state to an exponential panacea state of number in some regions of the world, which have seen both positive and negative effects on the patients receiving the treatment and also on the clinician & manufacturing societies at their own individual point of views, quite intricately.

- On the positive aspect, arthroplasty has majorly contributed towards restoring patient mobility and functional activity of the joint or bone in concern, through a quick or calculated recovery window, and relieving the patients of significant physical agony and pain, enabling them to return back to their intended lives, shredding off their degeneracy or ailments.

- However, at the same time, this approach to treating patients with osteoarthritis has often met with results, wherein the patients complained of a poorer quality of life or even further impaired mobility, which is totally against the primary purpose of arthroplasty.

- While, on the manufacturing aspects and clinical societies at large, have faced challenges in tackling situations in dealing with unforeseen situations with regards to arthroplasties gone wrong, implants failure, as was in the historic "*Capital Hip*"(by 3M) hazard in the UK from the 1990s to the early 2000s, wherein after repeated analysis and investigations, had all opined in almost a clear unanimously for the creation and maintenance of national arthroplasty databases, to gain a better position, should there be another such implant failure catastrophe, for a more efficient action.

- Such national arthroplasty databases, which later came to be known as 'registries', would contain all the possible relevant information regarding the implants used, surgical approach adopted, and all other patient case files, updated and filed mandatorily in coherence with clinical societies, clinical institutes, clinicians and at the same the patients also contributing to the database, through a standardized questionnaire and enclosure-based filing policy.

- The presence of such a comprehensive undiluted data bank, with a large pool of actual data, would prove to be highly essential for the biomedical research community and to the regulatory authorities, to predict and raise any red-flag scenarios, along with the cross-analyses of all the plausible reasons any particular implant or any newly introduced component of an implant has failed or have exhibited detrimental effects, could be detected early, and solved with very little to no margin for error.

- Through the use of a solid database registry, that could enable investigators from manufacturing to clinical to researcher aspect, get access to an uncorrupted data, and develop from a level field, the possible reasons, for an implant failure, in order to eradicate such occurrences in future for the benefit of mankind.

- Implant failures have been consistent and newer products continued to be getting recalled by manufacturing companies and even embroiled in lawsuits across the globe for endangering patient health, as in the ASR(Articular Surface Replacement XL / Hip Resurfacing Systems by DePuy – subsidiary of Johnson & Johnson) series failures and recalls of the 2010s from US & Australian markets primely, for adverse wear rates and poor survivability rates, causing spikes in revision rates, have made the relevance of arthroplasty registries more important than ever as on date, wherein several hundreds of implants from various manufacturers are getting implanted daily, all across the globe.

- The presence of such registries and the conduction of relevant research through the data availed through these platforms, therefore, acts as a watchdog to monitor the performance of the arthroplasty and the implants in use, and their combined short-to-long term outcome. Publications of such research have red-flagged the performance of another such implant thereby causing the manufacturer (Exactech) to recall their "*Connexion GXL*" product series comprising hip replacement components from worldwide markets, as recent as July 2021.

- These nationwide registries/registers, maintained by orthopaedic associations & govt bodies, are an online database, which encompasses the maximum possible pre-op/post-op data, regarding all the presenting happening and previously occurred joint arthroplasties, in the respective country.

- These data also contain crucial stats and figures, regarding the various implants/prostheses that are being widely utilized across the country, and the ones that are most preferred by clinicians/patients, the number of procedures, possible reasons for being favoured, revision rates in them, post-op recovery times, offset values, survival rates, etc.

- Based on these datasets, various statistical analysis is available on these registries themselves wherein, any particular surgeon may find how their respective patients are performing compared to the national benchmark, in terms of crucial parameters like revision rates and survivability. This information is widely regarded as one of the most authentic benchmark data libraries for research and publication on this particular domain, and therefore, it has been widely used for analysis/investigations and cited across publications of reputed journals from across the globe.

- Critical analysis has been widely done, as observed through intensive literature review across reputed journals, wherein the surgical approaches in arthroplasties to modular vs monobloc implant comparisons have been done, on a country-to-country basis or implant-to-implant basis, taking into account arthroplasty numbers and other intricate details/numbers from registries.

- A wide variety of the prevailing arthroplasty databases, such as the "*NARA*" (Nordic Arthroplasty Register), "*NJR*" (National Joint Registry of UK & Wales), "*AJRR*" (American Joint Replacement Registry), "*FIA*" (Finnish Arthroplasty Register), "*SAR*" & "*SHAR-SKAR*" (Swedish Arthroplasty Register – Swedish Hip Arthroplasty Registry & Swedish Knee Arthroplasty Register), "*RIAP*" (Italian Arthroplasty Registry), "*EPRD*" (Das Endoprothesenregister Deutschland/German Arthroplasty Registry), "*AAONJRR*" (Australian Orthopaedic Association National Joint Replacement Registry), to name a few, were factored in for the mainframe analyses of this research work.

- Very recently India joined the club, through its "*Indian Joint Registry*" or "*IJR*", modelled after the '*NJR*' of the UK, maintained by the '*Indian Society of Hip and Knee Surgeons (ISHKS)*'. Launched in 2019, but is said to have data since 2006. However, ever since its launch, very little publication has been observed across reputed journals that had used "*IJR*" data, as detailed as the other registries have used.

- Various attempts were made to access Indian hip and knee arthroplasty related data from the "*IJR*" sources, with no fruitful results.

- Several other important nations such as Japan, Brazil, China were tried for their respective arthroplasty data performed on their populace of patient cohort, linguistic translational issues further limited the horizons to include them into the research procedure.

- Apart from the arthroplasty databases, relevant information from various health regulatory authorities, their respective information portals, company and healthcare organization document archives for historical legacy data pertaining to implant performance and material usage properties, were also availed, in scenarios wherein usual registry couldn't provide intel on the same.

- These sources often helped to cross-verify the claims made by the scientific publications, company brochures, registry data, and to obtain the behind the scene rational behind those claims that were found to be of "gimmick" nature, and also of those which were profoundly true.

- This can be further explained through the case of dual mobility hip prostheses for which the British registry commented to have a "separate demography" of patients with 'unique' demands, which upon further excavation across relevant scientific publication is revealed, that not just patients aging 60 or more, with a progressively worsening osteoarthritic hip or knee, are lining up to receive a arthroplasty based solution to their problem, but also a comparative younger group of patient cohort, mostly aging less than 50 years, to a maximum of 55, with a particular need for a hyper-mobile bearing surface to compliment for their specific livelihood and personal need based requirements.

- These ranged from a livelihood specific requirement to perform physically demanding jobs, as in for labours and industrial workers, to those who by profession are dancers or other performing artists.

- While personal need-based requirements involved ability to freely involve and enhance intimate sexual performance, which was otherwise severely limited or partially/totally impaired due to an underlying condition of pre-mature osteoarthritis or a hip dysplasia, or a complicate avascular necrosis (AVN) of the femur/hip.

- Therefore, considering the wide spectrum of the patient cohort who are either in-line or already have their respective hip or knee, or both replaced, a holistic and thoroughly comprehensive understanding of the globally prevalent approach differentials is necessary to obtain a clear picture about how clinical practice is able to answer the patient requirements, and how they themselves feel about their undergone procedure, in co-relation with the implant design and regulatory practices, thereby fulfilling & justifying the title of this work, "*A Critical Overview of the Global Arthroplasty Practices and Outcome Scenarios from a Patient's Point-of-View*".

MODULE – III

"Present Scope of the Work."

Present Scope of the Work

The present scope of work regarding the topic of this thesis, based on the primary thorough analyses of the relevant literature and prevailing global arthroplasty practices, the following scope of work is identified, as is presented as below: -

- Precise comparative analysis of the arthroplasty performance of implants presently marketed in the major healthcare system nations, with a first world repute for the general scale of clinical and biomedical infrastructure or have been implanted in the recent past, with respect to its performance in its entire cohort of patients from Europe or the US, or in general the global performance.

- Few publications in reputed journals have highlighted and flagged the need for such a critical analysis of the implant-based performance study which assesses vital parameters like revision rates, short-term vis-à-vis long-term survivability, infection rates, and most importantly to what degree the said implants have alleviated patient lifestyle or relieving pain, or has it deteriorated to their pre-op standards, assessed from a patient's point of view.

- Critical analysis of implants most widely used in the selected Nation's respective healthcare organizations, and the possible reasons for it being so.

- Critical analysis of implants and arthroplasty practices / approach modalities of the declining utilization proportions across the global patient cohort, whether those implants are least preferred in a similar way in other global markets, and all possible outcomes, and other related cross-analyses, with the exploration of the plausible contributing factors behind the decline of a particular implant or an arthroplasty practice / approach modality as a whole.

- Development of a Comparative Analysis Report of the globally prevailing surgical approaches adopted for hip and knee arthroplasties of the general patient cohort, compared with practices around the globe, and further examining whether the surgical approach or technique adopted by surgeons, affects the success/failure of any implant on patients, on a short-term vis-à-vis long-term aspect.

- Role of conservative treatment methods in alleviating patient conditions, avoiding arthroplasty assessment through national statistical figures, and whether the conservative modes of treatment in both pre-op or post-op conditions, aid / augment the implant adaptation or immunoselection activities.

- Critical analysis with regards to the industry standards vis-à-vis governmental/regulatory body benchmark or regulation standards, conformation study of widely used implants and arthroplasty tools, whether region-specific changes or a common global standard is the general practice for implants in India.

- Implant failure response analysis in India, and possibly flagging any general concern in this regard, taking into account the perspectives of clinicians, manufacturing bodies/companies, regulatory agencies, and patient consensus.

- Assessment of the information or awareness levels in Indian patients, or the support consensus, they get in case of any failure scenario, and what are the prime requirements of Indian patients from arthroplasty procedures.

- Critical analysis of the extent of a patient secured in terms of risks exposure of India to other major nations/ arthroplasty markets.

- Development of a holistic and comprehensive picture of the Patient Reported Outcome Measures or PROMs scenarios, from the global arthroplasty recipient patient cohort, highlighting the general margin of difference brought to their respective lives, through the surgical replacement of their failing hip and knees.

- The margin of pre-operative vis-à-vis post-operative improvement in the functional capabilities, QoL and general relief from pain / instability.

- Identification of the major loopholes in the globally prevailing arthroplasty domain, and development of a possible way-out to resolve the major shortcomings and challenges, evaluated from a biomedical engineer's perspective to empower the general patient class, as a tangible outcome part of this work.

MODULE – IV

"Objectives and Key Questions of the Work."

Objectives and Key Questions of the Work.

***Objectives*: -**

- To study the prevailing differential approaches towards assessing the need for arthroplasty in various continents.
- To find out the predominant post-operative measures, including PROMs adopted to assess the success rate of THA, TKA, etc.
- To develop a comprehensive understanding of the standards and protocols (related to component design, its life expectancy, etc, or related to the quality of arthroplasty).
- To identify the present and prospective trends in arthroplasty-related health care.

Key Questions to be Examined: -

- What / Which is/are the most popularly used implant for primary THA, primary TKA, and primary UKA? What are the critical contributing factors beyond this popularity? What is the general patient-reported outcome for the particular implant? Does the same reciprocate to that of most popular implant devices of the UK, US, and AUS? Is the implant most popular in India, for the above-mentioned arthroplasty procedures, displaying similar functional, patient-reported, and general outcome/performance in the UK, US, and AUS?
- What is the general revision rate for THA, TKA, and UKA in Sweden/India vis-à-vis UK-US-AUS? Comparative analysis at both short- and long-term aspects.
- Analysis of the contributing factors and patient demographics to identify whether the rate has anything to do with the patient demographical parameters like anatomy, lifestyle, prime requirements post-op, BMI, etc.
- What are the success rates in terms of survivability, and patient satisfaction if non-similar implants/implant types are the most popular implant choices across India, the US, the UK, and AUS? Technical analysis between them from manufacturing to regulatory to implantation technique variance to assess if there's any variance present at all, as in does the most popular hip of UK is sold and implanted in the same way in India, or is subjected to similar standards like that of UK or contrary. Do implant manufacturers consider beyond design and packing specs, incorporating region-specific customizations to their products for better adaptation or survivability? <-- parameters like femoral offset, unique patient needs (squatting, etc.)
- Historically it has been observed and clinically reported that women over 45, are the most plagued group of patients who were either in line to receive a primary THA/TKA, or already with an implant. What are the global scenarios for the younger population beyond "45+ Women", since the younger population is receiving TKA, and THA in India at almost an equal rate to the 45+ Women bracket, if not more? What could be the major contributing factors to this situation?

- Considering the rise of the younger population receiving TKAs and THAs, has modular surgical approaches in arthroplasty aided patient recovery, performance, and survivability as the companies 'marketed' or clinicians 'promised'? Comparison of modern techniques such as MIS – Endoscopic to Robotic to Traditional open in India vis-à-vis UK, US, AUS.

- Considering the young patient population in mind, and with digital marketing by major implant companies, the respective patient group is reported to have a hype over dual mobility hip implants, which could possibly answer their hyperactive lifestyle requirements, 'better' than the conventional CoP implants. However, some clinicians hold the contrary view and refuse to go with dual mobility implants for these groups of patients, citing the lack of proper long-term peer-reviewed studies and technical attributes such as increased wear, due to increased movement of the implant components, and some clinicians feel dual mobility could be the last resort for patients undergoing multiple revisions.

- Analysis and verification of both the claims through reputed and trustworthy sources such as registry data (UK-US-AUS-SWE), government databases, insurance databases, and surgeon inputs, exploring possible issues that have arisen or at the chance of arising should this be applied for a large patient group.

- MoM implants are condemned worldwide for their increased wear rates, contrary to how they were initially marketed by the respective companies, causing arthroprosthetic cobaltism and metallosis in patients triggering other health issues, besides the deterioration of the implant site and neighboring tissue/muscles.

- What is the present status of post-op complexities / THA-TKA gone wrong in India vis-à-vis UK-US-AUS? Does MoM implant get implanted in large numbers at present-day despite regulatory sanctions/condemnations? If yes, what are the possible attributive factors for this to happen? If no, what are the patient and clinical POVs for the shift from MoM to MoP or CoP, as in primary or revision THA-TKAs?

- Do government-based insurance services recommend or approve such implants, in respective nations, wherein such implants have shown or are reported with detrimental effects? Does the use of cement for implant fixation, a prime driving force for future health complications as in thromboembolism/cardiac complications, etc., or is metallosis the culprit, or are both jointly responsible?

- The Indian population has an unique requirement from their THA or TKA, to be able to perform certain activities such as squatting, lifting weights, sitting cross-legged on the floors, etc. What percent of the patient group are able to perform these activities after their THA/TKA? What are their general opinion scores (0-100) about their procedure shortly after their implantation? What does the negatively opined patient group think could've gone wrong about their arthroplasty that doesn't fulfill their expectations? Do implant companies advertise or admit to having withstanding capabilities for such unique requirements or do they make any further optimizations to accommodate such capabilities? If it does, then what are the Indian Medical Device/Implants regulation says about such optimizations? Does the surgical approach technique have any influence to attain such criteria? If the surgical approach does influence the outcomes and overall results, then, does the retention of the cruciate ligaments during UKA beneficial in the Indian context? Does patelloplasty help for better patient mobility and less failure than the patellar resurfacing method?

- Comparing the unique demographical requirement from THA & TKA parameter, with that of the patient groups from UK-US-AUS, if any significant number of patients in those nations express to have certain capabilities, following their THA or TKA, and cross-verifying those results with other parameters we use for the Indian context.

- Analysis of implant certifying, licensing, and regulatory policies in India, and their on-ground practical effectiveness. Do implant manufacturers develop any product solely for the Indian market / launches their product for first use in India? If yes, do they opt for a "similar equivalence" route for implant certification, as in the USFDA, or are clinical trials mandatory?

- Are manufacturer-specified warranty policies/documents offered to the patients or intimated to the patients/patient families across Indian healthcare organizations? If it is done, what percent of those are being utilized by the Indian patient population for THA-TKA, vis-à-vis patient populations from the UK, US, and AUS?

- What are the most critical and important outcomes, that a patient feels a mandatory outcome for them, out of their arthroplasty procedure? Pain Relief, Faster Recovery, Less Risk Now-More Risk Later/More Risk Now-Low to No Risk Later, Economic considerations, ROM, anything else?

MODULE – V

"Methodology Adopted."

Methodology Adopted

Methodology Adopted / Plan of Work: -

- Selection of the Major nations from across the globe with a healthcare system and related infrastructure of general repute.
- Based on the same, the nations of United States of America, United Kingdom, Australia, Sweden, Germany, Singapore, India, Ireland, Italy, Switzerland, Norway, Brazil, Japan and China are selected.
- Relevant investigational search for the national arthroplasty databank from these countries are performed, and primary scrutinization of the same is done.
- China, Japan, Brazil and Italy are de-selected from the mainframe procedure of evaluating for the prevalent arthroplasty practice, due to linguistic and translational incapacities.
- Singapore is dropped due to non-existence of a nation-wide arthroplasty database. While, India and Ireland are partially kept in the procedure, due to both them being a starter in the global practice of maintaining an arthroplasty registry database, and implant usage record bank, both around the same time of 2016 – 2019. Considering their new and late entry, whatever portion of data that could be obtained from them, are evaluated and appropriately discussed within this report, without any special chapter dedicated for them.
- USA, UK, Sweden and Australian hip and knee arthroplasty practices and patient related outcome scenarios are the prime nations which are thoroughly evaluated and cross-examined against each other, and the obtained results with related discussions are presented in their respective chapters.
- Switzerland, Germany, Italy and Norway are excluded due to various other limitations, including most data being non-relevant to the purview of this work and incomplete otherwise.
- A Comparative Analyses report, based on the observed and noted practices and patient reported outcome scenarios is developed and annexed as the terminal end of the results/discussion module of this thesis work, wherein a detailed comparative discussion on various parameters that were evaluated for each of these nations is presented, along with other relevant facts, figures and tabulations.
- Comparative analysis and study of the survival rates of implants implanted in India, assessing the plausible failing or increasing – reasons – comparison – thereby extrapolating the success rate of THR, TKR, etc in the short vs long term and the patient vis-à-vis regulatory authority responses to the prevailing conditions.
- To flag any possible scenarios that might be beneficial/detrimental to any of patient communities from the nations discussed in great detail, or in global concern, those in receipt or in line to receive an arthroplasty-based resolution to their failing hip and knees.

- To assess the extent of the role played by the Indian patients in opining about the implant they are in line to receive, the factors they consider while making the decision in this regard, and finally, whether the opinions of Indian patients wherever applicable does gets counted or it is purely to the discretion of institutes or surgeons.

- Comparative analysis of patient and clinical interests with regards to arthroplasties in India vis-à-vis other major arthroplasty market nations as in US / EU.

- To identify and possibly flag the underlying or evolving challenges/risks that may turn up, with respect to the general arthroplasty practices of Indian surgeons vis-à-vis US/EU surgeons, from a wide scale data retrieved from registries, clinicians, and PROMs, in terms of patient health.

- A general assessment of the regulatory framework of the benchmarks and medical device/implant standards put in place by respective nations across the globe, compared to that of India, and the general compliance levels of the implants/medical devices in use to those regulatory standards or guidelines.

- Governmental healthcare regulatory authority sources such as the – NHS of United Kingdom, TGA of Australia, US FDA of the United States are also utilized to obtain crucial archived data on the legacy implants, and on those 'unpleasant' cases that are inferred to be 'suppressed' otherwise by the registry or manufacturing authority.

- Investigative Journalism based platforms such as the "ICIJ" – International Consortium of Investigational Journalism, were accessed to obtain various whistleblower accounts and archives of data, for the general understanding of the prevalent practices, all of which have been severely crucial to this research to comprehend a lot of scenarios, which not necessarily all are included within this thesis work, to avoid unnecessary complications.

MODULE – VI

"Results and Discussions."

Results and Discussions

Since the primary course of this research work involves the evaluation and scrutinization of the prevailing healthcare practices across four major nations of the United States of America, the United Kingdom, Australia and Sweden, the relevant results and discussions pertaining to these countries are therefore placed in separate chapters of this module in the following order: -

Chapter 1 = Australian Hip and Knee Arthroplasty Practices and Patient Related Outcome Scenarios.

Chapter 2 = United States of American Hip Arthroplasty Practices and Patient Related Outcome Scenarios.

Chapter 3 = United Kingdom Hip and Knee Arthroplasty Practices and Patient Related Outcome Scenarios.

Chapter 4 = Swedish Hip and Knee Arthroplasty Practices and Patient Related Outcome Scenarios.

Chapter 5 = Comparative Study Report on the Global Hip and Knee Arthroplasty Practices and Related Outcome Scenarios.

US based Knee Arthroplasty practices and Irish practices despite in the main frame analyses procedure of this work, are not placed within a separate chapter, are discussed appropriately in the "Comparative Study Report on the Global Hip and Knee Arthroplasty Practices and Related Outcome Scenarios" chapter of this module.

The above discussed chapters are therefore presented in the following pages of this thesis work/.

MODULE – VI

"Results & Discussion"

CHAPTER – 1

Australian Hip and Knee Arthroplasty Practices and Patient Related Outcome Scenarios.

Australian Hip & Knee Arthroplasty Practices & Related Outcome Scenarios.

(Primary Results & Related Observations with Inferences)

- ***Overall Australian Arthroplasty Numbers at a Glance:***

General Number of Australian Arthroplasty Numbers: -

Total No. of Arthroplasties Recorded [Hip + Knee] = **18,53,452.**
Total No. of Hip Arthroplasties Recorded [Total + Hemi] = **7,13,480** [**1999 – 2021**].
Total No. of Knee Arthroplasties Recorded [TKA + UKA] = **9,02,016** [**1999 – 2021**].
Total No. of Revision Knee Arthroplasties [Hip + Knee] = **1,61,579.**
Total No. of Revision Hip Arthroplasties = **83,206.**
Total No. of Revision Knee Arthroplasties = **78,373.**

Number of Australian Hip & Knee Arthroplasties in 2021: -

Total No. of Hip Arthroplasties = **52,787.**
Total No. of Knee Arthroplasties = **68,466.**

Preface of the Australian Arthroplasty Practices: -

Impact of COVID-19 on Australian Arthroplasty Practices & Patient Preferences: -

- There was a marked reduction in the overall arthroplasty numbers due to the COVID-19 Pandemic induced effects and is evidently visible across all segments of its Arthroplasty Data for the Pandemic Years compared to the Pre-Pandemic Years.

- Had the trend from the pre-pandemic years continued for the Arthroplasty practices on the Australian patients & healthcare system as a whole, then there would've been in all possibilities a much higher number of arthroplasties conducted, as much as 19,595 more procedures in the pandemic impacted years of 2020 & 2021. This pattern as a whole is in line with the globally prevalent scenarios and has been observed everywhere during the course of this investigation.

- Interestingly, during the post-pandemic or recovery year of 2021, Public Hospital based Arthroplasty procedures decreased by a sharp 14.90%, vis-à-vis 2019 pre-pandemic numbers.

- With respect to the decline in Public Hospitals for Arthroplasty in Australia, the Private Clinical Institutes & Hospitals had a sharp increase of 10.90% in their respective Annual Arthroplasty numbers of 2021, compared to their numbers from the pre-pandemic year of 2019.

- The comparative shift in Overall Arthroplasty Procedural Volume numbers from Pre-Pandemic to Post-Pandemic years, gives away a vital missing 4% of patients/case volume, which could be possibly pointed towards Arthroplasty Case Burden or Backlog.

- Another logic could also point to the fact that the generally reduced scope for mobility of susceptible patients, during the pandemic years might have mitigated the actual on-ground risk of non-arthritis & non-progressive diseases, worsening to only surgically treatable stage, which on paper accounted for the missing percent of the patient cohort, that neither went to a Private nor a Public Hospital / Clinical Institute for their arthroplasty. This could be furthermore reasoned by

the fact that reduced mobility of a vulnerably susceptible patient with aging bones or compromised bone integrity, would have lesser scope or chances of getting a Neck of Femur (NOF) Fracture.

- More Details on the PROMs aspect will be discussed in the later stages of this report.

Basics of Australian Arthroplasty Practices: -

- Amongst all the findings from the Australian Arthroplasty domain & from the AOANJRR, a segment that particularly stood out be uniquely presented is their 10, 15, and 20 Year Prostheses Benchmark list comprising important prostheses which have been in use for at least 20 Years to as on date, with an individual 350+ Hip & Knee Arthroplasty procedures registered implantations in the Registry database respectively, which could be a first of its kind amongst all other registries evaluated in this probe, and may be in others wherein the probe could not be extended due to certain paucities & limitations.

- Now, these prostheses which have been in such circulation & use, have all been listed in a table, wherein the prostheses combination has been named alongside a few more vital information concerning that particular implant model.

  For example, in the case 10 Year Prostheses Benchmark for Hip Arthroplasty, both the Femoral Stem Component & Acetabular Shell / Cup Component combinations have been listed with their respective number of registered/reported procedures or cases, number of revision cases linked with their primary usage. Data like the type of revision performed in revision arthroplasties of primaries wherein these were implanted in the first place as in whether the revision is a Total Hip Revision(involves Complete Debridement, thorough pulsatile lavage cleansing of the joint capsule site, and the whole implant is changed or replaced with/without modifications in type or configurations), or a Femoral / Acetabular specific revision arthroplasty(where either only one of Femoral or Acetabular components are revised/changed). Besides, their cumulative revision rates at various time points (2 Years, 5 Years, 10 Years, 15 Years, and 20 Years) of patient follow-up are also presented.

- The same thing is repeated for 15 Years and 20 Years Prostheses benchmarks.

- Another thing that stands out from this particular reporting regarding the 10-15 Years Benchmarks, is the “Superiority” & “Non-Inferiority Benchmark” standards. Accordingly, such implants which qualified for these two criteria were uniquely color coded – Green for Prosthesis Combinations which qualifies for a Superiority Benchmark; and Blue for Prosthesis Combinations which qualifies for a Non-Inferiority Benchmark.

- The registry defined the Superiority Benchmark for 10 Years as a standard wherein a prosthesis’s respective revision percent should be less than equal to 4.40% at 10 Years. The registry further reported that 9 Hip Prostheses Combinations qualified for the Superiority Benchmark.

- The registry defined the Non-Inferiority Benchmark for 10 Years to a standard wherein a prosthesis’s respective revision percent should be less than equal to 4.40% to a maximum of 5.2% at 10 Years. Using this method, 6 Hip Prostheses Combinations qualified for the Non-Inferiority Benchmark.

- The above was applied for both Hip & Knee Arthroplasty Prostheses Combinations. However, the reported or Registry published criteria vis-à-vis table for 15 Year Benchmarks for Hip & Knee Arthroplasty is quite ambiguous.
- The registry also added that "a prosthesis combination may not achieve a benchmark standard", "due to being utilized in small numbers, higher revision rates due to factors other than the prostheses used, as well as less satisfactory performance". The Australian Arthroplasty registry also clarifies that a prosthesis combination can have achieved a benchmark standard of either type, only if they have registered and continually running or observable revision rates that are comparatively lower than other non-benchmark prostheses combinations.

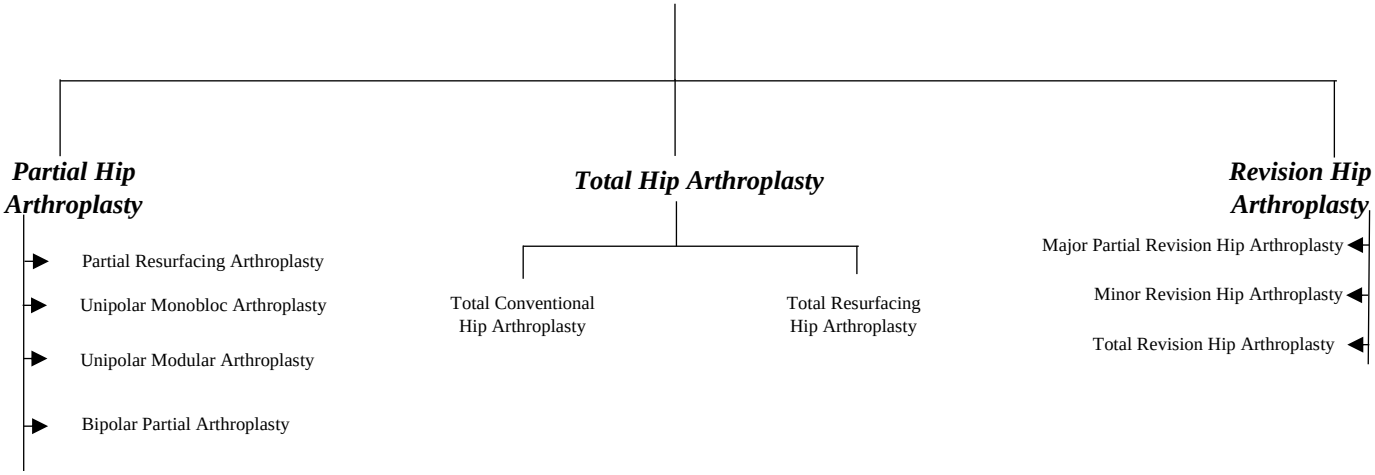
- However, for the 20-Year Benchmark, there were no Superiority & Non-Inferiority Classifications of the Hip & Knee Prostheses in active use for 20 Years on the Australian Patient Cohort, however, it generalized the set of implants which have been around for a while now.

- The AOANJRR states its primary motivation or influence to establish a nationwide orthopaedic registry was driven by the evident successes of other national registries from different countries of the world, and its contribution towards improving global patient health standards and arthroplasty practices in particular, with better prostheses utilization and failure management through a large-scale tracking mechanism. The Australian Registry goes on to particularly credit the Swedish Arthroplasty Registry (the oldest & possibly the first) as the primary inspiration major.

The Australian Hip Arthroplasty Practices and Prosthesis Utilization Scenario: -

- It was observed during the course of this probe, that like most other Nations of the world, Australia too had its own way of classifying Hip Arthroplasty, which was done as: -

Classification of Hip Arthroplasty in Australia



- The overall proportion of the Overall Revision Hip Arthroplasty declined from a peak of 12.90% in 2003 to 7.60% in 2021. Had the rate from the 2003s continued, there would've been an additional 2,791 number of hip revisions in 2021 from the presently existing scenario.

- Maintaining consistency with the global findings on the arthroplasty trends, the overall general percentage in numbers of annual hip arthroplasty performed has risen steeply by 95.10%, from the initial numbers of 2003, when the Registry started its operations.

- The distribution of the various forms of recognized hip arthroplasty modalities those were performed on the Australian patient cohort is presented through the following tabulation: -

Table 6.1.1 :- ***Tabulation illustrating the Distribution of Various recognized modalities of Hip Arthroplasty of all time, performed on the Australian patient cohort.***

AOANJRR 2022 : - Distribution of Hip Arthroplasty Cases across different types of Arthroplasty Procedure.

SL No.	Hip Category	No. of Cases	% of Overall
1	Partial Hip Arthroplasty	1,13,824	14.30%
2	Total Hip Arthroplasty	5,99,656	75.30%
3	Revision Hip Arthroplasty	83,206	10.40%
TOTAL		7,96,686	100%

- With regards to the Hip Arthroplasty outcomes, it was observed that the general ASA Grade-wise Patient Demographic classification, alongside their respective BMI metrics, were critical in assessing the relative risk involved with arthroplasty and the probabilistic outcome window in the true sense. These two parameters had a direct influence on the revision rate numbers, causes for revisions, prosthesis failure, and overall limited restoration of function, which was consistently observed across all other global regions examined during the course of this probe and in the case of the Australian arthroplasty scenario as well.

- The ASA & BMI linked data of the Australian patient cohort, receiving arthroplasty in in the respective nation's hospitals & clinics, was accessible from only 2012 and 2015 onwards for ASA Grade Score and BMI Index respectively.

- Accordingly, the linkage of the respective BMI Index metric data against the patients who received an arthroplasty presently stand as: - 62.60% for Primary Partial Hip Arthroplasty; 97.10 % for Primary Total Hip Arthroplasty & 88.10% for Revision Hip Replacement.

- Another interesting observation was that the partial hip procedures have a higher proportion of patients belonging to the ASA Grade III & IV categories compared to the patient cohort for the primary total hip replacement arthroplasty procedures in Australia. The only plausible logical explanation for this phenomenon of highly vulnerable patients having a procedure comparatively less durable than a Total Hip could be to limit the exposure to hospitalization & overall surgical trauma to as minimal as reasonably possible in individual cases. This reason is due to the fact that total hip arthroplasties require comparatively longer hospital stays, involving a longer recovery window when compared to partial hip arthroplasties which require very short hospital stays with faster recovery timelines.

- However, maybe for reasons unexplained and best known to the Registry and healthcare regulators in Australia, BMI data for patients aged less than 19 Years are not collected for any form of arthroplasty they undergo. The most conclusive logical explanation that this probe could possibly ascertain is that may be due to extremely low numbers of incidences of arthroplasty in very young patients, such as less than 19 Years of age. However, BMI data for young adults and teen patients who could be in line for an arthroplasty either due to a fracture or hip dysplasia, could be vital to predict the vulnerabilities of the young bone joint capsule, and other dynamics of human motion with respect to the body weight & height composition.

- The respective ASA-Grade of the patient linked distribution of hip arthroplasty procedures, across all the modalities are presented through the following tabulation: -

Distribution of the Patient Demographics of Hip Arthroplasty beneficiaries in Australia, based on their respective ASA Grade categories. [Data Since : ASA (2012-2021)].

SL No.	ASA Score	Partial Hip Arthro.		Total Hip Arthro.		Revision Hip Arthro.		Total	
		N	% of Overall	N	% of Overall	N	% of Overall	N	% of Overall
1	ASA 1	163	0.3	29,748	9.3	1,444	4	31,355	7.7
2	ASA 2	5,447	10.6	1,69,255	52.7	12,529	34.3	1,87,231	45.8
3	ASA 3	31,008	60.6	1,15,594	36	19,498	53.4	1,66,100	40.6
4	ASA 4	14,371	28.1	6,425	2	3,041	8.3	23,837	5.8
5	ASA 5	216	0.4	23	0	25	0.1	264	0.1
TOTAL		51,205	100	3,21,045	100	36,537	100	4,08,787	100

Table 6.1.2 :- ***Tabulation illustrating the Distribution of Various modalities of Hip Arthroplasty of the Australian Patient Cohort, as per their respective ASA-Grade based categorization, highlighting their general level of health co-morbidity statuses.***

- The respective BMI-Indices category wise distribution of the patient, linked distribution of the hip arthroplasty procedures, across all the modalities are presented as follows: -

Distribution of the Patient Demographics of Hip Arthroplasty beneficiaries in Australia, based on their respective ASA Grade categories. [Data Since : BMI (2015 - 2021)									
SL No.	BMI Category	Partial Hip Arthro.		Total Hip Arthro.		Revision Hip		Total Data Collc.	
		N	% of Overall	N	% of Overall	N	% of Overall	N	% of Overall
1	Underweight	2,232	9.9	2,650	1.1	424	1.7	5,306	1.8
2	Normal Weighed	11,182	49.5	55,606	22.1	5,846	23.8	72,634	24.3
3	Pre-Obese	6,449	28.5	92,377	36.7	8,457	34.4	1,07,283	35.9
4	Obese Class 1	1,998	8.8	62,183	24.7	5,841	23.8	70,022	23.4
5	Obese Class 2	534	2.4	26,185	10.4	2,527	10.3	29,246	9.8
6	Obese Class 3	215	1	12,702	5	1,472	6	14,389	4.8
TOTAL		22,610	100	3,21,045	100	24,567	100	2,98,880	100

Table 6.1.3 :- ***Tabulation illustrating the Distribution of Various modalities of Hip Arthroplasty of the Australian Patient Cohort, as per their respective Body-Mass Index (BMI) based categorization.***

- In line with the global scenario, the leading cause or indication for a primary THA in Australia is Osteoarthritis (OA), and related progression of the disease. Nearly 88.30% of all the Primary Conventional Hip Arthroplasties performed had OA as the prime/sole indication or cause for the arthroplasty surgery.

- While, the global buzz of Hip Resurfacing Arthroplasty has declined and decimated, quicker than possibly the propagators had initially estimated or predicted, due to the enormous set of life-threatening risks it comprised and the extensive number of globally spread post-operative failures, the practice of Hip Resurfacing in Australia has not yet totally ceased, but is on the declining trend. Hip Resurfacing in Australia, however, has a bigger number of overall procedure count than the partial arthroplasty modalities at 19,369 with a shared percent of 3.20%.

- Total Hip Arthroplasty or THA, was the most common form of hip arthroplasty performed on the Australian Patient Cohort, with 5,80,029 procedure case numbers that accounted for nearly 96.80% of all the Hip Arthroplasties performed.

- The distribution of conventional total hip arthroplasty vis-à-vis resurfacing hip arthroplasty is tabulated as follows: -

Table 6.1.4 :- ***Tabulation illustrating the dominance of Conventional THA over Resurfacing Hip Arthroplasty of the Australian Patient Cohort.***

Conventional THA vs Resurfacing Hip Arthroplasty of the Australian Patient Cohort of All Time.			
SL No.	Total Hip Arthroplasty Type	No. of Cases	% of Overall
1	Total Conventional Hip Arthroplasty	5,80,029	96.8
2	Total Resurfacing Hip Arthroplasty	19,369	3.2
TOTAL		5,99,398	100

- The general Revision Rate (RR) for Conventional THA is lesser than the Revision Rate for Resurfacing Hip Arthroplasty.

RR (Conventional THA) < RR (Resurfacing Hip Arthroplasty)

11.90 % < 14.90%

- Overcoming the pandemic-induced effects on arthroplasty numbers, the overall procedural count of arthroplasty number of 2021 is up by 41,984, compared to 2020, attributing to a 7.20% growth in the

arthroplasty numbers, and an overall growth of 142.60% since the initial arthroplasty numbers of 2003, when the AOANJRR started its operation.

- The mean age group of the Australian patient cohort receiving a hip arthroplasty is 67.8 years, with the least observable change in the 55 – 64 years old age group of the patient cohort, which had a share of 21.9% in 2003 in the overall hip arthroplasty numbers in Australia, is now only 23.4% in 2021, when the general numbers have grown exponentially.

- On a similar line, the overall revision rate of the youngest group of Australian patients receiving hip arthroplasty (aged less than 55 years), has remained fairly stagnant at 11.40% in 2021, compared to that of 11.70% in 2003, on broad terms.

- On the prostheses selection and use front, it was observed that Stryker's Exeter V40, DePuy Synthes's Corail, and Stryker's Accolade II (An upgraded version of Accolade) were the prostheses that were been used the most for primary THA of the Australian patient cohort.

- The Exeter V40 is a globally revered and one of the most used femoral stems used for primary THA globally, as far as this probe could examine, and had by far the single largest share in UK/Wales as stated by the National Joint Registry (NJR) as well. The NJR being one of the oldest registries that operate on a grand scale, with large-scale participation from multiple stakeholders- ranging from academic to clinical to industrial, supported by the British NHS and enforced by the mandatory reporting policy had a commanding influence or impact on the other European nations, and rightly so, propelling Exeter V40 to be the most used stem in Europe in not the world. Similar is the case for Corail, which is a long-term legacy product from DePuy Synthes, in wide usage & circulation in Europe and Australia, though with good to mixed outcomes across patient variants.

- However, the Accolade II was one of the flag-ship prostheses from Stryker that were launched for commercial circulation & implantation on the arthroplasty patient cohort, had a big share on the American hip prostheses numbers, but was surprisingly missing in the European arthroplasty domain, so far this probe could possibly scrutinize and examine, but, topped usage charts in Australia.

- It was found during the course of examining and evaluating arthroplasty practices in Australia, that in 2021 and relatively recent years, nearly a majority of all the primary hip arthroplasties were performed using the prostheses combinations that featured on the top 10 most used prostheses list, leaving out only a handful share of distribution for other prostheses combinations to be used in the primary hip arthroplasty of the Australian patient cohort.

- In 2021, nearly 67.80% of all primary hip arthroplasty utilized such Most Used Top 10 Prostheses Combinations, of which 7 out 10 were cementless prostheses.

- Comparing the same by fixation method-based prostheses usage it was found that for the case of Cemented femoral stems, the Top 10 prostheses accounted for nearly 93.90% of all cemented procedures vis-à-vis Top 10 Cementless accounting for nearly 78.40% of respective procedure.

- The acetabular shells, namely: Trident (Stryker), Trinity (Corin Group) and Pinnacle (DePuy Synthes) accounted for the most commonly deployed acetabular cups/shells in the Australian patient cohort for hip arthroplasty. It was further found on similar lines that exactly just like the case with femoral stems, for acetabular cup/shells as well, the top 10 acetabular prostheses accounted for nearly 87.80% of all the procedures in 2021, with all 10 of them being of cementless type.

- However, it was observed that the Australian registry has excluded Large femoral heads of MoM nature from their prostheses analysis, stating their diminished and very limited usage to around 2.80% of the current proportion of prostheses used, and having consistently extra-ordinarily much higher revision rates, than other bearing surfaces, at around 32.40% at 20 Years of patient follow-up time point.

- It was further observed during the course of this research, that when the global average of the revision rates for Large MoM femoral heads is compared to that of the rate of revision for large MoM femoral heads in Australia, the revision rate for the respective category of Australia is way higher than the global average across respective nations.

- Nearly most of the very limited utilization of such large-head MoM femoral prostheses, was applied as cementless fixation in the youngest section of the patients. This, however, produces a snowball effect, since these particular very young set of patients, most of them aging less than 40 years, live an average life-span long enough, to again fall into the requirement for a revision hip arthroplasty, thereby adding to the overall revision burden & general vulnerabilities from a variety of risks such an in-vivo metallosis to prostheses wearing & dislocation/subluxation in the long term, if not in the short-term, as some may debate.

- The Australian registry has also excluded small head MoM femoral prostheses, that come in femoral head sizes less than 32 mm in diameter and are excluded from the analysis since they're not used as of 2021 and their proportioning distribution share in overall hip arthroplasty comes at around 1%. This exclusion of femoral stems with heads that are less than 32 mm from the analysis stage, is an unusual thing compared to other major registries since 26 mm & 28 mm heads are still utilized across the other nations, though these may not always generate long-term positive outcomes, particularly the 22 mm heads which are notoriously famous for its high revision rates involved in most of the scenarios where it is utilized, and 28 – 32 mm sized femoral heads remains to be an optimal choice in most regions if not all.

- The AOANJRR besides excluding the above, has also excluded prostheses combinations that were no longer utilized in the modern day of 2021, in order to keep the registry reports "contemporaneous", and only those prostheses which are regularly implanted or in circulation as of present day are included into the vital analysis and reporting, and therefore data analysis for only these prostheses combinations were possible to be accessed by this research for the development of this report and the final thesis. These prostheses are termed as "*modern prostheses*" by the registry, and shall be referred, when necessary, by this report as well for general convenience.

- These exclusions as stated above, due to the explained reasons, have led to the further exclusion of approximately 1,04,658 hip arthroplasty cases from the overall examination and analysis of both the report and this research probe.

- On the prosthesis combination aspect, it was found that was around 1,464 femoral stem and acetabular shell combinations, that had less than 500 arthroplasty procedures registered in the database for their credit.

- However, such cases made up a bulk of the arthroplasty numbers in Australia, but any logically sound explanation was not presented for their exclusions, and reasons to suspect arise, when the registry categorically mentions and states that "a large number of prostheses combinations have been used in small numbers and have no recorded use in 2021". The intentions could be either solely to keep the database 'contemporaneous' or to suppress certain prostheses combinations used in small segments for arthroplasties that might have generated unfavourable outcomes. Though this was not particularly possible to verify the exact reason, due to multi-factorial issues, this was one of the genuine inferences that were inferred in the course of this research probe, while examining/evaluating Australian arthroplasty practices.

Leading Causes/Indications for Primary Total Hip Arthroplasty of the Australian Patients: -

- On the aspect of primary indication for hip arthroplasty, osteoarthritis or OA continues to remain as the sole major leading prime indication for hip arthroplasty, or in some cases it could be affirmed as the progression of the osteoarthritis as the cause/indication or motivation for hip arthroplasty. This scenario remains to be globally consistent across all the major registries and nations whose arthroplasty practices data were possible to be accessed during the course of this research investigation.

- In Australia, osteoarthritis is the leading cause or indication for primary total hip arthroplasty, followed by fracture of the Neck of the Femur (NOF) as the second leading cause or indication for primary total hip arthroplasty.

- Other indications such as osteonecrosis, hip dysplasia, rheumatoid arthritis (RA), and bone tumour were the 3rd, 4th, 5th, and 6th most leading primary indications for a hip arthroplasty or to be specific total hip arthroplasty. Further detailing on the indications and their related distribution statistics are presented in the tables enclosed separately.

- The respective revision rates as per primary indications were observed to be in the following order when compared and contrasted against each other: -

  RR (OA) < RR (Fracture of NOF)
  RR (OA) < RR (Hip Dysplasia) [at 2 – 2.5 Years of Patient Follow-up Timepoint]

- The prevailing cumulative revision rate percentages of primary total hip arthroplasty, based on their primary diagnoses or indication, during various time-points in the post-operative follow-up window is presented through the following tabulation: -

AOANJRR 2022:- Cumulative Revision Rate Percentages of Primary THAs by Primary Diagnoses Types of the Australian Patient Cohort.

SL No.	Primary Diagnosis	Total Cases	Total Revised	Primary %	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Osteoarthritis	3,97,261	13,098	87.6	1.6(1.6, 1.6)	2.3(2.3, 2.4)	2.9(2.8, 2.9)	4.4(4.3, 4.4)	6.3(6.2, 6.5)	8.4(8.1, 8.8)
2	Fractured Neck of Femur	24,801	1,163	5.5	3(2.8, 3.2)	4.2(4, 4.5)	5(4.7, 5.3)	6.9(6.5, 7.5)	9.4(8.4, 10.5)	
3	Osteonecrosis	14,583	718	3.2	2.5(2.3, 2.8)	3.5(3.2, 3.8)	4.4(4, 4.7)	6.7(6.1, 7.3)	9.7(8.7, 10.8)	12.3(10.4, 14.6)
4	Developmental Dysplasia	5,912	239	1.3	2(1.6, 2.4)	3(2.5, 3.4)	3.5(3.1, 4.1)	5(4.3, 5.7)	6.9(5.8, 8.1)	8.1(6.6, 10)
5	Rheumatoid Arthritis	3,573	173	0.8	2.6(2.1, 3.2)	3.5(2.9, 4.2)	4(3.4, 4.8)	5.5(4.6, 6.5)	7.9(6.5, 9.5)	
6	Tumor	2,552	137	0.6	4.7(3.8, 5.7)	7.1(5.9, 8.6)	8.4(6.9, 10.2)	11.9(9.2, 15.4)		
7	Other (5)	4,582	308	1	4.1(3.5, 4.7)	5.7(5, 6.5)	6.7(6, 7.6)	8.9(7.8, 10.1)	11.2(9.5, 13.1)	
TOTAL		4,53,264	15,836	100	Figures for Modern Prostheses only, i.e. Implant Components that are Currently on Circulation & Use in Australia.			Primary Diagnoses with >2000 Registered Procedures have been listed.		

Table 6.1.5 :- ***Tabulation illustrating the prevailing cumulative Revision Rate percentages of the Primary Total Hip Arthroplasties performed on the Australian patient cohort, categorized as per the respective Primary Diagnoses type for Primary, alongside the number of Primary & Revision procedures performed based on them.***

Revision Hip Arthroplasty based Practices and related Outcome Scenarios for the Australian Patients: -

- The Australian registry in various instances has stated that the age and gender of the patient cohort have a clear and significant influence on the revision rate outcomes. Now, though the idea of the gender-based influence on arthroplasty outcomes based on the basic anatomic and structural differences to life-style related differences, is quite acknowledged, discussed, and has been under wide consideration of the research community as well for quite some time now, the exact age-wise influence and variation of outcomes vis-à-vis procedure risks and implant failures have been comparatively been on the backseat when compared to the gender-based outcome analysis of hip arthroplasty.

- When examined for age-wise revision rate percent for hip arthroplasty performed on the Australian patient cohort, the following were inferred based on the reported facts, and figures: -

a. Patients aged > = 75 Years have a comparatively lower RR than the patients aged <55 Years or the youngest group of arthroplasty patients, after 3 months of post-op follow-up.
b. Now, at 6 months' time point of patient follow-up, the revision rate of the same > = 75 Years old patients has a comparatively lesser revision rate than that of the patients aged between 55 – 64 Years old.
c. Further on, when compared from the long-term point of view, the same patients aged > = 75 Years have a lesser revision rate than that of the patients aged between 65 and 74 Years after 4 years since their primary arthroplasty / at 4 years' time point of post-op patient follow-up.

Summarily for Overall Patients (No filter for gender/age applied),

RR (>=75 Years) < RR (< 55 Years) [at 3 Months Post-Op]
RR (>= 75 Years) < RR (55 – 64 Years) [at 6 Months Post-Op]
RR (>= 75 Years) < RR (65 – 74 Years) [at 4 Years Post-Op]

- When compared for gender-based revision rate differences, the following inferences were inferred based on the accessible and stated facts and figures: -

a. The Australian male patients were found to be having a comparatively higher revision rate than the revision rates of the Australian female patients at 3 months post-op follow-up time point, with the cumulative revision rate percent standing at 9.00% and 8.00% respectively for male and female patients receiving a hip arthroplasty treatment to their ailments.

b. However, this gender-based revision rate percent for both the male and female patients is quite high when this particular parameter and the related numbers are compared against the global average of male and female-based revision rates of hip arthroplasty.

c. Again, after thorough scrutinization and evaluation of the national arthroplasty registry databases and reports, for other nations, multiple loop-holes points and factors were observed, and corroborating all the general practices with stated documentary facts and figures, it was inferred quite a few times during the course of this investigation is that there could've possibly been a data suppression or 'filtration', to have a heavenly picture of the arthroplasty practice state in the respective region. Counting in the facts, this is plausible that either those numbers of revision were altered or adjusted in any way, for male and female-based revision rate numbers come quite low, or all the facts and figures are pristine and absolutely transparent, and in true reality the Australian male and female gender wise revision rate data show higher numbers. Both possibilities can be possible, is what that was inferred after careful examination of all factors intrinsic and extrinsic.

d. Males aged (> = 75 Years) have a higher revision rate than the revision rates of the male patients aged between 55 – 64 years and 65 – 74 years as well, in the first 4½ years post-op.

e. Furthermore, young male patients aging less than 55 years doesn't have a significantly different revision rate than the rate observed for male patients aging >= 75 years, in the immediate short term i.e., around at 3 months post-op period.

f. For female patients, it was found that their respective revision rates decrease with their increasing age. This age-linked increase/decrease variance in female revision rates is not uncommon and is evident in other regions as well.

g. For both male and female patients aging less than 75 years, prosthesis loosening remains as the most common reason or indication for a revision arthroplasty. However, for patients both male and female, aged 75 years or more, the most common reason for revision is fracture.

Summarily,

RR (Males >= 75 Years) > RR (Males 55 – 64 Years Old)
RR (Males >= 75 Years) > RR (Males 65 – 74 Years Old)
RR (Males <55 Years) ≈ RR (Males >= 75 Years) [at 3 months post-op]
RR (Females <55 Years) > RR (Females > = 75 Years) [at 3 months post-op]

For 1st 4½ Years Post-Op only

- The patient age-group and gender linked distribution of the revision rate percentages of the Australian patient recipients of THA during any various time-points in their post-operative follow-up window are presented through the following tabulation: -

Distribution of Patient Age-Group & Gender linked Cumulative Revision Rate percentages of Primary THA performed on the Australian Patient Cohort with Primary Diagnosis OA.

SL No.	Patient Gender & Age Group	Total Cases	No. of Revised	Post-Op 1 Year	Post-Op 3 Years	Post-Op 5 Years	Post-Op 10 Years	Post-Op 15 Years	Post-Op 20 Years
Australian Males		1,82,016	6,204	1.6(1.6, 1.7)	2.4(2.3, 2.5)	3.0(2.9, 3.1)	4.6(4.5, 4.7)	6.9(6.7, 7.2)	9.0(8.5, 9.6)
1	<55	23,357	868	1.6(1.4, 1.7)	2.5(2.3, 2.8)	3.2(2.9, 3.1)	4.9(4.5, 5.3)	7.4(6.7, 8.1)	9.3(8, 10.7)
2	55-64	47,203	1,574	1.5(1.4, 1.6)	2.2(2.1, 2.4)	2.7(2.6, 2.9)	4.3(4.0, 4.5)	6.7(6.2, 7.1)	8.8(7.9, 9.8)
3	65-74	64,205	2,118	1.5(1.4, 1.6)	2.2(2.1, 2.3)	2.8(2.7, 2.9)	4.4(4.2, 4.6)	6.7(6.3, 7.1)	9(8.1, 10)
4	>=75	47,211	1,644	1.9(1.8, 2.1)	2.8(2.6, 3.0)	3.4(3.2, 3.6)	5.0(4.8, 5.3)	7.2(6.5, 7.8)	
Australian Females		2,15,245	6,894	1.6(1.5, 1.6)	2.3(2.2, 2.3)	2.8(2.7, 2.8)	4.2(4.1, 4.3)	5.9(5.7, 6.1)	8(7.5, 8.5)
6	<55	18,048	760	1.8(1.6, 2.0)	2.8(2.5, 3.0)	3.5(3.2, 3.8)	5.4(4.9, 5.8)	7.5(6.8, 8.3)	9.4(8.3, 10.7)
7	55-64	46,378	1,635	1.5(1.4, 1.6)	2.3(2.1, 2.4)	2.8(2.7, 3.0)	4.5(4.2, 4.7)	6.3(5.9, 6.7)	9.0(8, 10)
8	65-74	78,483	2,433	1.5(1.4, 1.5)	2.2(2.1, 2.3)	2.6(2.5, 2.8)	4.0(3.8, 4.2)	5.8(5.5, 6.1)	7.5(6.8, 8.4)
9	>=75	72,336	2,066	1.7(1.6, 1.8)	2.2(2.1, 2.4)	2.7(2.5, 2.8)	3.8(3.6, 4.0)	5.0(4.6, 5.3)	6.9(5.7, 8.5)
Cumulative Total [All Age/Gender]		3,97,261	13,098	*Data for only Modern Prostheses[Prostheses on Current Circulation/Use in Australia] ; All MoM prostheses have been excluded.*					

Table 6.1.6 :- ***Tabulation illustrating the Patient Age-Group and Gender linked distribution of the Cumulative Revision Rate percentages of the Primary THA recipient Australian Patient Cohort .***

- While the general revision rate percentages across different time-points in the post-operative window, categorized as per the patient's respective ASA-Grade and BMI-category, is presented through the following tabulation: -

Distribution of the Cumulative Revision Rate percentages of the Primary THAs performed on the Australian Patient Cohort, based on their respective ASA-Grade wise categorization.									
SL No.	ASA Grade	Total Cases	No. of Revised	Post-Op 1 Year	Post-Op 2 Years	Post-Op 3 Years	Post-Op 4 Years	Post-Op 6 Years	Post-Op 8 Years
1	ASA 1	23,214	462	1.1(1, 1.3)	1.5(1.3, 1.7)	1.8(1.6, 2)	1.9(1.8, 2.1)	2.4(2.2, 2.7)	2.8(2.5, 3.2)
2	ASA 2	1,42,107	3,195	1.4(1.4, 1.5)	1.8(1.7, 1.9)	2.1(2, 2.2)	2.3(2.3, 2.4)	2.8(2.7, 2.9)	3.2(3.1, 3.4)
3	ASA 3	91,745	2,808	2.2(2.1, 2.3)	2.7(2.6, 2.8)	3(2.9, 3.2)	3.3(3.2, 3.4)	3.8(3.7, 4)	4.3(4.1, 4.6)
4	ASA 4	3,655	131	2.7(2.2, 3.3)	3.1(2.6, 3.7)	3.6(3, 4.3)	3.8(3.2, 4.6)	4.7(3.9, 5.7)	5.4(4.2, 6.9)
6	ASA 5	12	1	0	0	0	0	0	
TOTAL		2,60,733	6,597	*Data for only Modern Prostheses [Prostheses on Current Circulation/Use in Australia] ; All MoM prostheses have been excluded.*					

Table 6.1.7 :- ***Tabulation illustrating the Patient's ASA-Grade classification linked distribution of the Cumulative Revision Rate percentages of the Primary THA recipient Australian Patient Cohort .***

Distribution of the Cumulative Revision Rate percentages of the Primary THAs performed on the Australian Patient Cohort, based on their respective BMI-Category based categorization.									
SL No.	BMI Category Group	Total Cases	No. of Revised	1 Yr	2 Years	3 Years	4 Years	5 Years	6 Years
1	Underweight (<18.50)	1,539	24	1.2 (0.7, 1.9)	1.2 (0.8, 2.0)	1.2(0.8, 2)	1.9(1.2, 2.9)	2.1(1.3, 3.2)	2.5 (1.5, 4.0)
2	Normal (18.50 - 24.99)	44,311	864	1.3 (1.2, 1.4)	1.7 (1.5, 1.8)	2(1.8, 2.1)	2.2(2.1, 2.4)	2.5(2.3, 2.7)	2.8(2.6, 3.0)
3	Pre Obese (25.00 - 29.99)	79,070	1,604	1.4 (1.3, 1.5)	1.8(1.7, 1.9)	2.1(2, 2.2)	2.3(2.2, 2.4)	2.5(2.4, 2.7)	2.8(2.6, 2.9)
4	Obese Class 1 (30.00 - 34.99)	54,930	1,326	1.8(1.7, 1.9)	2.2 (2.1, 2.3)	2.5(2.4, 2.7)	2.7(2.6, 2.9)	3(2.8, 3.2)	3.2(3.0, 3.4)
6	Obese Class 2 (35.00 - 39.99)	23,445	724	2.4 (2.2, 2.6)	2.9 (2.6, 3.1)	3.2(3,3.5)	3.5(3.2, 3.8)	3.7(3.4, 4)	3.9(3.6, 4.2)
7	Obese Class 3 (>=40.00)	11,318	477	3.4 (3.1, 3.8)	4(3.7,4.4)	4.4(4, 4.8)	4.6(4.2, 5)	4.8(4.4, 5.3)	5.1(4.6, 5.6)
TOTAL		2,14,613	5,019	*Data for only Modern Prostheses [Prostheses on Current Circulation/Use in Australia] ; All MoM prostheses have been excluded.*					

Table 6.1.8 :- ***Tabulation illustrating the Patient's BMI-based classification linked distribution of the Cumulative Revision Rate percentages of the Primary THA recipient Australian Patient Cohort .***

- Inspecting the reported facts & figures, and corroborating them with the general logic and principles of implant design, biomechanics and biomaterials, it is affirmed that in the first 11 years post-op, the incidences of dislocation and subluxation, along with post-surgical infection, happens to be the most common causes for revision. While, for the later stages of the post-op period, to nearly around the next or later 11 years, loosening becomes the pre-dominant villain for a revision arthroplasty.

- Loosening of the prostheses in the initial few years of the post operative period, reflects the failure of both the prostheses and the arthroplasty procedure as a whole, to facilitate appropriate adhesion and fixation of the foreign prosthesis component into the joint capsule. However, for loosening of the prostheses in the later phases of the post-operative period reflects implant module's fixation loss not due to lysis and bone resorption and in some rare cases hyper-activity of the patient itself. This is due to the fact that the foreign

prostheses material remains to be prone to the highest vulnerabilities from a wide gamut of risks such as infections, immune-response rejection and prosthesis dislocations.

- Once the patient and the prosthesis combination withstand and lives through this particular risk zone window period, it could be safely assumed that the prostheses are well accepted and the reconstructed joint is in proper functioning. Therefore, any events in the long-term leading to prostheses wear and loosening in particular could be attributed to other extraneous factors such as life-style, exposure range and types of stresses it had to endure, osteolysis all come into play which could either singly or collectively cause a detrimental effect on reconstructed artificial joint, causing a loosening, or as some other registries and journals term it "aseptic loosening".

- In short implant loosening can take place due to a consolidated or an individual effect from inadequate initial fixation, loss of biomechanical capabilities & fixation over prolonged fatigue exposure, or due an anatomical fixation loss resulting from a particle induced osteolysis in and around the region of the implant.

- The top four revised components or revision procedures performed for the Australian hip arthroplasty patient cohort, with osteoarthritis as their primary indication were: - Femoral Component Revision, Femoral Head / Polyethylene Articular surface bearing Insert Replacement/Change Revision, Acetabular component Revision and Total Hip Revision Arthroplasty (complete overhaul / change of all the implants and related components).

- The distribution of the number of revision hip procedures performed based on the most common revision activity practices / replaced items during revision hip arthroplasties in Australian arthroplasty practices, is presented through the following tabulation: -

AOANJRR 2022 : Most Commonly Reported Revision Activities / Components Revised during Revision Hip Arthroplasty of the Australian Patient Cohort.

SL No.	Type of Revision / Component Revised during Revision Arthroplasty	No. of Cases	% of Overall
1	Femoral Component	4,330	33.10%
2	Femoral Head / Insert change	3,203	24.50%
3	Acetabular Component	2,486	19.00%
4	Total Hip Revision (Both F & A Revised)	1,463	11.20%
5	Head only	652	5.00%
6	Cement Spacer	506	3.90%
7	Minor Components	228	1.70%
8	Insert Only	131	1.00%
9	Removal of Prostheses	70	0.50%
10	Re-insertion of Components	19	0.10%
11	Bipolar Head & Femoral	3	0.00%
12	Bipolar Only	2	0.00%
13	Total Femoral	2	0.00%
14	Cement Only	1	0.00%
15	Saddle	1	0.00%
16	Head/Neck	1	0.00%
TOTAL		13,098	100.00%

All MoM Procedures Excluded ; Femoral heads are usually replaced when the acetabular component or femoral stem is revised.
Figures for Modern Prostheses only, i.e. Implant Components that are Currently on Circulation & Use in Australia[2021].

Table 6.1.9 :- ***Tabulation illustrating Most Common Revision Practices during Revision Hip Arthroplasties of the failing Primary THAs of the Australian Patient Cohort, expressed in terms of the respective Revision activity performed during the procedure.***

- For patients who had received a primary hip arthroplasty, due to a primary diagnosis of progressive osteoarthritis, the common reasons for a revision arthroplasty were Infection, Dislocation / Subluxation of the Prosthesis and Periprosthetic fracture.

- Interestingly, while analysing and exploring the arthroplasty practices through the Australian registries published data and other facts & figures, it is observed that possibly for the first time, across all the nations and national registries evaluated so far, during the course of this investigation, there is a public acknowledgement of some of the failures & negative outcome parameters which are otherwise undesirous, such as "Leg Length Discrepancy", "Mispositioning" and "Incorrect Sizing"(of prosthesis for usage). While these factors and parameters are named for the first time in a registry as a contributing factor for revision arthroplasty, their respective shares in overall numbers of revision arthroplasty are: -

    a. Leg Length Discrepancy was the primary indicator/sole reason for 229 Revision Hip Arthroplasties in 2021, which was 1.70% of all Revisions in 2021.
    b. Mispositioning of the Prosthesis was the primary indicator/sole reason for 201 Revision Hip Arthroplasties in 2021, which was nearly 1.50% of all Revisions in 2021.
    c. Implantation of Incorrectly Sized prosthesis or its components was the primary indicator/sole reason for 84 Revision Hip Arthroplasties in 2021, which accounted for a small 0.60% of all Revisions in 2021.

- The overall most commonly cited reasons for the revision hip arthroplasty of the Australian patient cohort are presented through the following tabulation: -

Table 6.1.10 :- ***Tabulation illustrating Most Commonly cited Reasons for the Revision Hip Arthroplasties of the failing Primary THAs of the Australian Patient Cohort.***

AOANJRR 2022 : Most Commonly cited Reasons for the Revision Hip Arthroplasties of Australian Patient Cohort with OA as their Primary Diagnosis / Indication.

SL No.	Reason for Revision	No. of Cases	% of Overall
1	Infection	2,972	22.70%
2	Prosthesis Dislocation / Instability	2,879	22.00%
3	Fracture	2,856	21.80%
4	Loosening	2,753	21.00%
5	Pain	255	1.90%
6	Leg Length Discrepancy	229	1.70%
7	Malposition	201	1.50%
8	Lysis	164	1.30%
9	Implant Breakage Stem	125	1.00%
10	Implant Breakage of Acetabular Insert	102	0.80%
11	Incorrect Sizing	84	0.60%
12	Acetabular Insert Wearing	79	0.60%
13	Metallosis & Other Metal related Pathology	59	0.50%
14	Acetabular Implant Breakage	46	0.40%
15	Femoral Head Implant Breakage	23	0.20%
16	Progression of Disease	1	0.00%
17	Other	270	2.10%
TOTAL		13,098	100.00%

All MoM Procedures Excluded ; Figures for Modern Prostheses only, i.e. Implant Components that are Currently on Circulation & Use in Australia.[2021]

- Appropriate acknowledgment and publication of details encircling around minute such facts are significant, for a reason that these issues are not rare, rather these are extremely common in parts of South Asia, if non-scientific sources are to be factored in and evaluated. During the course of this research, it was observed that numerous news articles, clinical blogs, YouTube videos of patients from the West Asian, African nations arriving in South Asian countries popular for medical tourism such as India, to get conditions like the above getting fixed. Since such procedures and incidents operate and happen beyond the horizons of

a national arthroplasty registry or a healthcare database or any particular scientific article, these cases often go unreported and unexplored for their ultimate or final outcomes, i.e., whether these revision surgeries that take places in clinical centers, other the hospital or centre where their initial primary was conducted.

- Such exploration and related scrutinization of unreported or missed out cases are very critically necessary to be included under the scientific and critical analyses to evaluate the general outcome and pattern of such cases occurring all across the globe.

Revision Scenarios in Australian Hip Arthroplasty: - Impact of Patient Age and Fixation Methods

- The Australian registry stated at a point that "*the outcome with respect to fixation varies with age*", this particular statement was investigated further during this course of the research, and was observed that: -

a. Patients belonging to the youngest category of arthroplasty patients as per global conventions, i.e., in the age group less than 55 Years, had no difference in respective revision rates when they are compared separately by the fixation method utilized in their arthroplasty procedure to fixate the prosthesis component into their anatomy. Cemented, Non-Cemented and Hybrid Fixation (Femoral Stem is added with Cement; Acetabular Shell / Cup remains to be non-cemented), were considered for this particular analysis.

b. While for patients aged between 55 – 64 Years, there's a higher revision rate in the first succeeding month for cementless fixation compared to the hybrid fixation method, however this difference in respective revision rates, flattens out after 2 months into the post-operative period.

c. The cementless fixations were utilized in much higher proportions than cemented and hybrid fixation techniques for almost all age-group of patients who had received a primary total hip arthroplasty, due to a primary indication of osteoarthritis. However, for particularly cementless fixations on patients aged > = 75 years, the observed overall revision rate is higher compared to the cemented and hybrid fixation revision rate results, in the same age group category, during all time periods of post-operative follow-up.

d. On the other hand, the cemented and hybrid fixation methods, showed no difference in their respective revision rates across all follow-up time points, in the post-operative period for the same patient age group category, i.e., the >=75 years group of patient cohort.

e. The above inference is a classic example that at very old age or seniority, bone matrix strength decreases several-fold compared to younger sub-groups, and thereby, its inherent capability to re-adapt to changes in the force or stress distribution it is exposed to, and hence requiring the aid of an external supportive agent in the form of bone cement to augment the prosthesis adhesion and gripping properties, such that the leftover femur and the prosthesis perform in absolute synchronous harmony for daily activities and mobility.

f. Similarly, it was found that the reported revision rates for cementless fixation used in primary total hip arthroplasty of patients belonging to 65 – 74 years of age (the prime age group) were slightly higher than hybrid and cemented fixation groups, which again proves the previous point.

- The detailed tabulation of revision rates of primary total hip arthroplasty, as per fixation methods utilized for primary, across different age-group of patients with primary diagnosis osteoarthritis is presented as follows: -

AOANJRR 2022 : Cumulative Revision Percent of Primary THA by Fixation Methods for Different Age-Groups of Australian Patients with OA as their Primary Diagnosis.

SL No.	Fixation Method	No. of Cases	No. of Revisions	1 Year	3 Years	5 Years	10 Years	15 Years	16 Years
A.	<55 Years Age-Group	36,766	1,295	1.7(1.6, 1.8)	2.6(2.5, 2.8)	3.3(3.1, 3.5)	4.9(4.6, 5.3)	6.5(6.0, 7.1)	7.2(6.5, 8.1)
1	Cemented Hip	257	16	3.2(1.6, 6.3)	4(2.2, 7.4)	4.5(2.5, 8.0)	8.8(4.9, 15.8)		
2	Non-Cemented Hip	29,549	1,042	1.7(1.6, 1.9)	2.7(2.5, 2.9)	3.4(3.2, 3.6)	4.9(4.6, 5.3)	6.3(5.7, 6.9)	
3	Hybrid Hip	6,960	237	1.7(1.4, 2)	2.3(2, 2.7)	2.9(2.5, 3.4)	4.8(4.1, 5.6)	7.1(5.9, 8.5)	
B.	55 - 64 Years Age-Group	84,099	2,623	1.6(1.5, 1.7)	2.3(2.2, 2.4)	2.8(2.7, 2.9)	4.2(4.1, 4.4)	5.9(5.6, 6.2)	7.5(6.7, 8.3)
1	Cemented Hip	763	28	1.9(1.1, 3.1)	2.6(1.6, 4.0)	2.9(1.9, 4.4)	3.8(2.6, 5.7)	6.4(3.8, 10.7)	
2	Non-Cemented Hip	62,350	1,893	1.6(1.5, 1.7)	2.3(2.2, 2.5)	2.8(2.7, 3.0)	4.1(3.9, 4.4)	5.7(5.3, 6.1)	7.4(6.4, 8.5)
3	Hybrid Hip	20,986	702	1.4(1.3, 1.6)	2.1(1.9,2.3)	2.7(2.5, 3.0)	4.5(4.1, 4.9)	6.2(5.6, 6.9)	7.8(6.8, 9.1)
C.	65 - 74 Years Age-Group	1,30,937	3,797	1.5(1.4, 1.5)	2.2(2.1, 2.2)	2.7(2.6, 2.8)	3.9(3.8, 4.1)	5.5(5.2, 5.7)	
1	Cemented Hip	2,254	67	1.3(0.9, 1.9)	1.9(1.4, 2.6)	2.5(1.9, 3.2)	4.1(3.1, 5.4)	5.8(3.9, 8.5)	
2	Non-Cemented Hip	81,132	2,388	1.6(1.6, 1.7)	2.3(2.2, 2.5)	2.8(2.7, 2.9)	4(3.8, 4.2)	5.5(5.2, 5.9)	7.1(5.7, 8.8)
3	Hybrid Hip	47,551	1,342	1.2(1.1, 1.3)	1.9(1.7, 2.0)	2.4(2.3, 2.6)	3.8(3.5, 4)	5.3(4.9, 5.7)	6.4(5.6, 7.4)
D	>= 75 Years Age-Group	1,09,459	3,299	1.8(1.7, 1.9)	2.4(2.4, 2.5)	2.9(2.8, 3.1)	4.2(4, 4.3)		
1	Cemented Hip	4,072	95	1.3(1, 1.7)	1.9(1.5, 2.4)	2.6(2.1, 3.2)	3(2.4, 3.7)		
2	Non-Cemented Hip	47,183	1,697	2.3(2.2, 2.4)	3.0(2.9, 3.2)	3.5(3.3, 3.7)	4.9(4.6, 5.2)	7.1(6.4, 7.8)	
3	Hybrid Hip	58,204	1,507	1.4(1.3, 1.5)	2(1.9, 2.1)	2.5(2.4, 2.7)	3.7(3.4, 3.9)	4.7(4.4, 5.1)	
TOTAL		3,61,261	11,014						

Includes Mixed Ceramic / Mixed Ceramic and Cross-linked Polyethylene(XLPE) bearing surfaces ;
Restricted to Modern Prostheses [Prostheses in Current Circulation/Use in Australia].

Table 6.1.11 : - ***Cumulative Revision Rate percent of primary total hip arthroplasty performed on the Australian patient cohort with primary diagnosis OA, compared according to 4 different age groups (<55 Years, 55-64Years, 65-74Years and >=75 Years) and the fixation methods(Cemented, Non-Cemented & Hybrid) utilized during their respective primaries.***

- On the Implant Prostheses fixation method utilization aspect, an unique scenario is note for the Australian hip arthroplasty practices, wherein it was observed that Cementless and Hybrid Fixation cases made up the bulk of hip arthroplasty cases consistently through the entire year-wise records ever since 2003 to 2021 of the registry database, and are way higher than the global average share of Cementless & Hybrid Fixation cases, while Cemented fixation in hip arthroplasty continues to decline steadily.

- Such continued and steady domination of non-Cemented and more uniquely Hybrid fixation methods, over cemented fixations, is uncommon, against the other nations evaluated for their respective arthroplasty practices. Whether, such decline of cemented fixation has any link with the rising concerns for cardio-pulmonary risks involved arising from cemented fixation, as reported in some parts of the world, could not be pin-pointedly ascertained, due to lack of relevant literature and regulatory documentation though the expanse of the length & widths of Australian registry and healthcare databases.

- The decline of the Cemented fixation cases for primary THA of the Australian patient cohort was quite an expanse one, as it declined from 13.9% in 2003 to just 2.1% in 2021.

- The growth of Cementless fixation cases for primary THA of the Australian patient cohort was from 51.30% in 2003 to 61.60% in 2021, thereby implying an all-time majority lead on the fixation choice for hip arthroplasty in the Australian arthroplasty segment.

- The Hybrid fixation cases for primary THA of the Australian patient cohort rose from 34.80 % in 2003 to 36.30% in 2021.

- Non-cemented fixation based primary total hip arthroplasties are most sought after practice for patients without any major complexities and with a primary diagnosis of worsening osteoarthritis, which is closely followed by hybrid fixation methods (cemented stem with non-cemented acetabular shell / cup), in Australian hip arthroplasty practices.

- The general cumulative revision percent of the Australian patients with primary diagnosis osteoarthritis, who had received a primary total hip arthroplasty treatment, as per fixation methods used is presented as follows: -

AOANJRR 2022 : Cumulative Revision Percent of Primary THA by Fixation Methods for Australian Patients with OA as their Primary Diagnosis.									
SL No.	Fixation Method	No. of Cases	No. of Revisions	1 Year	3 Years	5 Years	10 Years	15 Years	16 Years
1	Cemented Hip	7,346	206	1.4(1.2, 1.7)	2.1(1.8, 2.4)	2.6(2.3, 3)	3.8(3.2, 4.5)	5.3(4.1, 6.7)	
2	Non-Cemented Hip	2,20,214	7,020	1.8(1.7, 1.8)	2.5(2.5, 2.6)	3(3, 3.1)	4.4(4.3, 4.5)	6(5.7, 6.2)	7.5(6.8, 8.3)
3	Hybrid Hip	1,33,701	3,788	1.3(1.3, 1.4)	2.0(1.9, 2.1)	2.5(2.5, 2.6)	3.9(3.8, 4.0)	5.4(5.2, 5.7)	6.6(6, 7.1)
TOTAL		3,61,261	11,014						
Includes Mixed Ceramic / Mixed Ceramic and Cross-linked Polyethylene(XLPE) bearing surfaces ; Restricted to prostheses in 2021 use									

Table 6.1.12 : - ***The overall cumulative Revision Percent of Primary Total Hip Arthroplasty by all Fixation Methods (Cemented, Non-Cemented and Hybrid) utilized for Australian Patients with primary diagnosis osteoarthritis.***

Patient-Reported Outcome Measures [PROMs] for Hip Arthroplasty of the Australian Patient Cohort: -

- The general practice of capturing patient reported outcome measures or PROMs as a critical and essentially vital parameter to ascertain the relative success or failure and fulfilment of the procedure objectives, by the regulatory and healthcare agencies in Australia, still lags much behind the global practice average, especially when other nations with reputed healthcare system are considered.

- This is due to the fact, that PROMs reporting still is not made mandatory for reporting or capturing, and whatever exists, belongs to the voluntary submission of data, outside of the globally prevailing protocols of capturing through the standardized MDS or Minimum Data Set forms.

- While, the actual on-ground practise of PROMs reporting as of the present pilot roll-out stages is performed through the arthroplasty conducting surgeons or through clinics and hospital staff through a separate portal (outside of the mainframe arthroplasty registry), though the entire procedure is governed and regulated by the same healthcare and academic institutions.

- As per the Australian Registry's 'June 2022 update on PROMs National Roll-Out, there were 217 participating institutions (Hospitals, Clinical Research Institutes, Clinics), with 733 participating arthroplasty surgeons, reporting for Pre-Operative PROMs for 55,120 cases & Post-Operative PROMs for 33,686 cases, with a general Pre-Operative PROMs Completion/Coverage Rate of 77.50% & Post-Operative Completion Rate of 66.10%.

- Around 84.7 % of the Patients reported change following Hip, Knee, and Shoulder Arthroplasty to be as "Much Better", in their post-operative evaluation vis-à-vis their QoL and functioning in the Pre-Op stage.

- Around 85.9% of the Patients were "Very Satisfied" or "Satisfied", following Hip, Knee, and Shoulder Arthroplasty in their Post-Op evaluation vis-à-vis their Pre-Op State.

- On the Patient Reported Outcomes Measures (PROMs) aspect of the hip arthroplasty patient cohort, in Australia, it was observed that much like the European practices of PROMs capture and measuring, the Australian Registry – AOANJRR uses the EuroQoL Visual Analogue Scale (EQ-VAS), the EuroQoL - 5 Dimensions-5Levels (EQ-5D-5L) and Oxford Hip Scores as the primary PROMs capturing tool and outcome measuring/benchmarking parameter.

- Both the OHS & EQ-VAS / EQ-5D-5L are globally accepted and well validated across clinical societies, health regulatory bodies, research institutes, hospitals and arthroplasty surgeons, as a definitive tool to get a proper scientifically explainable and logical response from the patient for best possible diagnosis.

- While the EQ-VAS / EQ-5D-5L is used in the exact similar form for knee arthroplasty as well, the Oxford Hip Score is also utilized for knee arthroplasty related PROMs recording with slight modifications such as replacing hip parameters and the 'hip' name-from-the-score with knee parameters and 'knee' respectively.

- Now, the Australian practices of PROMs recording/capturing, are presently only at its pilot rollout stage, which is facilitated through a separate portal, and not through the usual portal of arthroplasty reporting, through which the patient and the arthroplasty performing surgeon has to manually enter. This reporting procedure is still in its very infancy as was inferred after critically examining the published and other related accessible data in this regard, and therefore still has a long way to go.

- Considering the PROMs capturing mechanism in Australia is still in its primary roll-out or infancy stages, the number of actual verified patients with pre-operative and post-operative stated PROM inputs is generally lower, than it would ideally be, as per the overall arthroplasty scenario scale in Australia.

- Now since a lot smaller number of patients are actually reporting their respective patient-reported outcome measures, compared to the original number of recipients of an arthroplasty whether hip or knee, have participated in the process, therefore it is hard to track or get the actual real-time patients' own opinions on the treatment they had received, and the improvement/degradation in their general living standards after a foreign prosthesis has replaced their diseased joint / failing bone ends through an arthroplasty procedure.

- It is therefore inferred by this research that making PROMs capturing mandatory and re-routing the recording process from a separate portal to the mainframe MDS (Minimum Data Set) entry register or database, would channel the lost PROMs data into the mainstream enabling a higher and maximum amount of data possible.

- The basic findings of the PROMs responses from Australian hip arthroplasty patient cohort, reveal that on general broad terms, the patients have sensed a positive change in their respective life and health standards following a hip arthroplasty, vis-à-vis their life and health standard levels during the pre-operative period.

- When the PROMs scores obtained was tallied and compared against the PROMs for revision hip arthroplasties that were due to the most terrible causes such as a severe infection attack post-op, it was found that with increasing ASA Grades of the patients which signified the general morbidity level of the patient, the resulting post-op PROMs score, following a revision hip arthroplasty decreased. The scenario was identical and similar when the BMI Indices of the respective patients are compared in the same format, wherein with increasing BMI Index, the resulting post-op PROMs score decreases.

- Now, though on first glance, the general observation that could possibly arise from the above-mentioned findings is that it highlights the need for a healthy lifestyle to stay fit and keep the BMI under control, much in line with the global buzz/hype of fitness in the present day. Having said that, another counter argument arises, that it is logically acceptable that an increasing ASA literally and practically makes a patient closer to near death or death situations, and therefore, on expected lines, the PROMs outcomes from a Higher ASA graded person who has faced the trauma of a revision arthroplasty would definitely be lower than a normal person or a person who has a lower ASA grade, undergoing similar revision procedures. However, the question arises how a higher BMI could directly be implied or attributed

towards a greater risk involvement, or as a cause or catalyst for poor recovery/suppressed and lowered response to medications and rehabilitative post-operative treatments, or being highly prone for infections, thereby resulting for comparatively lower PROM scores.

- Though extremely overweight or highly obese patients could be point of concern due to related other non-arthroplasty & non-orthopaedic related risks and conditions, but there have quite a few examples on the practical life wherein it is seen a person/patient with a healthy body or with a higher BMI is more endemically and systematically fit than a fitness freak patient.

<u>Australian Hip Arthroplasty Practices: - Oxford Hip Score based PROMs: -</u>

- The overall Oxford Hip Score of the prospective patients for primary THA and recipient patients were duly captured pre- and post-operatively, and their relative mean and median values are calculated and are presented through following tabulation: -

AOANJRR 2022 : Mean Pre-Op & Post-Op Oxford Hip Score PROMs capture for Primary THA in Australian Cohort with Primary Diagnosis OA.

SL No.	Type of Arthroplasty	Number of Cases	Pre-Operative		Number of Cases	Post-Operative	
			Mean ± S.D	Median		Mean ± S.D	Median
1	Total Hip Arthroplasty	13,409	20.69 ± 8.92	21	8,484	41.24 ± 7.44	44

Data compiled only for prostheses used for THA in 2021 for the Australian cohort ; PROMs Reporting is still on roll-out stages in AUS & therefore is not mandatory for all patients to fill in ; Interested parties / Institutes participating can encourage PROMs coverage by allowing patients to register their feedback on a separate Registry governed portal for PROMs capture.

Table 6.1.13 : - ***The Mean Pre-Operative and Post-Operative Oxford Hip Scores (O.H.S) recorded for Primary Total Hip Arthroplasty (THA) of the Australian Patient Cohort with Primary Diagnosis OA.***

- In line with the above-mentioned observations and inferences, the pre-operative OHS is found to be decreasing with an increasing ASA and BMI grade. However, surprisingly, for the normal group of patients who doesn't require a revision, it is observed that the post-operative improvement is similar in both the categories.

- Australian patients belonging to the Obese Class 3 of the globally accepted and used BMI Indices format, who had received a primary hip arthroplasty, formulated the largest pre-op vis-à-vis post-op, change in the PROMs scores, based on 771 Pre-Op and 487 Post-Op OHS PROMs responses.

Mean Pre-Operative PROM Score = **16.22** [**15.55, 16.88**]

↓ **Net Change = +22.80[22.00, 23.60]**

Mean Post-Operative PROM Score = **39.02** [**38.32, 39.71**]

- The Australian patients belonging to the Obese Class 2 of the globally accepted and used BMI Indices format, who had received a primary hip arthroplasty, formulated the second largest pre-op vis-à-vis post-op, change in the PROMs scores, based on 1,514 Pre-Op and 981 Post-Op OHS PROMs responses.

Mean Pre-Operative PROM Score = **17.36** [**16.84, 17.87**]

↓ **Net Change = +21.56[20.99, 22.12]**

Mean Post-Operative PROM Score = **38.91** [**38.38, 39.44**]

- Overall, the observed and noted changes in the Oxford Hip Scores of the Australian Patient Cohort, undergoing primary total hip arthroplasty with primary diagnosis OA or osteoarthritis, as per patient's respective ASA Grade and BMI Indices categories are as follows: -

AOANJRR 2022:- Mean Pre-Op & Post-Op Oxford Hip Score (O.H.S) in Primary THA of Australian Patient Cohort with Primary Diagnosis OA by BMI Categories.						
SL No.	BMI Category	Pre-Operative		Post-Operative		Change in OHS [Pre-Op vis-à-vis Post Op]
		No. of Cases	Mean	No. of Cases	Mean	
1	Underweight (<18.50)	84	21.75	52	43.62	21.86
2	Normal(18.5-24.99)	2,618	22.16	1,713	41.86	19.7
3	Pre-Obese(25-29.99)	4,787	21.17	2,986	41.13	19.96
4	Obese Class 1(30-34.99)	3,517	19.15	2,196	40.15	21
5	Obese Class 2(35-39.99)	1,514	17.36	981	38.91	21.56
6	Obese Class 3(>= 40)	771	16.22	487	39.02	22.8
Restricted to Modern Prostheses only ; Adjusted for Age, Gender & ASA Category ; PROMs reporting is Self-Discretionary as on date in Australia.						

Table 6.1.14 : - ***Mean Pre-Operative vis-à-vis Post-Operative Oxford Hip Score (O.H.S) for Primary Total Hip Arthroplasty (THA) of the Australian Patient Cohort with Primary Diagnosis OA as per Patient's respective BMI Category.***

AOANJRR 2022:- Mean Pre-Op & Post-Op Oxford Hip Score (O.H.S) in Primary THA of Australian Patient Cohort with Primary Diagnosis OA as per ASA Categories.						
SL No.	ASA Category	Pre-Operative		Post-Operative		Change in OHS [Pre-Op vis-à-vis Post Op]
		No. of Cases	Mean	No. of Cases	Mean	
1	ASA 1	1,129	23.02	687	42.58	19.56
2	ASA 2	7,553	20.67	4,830	41.12	20.45
3	ASA 3	4,575	18.58	2,879	39.44	20.86
4	ASA 4	140	14.85	84	37.59	22.73
Restricted to Modern Prostheses only ; Adjusted for Age, Gender & BMI Category ; PROMs reporting is Self-Discretionary as on date in Australia.						

Table 6.1.15 : - ***Mean Pre-Operative vis-à-vis Post-Operative Oxford Hip Score (O.H.S) for Primary Total Hip Arthroplasty (THA) of the Australian Patient Cohort with Primary Diagnosis OA as per Patient's respective ASA Category.***

- The impact or general outcome of the Oxford Hip Score as per the fixation method utilized in the primary THA of patients aged both <75 and >= 75 years in Australia, with the biggest margin of pre-op vs post-op change/improvement in the OHS score observed in cemented categories for both the age groups, while the cementless or non-cemented category came a close second in both the age groups, implying a small margin of difference based on the fixation method utilized on PROMs outcome in THAs. The overall scenario based on this condition is presented as follows: -

AOANJRR 2022 : Mean Pre-Op & Post-Op Oxford Hip Score for Primary THA of the Australian Patient Cohort With Primary Diagnosis OA as per the Fixation Method utilized.							
SL No.	Age Group	Femoral Fixation Method	Pre-Operative		Post-Operative		Change in OHS [Pre-Op vis-à-vis Post Op]
			No. of Cases	Mean	No. of Cases	Mean	
1	<75	Non-Cemented	6,697	19.83(19.47, 20.20)	4,031	40.38(40.00, 40.75)	20.54(20.27, 20.82)
2		Cemented	3,418	18.74(18.32, 19.16)	2,371	39.62(39.20, 40.04)	20.88(20.51, 21.25)
3	>=75	Non-Cemented	1,047	20.39(19.79, 21.00)	620	39.78(39.14, 40.42)	19.39(18.68, 20.09)
4		Cemented	1,893	19.27(18.78, 19.76)	1,211	39.86(39.35, 40.37)	20.59(20.08, 21.11)
Restricted to Prostheses in 2021 usage ; Adjusted for gender, ASA Score and BMI Category							

Table 6.1.16 : - ***Mean Pre-Operative and Post-Operative Oxford Hip Score and the Respective Change in Pre-Op vis-à-vis Post-Op OHS Score for Primary THA of the Australian Patient Cohort with Primary Diagnosis OA, as per Fixation Method used.***

- The Mean Oxford Hip Scores of the patients in Australia who had received a primary total hip arthroplasty when compared using the respective patient gender groups, against two subsets of age groups: less than 65 and greater than equal to 65, gives an interesting scenario, wherein it is seen that patients irrespective of their gender, who had age of less than 65 Years, registered the biggest Pre-Op vis-à-vis post-Op change in their respective Oxford Hip Scores or OHS.

- Male primary THA patients aged less than 65 Years had a mean net positive improvement or gain in their post-operative OHS scores, by a difference of **20.91** score points, while Female primary THA patients, belonging to the same age-group category posted a net mean positive improvement or gain in their post-operative OHS scores by even a slightly greater margin of **21.76** score points.

- This particular findings re-affirms that although the youngest age group, who doesn't belong to the prime age-group category for arthroplasty, which is around 65 – 75 years of age, bears a significant risk of postoperative prosthesis failure, due to their hyperactive lifestyle, mobility and other factors that often as reported promulgates to periprosthetic fractures, but it is this category of patients, who are actually benefitted the most, through the means of an artificial joint replacement that relieves them from their existing clutches of disability or ailments, that is evident through their own self-analysis based PROM reporting of OHS scores.

- The other details regarding the above, are presented through the following table: -

AOANJRR 2022 : Mean Pre-Op & Post-Op Oxford Hip Score in Primary THA by Gender and Age of Australian Patients with OA as their Primary Diagnosis							
SL No.	Patient Gender	Age	Pre-Operative		Post-Operative		Change in OHS [Pre-Op vis-à-vis Post Op]
			No. of Cases [N]	Mean	No. of Cases [N]	Mean	
1	Male	<65	2,868	19.54(19.12, 19.97)	1,753	40.46 (40.02, 40.90)	20.91(20.49, 21.33)
2		>= 65	3,393	21.31(20.90, 21.71)	2,182	40.89 (40.48, 41.31)	19.59(19.21, 19.97)
3	Female	<65	2,571	17.55(17.11, 17.99)	1,628	39.31(38.36, 39.76)	21.76(21.32, 22.20)
4		>= 65	4,577	18.94(18.55, 19.33)	2,921	39.27(38.88, 39.67)	20.33(20, 20.66)
PROMs Reporting Not Mandatory Yet & in Roll-Out phases ; Restricted to Prostheses in 2021 use ; Adjusted for ASA score and BMI Category							

Table 6.1.17 : - ***Mean Pre-Operative and Post-Operative Oxford Hip Score and the Respective Change in Pre-Op vis-à-vis Post-Op OHS Score for Primary THA of the Australian Patient Cohort with Primary Diagnosis OA, as per respective Patient Gender and Age Groups segregated into two groups (<65 & >=65).***

<u>Australian Hip Arthroplasty Practices: - EQ-VAS / EQ-5D-5L based PROMs: -</u>

- In Australian hip arthroplasty practices, patient-reported outcome measures are also captured through the EuroQoL Visual Analogue Scale (EQ-VAS) and the EQ-5D-5L (EuroQoL-5Dimensions-5Levels) based patient-reported outcome capturing tools, both during preoperative and post-operative stages.

- The mean pre-operative EQ-VAS score for the THA recipient patient cohort in Australia was 66.50. The mean EQ-VAS score improved to 80.48, in the subsequent post-operative window of the same Australian patient cohort.

- Since the EQ-VAS score is all about the general health status and the relative functionality in daily conditions, the pre-op vis-à-vis post-op change in the score, highlights, exactly the direction of improvement or degradation in the patient's lives.

- Australian female patients, aged less than 65 years of age i.e., less than the core group of arthroplasty recipients, posted the biggest margin of improvement in their pre-to-post score, wherein the score improved by a mean of 16.66 points, and maximum to 17.61 points.

- Comparatively male Australian patients who received a primary THA-based intervention for their failing hips, posted a lower improvement margin than their equivalent female counterparts, across all age-group categorizations.

- The best improvement score for Australian male recipients of primary THA was for those who aged less than 65, with a mean score of 14.98 points and a maximum of 15.89 points. While male patients aged greater than 65, posted the worst margin of mean improvement in the EQ-VAS scores, at 11.27 points.

- The mean and median pre-operative and post-operative scores for Australian primary THA recipients are presented through the following tabulation: -

AOANJRR 2022 : Mean Pre-Op & Post-Op EQ-VAS(EuroQoL Visual Analogue Scale) PROMs capture for Primary THA in Australian Cohort with Primary Diagnosis Osteoarthritis.							
SL No.	Type of Arthroplasty	Number of Cases	Pre-Operative		Number of Cases	Post-Operative	
			Mean ± S.D	Median		Mean ± S.D	Median
1	Total Hip Arthroplasty	13,418	66.50 ± 20.07	73	8,461	80.48 ± 16.24	85
Data compiled only for prostheses used for THA in 2021 for the Australian cohort ; PROMs Reporting is still on roll-out stages in AUS & therefore is not mandatory for all patients to fill in ; Interested parties / Institutes participating can encourage PROMs coverage by allowing patients to register their feedback on a separate Registry governed portal for PROMs capture.							

Table 6.1.18 : - ***Tabulation illustrating the Mean & Median Pre-Operative and Post-Operative EQ-VAS scores as PROMs responses of the Australian Patient Cohort with Primary Diagnosis OA, receiving a primary THA as an intervention for their disease.***

- The patient gender and age-linked distribution of the mean pre-operative and post-operative EQ-VAS scores, with respective changes in their scores are presented through the following tabulation: -

Net Changes in the Mean Pre-Op & Post-Op EQ-VAS Health Score of Australian Patients with OA, to have undergone a Primary THA, categorized as per Patient Gender and Age-Group.							
SL No.	Patient Gender	Age	Pre-Operative		Post-Operative		Change in Score
			No. of Cases [N]	Mean (95% C.I)	No. of Cases [N]	Mean (95% C.I)	
1	Male	<65	2,866	62.37(61.39, 63.34)	1,750	77.34(76.36, 78.33)	14.98(14.07, 15.89)
2		>= 65	3,403	67.94(67, 68.88)	2,167	79.21(78.27, 80.15)	11.27(10.44, 12.09)
3	Female	<65	2,572	60.74(59.73, 61.74)	1,630	77.40(76.39, 78.41)	16.66(15.72, 17.61)
4		>= 65	4,577	64.67(63.78, 65.56)	2,914	78.24(77.35, 79.13)	13.57(12.86, 14.28)
PROMs Reporting Not Mandatory Yet & in Roll-Out phases ; Restricted to Prostheses in 2021 use ;							

Table 6.1.19 : - ***Tabulation illustrating the Change in Mean Pre-Operative and Post-Operative EQ-VAS scores as PROMs responses of the Australian Patient Cohort with Primary Diagnosis OA, to signify the general sense of health quality and living standards improvement, through a Primary THA based intervention for their disease.***

- Australian patients with the highest co-morbidity level, categorized as an ASA Grade 4 patient undergoing a primary THA as an intervention to alleviate their diseased condition, primarily due to a progressively worsening osteoarthritis, posted the lowest mean pre-vis-à-vis post-operative improvement their general health quality and living standards, as indicated through the EQ-VAS score.

- While the best improvement based on the general co-morbidity level of the patient categorized by the ASA Grade, was of the patients belong to ASA – 2, with a positive change of 14.13 points between the mean post-operative and pre-operative EQ-VAS scores. The overall distribution of the ASA grade-based distribution of mean scores and their relative change, categorized as per the ASA category is given by the following tabulation: -

Net Changes in the Mean Pre-Op & Post-Op EQ-VAS Health Score of Australian Patients with OA as their Primary Diagnosis, undergoing a Primary THA categorized their respective by ASA Grading as per General Co-Morbidity Status.						
SL No.	ASA Category	Pre-Operative		Post-Operative		Change in Score
		No. of Cases [N]	Mean	No. of Cases [N]	Mean	
1	ASA 1	1,130	70.61 (69.39, 71.83)	684	84.11 (82.88, 85.35)	13.50 (12.05, 14.95)
2	ASA 2	7,558	66.77 (66.26, 67.29)	4,811	80.91(80.39, 81.42)	14.13(13.58, 14.69)
3	ASA 3	4,579	62.35 (61.77, 62.93)	2,877	75.96 (75.37, 76.54)	13.61 (12.89, 14.32)
4	ASA 4	139	58.62 (55.35, 61.89)	84	70.22 (66.86, 73.58)	11.60 (7.44, 15.76)
PROMs Reporting Not Mandatory Yet & in Roll-Out phases ; Restricted to Prostheses in 2021 use ; Adjusted for ASA score and BMI Category						

Table 6.1.20 : - ***Tabulation illustrating the Change in Mean Pre-Operative and Post-Operative EQ-VAS scores as PROMs responses of the Australian Patient Cohort with Primary Diagnosis OA, undergoing a Primary THA based intervention for their disease, categorized as per their ASA-Grade categorization as per their respective Co-Morbidity statuses.***

- The improvement of the Australian patients undergoing a primary THA based on various parameters of outcome as generally described by the patients are tabulated and plotted as follows: -

AOANJRR 2022 : Pre-Op vis-à-vis Post-Op Changes in EQ-VAS Health Score & Quality of Life(QoL) post Primary THA of Australian patients with Primary Diagnosis OA.					
SL No.	**Outcome Parameter**	**Better**	**No Change**	**Worse**	**Total**
1	**Mobility**	**82.3**	**14**	**3.7**	**100**
2	**Personal Care**	**56.3**	**38.9**	**4.8**	**100**
4	**Pain / Discomfort**	**84.6**	**12.8**	**2.6**	**100**
5	**Anxiety / Depression**	**39.8**	**53.4**	**6.8**	**100**
6	**EQ-VAS Health Score Change**	**74.3**	**5.3**	**20.4**	**100**

Table 6.1.21 : - ***Tabulation illustrating the Australian Patient Described Upgradation/Degradation of their General Health Status and Living Standards, in terms of various broad Outcome Parameters, post-operatively to a Primary THA intervention for their failing hips due to worsening Osteoarthritis.***

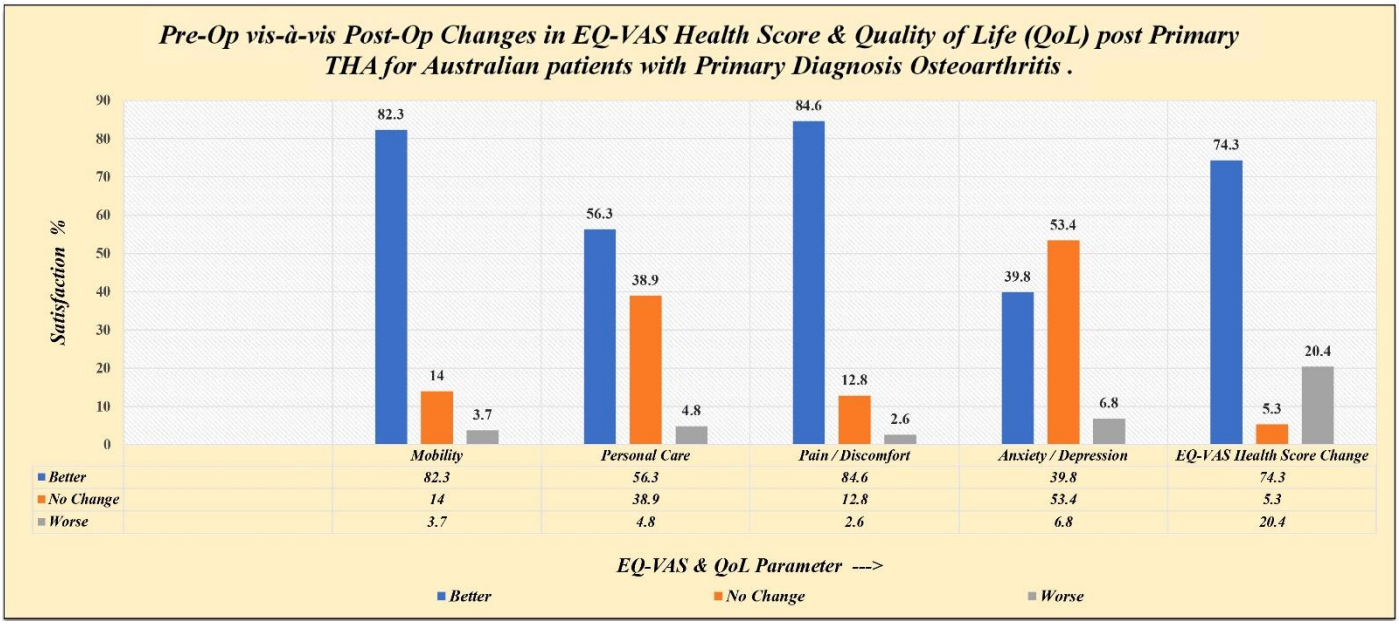


Figure 6.1.1 : - ***Graph Plot of "Patient Satisfaction% vs EuroQoL Health Outcome Parameter" illustrating the Australian Patient Described Upgradation/Degradation of their General Health Status and Living Standards, in terms of various broad Outcome Parameters, post-operatively to a Primary THA intervention for their failing hips due to worsening Osteoarthritis.***

General Australian Patient-Reported Satisfaction Levels from their Total Hip Arthroplasty.

- The general level of patient reported satisfaction from their undergone primary total hip arthroplasty procedure is critical to exemplify the extent of the justification of a surgical hip replacement intervention for non-critical and non-fracture-based patients.

- This is captured through the mean pre-operative vis-à-vis post-operative patient reported satisfaction levels, which are presented through the following tabulations and related graph plots: -

General level of Australian Patient Reported Satisfaction from the undergone Primary THA categorized as per Patient Gender & Age-Group for patients with a Primary Diagnosis of Progressively Worsening Osteoarthritis.

SL No.	Gender	Age	Very Satisfied			Satisfied			Neutral			Dissatisfied			Very Dis-satisfied			TOTAL		
			No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category
1	MALE	<65	1,347	76.9	21.7	250	14.3	18.3	57	3.3	15.8	30	1.7	17.1	67	3.8	17.9	1,751	100	20.7
		>= 65	1,586	72.8	25.6	358	16.4	26.2	78	3.6	21.6	43	2	24.6	115	5.3	30.7	2,180	100	25.7
2	FEMALE	<65	1,204	74.2	19.4	242	14.9	17.7	69	4.3	19.1	40	2.5	22.9	67	4.1	17.9	1,622	100	19.1
		>= 65	2,058	70.5	33.2	515	17.6	37.7	157	5.4	43.5	62	2.1	35.4	126	4.3	33.6	2,918	100	34.4
TOTAL			6,195	73.1	100	1,365	16.1	100	361	4.3	100	175	2.1	100	375	4.4	100	8,471	100	100

Table 6.1.22 : - ***Tabulation illustrating the Australian Patient Gender and Age-Group linked distribution of the General Patient Reported Satisfaction level from their undergone Primary THA based intervention for their primary diagnosis of Progressively Worsening Osteoarthritis.***

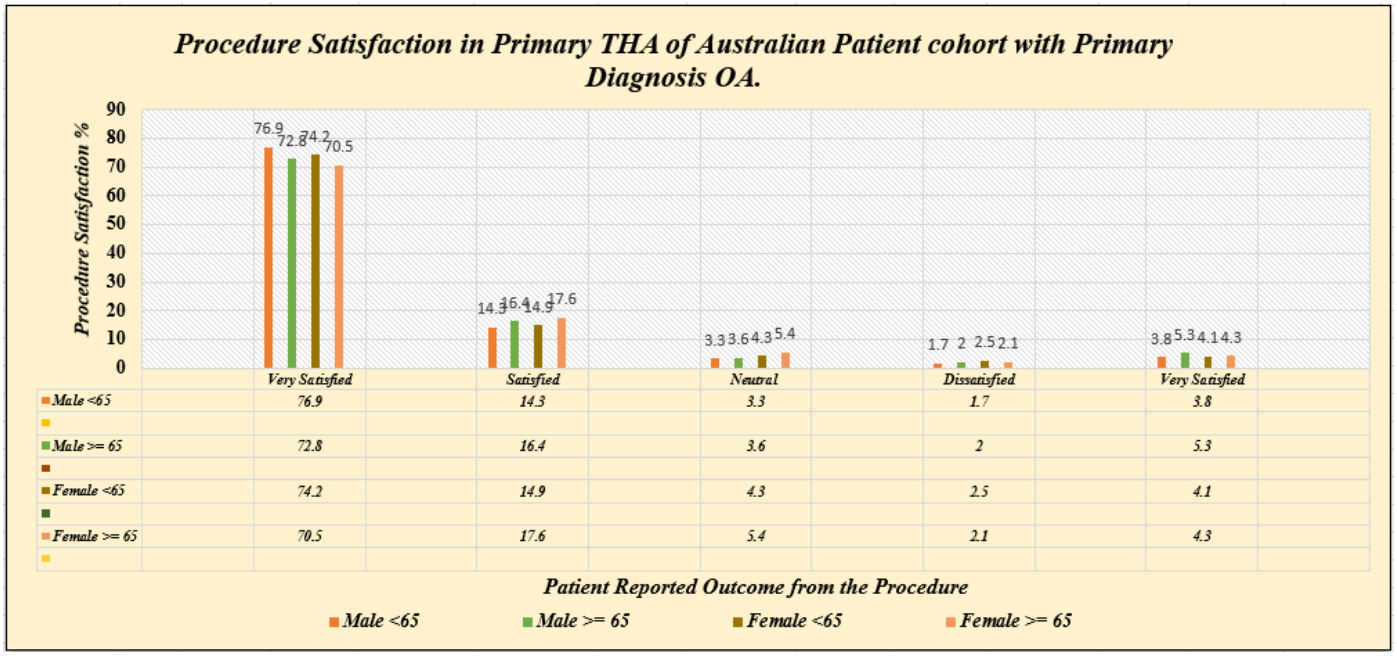


Figure 6.1.2 : - ***Graph Plot of "Patient Satisfaction% vs Patient Satisfactory Level Outcome Parameter" described by the Australian Patient, post-operatively to a Primary THA intervention for their failing hips due to worsening Osteoarthritis.***

AOANJRR 2022 : Patient expressed Procedure satisfaction for Primary THA in Australian Cohort with Primary Diagnosis Osteoarthritis.

SL No.	Type of Arthroplasty	Very Satisfied		Satisfied		Neutral		Dis-satisfied		Very Dis-satisfied		TOTAL	
		No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall
1	Total Hip Arthroplasty	6,195	73.10%	1,365	16.10%	361	4.30%	175	2.10%	375	4.40%	8,471	100%

Data compiled only for prostheses used for THA in 2021 for the Australian cohort ; PROMs Reporting is still on roll-out stages in AUS & therefore is not mandatory for all patients to fill in ; Interested parties / Institutes participating can encourage PROMs coverage by allowing patients to register their feedback on a separate Registry governed portal for PROMs capture.

Table 6.1.23 : - ***Tabulation illustrating the Overall Australian Patient Reported Satisfaction level from their undergone Primary THA based intervention for their primary diagnosis of Progressively Worsening Osteoarthritis.***

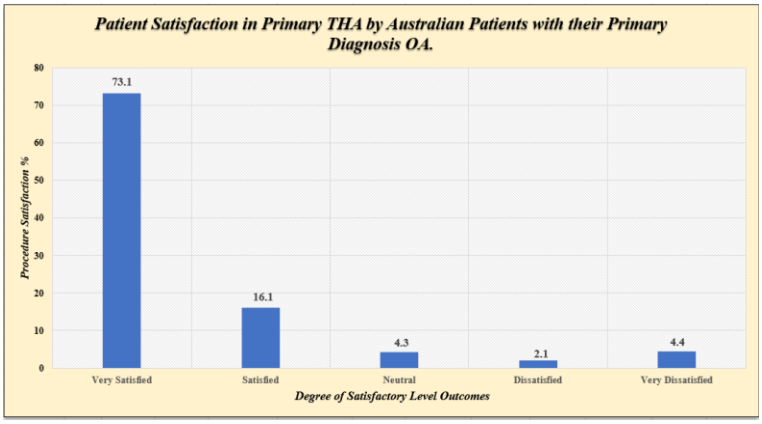


Figure 6.1.3 :- ***Graph plot to illustrate the Overall Australian Patient Reported Satisfaction levels from their undergone Primary THA procedure, as much was plausible to track by this research probe.***

- The satisfaction level from the undergone primary total hip arthroplasty procedure as described by the Australian patients, categorized as per the fixation method applied and their respective age-group is tabulated and plotted as follows: -

General level of Patient Reported Satisfaction of Australian Patient Cohort with Primary Diagnosis OA, from their undergone Primary THA, compared whether Cement was used for the Fixation of the Patient Cohort and their relative Age-Group.

SL No.	Gender	Age	Very Satisfied			Satisfied			Neutral			Dissatisfied			Very Dis-satisfied			TOTAL		
			No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this	No. of Cases	% of Overall	% of this Category
1	Non-Cemented	<75	3,007	74.7	49.9	615	15.3	46.7	164	4.1	47.1	69	1.7	41.3	169	4.2	46.4	4,024	100	49
	Cemented		1,704	71.9	28.3	388	16.4	29.5	108	4.6	31	54	2.3	32.3	115	4.9	31.6	2,369	100	28.8
2	Non-Cemented	>= 75	439	71	7.3	114	18.4	8.7	20	3.2	5.7	21	3.4	12.6	24	3.9	6.6	618	100	7.5
	Cemented		874	72.3	14.5	200	16.5	15.2	56	4.6	16.1	23	1.9	13.8	56	4.6	15.4	1,209	100	14.7
TOTAL			6,024	73.3	100	1,317	16	100	348	4.2	100	167	2	100	364	4.4	100	8,220	100	100

Table 6.1.24 : - ***Tabulation illustrating the Overall Australian Patient Reported Satisfaction level from their undergone Primary THA based intervention for their primary diagnosis of Progressively Worsening Osteoarthritis, categorized as per whether Cement was utilized for the fixation, and their respective Age-Group.***

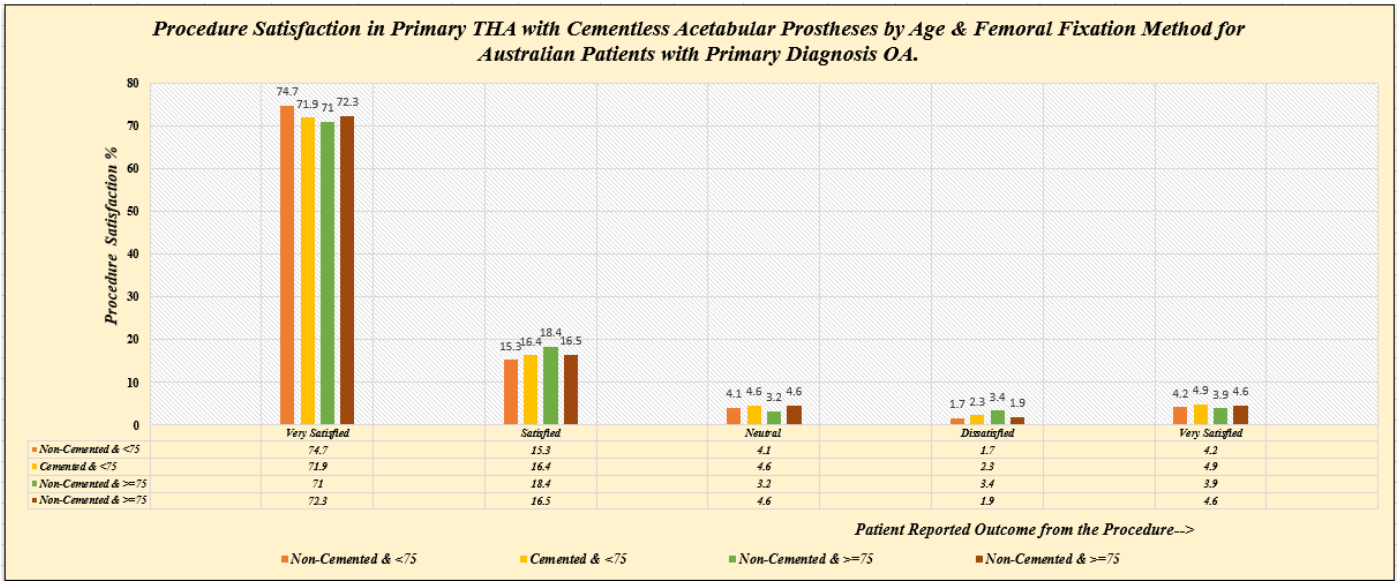


Figure 6.1.4 : - ***Graph Plot of "Patient Satisfaction% vs Patient Satisfactory Level Outcome Parameter" described by the Australian Patient, post-operatively to a Primary THA intervention as per their Age-Group and Cement Utilization status for the prosthesis fixation during the arthroplasty procedure.***

The Prosthesis Specific Aspect of Hip Arthroplasty in Australia: -

- The prosthesis-specific aspects such as the type of prosthesis used for primary or partial hip arthroplasty, their respective size, the material of their making, their related and inter-related parameters, with respect to the outcomes in terms of revision rates and other metrics are discussed hereon in this part.

- The Australian registry has widely published data on respective implant performance and other related factors, and also certain special forms of prosthesis that are more sophisticated or modern in existence, which have been in use and circulation in other parts of the world as well, but the Australian registry database provides a more comprehensive data regarding their outcome patterns.

- One such example could be the use of "**Mini-Hip**" or in biomedical terms, 'Mini Femoral Stems, also known and referred to as Mini-Stems. Now, although there's been a wide utilization of such mini-stems across the globe and particularly in the UK (since the UK was evaluated during the course of this research), for whom, there was a separate segment of reporting in its nationwide arthroplasty database, so far there was no proper registry officiated definition given or applied for such stems, as was found during the course of this investigation.

- The Australian registry defined a mini-stem as a "***Short Cementless femoral stem, where fixation is designed to be entirely metaphyseal***", i.e., the fixation of the stem is only till the metaphyseal region of the calcified bone, where active bone growth occurs, aiming the stem is resorbed into the bone structural complex by the means of natural adaptation and fixation.

- These femoral stems are also aimed to enable femoral neck sparing, in patients to be specific in young patients who have otherwise a good femoral integrity, and the neck region is also intact, with damages confined only to the acetabular socket or femoral head, as is observed in the case of hip dysplasia when the hip joint is not adequately developed due to the acetabulum being too shallow for the femoral head to fit in.

- Such mini-stems have been utilized in other indications as well, other than hip dysplasia.

- There was a total of 7,528 mini-stem-based arthroplasty procedures in Australia, with 1,504 of them happening in 2021 itself, accounting for a 10.90% YoY increase since its usage numbers from 2020. Now, though these represent less than 1.90% of all procedure numbers, the basic outcomes arising out of a mini-stem-based hip arthroplasty is concerned are encouraging, if results for the Australian patient cohort are to be concerned with. These are discussed as follows: -

  a. The 8 Year cumulative revision rate for primary total hip arthroplasty using a mini femoral stem is 2.80% compared to the 3.70% average for other femoral stems. Beyond 8 years, no data regarding the usage of Mini-Stems were available for access.

  b. Mini-stems have a low revision rate in the immediate post-operative period, as is observed when the 6 months patient follow-up data is considered, however, these mini femoral stems or mini-stems in general involve the risks of a periprosthetic fracture and loosening, in greater proportions than the conventional stems, since the acceptance and fixation of such stems is almost dependent on the natural anatomical properties, albeit such risks converting to actual failure numbers are very low.

  c. The performance of Mini stems and how their respective performance stand out against the conventional femoral stems in terms of patient-based outcome, i.e., through revision rate analysis are presented as follows: -

AOANJRR 2022 : Cumulative Revision Percent of Comparison between Mini-Stems vs Standard/Conventional Femoral Stems used for Primary THA of the Australian Patient Cohort with Primary Diagnosis OA.

SL No.	Stem Type	No. of Cases	No. of Revisions	1 Year	3 Years	5 Years	8 Years	15 Years	20 Years
1	Mini Stem	7,528	166	1.8(1.5, 2.1)	2.3(2, 2.7)	2.8(2.3, 3.3)	2.8(2.4, 3.4)		
2	Other Femoral Stem	3,89,733	12,932	1.6(1.5, 1.6)	2.3(2.3, 2.4)	2.9(2.8, 2.9)	3.7(3.6, 3.8)	6.3(6.2, 6.5)	8.4(8.1, 8.8)
TOTAL		3,97,261	13,098						

Table 6.1.25 : - ***The overall cumulative Revision Percent comparison between the Mini-Stems vs Standard/Conventional Femoral Stems used for the Primary Total Hip Arthroplasty of the Australian Patient Cohort with primary diagnosis OA.***

AOANJRR 2022 : Cumulative Revision Percent of the 6 Different Mini-Stems that are Recorded with the Registry Database for Primary THA on Australian Patients with Primary Diagnosis OA, with atleast 50 Reported Procedures.						
SL No.	Stem Name [Mfg.Co./Supplier] - ODEP Rating	Total No. of Cases	No. of Revisions	1 Year	3 Years	5 Years
1	Mini Hip [Corin Group] - 10A*	1,271	42	2.4(1.7, 3.4)	3.1(2.2, 4.2)	3.6(2.6, 4.8)
2	Mini Max [Medacta Int'l] - Unrated	379	21	4.5(2.8, 7.2)	5.8(3.8, 8.8)	
3	Optimys [Mathys/Enovis] - 7A*	2,448	45	1.3(0.9, 1.8)	1.9(1.4, 2.6)	2.8(2.0, 3.9)
4	Taperloc Microplasty [ZimmerBiomet] - 10A	3,395	56	1.6(1.2, 2.1)	1.8(1.4, 2.4)	1.8(1.4, 2.4)
6	Other Mini Stems [2]	35	2	2.9(0.4, 18.6)	5.9(1.5, 21.6)	5.9(1.5, 21.6)
TOTAL		7,528	166	Restricted to Modern Prostheses Only ; All MoM Procedures Excluded; Historical 5Years Data was Available at the time of this Compilation.		

Table 6.1.26 : - ***The overall cumulative Revision Percent of the 6 Different Mini-Stems with a minimum of 50 individual registered arthroplasty procedures that had their usage recorded within the Registry database for Primary Total Hip Arthroplasty of the Australian Patients with Primary Diagnosis OA, along with their ODEP Rating Status.***

- Such modern designs of prosthesis sophistication find limited utilization for the general proportion of patients and therefore it is essential to evaluate and present the most commonly utilized prostheses combinations, based on the respective fixation method deployed to implant them on the patient.

- The Exeter V40 femoral stem and head combination is the most commonly deployed femoral component for primary THAs of the Australian patient cohort, with a cemented fixation, along with other acetabular combinations, though in general the utilization numbers with a cemented approach are comparatively lower than what is usually seen in other nations which were evaluated during this research process.

- The most commonly utilized cemented total hip prostheses combinations, with both femoral and acetabular components for primary total hip arthroplasty of the Australian patient cohort are presented as follows: -

Distribution of the Cumulative Revision Percent of Cemented Modern Prosthesis Combinations(in Current Circulation & Use) used in Primary Total Hip Arthroplasty of the Australian Patient Cohort with atleast >500 Procedures [Data Period : 1st September, 1999 to 31st December, 2021], along with respective Manufacturer/Supplier details & ODEP Rating Statuses.												
SL No.	Femoral Component	Acetabular Component	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Total No. of Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	C-Stem AMT	Marathon	Depuy Synthes	15A*/7A[C-Stem AMT] ; 13A*[Marathon]	610	18	1.9(1.1, 3.4)	2.5(1.5, 4.2)	3(1.9, 4.9)			
2	CPCS	Reflection (Cup)	Smith & Nephew	15A[CPCS] ; 15A* / 15A / Lapsed	1,095	98	2(1.3, 3.1)	3.1(2.2, 4.4)	4(2.9, 5.5)	8.7(6.8, 11.3)	19.1(15.4, 23.5)	
3	CPT	ZCA	Zimmer Biomet	15A*[CPT(CoCr)]/ODEP Rating Withdrawn[CPT(SS)] ; 15A*	1,047	51	1(0.5, 1.8)	2.3(1.6, 3.5)	2.9(2, 4.2)	5.1(3.7, 6.9)	7.1(5.1, 9.9)	12.2(8.2, 17.7)
4	Exeter V40	Contemporary	Stryker	15A* / 15A* [Both]	5,704	374	1.7(1.4, 2.1)	2.9(2.5, 3.4)	3.6(3.1, 4.1)	6.2(5.5, 7)	9.8(8.7, 11)	
5		Exeter Contemporary			3,438	195	1.4(1.1, 1.9)	2.4(1.9, 2.9)	3.1(2.6, 3.8)	4.8(4.1, 5.7)	8.3(7, 9.7)	
6		Exeter X3 Rimfit			5,237	141	1.5(1.2, 1.9)	2.3(1.9, 2.8)	2.9(2.4, 3.4)	3.6(3, 4.3)		
7	Spectron EF	Reflection (Cup)	Smith & Nephew	15A[Spectron-EF] ; 15A* / 15A / Lapsed[Reflection(Cup)]	1,662	137	1.1(0.7, 1.7)	1.8(1.3, 2.6)	2.9(2.2, 3.9)	7.2(5.9, 8.8)	13.3(11.1, 15.9)	18.4(14.6, 23)
8	Other [263]				5,523	259	2.7(2.3, 3.2)	3.8(3.3, 4.3)	4.4(3.9, 5.1)	6.5(5.6, 7.5)	10.8(8.9, 13)	
Cumulative Total					24,316	1,273	*Figures are of Modern Prostheses in Circulation/Use as of 2021 only ; Some Cementless Components have been Cemented for Patient Specific Requirements ; All MoM procedures are excluded for Reasons discussed separately ;*					

Table 6.1.27 : - ***Tabulation illustrating the Most Commonly Utilized Cemented Total Hip Prostheses Combinations[Femoral + Acetabular] for the Primary THA of the Australian Patient Cohort, along with their Cumulative Revision Rate percentages across various Post-operative follow-up time points and ODEP Rating Statuses.***

- Comparatively, non-cemented and hybrid fixation based hip prostheses combinations were implanted in greater proportions on the general Australian patient cohort, with majority of the utilized prostheses with an ODEP Rating status.

- The Corail stem by DePuy Synthes is the most commonly deployed femoral stem for the non-cemented primary total hip arthroplasty of the Australian patient cohort, with the Pinnacle acetabular prostheses unit from the same manufacturer. While, it was the Exeter V40 with Trident acetabular shell, both from Stryker, dominating the usage numbers for hybrid fixations.

- The overall scenario of the most popular implants utilized for non-cemented and hybrid fixation based primary total hip arthroplasty of the Australian patient cohort, along with their relative cumulative revision rate percentages across multiple post-operative timepoints, and their manufacturer/supplier details are presented through the following tabulations: -

Distribution of the Cumulative Revision percentages of Cementless Modern Prosthesis Combinations(in Current Circulation & Use) used in Primary Total Hip Arthroplasty of the Australian Patient Cohort with atleast >500 Procedures [Data Period : 1st September, 1999 to 31st December, 2021].

SL No.	Femoral Component	Acetabular Component	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	AMIStem H	Mpact	Medacta International	10A|AMIStemH| ; 7A|Mpact|	2,443	57	2(1.5, 2.7)	2.7(2.1, 3.6)	3.4(2.5, 4.7)			
2		Versafit Cup CC	Medacta International	Versafit Cup CC [ODEP Rating Withdrawn]	3,412	75	1.5(1.1, 1.9)	2(1.6, 2.6)	2.9(2.3, 3.7)			
3	Accolade II	Trident(Shell)	Stryker	10A [Accolade] ; 15A* [Trident(Shell)]	11,960	275	1.8(1.6, 2.1)	2.5(2.2, 2.8)	2.9(2.5, 3.3)			
4		Trident / Tritanium (Shell)		10A ; 3A/7A|Trident Tritanium|	3,183	87	2.2(1.8, 2.8)	3.1(2.5, 3.8)	3.5(2.8, 4.4)			
5	Alloclassic	Allofit	Zimmer Biomet	10A/15A*/ODEP Rating Withdrawn[Alloclassic] ; 15A*/10A[Allofit]	3,963	188	1.6(1.2, 2)	2.3(1.9, 2.9)	3(2.5, 3.5)	4.8(4.1, 5.6)	6.8(5.8, 8)	
6		Fitmore*		10A/15A*/Withdrawn [Alloclassic] ; 15A*/10A*[Fitmore]	726	53	4.4(3.1, 6.2)	5.4(4, 7.3)	5.8(4.4, 7.8)	7.8(6, 10.3)	7.8(6, 10.3)	
7		Trabecular Metal (Shell)*		15A*[TrabecularMetal]	1,060	53	2.3(1.5, 3.4)	2.9(2, 4.1)	4(3, 5.4)	5.1(3.9, 6.7)	5.9(4.5, 7.8)	
8		Trilogy *		15A*[Trilogy]	945	21	0.6(0.3, 1.4)	0.9(0.4, 1.7)	1.1(0.6, 2)	2.5(1.6, 3.8)	2.7(1.7, 4.2)	
9	Anthology	R3	Smith & Nephew	13A*[Both Anthology&R3]	8,036	257	2(1.7, 2.3)	2.6(2.2, 2.9)	2.9(2.5, 3.3)	3.7(3.3, 4.2)		
10		Reflection (Shell)		13A* ; 15A*	907	31	1.9(1.2, 3)	2.2(1.4, 3.4)	2.6(1.7, 3.8)	3.4(2.4, 4.9)	3.9(2.7, 5.6)	
11	Avenir	Continuum	Zimmer Biomet	Pre-Entry A*/7A|Avenir| ; 13A|Continuum|	1,765	62	2.7(2, 3.5)	3(2.3, 4)	3.5(2.7, 4.6)	3.9(3.1, 5.1)		
12		Trilogy *		15A*[Trilogy]	626	12	1(0.4, 2.1)	1.1(0.5, 2.3)	1.3(0.6, 2.6)	2.1(1.1, 3.8)		
13	C2	Delta-TT	Lima Corporate	7A|C2| ; 10A*[Delta-TT]	1,022	26	1.3(0.8, 2.2)	2.1(1.4, 3.3)	2.6(1.7, 3.9)	3.8(2.3, 6.1)		
14	CLS	Allofit	Zimmer Biomet	15A*[CLS] ; 15A*/10A*[Allofit]	501	29	1.8(0.9, 3.4)	3.4(2.2, 5.5)	4.1(2.6, 6.2)	5.2(3.6, 7.7)	7.2(4.9, 10.5)	
15		Fitmore		15A*[CLS];15A*/10A* [Fitmore]	612	19	1.3(0.7, 2.6)	2.3(1.4, 4)	2.6(1.6, 4.4)	4.3(2.5, 7.3)		
16	Corail	Fitmore*	Depuy Synthes ; Zimmer Biomet	10A|Corail| ; 15A*/10A*[Fitmore]	513	14	2.2(1.2, 3.8)	2.3(1.3, 4.1)	2.3(1.3, 4.1)	3.4(1.9, 6.1)		
17		G7	Depuy Synthes ; Zimmer	10A|Corail| ; 7A|G7|	505	6	0.8(0.3, 2.2)					
18		Pinnacle	Depuy Synthes	10A|Corail| ; 15A* / 10A*[Pinnacle]	59,111	2,167	1.7(1.6, 1.8)	2.6(2.5, 2.7)	3.2(3.1, 3.4)	4.9(4.7, 5.2)		
19		Pinnacle *MoM			966	133	2.2(1.4, 3.3)	3.7(2.6, 5.1)	5.9(4.6, 7.6)	12.3(10.3, 14.6)		
20		Trinity	Depuy Synthes ; Corin Group	10A|Corail|;10A*[Trinity]	994	16	1.5(0.9, 2.5)	1.8(1.1, 2.9)	1.8(1.1, 2.9)			
21	EVOK	Logical G	Amplitude Ortho ; Signature Orthopedics	Unrated ; 5A*|Logical G|	549	14	2.1(1.2, 3.8)	3.3(1.9, 5.9)				
22	H-Max	Delta-TT	Lima Corporate	ODEP Rating Withdrawn/3A/7A*[H-Max] ; 10A*[DeltaTT]	1,680	75	1.9(1.4, 2.7)	3.5(2.7, 4.5)	4.2(3.3, 5.3)	7.7(5.2, 11.5)		
23	HACTIV	Logical G	Evolutis ; Signature Orthopedics	13A*|Hactiv|;5A* |LogicalG|	1,309	58	3.9(2.9, 5.1)	4.6(3.6, 6)				
24		Saturne	Evolutis ; Amplitude Ortho	13A* ; 10A/ODEP Lapsed[Saturne]	598	12	1.6(0.9, 3.2)	2.4(1.3, 4.5)	2.4(1.3, 4.5)			
25	M/L Taper	Allofit	Zimmer Biomet	15A*[M/L Taper];15A*/10A[Allofit]	752	25	1.6(0.9, 2.8)	1.9(1.1, 3.2)	2.2(1.3, 3.6)	4.2(2.6, 6.7)		
26		Continuum		15A*; 13A|Continuum|	1,623	63	2.4(1.8, 3.3)	3.4(2.6, 4.4)		4.6(3.5, 6)		
27		Trilogy		15A*[Both]	900	34	1.2(0.7, 2.2)	1.6(0.9, 2.6)		4(2.8, 5.7)		
28	MasterLoc	Mpact	Medacta International	Pre-Entry A*[MasterLoc] ; 7A|Mpact|	636	10	1.5(0.8, 2.8)	1.5(0.8, 2.8)				
29		Versafit Cup CC	Medacta International	Pre-Entry A* ; ODEP Rating Withdrawn	596	5	0.9(0.3, 2.3)	1.2(0.5, 2.9)				
30	Metafix	Trinity	Corin Group	13A/5A* [Metafix]; 10A*[Trinity]	13,339	268	1.5(1.3, 1.7)	2.2(1.9, 2.5)	2.5(2.2, 2.9)	4.2(3, 6)		
31	MiniHip	Trinity		10A*[Mini Hip]	1,167	39	2.5(1.8, 3.6)	3.2(2.3, 4.4)	3.5(2.5, 4.8)			
32	Omnifit	Trident (Shell)	Stryker	Unrated[Omnifit]; 15A*[Trident(Shell)]	1,272	88	1.9(1.3, 2.8)	3.2(2.3, 4.3)	4.1(3.1, 5.4)	5.6(4.4, 7)		
33	Optimys	RM Cup	Mathys Ltd Bettlach	7A*[Optimys] ; 7A*[RM Cup]	2,009	35	1.4(0.9, 2)	1.8(1.3, 2.6)	2.5(1.7, 3.8)			
34		seleXys		7A* ; ODEP Withdrawn	560	12	0.7(0.3, 2)	1.9(1, 3.6)	3.1(1.7, 5.5)			
35	Origin	Logical G	Signature Orthopedics	5A*|Origin| ; 5A|Logical G|	2,523	73	2.2(1.7, 2.9)	3.1(2.5, 4)	3.7(2.8, 4.7)			
36	Paragon	Acetabular Shell (Global)	Corin Group ; Opcn Access	Unrated [Both]	4,153	82	1.5(1.2, 2)	1.9(1.5, 2.3)	2.3(1.8, 3)			
37		Novae	Corin Group ; SERF	Unrated[Paragon] ; 10A/7B[Novae]	868	17	0.9(0.5, 1.8)	1.9(1.2, 3.2)	2.1(1.3, 3.4)			
38		Trinity	Corin Group	Unrated [Both] ; 10A*[Trinity]	1,879	33	1.8(1.2, 2.5)	2(1.4, 2.9)	2(1.4, 2.9)			
39	PolarStem	EP-Fit Plus	Smith & Nephew	10A*/5A[Polarstem] ; 15A*[EP-Fit Plus]	2,377	11	0.2(0.1, 0.5)	0.5(0.2, 0.9)	0.5(0.3, 1)			
40		R3		13A*[R3]	15,314	423	2(1.8, 2.3)	2.6(2.3, 2.9)	3.1(2.8, 3.4)	4.3(3.6, 5.1)		
41	Profemur L	Dynasty	MicroPort Orthopedics	7A/5A*/13A*[Profemur-L] ; Unrated[Dynasty]	1,889	93	3.6(2.8, 4.5)	4.7(3.8, 5.8)	5.3(4.3, 6.6)			
42		Procotyl L		10A* |Procotyl L|	1,136	22	1.4(0.8, 2.3)	2.2(1.4, 3.4)	2.5(1.6, 3.8)			
43	Quadra H	Mpact	Medacta International	13A*[QuadraH] ; 7A|Mpact|	5,390	178	2.1(1.7, 2.5)	3.2(2.8, 3.8)	4.5(3.8, 5.4)			
44		Trident (Shell)	Medacta International ; Stryker	13A* ; 15A*[Trident(Shell)]	711	23	1.6(0.9, 2.8)	2.8(1.8, 4.3)	3.5(2.3, 5.4)			
45		Versafit Cup CC	Medacta International	7A*/ ODEP Withdrawn [Versafit]	9,848	340	1.8(1.6, 2.1)	2.6(2.3, 3)	3.2(2.8, 3.6)	6.2(5.2, 7.4)	7.8(6.7, 9)	
46		Versafit Cup DM		Versafit DM Version Unrated	837	39	3.6(2.5, 5.1)	5.2(3.8, 7.1)	5.5(4, 7.6)			
47	S-ROM	Pinnacle	Depuy Synthes	15A|S-ROM| ; 15A*/10A*[Pinnacle]	3,679	222	2.4(2, 3)	4(3.4, 4.7)	4.7(4, 5.4)	6.2(5.4, 7.1)		
48	SL-Plus	EP-Fit Plus	Smith & Nephew	13A|SL Plus| ; 15A*[EP-Fit Plus]	1,217	48	1.6(1, 2.4)	2.1(1.4, 3.1)	2.7(1.9, 3.8)	3.8(2.8, 5.1)		
49		R3		13A*[R3]	1,805	107	2.6(1.9, 3.4)	4(3.2, 5)	4.4(3.5, 5.4)	6.6(5.4, 8)		
50	Secur-Fit	Trident (Shell)	Depuy Synthes[Secur-Fit/Plus] ; Stryker	Unrated ; 15A*[Trident]	10,447	506	1.9(1.7, 2.2)	2.9(2.6, 3.3)	3.6(3.3, 4)	4.8(4.3, 5.2)	6.2(5.7, 6.9)	7.8(6.7, 9)
51	Secur-Fit Plus	Trident (Shell)			6,326	256	1.3(1, 1.6)	2(1.6, 2.3)	2.5(2.1, 2.9)	3.5(3.1, 4.1)	4.8(4.2, 5.4)	5.9(5.1, 6.9)
52	Summit	Pinnacle	Depuy Synthes	15A/7A|Summit| ; 15A*[Pinnacle]	5,719	178	1.5(1.2, 1.8)	2.1(1.8, 2.6)	2.4(2, 2.8)	3.5(3, 4.1)	5.6(4.5, 7)	
53		Pinnacle *MoM			784	87	1.5(0.9, 2.7)	2.2(1.4, 3.5)	3.5(2.4, 5.1)	8.7(6.8, 11)	11.4(9.2, 14.1)	
54	Synergy	R3	Smith & Nephew	15A*[Synergy] ; 13A*[R3]	5,363	177	1.8(1.5, 2.2)	2.4(2, 2.9)	2.8(2.4, 3.3)	3.8(3.3, 4.4)		
55		Reflection (Shell)		15A* [Both]	7,878	422	1.5(1.3, 1.8)	2.3(2, 2.7)	2.7(2.3, 3.1)	4(3.5, 4.4)	5.8(5.2, 6.4)	8.8(7.7, 10.1)
56	Taperloc	Continuum	Zimmer Biomet	15A/15A*[Taperloc] ; 13A|Continuum|	778	17	1.7(1, 2.9)	2.3(1.4, 3.7)				
57		G7		15A/15A*[Taperloc] ; 7A|G7|	4,194	109	2.2(1.8, 2.7)	2.7(2.2, 3.3)	2.9(2.4, 3.6)			
58	Taperloc Microplasty	Continuum		10A|Taperloc Microplasty| ; 13A|Continuum|	571	18	2.8(1.7, 4.5)	3.3(2.1, 5.1)	3.3(2.1, 5.1)			
59		G7		10A ; 7A	3,023	36	1.2(0.9, 1.7)	1.3(0.9, 1.8)	1.3(0.9, 1.8)			
60	Tri-Fit TS	Trinity	Corin Group	7A|TriFit TS\];10A|Trinity|	4,466	96	1.2(0.9, 1.6)	2(1.6, 2.5)	2.3(1.8, 2.8)			
61	Tri-Lock	Pinnacle	Depuy Synthes	10A*[Tri-Lock] ; 15A*[Pinnacle]	1,126	32	1.5(1, 2.5)	2.4(1.6, 3.5)	2.8(1.9, 4)	3.3(2.3, 4.8)		
62	VerSys	Trilogy*	Zimmer Biomet	15A*/15A[VerSys] ; 15A*[Trilogy]	4,495	266	2.6(2.2, 3.1)	3.4(2.9, 4)	4(3.5, 4.6)	5.3(4.7, 6.1)	6.4(5.7, 7.3)	7.2(6.3, 8.1)
63	twinSys [C.Less]	RM Cup	Mathys Ltd Bettlach	13A*[twinSys(Cementless)] ; 7A*[RM Cup]	1,397	50	2.3(1.6, 3.2)	3.1(2.3, 4.2)	3.4(2.6, 4.6)			
64	Other Prosthesis Combinations [576]				19,102	854	2.6(2.4, 2.9)	3.8(3.5, 4.1)	4.4(4.1, 4.7)	6(5.6, 6.5)	7.6(6.9, 8.5)	
	TOTAL				2,59,535	9,134	*Figures are of Only Modern Prostheses of 2021 Use ; Procedures using MoM prostheses have been Included in the List ; MoM denotes MoM prostheses with >32mm Femoral Head Size ; "*" Denotes Prosthesis Combinations with No Reported Usage for Primary THA in 2021.*					

Table 6.1.28 : - ***Tabulation illustrating the Distribution of the Most Commonly utilized Non-Cemented Hip Prostheses Combinations for the Primary Total Hip Arthroplasty of the Australian Patient Cohort, with their relative Revision rate percentages across multiple post-operative timepoints, Manufacturer/Supplier firm details and their ODEP Rating statuses.***

Distribution of the Cumulative Revision Percent of Modern Prosthesis Combinations(in Current Circulation & Use) used in Primary Total Hip Arthroplasty of the Australian Patient Cohort with atleast >500 Procedures through Hybrid Fixation Method. [Data Period : 1st September, 1999 to 31st December, 2021].

SL No.	Femoral Component	Acetabular Component	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Absolut	Acetabular Shell (Global)	Corin Group ; Open Access / Turnkey Supplier	Unrated [Both]	863	23	1.5(0.9, 2.6)	2.3(1.5, 3.6)				
2		Trinity	Corin Group	Unrated ; 10A* / 5A* [Trinity]	530	9	1.7(0.9, 3.3)					
3	C-Stem AMT	Pinnacle	Depuy Synthes	15A*/7A[C-Stem AMT] ; 15A*/10A*[Pinnacle]	5,952	169	1.5(1.2, 1.9)	2.4(2, 2.9)	3.3(2.8, 3.8)	4.9(4, 6.1)		
4	CPCS	R3	Smith & Nephew	15A[CPCS] ; 13A*[R3]	8,043	272	2.1(1.8, 2.5)	3(2.6, 3.4)	3.4(3, 3.9)	5(4.3, 5.9)		
5		Reflection (Shell)		15A[CPCS] ; 15A*[Reflection(Shell)]	3,128	130	0.9(0.6, 1.3)	1.3(1, 1.8)	1.7(1.3, 2.3)	3.7(3, 4.5)	6.8(5.6, 8.4)	
6	CPT	Allofit	Zimmer Biomet	15A*[CPT(CoCr)]/ODEP Rating Withdrawn[CPT(SS)] ; 15A*/10A[Allofit]	1,748	60	1.3(0.9, 2)	1.9(1.4, 2.7)	3.1(2.3, 4.2)	5.2(4, 6.9)	6.1(4.5, 8.2)	
7		Continuum		15A*[CPT(CoCr)]/ODEP Rating Withdrawn[CPT(SS)] ; 13A[Continuum]	3,362	178	2.9(2.4, 3.5)	4(3.4, 4.8)	4.7(4, 5.5)	7.1(5.9, 8.4)		
8		G7		15A*[CPT(CoCr)]/ODEP Rating Withdrawn[CPT(SS)] ; 7A [G7]	2,249	66	3(2.3, 3.9)	3.7(2.8, 4.9)				
9		Trabecular Metal (Shell)		15A*[CPT(CoCr)]/ODEP Rating Withdrawn[CPT(SS)] ; 15A*[TrabecularMetal]	2,478	126	2.5(1.9, 3.2)	3.5(2.8, 4.3)	4.5(3.7, 5.5)	6.5(5.4, 7.9)	9.6(7.4, 12.3)	
10		Trilogy		15A*[CPT(CoCr)]/ODEP Rating Withdrawn[CPT(SS)] ; 15A*[Trilogy]	8,776	442	1.9(1.6, 2.2)	2.8(2.5, 3.2)	3.7(3.3, 4.1)	5.6(5, 6.1)	7.3(6.5, 8.1)	8.1(7, 9.3)
11	Evolve	Logical G	Signature Orthopedics	5A/ODEP Lapsed [Evolve] ; 5A* [Logical G]	2,167	47	1.6(1.2, 2.3)	2.1(1.5, 2.8)	2.5(1.8, 3.4)			
12	Exeter V40	Fixa	Stryker ; Adler Ortho	15A*[E.V40] ; 3A [Fixa]	810	29	2.1(1.3, 3.4)	2.7(1.8, 4.1)	3(2, 4.5)			
13		Pinnacle	Stryker ; Depuy Synthes	15A*[E.V40] ; 15A*/10A*[Pinnacle]	2,484	70	1.5(1.1, 2)	2(1.5, 2.7)	2.3(1.7, 3)	4.2(3.1, 5.5)		
14		R3	Stryker;Smith&Nephew	15A*[E.V40] ; 13A*[R3]	2,578	98	2.2(1.7, 2.8)	3(2.4, 3.8)	3.8(3.1, 4.6)	4.4(3.6, 5.4)		
15		Trabecular Metal (Shell)	Stryker;Zimmer Biomet	15A*[Both]	571	29	2.9(1.8, 4.6)	3.5(2.2, 5.4)	4.2(2.8, 6.3)	6(4.1, 8.6)		
16		Trident (Shell)	Stryker		81,158	2,458	1.3(1.2, 1.4)	2(1.9, 2.1)	2.5(2.4, 2.7)	3.9(3.7, 4.1)	5.6(5.3, 5.9)	7(6.3, 7.7)
17		Trident / Tritanium (Shell)		15A*[E.V40] ; 3A/7A [Trident/Tritanium(Shell)]	5,867	183	1.8(1.5, 2.2)	2.6(2.2, 3.1)	3.3(2.8, 3.9)	4.6(3.8, 5.6)		
18		Trilogy*	Zimmer Biomet	15A* [Both]	604	20	1.7(0.9, 3.1)	2.4(1.4, 4)	2.6(1.5, 4.2)	3.5(2.2, 5.5)	3.9(2.5, 6)	
19	MS-30	Allofit*		15A*[MS-30] ; 15A*/10A*[Allofit]	1,336	52	1.1(0.6, 1.8)	1.6(1, 2.4)	2.2(1.5, 3.1)	3.8(2.8, 5.1)	6.5(4.7, 9)	
20		Continuum		15A*[MS-30] ; 13A[Continuum]	933	19	1.6(1, 2.7)	1.9(1.2, 3)	2.1(1.3, 3.4)			
21		Fitmore		15A*[MS-30] ; 15A*/10A*[Fitmore]	645	22	1.6(0.9, 2.9)	2.1(1.2, 3.6)	3.4(2.1, 5.4)	4.4(2.8, 6.8)	5.5(3.2, 9.2)	
22		G7		15A*[MS-30] ; 7A[G7]	818	12	1.3(0.7, 2.4)	2(1.1, 3.8)				
23	Omnifit	Trident (Shell)	Stryker	Unrated[Omnifit]; 15A*[Trident(Shell)]	2,989	109	1.8(1.4, 2.3)	2.7(2.2, 3.4)	3(2.4, 3.7)	3.7(3, 4.5)	4.7(3.7, 5.8)	5.7(4.3, 7.4)
24	Quadra-C	Mpact	Medacta International	7A*[QuadraC] ; 7A[Mpact]	3,597	52	1.2(0.9, 1.6)	1.7(1.3, 2.3)	2(1.4, 2.8)			
25		VersafitCup CC		7A*[QuadraC] ; Versafit Cup CC [ODEP Rating Withdrawn]	1,619	31	1.6(1.1, 2.3)	1.8(1.2, 2.6)	2(1.4, 3)			
26	Short Exeter V40	Trident (Shell)	Stryker	Unrated[Short E.V40]; 15A*[Trident(Shell)]	3,374	55	1.1(0.8, 1.6)	1.8(1.4, 2.4)	2.4(1.8, 3.2)			
27	Spectron-EF	R3	Smith & Nephew	15A[Spectron EF] ; 13A*[R3]	2,334	97	1.7(1.3, 2.4)	2.9(2.2, 3.6)	3.7(2.9, 4.6)	5.6(4.5, 6.9)		
28		Reflection (Shell)*		15A[Spectron EF] ; 15A* [Reflection(Shell)]	5,203	357	1.1(0.9, 1.5)	2(1.6, 2.4)	2.8(2.4, 3.3)	5.5(4.8, 6.2)	9.4(8.4, 10.6)	13.2(11.4, 15.2)
29	Taper Fit	Trinity	Corin Group	15A[TaperFit] ; 10A*[Trinity]	3,683	77	1.5(1.2, 2)	2.4(1.9, 3.1)	3(2.3, 3.9)			
30	X-Acta	Mpact	Medacta International	5A*[X-Acta] ; 7A[Mpact]	637	12	1.7(0.9, 3.1)	2.3(1.3, 4.1)	2.3(1.3, 4.1)			
31		VersafitCup CC		5A*[X-Acta] ; ODEP Rating Withdrawn[Versafit Cup CC]	671	9	0.9(0.4, 2.1)	1.1(0.5, 2.4)	1.7(0.9, 3.3)			
32	twinSys [Cemented(ctd)]	RM Cup	Mathys Ltd Bettlach	13A*/10A*[twinSys] ; 7A*[RM Cup]	561	13	2(1.1, 3.6)	2.6(1.5, 4.5)	2.6(1.5, 4.5)			
33	Other Prothesis Combinations [523]				9,934	384	2.2(1.9, 2.5)	3.2(2.8, 3.6)	4(3.6, 4.5)	6(5.3, 6.8)	8.8(7.4, 10.4)	
TOTAL					1,71,702	5,710	*Figures are of Only Modern Prostheses of 2021 Use ; Procedures using MoM prostheses have been Included in the List ; MoM denotes MoM prostheses with >32mm Femoral Head Size ; "*" Denotes Prosthesis Combinations with No Reported Usage for Primary THA in 2021.*					

Table 6.1.29 : - ***Tabulation illustrating the Distribution of the Most Commonly utilized Hybrid fixation based Hip Prostheses Combinations for the Primary Total Hip Arthroplasty of the Australian Patient Cohort, with their relative Revision rate percentages across multiple post-operative timepoints, Manufacturer/Supplier firm details and their ODEP Rating statuses.***

Australian Hip Arthroplasty Practices: - Influence of XLPE/Non-XLPE & Bearing Surface on Outcome Scenarios.

- With respect to the hip bearing surfaces utilized and their related respective data, besides the usual Metal, Polymer, and Ceramic bearing surfaces, another additional bearing surface material is named across the Australian registry database, which are, '*Ceramicised metal'*.

- Upon further exploration, it is found that the above-mentioned term, "Ceramicised metal" is a sophisticated name attributed to ceramic-coated metal-bearing surfaces. These are manufactured to combine the properties of metal and ceramics. This combination of two distinct material properties is evident and available only at

the surface level since it involves the process of surface coating or infiltrating a metal structure surface with a ceramic material to enhance its properties and performance.

- Such processes often involve, a ceramic material such as alumina or zirconium oxide to be applied on to the surface of a metal substrate typically through specialized techniques such as thermal spraying, chemical vapor deposition, etc. Once coated, these ceramic materials formulate a protective covering over the metal base layer surface providing several benefits, such as enhanced thermal and corrosion resistance, but the most important aspect of improving bearing surface articulation characteristics, by reducing wear and particulate debris formation and thereby subsequent accumulation in and around the joint region.

- This is often done by manufacturers to sell their metal bearing products, which either previously had an issue of metal debris wear or a metallosis problem, or any other issues, by coating the surface with another material type or a similar material type that has a better legacy or repute, is something that is done, by many implant prosthesis manufacturers, suppliers and vendors. Just like the ceramic coating of the inherently metal prosthesis, instances and commercial circulation of condemned metal prostheses materials such as Cobalt Chromium (CoCr), have been coated with Titanium Nitride (TiN) layering, that not only provide a refurbished look to the product, but also provides for a platform, which the marketing forces of these respective enterprises utilize for commercial sale.

- Though, instances of TiN coating were not found across the Australian Registry database, as far as this research probe could access and proceed, it is in real-life practice in other parts of the world, especially in South Asian nations like India. Similarly, the exact ceramic coating details and patterns were not very prominently displayed, though it could be possible to be excavated out, if there's sufficient time and other resources.

- The Australian Registry has reported on 10 bearing surfaces of which, 8 have been utilized for more than individual/respective 5,000 arthroplasty procedure cases.

- Ceramicised metal and Highly Cross-linked Polyethylene or HXLPE are said to have the lowest revision rates at 10 Years' time point of patient follow-up in Australia. Further details on this regard will be discussed along with the concerned table of data, presented within this chapter.

- The Australian Registry has further stated that this type of Ceramicised metal hip prosthesis (femoral stems), is offered and is reportedly allowed for human utilization, only in accompaniment of a HXLPE-based acetabular liner/shell. Now, this type of prosthesis configuration is offered only by a single company in Australia (Smith & Nephew), and therefore, such prosthesis products are termed "single-company products". However, the relative number of procedures performed using these combinations is very low.

- The material configuration data for bearing surfaces was available for 5,10,454 individual procedures, of which, Metal and XLPE combinations had the biggest share with 1,86,339 procedures, followed by Ceramic and XLPE combinations with 1,24,435 procedures. Unlike the nations studied, for the purpose of this research, Ceramic and Ceramic combination bearing surfaces are still in significant circulation for application in a hip arthroplasty procedure. Such ceramic and ceramic-bearing surfaces were utilized in 1,03,169 procedures.

- The arthroplasty practices in Australia revealed that XLPE was the leading choice of polymer material for developing the articulating surface bearing to be embedded within the acetabular prosthesis component, to provide optimal articulation of the incoming femoral head. Again, unlike the other nations, that were evaluated for their respective arthroplasty practices, the Australian arthroplasty domain, utilized XLPE as their leading and best choice material for the previously stated purpose of hip prosthesis.

- Analysing the reported facts and figures by the Australian registry, it is found that XLPE was utilized across 3,06,639 individual arthroplasty procedures in Australia for primary total hip arthroplasty, between 2003 to 2021. This includes 32,329 arthroplasty procedures that used XLPE with infused anti-oxidant.

- In 2021, XLPE bearings alone accounted for usage in nearly 97.20% of all procedures as the articulating liner.

- Such dominant utilization of XLPE bearings as articulating liners of hip prostheses used for hip arthroplasty, is reasoned by the fact that XLPE-based articulating bearings answered the prime issue of polymer articulating surface getting worn out either faster than expected, due to increased friction-induced wearing or may be due to the natural principles of degradation, caused by the articulation of the femoral head component of stem. In such situations, the wear in itself may lead to a bigger scale of joint/implant failure.

- XLPE due to its inherent characteristics and properties has shown excellent results in improving the articular surface life, through its enhanced wear resistance properties. Therefore, the revision rates of arthroplasties that have used an XLPE-based component fared much better than other conventional polymeric articular bearing surfaces (UHMWPE / HDPE). XLPE has a lower rate of revision compared to non-XLPE prosthesis articular bearing surfaces after 1 year of post-operative follow-up. This difference further widens and increases with time and at 20 years of the postoperative period, the cumulative revision percent margin is 7.1% and 17.80% respectively.

- Similarly, the cumulative incidences of prosthesis loosening and prosthesis dislocation/subluxation-related post-op joint instability at 20 years is 1.1% and 1.2% for XLPE, compared to 4.80% and 1.40% for the non-XLPE bearings respectively.

- It is inferred from the presented facts and figures from the Australian registry, that the use of XLPE is associated with the increased use of larger femoral heads compared to non-XLPE.

- Now, it is a known fact that XLPE offers better protection against polymeric wear and particulate debris risks, than conventional polyethylene. While at the same time larger femoral heads as observed across the globe, inherently possessed a greater risk due to periprosthetic fracture or loosening or prosthetic dislocation/subluxation. Combining the two traits, i.e., good wear characteristics of XLPE with larger femoral heads, therefore mitigates the risks of accelerated acetabular liner decay leading to debris accumulation at the implantation site, adding to the revision arthroplasty burden, which would have been the case, if HDPE or UHMWPE was used in place of XLPE.

Summarily for 20 Year Post-Op horizon,

$R.R_{\text{Aseptic Loosening}}$ [XLPE] = 1.10%

$R.R_{\text{Dislocation \& Subluxation Induced Instability}}$ [XLPE] = 1.20%

$R.R_{\text{Aseptic Loosening}}$ [Conventional Polymer (HDPE/UHMWPE)] = 4.80 %

$R.R_{\text{Dislocation \& Subluxation Induced Instability}}$[Conventional Polymer (HDPE/UHMWPE)] = 1.40 %

Overall R.R [XLPE] = 7.10 %

Overall RR [Non-XLPE] = 17.8%

- Interestingly, for Non-XLPE variants of prostheses implanted with femoral heads sized less than 32 mm and sized 32 mm, there was no significant difference between the respective revision rates.

- While femoral head sizes > 32 mm are mostly used with XLPE bearings have moderate to good results, but almost negligibly with a non-XLPE bearing.

- Large femoral heads that are coming in sizes greater than 32 mm were used in 82.80% of all the 3,06,639 procedures that were done using an XLPE bearing, and in only 20.90% of the non-XLPE arthroplasty procedures in Australia.

- When using XLPE bearings with 32 mm femoral heads, the rate of revision is lower than less than 32 mm sized femoral heads, after 9 months of arthroplasty i.e., in the immediate short-term. When compared with > 32 mm femoral head sizes, the 32 mm heads had a better RR after 1 month.

- The stated facts and figures along with other information from the Australian Registry and other arthroplasty domain sources from Australia, reaffirms the previously theorized fact from this research probe, that the increased utilization of larger femoral heads with XLPE bearings has directly contributed towards a reduction in the dislocation of the femoral head or subluxation of the prosthesis and other post-operative prostheses instability issues.

- For all the femoral stem materials – Metal, Ceramic and Ceramicised Metal, prostheses versions with an XLPE bearing variant, reported and registered a better short-term vis-à-vis long-term revision rate, than the same femoral stem when used with a non-XLPE bearing variant.

- With regards to XLPE bearings, many global distributors and manufacturers of hip prostheses have marketed separate versions of XLPE bearings, marked to be enriched with 'performance enhancing' ingredients such as Anti-Oxidant and Vitamin E. Such instances of Anti-Oxidant infused XLPE bearings, Vitamin E infused/enriched XLPE bearings, and Anti-biotic infused XLPE bearings were found several times during the course of this probe while analyzing the implant-specific usage and its outcome in terms of cumulative revision rates across various time points in the postoperative period.

- The Australian Registry AOANJRR, in its first-of-its-kind separate analysis of specific acetabular components, those of XLPE and XLPE + Anti-Oxidant variants, published in its report of 2021, that neither there were any significant gains facilitated by the inclusion of anti-oxidants, and nor the presence of anti-oxidant helped in the revision rate aspects in any way. The registry reasons that this sort of separate analysis study of acetabular components that have both XLPE and XLPE with anti-oxidants was necessitated by the fact there was a nearly 20.30% surge in arthroplasty procedures in Australia, that used an anti-oxidant-based XLPE bearing in 2021, compared to even 2020.

- Albeit there are a plethora of publications and company sponsored / shadow-biased articles in various journals that support and theorize the concept of the benefits that antioxidant-infused acetabular liners have over conventional XLPE or standard polymer liners, the Registry came out quite boldly based on reported actual on ground real figures, to counter the presented narrative, or to some extent bust the marketing gimmicks aired by the prosthesis makers.

- Corin Group's "Trinity" is the only acetabular shell with both the types of polyethylene reported for usage in Australian patients for hip arthroplasty, and there were no observable significant differences when the respective revision rates for XLPE and XLPE with Anti-Oxidant are compared, for this particular implant brand.

AOANJRR 2022 : Cumulative Revision Percent of the "Trinity" Acetabular Cup & Shell with both XLPE & XLPE + Anti-Oxidant variants in Primary THA for Patients with Primary Diagnosis OA.

SL No.	Prosthesis Name [Mfg. Company]	Polyethylene Type	Total Revision Cases using the Prosthesis	Total No. of Cases	1 Year	2 Years	3 Years	5 Years	7 Years
	Trinity	OVERALL	346	18,468	1.5(1.3, 1.7)	1.8(1.6, 2.0)	2.2(1.9, 2.4)	2.4(2.2, 2.7)	2.7(2.3, 3.1)
1	Trinity [Corin Group]	XLPE	36	1,589	1.3(0.8, 1.9)	1.8(1.3, 2.6)	2.2(1.6, 3.0)	2.3(1.6, 3.1)	2.5(1.8, 3.5)
		XLPE + Anti-oxidant	310	16,879	1.5(1.3, 1.7)	1.8(1.6, 2.0)	2.2(1.9, 2.4)	2.5(2.2, 2.8)	2.7(2.3, 3.2)

Table 6.1.30 : - ***Cumulative Revision Percent of the Trinity Acetabular Cup & Shell with both XLPE and XLPE + Antioxidant variants for Primary THA of Patients with Primary Diagnosis OA.***

- While for Anti-biotic infused bearings, it is understandable it might be aimed to provide a reliable bearing option primarily for revision arthroplasties, which are often plagued by the incidences and risks of dangerous infections, such as the *Staphylococcus aureus* or *Pseudomonas aeruginosa*, which are very common and are virulent / pro-active enough to spread rapidly and formulate biofilm layers on the implanted prosthesis surface and adjoining areas.

- The four main groups of femoral head types based on their head sizes of ceramic origin were analyzed. These were the: **<= 28** mm, **32** mm, **36 – 38** mm, and **>= 40** mm sized femoral heads. For limited numbers, the head sizes 36 mm and 38 mm was combined into a single group of 36 – 38 mm femoral heads, though it should be noted 37 mm or odd-sized femoral heads are not conventionally used or produced unless specified customization is ordered and a patient-specific customized prosthesis unit is developed, as was observed and accordingly inferred during the course of this research probe.

- Based on the above scenarios and categorizations, specific analyses in this regard have led to the following findings: -
    a. Mixed Ceramic Femoral heads that are sized <=28 mm, have a higher revision rate than 32 mm femoral heads, in the first 3 months of the post-operative period. Further on it is found that even in the relative post-operative long term at 10 Years, and during the time until 10 Years, at all instances, such smaller-sized ceramic femoral heads posted comparatively higher revision rates than the 32 mm heads.

    b. These trends of higher revision rates of the <= 28 mm heads, were similarly observed when they were compared against other femoral head groups of 36 – 38 mm and >= 40 mm heads.

    c. At the time point of 10 years, <=28 mm femoral heads had an approximate mean revision rate of 5.20%, with some instances of it going as high as 7.50%. This however was not the case for 32 mm heads which had a rate of 3.90% with a maximum high of 4.50%.

    d. On the other hand, the femoral heads with sizes between 36 – 38 mm and the >= 40 mm sized ones had no differences in the revision rates, at all points of patient-follow up during the post-op period.

    e. Similarly, when compared to 32 mm head sizes, there was no significant difference between its own revision rates with that of the 36 – 38 mm and the >= 40 mm sized ones during the entirety of the postoperative period, as far as the post-op data was available to this probe.

    f. Smaller femoral heads (<= 28 mm) continued to register a greater number of revisions than the larger sized 32 and 36-sized heads, in Australia, which was fairly consistent with the global scenario in this particular regard.

    g. It was also inferred that the merger of 36 mm and 38 mm femoral heads into a single group of data reporting, spurs no concerns of any data alteration or plausible suppression. This is because fairly in all the nations whose respective arthroplasty practices were studied and evaluated during this research have presented similar inferences regarding the 36 mm and 38 mm femoral heads, and these bore relatively acceptable results in immediate short-term to long-term in terms of patient follow-up. The general similarity of outcomes in the above-mentioned particular category, therefore formulates the primary basis of such inferences.

    h. The 32 mm sized femoral head continues to be a popular choice and head with the most favourable results garnering a positive opinion amongst the patient cohort and clinicians as seen across the world, albeit the utilization numbers of this particular sized prosthesis still lag behind the 36 – 38

mm sized heads by quite some margin, which could be due to multi-factorial reasons including geographical linked anatomical differences, the Australian patients have from other patient groups in other parts of the world. These 32 mm femoral heads have a very low revision rate in the immediate short term vis-à-vis in the long term when compared against other femoral head sizes. The findings of a favourable outcome from a 32 mm femoral head are applicable for MoM hip prostheses as well, as far as the Australian patient data is concerned.

- The detailed tabulation of the femoral head size and its relative revision rate data across different time points in the postoperative period is presented as follows: -

AOANJRR 2022 : Cumulative Revision Percent of Mixed Ceramic/Mixed Ceramic Primary THA by Femoral Head Size with Primary Diagnosis OA.

SL No.	Femoral Head Sizes	Total No. of Cases	Total No. of Revisions	1 Year	3 Years	5 Years	10 Years	15 Years	20 Years
1	< = 28 mm Head Size	633	31	3.1(2.0, 4.7)	3.6(2.4, 5.4)	4.0(2.7, 6.0)	5.2(3.5, 7.5)	5.9(4.1, 8.5)	
2	32 mm Head Size	9,867	267	1.5(1.3, 1.7)	2.1(1.8, 2.4)	2.6(2.3, 2.9)	3.9(3.4, 4.5)		
3	36 - 38 mm Head Size	40,310	1,186	1.4(1.2, 1.5)	2.1(2.0, 2.2)	2.6(2.4, 2.8)	4.0(3.8, 4.3)	6.1(5.3, 7.0)	
4	>= 40 mm Head Size	3,812	100	1.4(1.1, 1.9)	2.2(1.8, 2.8)	3.0(2.4, 3.7)	4.0(3.2, 5.2)		
TOTAL		54,622	1,584	Restricted to prostheses of 2021 use.					

Table 6.1.31 :- ***Comparative data representing the cumulative Revision Percent of the Mixed Ceramic and Ceramic Femoral Hip Prosthesis, as per the Head Size, utilized in Primary Total Arthroplasty for the Australian patients with OA.***

- Constrained acetabular prostheses used in Australian patients had a higher chance of requiring a revision than the conventional acetabular prosthesis.

- Overall scenario of hip prosthesis bearing performances is presented as follows: -

AOANJRR 2022 : Cumulative Revision % of Primary THA by Commonly Used Bearing Surfaces in Patients with Primary Diagnosis OA.

SL No.	Bearing Surface Used	Total No. of Cases	Total No. of Revisions	1 Year	3 Years	5 Years	10 Years	15 Years	20 Years
1	Ceramic / Ceramic [CoC]	1,03,169	4,552	1.5(1.4, 1.6)	2.4(2.3, 2.4)	3.0(2.9, 3.1)	4.8(4.7, 5.0)	6.9(6.7, 7.2)	9.3(8.8, 9.8)
2	Ceramic / Non-XLPE [CoP]	9,351	661	1.8(1.6, 2.1)	3.1(2.7, 3.5)	3.6(3.3, 4.1)	6.9(6.3, 7.6)	11.5(0.6, 12.5)	15.8(14.5, 17.3)
3	Ceramic / XLPE [CoP]	1,24,435	3,407	1.7(1.6, 1.8)	2.4(2.3, 2.5)	2.9(2.8, 3.0)	4.0(3.9, 4.2)	5.5(5.1, 5.9)	6.8(6, 7.6)
4	Ceramic / Metal [CoM]	299	28	1.7(0.7, 4.0)	3.7(2.1, 6.6)	4.4(2.6, 7.4)	8.3(5.7, 12.2)		
5	MoM >32mm	14,422	3,654	1.7(1.5, 1.9)	5.7(5.3, 6.1)	11.8(11.3, 12.3)	22.6(21.9, 23.3)	28.5(27.7, 29.3)	31.4(30.1, 32.8)
6	MoM <=32mm	5,143	467	1.6(1.3, 2)	3.3(2.9, 3.8)	4.4(3.9, 5.0)	6.8(6.1, 7.6)	9.6(8.8, 10.5)	12.1(10.9, 13.3)
7	Metal / Non-XLPE [MoM]	35,581	3,048	1.4(1.3, 1.5)	2.5(2.3, 2.7)	3.5(3.3, 3.7)	6.4(6.2, 6.7)	10.8(10.4, 11.3)	15.4(14.8, 16.1)
8	Metal / XLPE [MoM]	1,86,339	6,850	1.6(1.6, 1.7)	2.4(2.3, 2.5)	3.0(2.9, 3.1)	4.5(4.4, 4.6)	6.2(6.0, 6.4)	7.7(7.2, 8.2)
9	Ceramic Coated Metal / Non-XLPE	304	57	1.6(0.7, 3.9)	3.7(2.1, 6.6)	4.1(2.3, 7.0)	12.5(9.0, 17.3)	21.8(16.8, 28.1)	
11	Ceramic Coated Metal / XLPE	31,411	951	1.9(1.7, 2)	2.4(2.2, 2.6)	2.8(2.6, 3.0)	3.8(3.6, 4.1)	5.0(4.6, 5.5)	
TOTAL		5,10,454	23,675						

Excludes 325 procedures with unknown bearing surfaces ; 1 procedure with Ceramic Coated Metal / Ceramic Bearing Surface ; 8 Procedures with Metal/Ceramic Bearing surface.

Table 6.1.32 :- ***Overall Comparative data of the Cumulative Revision Percent of Primary Total Hip Arthroplasty as the Commonly utilized Hip Prosthesis Bearings, in the Australian Patients with Primary Diagnosis OA.***

[Note the MoM hip prostheses performances in terms of revision percent, with and without the 32 mm femoral head sizes.]

- As discussed earlier, the plausible risks associated with large sized used femoral heads when used with non-XLPE bearings were possibly avoided, through the categorical usage of large heads with XLPE bearings only, which was evidently clear as per the Australian Registry data regarding the same. The overall data regarding femoral head data compared with the bearing data is presented as follows: -

AOANJRR 2022 : Cumulative Revision % of Primary THA by Polyethylene Type and Femoral Head Size used in Patients with Primary Diagnosis OA										
SL No.	Polyethylene Type	Head Size	Total No. of Cases	Total No. of Revision	1 Year	3 Years	5 Years	10 Years	15 Years	20 Years
Non-XLPE			17,797	1,249	1.5(1.4, 1.7)	2.7(2.5, 3.0)	3.5(3.2, 3.8)	6.9(6.4, 7.3)	12.1(11.4, 12.9)	17.8(16.4, 19.3)
1	Non-XLPE	<32 mm	14,084	1,059	1.5(1.3, 1.7)	2.7(2.4, 3.0)	3.5(3.2, 3.8)	7.0(6.5, 7.5)	12.3(11.5, 13.1)	18.0(16.6, 19.6)
		32 mm	3,633	187	1.6(1.2, 2.1)	2.7(2.2, 3.3)	3.5(2.9, 4.2)	6.3(5.4, 7.4)	10.3(8.5, 12.5)	
		> 32 mm	80	3	2.9(0.7, 11.3)	4.6(1.5, 13.6)	4.6(1.5, 13.6)			
XLPE			3,06,639	9,430	1.6(1.6, 1.7)	2.4(2.3, 2.4)	2.9(2.8, 3.0)	4.2(4.1, 4.3)	5.7(5.6, 5.9)	7.1(6.6, 7.6)
2	XLPE	<32 mm	52,780	2,115	1.6(1.5, 1.7)	2.4(2.3, 2.5)	3.0(2.8, 3.2)	4.4(4.2, 4.6)	6.0(5.7, 6.2)	7.4(6.8, 7.9)
		32 mm	1,26,168	3,649	1.6(1.5, 1.7)	2.3(2.2, 2.4)	2.7(2.6, 2.8)	3.9(3.8, 4.1)	5.2(4.9, 5.6)	
		> 32 mm	1,27,691	3,666	1.7(1.6, 1.8)	2.4(2.3, 2.5)	3(2.9, 3.1)	4.4(4.3, 4.6)	6.2(5.7, 6.7)	
TOTAL			3,24,436	10,679						

Table 6.1.33 :- ***Overall comparative data on the Cumulative Revision Percent of XLPE and Non-XLPE Polyethylene bearings, when used in combination with Different Femoral Head Sizes for the Primary Total Hip Arthroplasty of Australian patients with primary diagnosis OA, across different time points of the postoperative period.***

- A comparative analysis between the long-term mean revision rate scenarios for an acetabular prosthesis both XLPE and Non-XLPE variants available for clinical utilization on the Australian patient cohort is done to highlight and exemplify the above-discussed comparisons between the two material types.

- The Reflection Cup & Shell acetabular prosthesis unit by Smith & Nephew which is utilized globally is selected as the particular prosthesis model with both types of polymer material variants available. The comparative data yet again consolidating the above-mentioned discussions is therefore presented through the following tabulation: -

Comparative analyses tabulation to illustrate the Differences in the Cumulative Revision Rate percentages of the Primary THAs performed using the "Reflection" Cup & Shell with Both XLPE & Non-XLPE Variants on the Australian Patients with a Primary Diagnosis of Osteoarthritis. [Highlighting the Difference in the Long-Term RRs for Non-XLPE vis-a-vis XLPE versions].									
SL No.	Prosthesis Name [Mfg. Company / Supplier]	Polyethylene Type	Total No. of Cases	No. of Revised	Post-Op 5 Years	Post-Op 10 Years	Post-Op 12 Years	Post-Op 15 Years	Post-Op 17 Years
1	Reflection (Cup) [Smith & Nephew]	Non-XLPE	1,027	163	3.2(2.3, 4.6)	11.0(9.0, 13.4)	15.2(12.8, 18.1)	23.1(19.9, 26.7)	24.4(21.0, 28.2)
		XLPE	1,284	48	2.8(2.0, 4.0)	4.3(3.1, 5.8)	4.5(3.3, 6.1)	5.7(4.2, 7.8)	5.7(4.2, 7.8)
CATEGORY TOTAL			2,311	211	3.0(2.4, 3.8)	7.7(6.5, 9.1)	10.2(8.7, 11.9)	15.6(13.6, 18.0)	16.7(14.4, 19.2)
2	Reflection (Shell) [Smith & Nephew]	Non-XLPE	2,225	339	4.4(3.6, 5.4)	9.8(8.6, 11.3)	13.2(11.7, 14.9)	17.3(15.5, 19.3)	20.4(18.4, 22.7)
		XLPE	12,046	431	2.1(1.8, 2.3)	3.2(2.9, 3.6)	3.6(3.3, 4.0)	4.6(4.1, 5.1)	5.3(4.7, 5.9)
CATEGORY TOTAL			14,271	770	2.4(2.2, 2.7)	4.3(3.9, 4.7)	5.3(4.9, 5.7)	6.9(6.4, 7.4)	8.3(7.6, 9.0)
OVERALL TOTAL			16,582	981					

Table 6.1.34 :- ***Tabulation illustrating the comparative differences in the Long-Term Revision Rate percentages of a Prosthesis Model unit's Cup and Shell version with both XLPE and non-XLPE variants.***

Dual Mobility Hips Utilization Scenario for Hip Arthroplasty in Australia: -.

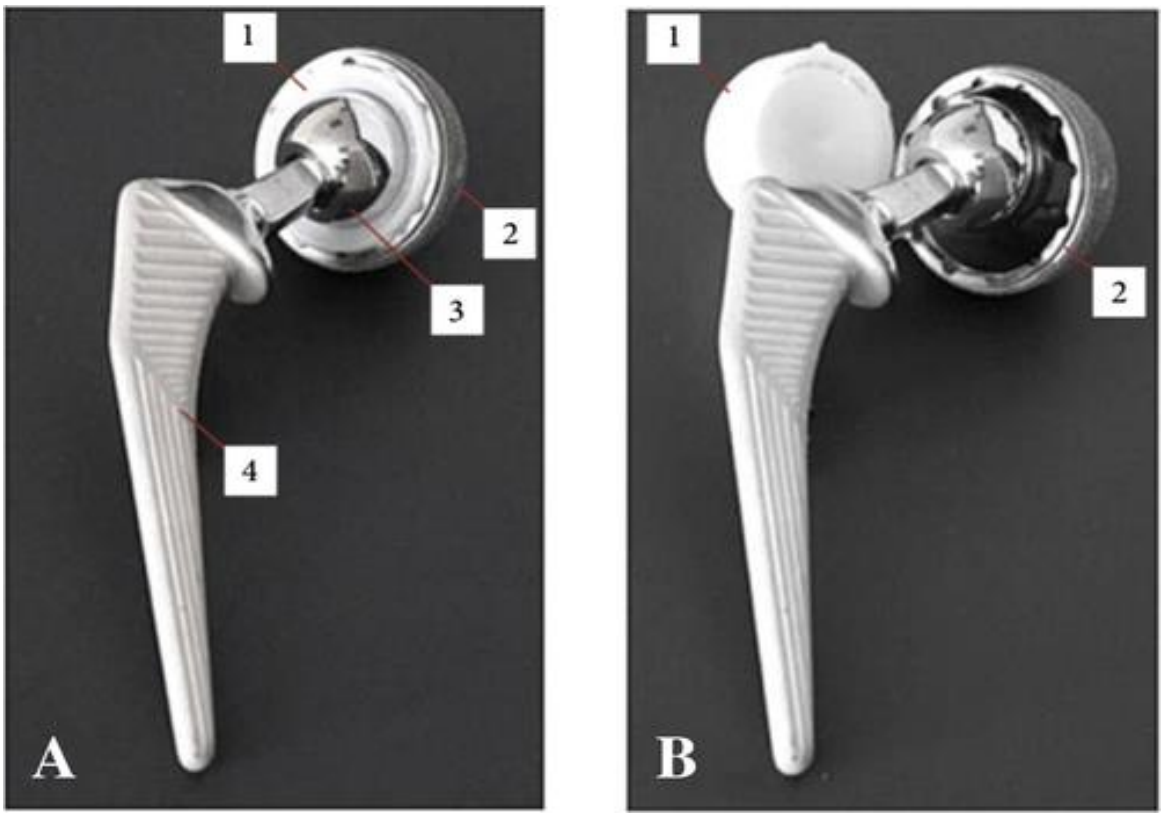


Figure 6.1.5 :- ***A Dual Mobility Hip Prostheses System ; (Image A) 1: Acetabular Liner; 2: Acetabular Shell; 3:Femoral Head; 4:Femoral Stem. Image B: Demonstration of the acetabular liner dislocation from the main prosthesis.***

- In Dual Mobility Hips, both the polyethylene acetabular liner undergoes a mobile or rotatory/gliding action in sync or with the driving influence of the femoral head, that it holds, about their own positions. These sorts of hyper-mobile components within hip prostheses are aimed to address the life-style related demands of the youngest to the comparatively younger group of patients, aging less than 55 years, other the prime age groups of patients, to answer or in some way provide an option for them to pursue the modern day hyper-active lifestyle movements, without any hindrances, which would otherwise be the case for a conventional monobloc hip prosthesis.

- Now, this sort of ability of a dual motion activity, where two critical bearing surfaces are in a mobile state, performing gliding, sliding, and rotating motions, leads to the terming of such kind of prostheses as 'Dual Mobility'.

- However, this innovation in hip prostheses too came with its own limitations, which was the issue of IPD or Intra-Prosthetic Dislocation.

- For, the case of dislocations of conventional hip prostheses, the prosthesis as a whole, or any particular component, whether be it the femoral stem head or the acetabular cup or shell, dislocates by losing bearing surface contact, to either remain within the alignment or to dislocate and dislodge further away to completely go out of the alignment of the hip-femur joint, resulting in a subluxation incidence.

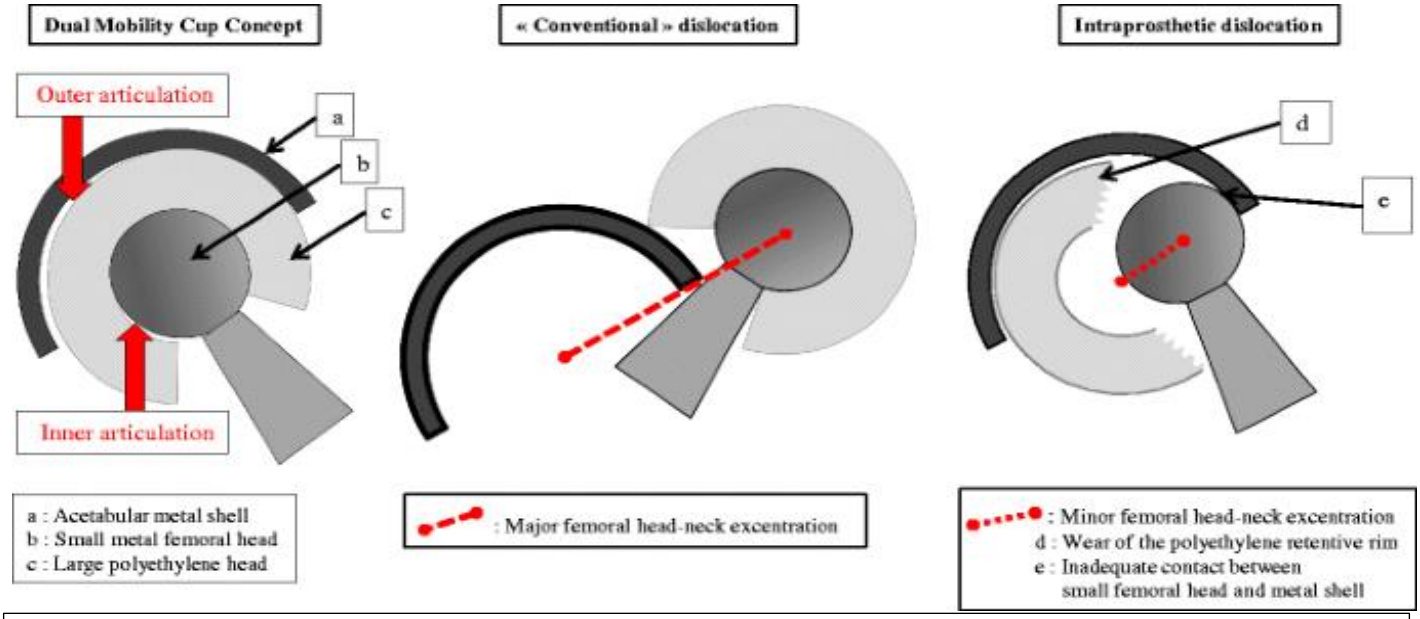


Figure 6.1.6 :- ***Description of a typical Dual Mobility Hip mobility design and the Difference of an Intra Prosthetic Dislocation of a DM Hip to that of Conventional Dislocation Incidences. [Langlois, J., El Hage, S. & Hamadouche, M. Intraprosthetic dislocation: a potentially serious complication of dual mobility acetabular cups. Skeletal Radiol 43, 1013–1016 (2014).]***

- While, for DM Hips, as is seen across the world, during the IPD incidences, either the femoral head glides beyond the polyethylene dish bearing angle, to come out of the acetabulum, or both the mobile polyethylene acetabular liner and the femoral head due to an extreme motion, falls out of alignment and place, thereby impairing the artificially reconstructed hip joint.

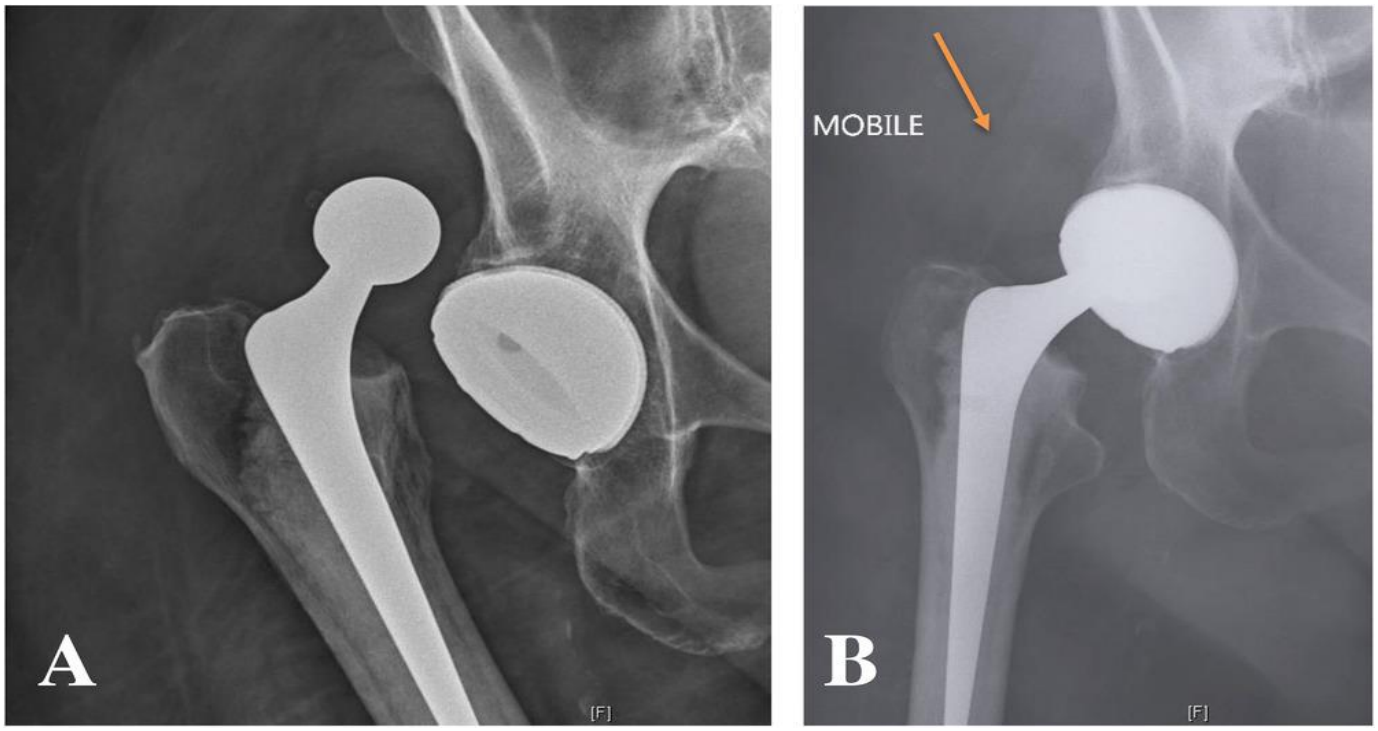


Figure 6.1.7 : - ***Image A: Pictorial Description of a Superior Dislocation of a Dual Hip Prosthesis, before Closed Reduction Techniques are applied to restore the joint conformity. Image B: Post-Reduction X-Ray image demonstrating the eccentric positioning of the femoral head in the acetabular shell, and a subtle circular opacity indicated by the orange arrow. [Fox, OJK, Cairns, SL, Jarman, PG. Recurrent and radiographically unrecognized iatrogenic intra-prosthesis hip dislocations. JACEP Open. 2020; 1: 419–422]***

- The overall scenario of Dual Mobility Hips utilized for primary total hip arthroplasty in Australia is examined during this research where it is found that the nearly globally consistent picture of rising popularity or increased usage of DM Hips, is applicable for Australian arthroplasty practices as well.

- However, the relative share of Dual Mobility Hips in the overall number of hip arthroplasties conducted all across, is staggeringly big compared to other nations which were evaluated during this research probe. As per Australian registry database sources, DM Hips have been utilized for nearly 21,198 primary total hip arthroplasties in 2021 alone, which corresponds to a striking 22.30% YoY increase since 2020 in Australia. The numbers and the increase in DM hips in Australia could certainly be one of the biggest among all other national scenarios in this regard, if not the biggest.

- The utilization of Dual Mobility Hips in Australian arthroplasty practices was consistent with global practices in many ways, including the primary indications it is used for. In Australia, DM Hips were primarily used to fix Neck of Femur (N.O.F) Fractures, Tumours, and Failed Internal Fixations of Conventional Hips. However, the usage pattern of DM Hips for re-revision arthroplasty implantation was not possible to excavate for the Australian arthroplasty domain.

- The bigger surprise revelation was that despite DM Hip prostheses being increasingly utilized for fixating NOF Fractures in greater proportions than conventional hips, no mentions of re-revision cases for such particular arthroplasties were observed anywhere on relevant sources channels and the registry of Australia.

- The Australian registry reports a contradictory scenario for DM Hips in Australia. They report that for all diagnoses combined, DM Hips have a higher revision rate compared to conventional hip prostheses. Now, this aligns with the globally consistent picture with regards to DM Hips, since these register comparatively higher rates of revision, in other nations as well, at least what was found during this research probe.

- However, the contradiction builds up, where the registry states, that for the diagnosis of osteoarthritis, there were no significant differences in the overall rates of revision, when a dual mobility hip prosthesis is utilized. Albeit, such prostheses were majorly used for fixing fractured NOFs, and repairing failed internal fixation cases for which they are already said to be having higher revision rates, for osteoarthritis which also happens to be the overall leading primary indicator for all arthroplasties conducted, it is reported to have no differences in revision rates, compared to when a conventional prosthesis is used.

- Such contradictions regarding the Dual Mobility hips in Australia, continues when it is reported that DM Hips had a lower revision rate for dislocation/subluxation and instability indication reasons compared to conventional hips. This comes when DM Hips itself, due to its own designing limitations is plagued by the issue of intra-prosthetic dislocations, and the registry declaring these hips were performing better in terms of dislocation, may very well be reasoned, what the National Joint Registry or NJR of the UK-Wales has termed “systematic co-ordinated argument”, between the stakeholders involved.

- While it remains to be globally noted and due accredited that DM hips are best fit for the youngest groups of patients suffering a NOF Fracture, or a dysplasia, or in somewhat rare incidences rare to limited occurrences of progressively damaged hip joint due to osteoarthritis, and for the senior-most group of patients (aging above 80 years), who had either suffered from multiple revision arthroplasties or have undergone their first primary, due to osteoarthritis. The global usage of DM Hips in arthroplasties across the globe, when compared by the respective age groups of the patients, wherein these were implanted, was compared and studied, and the above hypothesis, was somewhat more consolidated and stronger.

- The above understanding arises from the idea, that the patients in the youngest age groups (less than 55 years) are supposed to be having a hyper-active lifestyle, that involves a wide array of actions and mobility, linked either directly or indirectly with their lifestyle, notwithstanding, their inherent requirements of

performing certain other activities, which is not as much as expected for the patients in their 65 – 75 or higher ages.

- Again, these patients who are relatively young can or are expected to be able to withstand the mental, physical, and economic trauma of an end-of-life degeneracy-related revision arthroplasty, or an IPD-caused revision arthroplasty, which is certainly not the case for patients at their terminal stages of expected life-spans.

- Factoring in all the above-mentioned conditions, it is plausible that dual mobility hips despite all of their presently rising popularity, have not yet emerged to be the first go-to option for primary arthroplasties of patients aged between 60 – 75 years, which forms nearly the bulk of the worldwide arthroplasty patient traffic.

- Surprisingly, amidst the presence of all such conditions, no age-linked data of DM Hip usage was reported or published by the Registry, nor was it accessible for utilization in the analyses and critical evaluation processes of this research probe.

- Many of the DM Hips that were found to be used for the greatest number of implantations in hip arthroplasties of the Australian patients, were not ODEP rated, as this report is being written. The Australian practice might not involve a declared policy for ODEP rated or any other prosthesis benchmarking standard benchmarked prostheses only, but it is assumable that the occurrences of the maximal number of the globally accepted and ISAR / IPBWG acknowledged, recommended ODEP-rated prostheses on the most used lists, signifies a safe and sound arthroplasty practice as far prostheses utilized is concerned. This is evident from the following tabulation, developed from the data accessed from the Australian registry for the purposes of this research: -

AOANJRR 2022 :- Cumulative Revision Percent of Dual Mobility Hip Prosthesis used for Primary THA for All Diagnoses of the Australian Patient Cohort.

SL No.	Dual Mobility Insert	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	2M	ImplantCast GmbH	Unrated	487	18	2.3(1.3, 4.1)	4(2.3, 6.9)	4.9(2.8, 8.6)			
2	Active Articulation	Zimmer Biomet	Unrated	4,257	89	2(1.6, 2.6)	2.7(2.1, 3.4)				
3	Avantage	Zimmer Biomet	ODEP Rating Withdrawn / 10A / 7A	321	12	3.1(1.6, 5.9)	3.6(2, 6.7)	5.9(3, 11.4)			
4	Bi-Mentum	Depuy Synthes	7A/10A	102	3						
5	Custom Made(Signature)	Signature Orthopedics	Unrated	104	1						
6	Dual Mobility Cup	Open Access / Turnkey Supplier	Unrated	95	3	1.1(0.1, 7.2)	3.5(1.1, 10.5)				
7	MDM (Dual Mobility)	Stryker	7A/7A*	2,596	67	1.9(1.4, 2.5)	2.7(2.1, 3.5)	3.3(2.5, 4.3)			
8	Novae E	SERF	10A	1,586	32	1(0.6, 1.7)	2.2(1.5, 3.2)	2.3(1.6, 3.3)			
9	PolarCup	Smith & Nephew	5A/10A*	1,028	50	2.9(2, 4.1)	4.6(3.4, 6.2)	5.6(4.1, 7.6)	7.8(5.4, 11.2)		
10	Restoration	Stryker	Unrated	5,007	158	2.5(2.1, 3)	3.3(2.8, 3.9)	4.1(3.4, 4.9)			
11	Saturne	Amplitude	10A / ODEP Rating Withdrawn	1,147	27	1.5(0.9, 2.5)	2.6(1.7, 3.9)	3.3(2.1, 5.2)			
12	Trinity	Corin Group	10A*	2,942	42	1.4(1, 1.9)	1.7(1.2, 2.4)				
13	Versafit	Medacta International	Unrated	1,477	51	2.7(2, 3.7)	3.9(3, 5.2)	4.2(3.1, 5.5)			
14	Other DM Hips [6]			49	1	2.3(0.3, 15.4)					
TOTAL				21,198	554						

Table 6.1.35 :- ***Cumulative Revision Percent of the various Dual Mobility Hip Prostheses that were used for Primary Total Hip Arthroplasty for all diagnoses of the Australian Patient Cohort.***

[Note: - 6 Individual Prostheses were not ODEP Rated, while 2 Prostheses had their ODEP Rating Withdrawn for at least one of their commercially circulating variants, out of the 13 Prostheses Data that were accessed].

Hip Arthroplasty Practices Concerning Fractured Neck-of-Femur (NOF) Cases of the Australian Patient Cohort: -

- There have been 24,801 cases of primary total hip arthroplasty, that were due to fractured NOF, with a cumulative revision percent of 9.40% at 15 Years, causing nearly 1,163 revision arthroplasty cases, out the previously stated primaries.

- The revision rate for Fractured NOF cases of patients belonging to ASA II, III, IV were comparatively higher than that of the patients who belonged to ASA I group. This is possibly due to the general differences due to dislocation and instability related vulnerabilities with an increasing ASA score.

- Australian patients belonging to the ASA III category, had proportionately higher number of total hip arthroplasties for fractured neck of femur, than that of progressive osteoarthritis induced damages of the hip joint.

- The patients who had a respective BMI score, corresponding to the BMI 2 and BMI 3 categories of the global BMI Index metric, had a greater revision rate, than the patients with a normal BMI, when particularly fractured neck of femur cases were studied.

- The most common reasons for revisions as per ASA score, as was inferred after critical examination of the Australian arthroplasty practices are presented as follows: -

ASA Grade	**Most Common Reasons for Revisions**
ASA 1 / ASA I	Fracture / Periprosthetic Fracture, Prosthesis Dislocation / Subluxation, Instability and Aseptic Loosening.
ASA 2 / ASA II	Fracture/Periprosthetic Fracture, Prosthesis Dislocation/Subluxation, Instability and Aseptic Loosening.
ASA 3 / ASA III	Prosthesis Dislocation/Subluxation, Instability, Fracture/Periprosthetic Fracture and Infection.
ASA 4 / ASA IV	Infection, Prosthesis Dislocation/Subluxation, Instability and Fracture/Periprosthetic Fracture.
The reasons for revisions for respective ASA grades, are presented in decreasing order of their occurrence/incidences for revision arthroplasty.	

- The analysis of fractured NOF cases in Australia, further reveals that arthroplasties using hybrid fixation, dominated in way higher numbers than cemented and non-cemented arthroplasties done for the same primary diagnosis. Hybrid fixation was applied in 15,102, while cemented and non-cemented arthroplasties accounted for 1,448 and 6,084 respective arthroplasties out of the total 24,801 arthroplasty cases that were recorded in the database, to be of fractured NOF origin.

- This scenario of hybrid fixations dominating over the traditional cemented and cementless approaches of prosthesis fixation, was a contrasting scenario from the usual global picture on this regard, i.e., for particular fractured NOF caused arthroplasty procedures.

- The brief idea of the revision rates between these three fixation methods utilized are presented, summarily as follows: -

$$RR_{Fractured.NOF}\,[\text{Cemented}] < RR_{Fractured.NOF}\,[\text{Non-Cemented}]$$
$$RR_{Fractured.NOF}\,[\text{Non-Cemented}] = RR_{Fractured.NOF}\,[\text{Hybrid}]$$

$RR_{Fractured.NOF}$ [Non-Cemented] > $RR_{Fractured.NOF}$ [Hybrid]

AOANJRR 2022 : Cumulative Revision Percent of Primary THA by Fixation Methods for Patients with Primary Diagnosis Fractured Neck of Femur (NOF). [Highlights an Interesting Scenario wherein Hybrid Fixation Nos. dominate the Cemented & Non-Cemented Fixations Nos. against the Global Scenario].									
SL No.	Fixation Method	Total No. of Cases	No. of Revisions	1 Year	2 Years	3 Years	5 Years	7 Years	10 Years
1	Cemented	1,448	48	2.6(1.9, 3.6)	3.1(2.3, 4.2)	3.5(2.6, 4.7)	4.0(3.0, 5.3)	4.2(3.1, 5.6)	4.2(3.1, 5.6)
2	Non-Cemented	6,084	347	3.9(3.5, 4.5)	4.5(4.0, 5.1)	5.2(4.7, 5.9)	5.9(5.2, 6.5)	6.5(5.8, 7.3)	8.0(7.0, 9.1)
3	Hybrid	15,102	655	2.7(2.5, 3.0)	3.4(3.1, 3.7)	3.9(3.6, 4.3)	4.8(4.5, 5.3)	6.0(5.5, 6.5)	6.8(6.2, 7.5)
	TOTAL	22,634	1,050	Includes Mixed Ceramic/Mixed Ceramic & XLPE Bearing Surfaces ; Restricted to prostheses in 2021 use.					

Table 6.1.36 : - ***Cumulative Revision Percent of Primary THA by the Fixation Method applied on Australian Patients with a Primary Diagnosis of Fractured Neck of Femur (NOF).***

- It is practically reasonable to say, there's too an age-linked influence on the general outcomes of an arthroplasty procedure that was done due a fracture of the NOF indication and the fixation method utilized in the procedure.

- For patients who aged less than 70 Years there's roughly no significant difference, in terms of revision rates of primary arthroplasties that used cemented and non-cemented fixation methods. However, when compared against the hybrid fixation methods, which has been the dominant practice for fractured NOF cases in Australia, the rates for non-cemented turns out to be marginally higher than that of the hybrid ones, for the same patient group, in the initial few months post-op, after which this too flattens out.

- While, for patients aging greater than equal to 70 years, the general outcomes of revision rates are presented summarily as follows: -

$RR_{Fractured.NOF}$ [Non-Cemented] = 2 x [$RR_{Fractured.NOF}$ {Hybrid}] …3 Months Post-Op
$RR_{Fractured.NOF}$ [Non-Cemented] > $RR_{Fractured.NOF}$ [Cemented]
$RR_{Fractured.NOF}$ [Cemented] = $RR_{Fractured.NOF}$ [Hybrid] [Entire Post-Op Period]

- The age-group wise revision rates of primary THAs, performed on Australian patients with a primary diagnosis of a Fractured NOF as per the respective fixation method used in the arthroplasty procedure is presented as follows: -

AOANJRR 2022 : Cumulative Revision Percent of Primary THA by Fixation Methods for Australian Patients Aged <70 & >=70 Years with Fractured NOF as their Primary Diagnosis.									
SL No.	Fixation Method	No. of Cases	No. of Revisions	1 Year	2 Years	3 Years	5 Years	7 Years	10 Years
A.	<70 Years Age Group	7,333	389	3.3(2.9, 3.7)	4.1(3.6, 4.6)	4.7(4.2, 5.2)	5.5(4.9, 6.1)	6.3(5.7, 7.1)	7.6(6.8, 8.6)
1	Cemented Hip	310	17	5(3.0, 8.3)	5.4(3.3, 8.8)	5.9(3.7, 9.6)	6.7(4.1, 10.8)	6.7(4.1, 10.8)	
2	Non-Cemented Hip	2,437	132	3.7(3.0, 4.5)	4.3(3.5, 5.2)	5.0(4.2, 6.0)	5.4(4.6, 6.5)	5.9(4.9, 7.0)	7.2(5.9, 8.7)
3	Hybrid Hip	4,586	240	2.9(2.5, 3.5)	3.9(3.4, 4.5)	4.4(3.8, 5.1)	5.5(4.8, 6.3)	6.7(5.8, 7.7)	8.0(6.8, 9.4)
B.	>= 70 Years Age Group	15,301	661	2.9(2.7, 3.2)	3.5(3.2, 3.8)	4.0(3.7, 4.4)	4.8(4.5, 5.3)	5.8(5.3, 6.3)	6.6(6.0, 7.3)
1	Cemented Hip	1,138	31	2.0(1.3, 3.0)	2.5(1.7, 3.6)	2.8(2.0, 4.1)	3.2(2.2, 4.7)	3.5(2.4, 5.1)	
2	Non-Cemented Hip	3,647	215	4.1(3.5, 4.8)	4.7(4.0, 5.5)	5.4(4.7, 6.2)	6.1(5.3, 7.1)	7.0(6.0, 8.1)	8.6(7.3, 10.2)
3	Hybrid Hip	10,516	415	2.6(2.3, 2.9)	3.2(2.9, 3.6)	3.7(3.3, 4.1)	4.6(4.1, 5.1)	5.6(5.1, 6.3)	6.1(5.4, 6.9)
	TOTAL	22,634	1,050	Includes Mixed Ceramic / Mixed Ceramic & XLPE Bearing surfaces ; Restricted to prostheses in 2021 use.					

Table 6.1.37 :-***Cumulative Revision Percent of Primary THA by Age-Group of the Australian Patients with a Primary Diagnosis of a Fractured NOF, and the respective Fixation Method utilized in the Arthroplasty procedure.***

- The outcomes of primary total hip arthroplasties conducted for a primary indication of a fractured neck of femur (NOF) diagnosis, as per the modularity or hip prostheses class utilized for the arthroplasty, in terms of revision rates, as per age-group of the recipient patients, across various post-op follow-up time points is presented in the following tabulation: -

AOANJRR 2022 : Cumulative Revision % of Primary THA by Age-Group & Hip Class of Australian Patients with Primary Diagnosis Fractured NOF.									
SL No/	Hip Class / Modularity of Hip Prosthesis	No. of Cases	No. of Revisions	1 Year	2 Years	3 Years	5 Years	7 Years	10 Years
1	<70 Years Aged Patients	13,825	909	3.2(2.9, 3.5)	4.4(4.1, 4.8)	5.5(5.1, 5.9)	6.8(6.4, 7.4)	8.2(7.6, 8.8)	10.0(9.3, 10.8)
A.	Unipolar Monoblock	701	66	4.7(3.2, 6.8)	6.8(5.0, 9.3)	9.5(7.2, 12.5)	11.6(8.9, 14.9)	12.9(10.0, 16.6)	14.7(11.3, 19.0)
B.	Unipolar Modular	2,949	273	3.0(2.5, 3.8)	4.5(5.0, 9.3)	6.5(5.6, 7.7)	9.8(8.6,11.2)	12.2(10.7, 13.9)	15.9(14.0, 18.1)
C.	Bipolar	2,286	129	3.2(2.5, 4.0)	4.8(3.9, 5.9)	5.8(4.8, 7.0)	6.6(5.5, 8.0)	7.9(6.5, 9.6)	8.8(7.2, 10.8)
D.	Total Conventional	7,889	441	3.2(2.8, 3.6)	4.1(3.7, 4.6)	4.7(4.3, 5.3)	5.5(5.0, 6.1)	6.4(5.8, 7.1)	7.7(6.9, 8.6)
2	> = 70 Aged Patients	1,00,233	3,217	2.4(2.3, 2.5)	3.1(2.9, 3.2)	3.5(3.4, 3.7)	4.3(4.1, 4.5)	5.1(4.9, 5.3)	6.0(5.7, 6.3)
A.	Unipolar Monoblock	21,028	773	3.1(2.9, 3.4)	4.2(3.9, 4.5)	4.8(4.4, 5.1)	5.4(5.0, 5.8)	6.1(5.6, 6.6)	6.8(6.2, 7.5)
B.	Unipolar Modular	39,487	1,110	1.9(1.7, 2.0)	2.5(2.3, 2.7)	3.0(2.8, 3.2)	3.9(3.7, 4.2)	4.8(4.4, 5.1)	6.1(5.5, 6.6)
C.	Bipolar	22,806	612	2.3(2.1, 2.5)	2.7(2.5, 3.0)	3.2(2.9, 3.5)	3.7(3.4, 4.0)	4.1(3.7, 4.5)	4.8(4.2, 5.4)
D.	Total Conventional	16,912	722	2.9(2.6, 3.1)	3.5(3.2, 3.8)	4.0(3.7, 4.3)	4.7(4.4, 5.1)	5.7(5.2, 6.2)	6.5(5.9, 7.1)
TOTAL		1,14,058	4,126	All MoM prostheses excluded ; Restricted to prostheses in 2021 use					

Table 6.1.38 :-***Cumulative Revision Percent of Primary THA by Age-Group of the Australian Patients with a Primary Diagnosis of a Fractured NOF, and Modularity of the Hip Prostheses utilized.***

- The outcomes of primary THAs performed for a primary indication of a fractured neck of femur (NOF) diagnosis on the Australian patients, as per the sizes of the femoral heads used, as part of the hip prosthesis unit, in terms of revision rates, across various post-operative follow-up time points are presented as follows: -

AOANJRR 2022 : Cumulative Revision Percent of Primary THA by Femoral Head Sizes for Patients with Fractured NOF as their Primary Diagnosis.									
SL No.	Femoral Head Size	No. of Cases	No. of Revisions	1 Year	2 Years	3 Years	5 Years	7 Years	10 Years
1	<32 mm	6,707	298	2.9(2.5, 3.3)	3.6(3.1, 4.1)	4.1(3.6, 4.6)	4.8(4.2, 5.5)	5.8(5.1, 6.7)	6.9(5.9, 8.0)
2	32 mm	9,711	469	3.0(2.7, 3.4)	3.7(3.3, 4.1)	4.2(3.8, 4.7)	5.0(4.5, 5.5)	5.8(5.3, 6.4)	6.6(5.9, 7.3)
3	> 32 mm	8,382	396	3.0(2.7, 3.4)	3.8(3.4, 4.2)	4.3(3.8, 4.8)	5.1(4.6, 5.7)	6.2(5.5, 6.9)	7.5(6.6, 8.5)
TOTAL		24,800	1,163	All MoM prostheses excluded ; Restricted to prostheses in 2021 use.					

Table 6.1.39 :-***Cumulative Revision Percent of Primary THA by the Femoral Head Sizes used on Australian patients with a Primary Diagnosis of a Fractured Neck of Femur (NOF).***

- For fractured Neck of Femur diagnoses in Australia, conventional acetabular prostheses of both constrained & non-constrained types were the primary choice to be utilized for primary THAs, over Dual Mobility or DM Hip based acetabular shell liners prostheses. The relative comparative performance in terms of observed revision rates across multiple postoperative time-points both either of the acetabular prostheses types is presented through the following tabulation: -

AOANJRR 2022 : Cumulative Revision % of Primary THA by Acetabular Type in Australian Patients with Primary Diagnosis of Fractured Neck of Femur.									
SL No/	Acetabular Type	No. of Cases	No. of Revisions	1 Year	2 Years	3 Years	5 Years	7 Years	10 Years
1	Constrained Prosthesis	240	10	4.1(2.1, 7.7)	4.6(2.5, 8.4)	4.6(2.5, 8.4)	4.6(2.5, 8.4)		
2	Other Acetabular Prosthesis	24,561	1,153	3.0(2.8, 3.2)	3.0(2.8, 3.2)	4.2(3.9, 4.5)	5.0(4.7, 5.3)	5.9(5.6, 6.3)	6.9(6.5, 7.5)
TOTAL		24,801	1,163	All MoM prostheses excluded ; Restricted to prostheses in 2021 use.					

Table 6.1.40 :-***Cumulative Revision Percent of Primary THA by the type of Acetabular Prostheses used on the Australian patients with a Primary Diagnosis of a Fractured Neck of Femur (NOF).***

- As pre-discussed on the previous segment, Dual Mobility or DM hip prostheses were found to be having comparatively better outcomes in terms of cumulative revision rates during various time-points in their respective post-operative window than conventional acetabular prostheses, particularly when the respective patient is operated on the diagnoses of a fractured neck-of-femur (NOF), in Australian hip arthroplasty practices. Though detailed long-term large-scale analysis of the said phenomenon is yet to be documented and relevantly studied, but as of the present day the above statement is based on the on-ground obtained facts and figures, which is presented through the following tabulation: -

Comparative distribution of the Cumulative Revision Rate percentages of the Primary THA by Acetabular Mobility design types in Australian Patients with a Primary Diagnosis of Fractured Neck of Femur (NOF).									
SL No/	Acetabular Type	No. of Cases	No. of Revisions	Post-Op 1 Year	Post-Op 2 Years	Post-Op 3 Years	Post-Op 5 Years	Post-Op 7 Years	Post-Op 10 Years
1	Dual Mobility(DM) Prosthesis	4,128	130	2.6(2.1, 3.1)	3.2(2.7, 3.9)	3.6(3.0, 4.3)	4.2(3.5, 5.1)	5.7(4.2, 7.7)	
2	Conventional Acetabular Prostheses	20,673	1,033	3.1(2.8, 3.3)	3.8(3.5, 4.0)	4.3(4.0, 4.6)	5.1(4.8, 5.5)	6.0(5.6, 6.4)	7.1(6.6, 7.6)
TOTAL		24,801	1,163	All MoM prostheses excluded ; Restricted to prostheses in 2021 use.					

Table 6.1.41 :-***Cumulative Revision Percent of Primary THA by the type of Acetabular Mobility Design type of the Prostheses used on the Australian patients with a Primary Diagnosis of a Fractured Neck of Femur (NOF).***

Resurfacing Hip Arthroplasty Practices in Australia: -

- Subsequently, the much talked about debacle story of resurfacing hip arthroplasty practices in Australia, was studied and critically analyzed from the verified sources of the Australian Registry, TGA and relevant prostheses manufacturer brochures and journals.

- Surprisingly, amidst all the backlash, resurfacing hip arthroplasty and its related prostheses have received globally due to its own de-merits and failures, resurfacing in Australia, has not yet been totally abolished, and still practiced in small numbers, which the TGA has a thorough regulation upon, and it is critically mandated for the clinicians and healthcare providers in Australia, to only go for ultra-large sized resurfacing heads with XLPE bearings only for young males, and not for females, as per numerous internal and public notifications, circulars, warning letters that were accessed by this research probe. The prostheses that were utilized for such operations, are separately ear-marked both by the Registry and the TGA bodies, and are corroborated for their ODEP status, with other related information, in separate tabulations, which is presented in this chapter for Prosthesis Specific analyses.

- It is also found that with the usage of such ultra-large sized resurfacing heads specifically femoral head sizes 50 mm up to 54 mm, on the Australian patients, was comparatively safer, than other ultra-large and large resurfacing femoral heads such as <= 44 mm and 45 – 49 mm head sizes.

- The above statement could be justified by the fact that such <= 44 mm sized resurfacing femoral heads had a mean revision rate of 31.30% with the maximum rate as high as 35.30%. While the 45 – 49 mm head sizes had a mean revision rate of 14.80% with a maximum rate of 16.60%.

- While for the case of >= 55 mm resurfacing femoral heads, it was 3.90% with a maximum of 6.00% at 15 years of post-op follow-up time point. The 50 – 54 mm sized resurfacing femoral heads had a mean revision rate of 8.10% with a maximum of 9.10% at 20 years' time of post-operative follow-up.

AOANJRR 2022 : Cumulative Revision Percent of Primary Total Resurfacing Arthroplasty by Resurfacing Femoral Head Sizes in Australian Patients with Primary Diagnosis OA.

SL No.	Femoral Head Size	No. of Cases	No. of Revisions	1 Year	3 Years	5 Years	10 Years	15 Years	20 Years
1	<=44mm	882	233	2.6(1.7, 3.9)	5.6(4.3, 7.4)	9.3(7.6, 11.5)	19.7(17.2, 22.6)	26.3(23.4, 29.4)	31.3(27.6, 35.3)
2	45-49 mm	2,878	304	1.7(1.3, 2.3)	3.3(2.7, 4.0)	4.5(3.8, 5.4)	9.1(8.0, 10.3)	12.6(11.2, 14.1)	14.8(13.2, 16.6)
3	50-54 mm	9,762	482	1.1(0.9, 1.3)	1.7(1.5, 2.0)	2.2(1.9, 2.5)	4.0(3.6, 4.4)	6.2(5.6, 6.8)	8.1(7.3, 9.1)
4	>= 55 mm	826	23	0.6(0.3, 1.5)	0.8(0.3, 1.7)	1.0(0.5, 2.1)	2.1(1.2, 3.6)	3.9(2.5, 6.0)	
TOTAL		14,348	1,042	Restricted to prostheses in 2021 Use.					

Table 6.1.42 : -***The overall cumulative revision percent of Primary Total Resurfacing Hip Arthroplasty by Resurfacing Femoral Head Sizes used in Australian Patients with Primary Diagnosis Osteoarthritis.***

Note:- The alarmingly high revision percent at 15/20 Years for <=44 to 49 mm series of resurfacing femoral head and its relative difference with femoral head sizes for 50+ mm sizes. sizes.

- Categorizing the usage scenario of the various sizes of the resurfacing femoral heads on the Australian patient cohort and the related outcome on the cumulative revision rate percentages, across different time-points during their respective post-operative window, categorized as per the patient gender is presented as follows: -

Distribution of the Patient Gender linked Cumulative Revision Rate percentage of the Primary Resurfacing Hip Arthroplasties, performed on the Australian Patient Cohort categorized as per the Resurfacing Femoral Head sizes utilized.

SL No.	Gender & Resurfacing Femoral Heads.	No. of Cases	No. of Revisions	1 Year	3 Years	5 Years	10 Years	15 Years	20 Years
MALE PATIENTS		11,892	580	1.2(1.0, 1.4)	1.8(1.6, 2.1)	2.3(2.1, 2.6)	4.1(3.7, 4.5)	6.2(5.7, 6.8)	8.2(7.4, 9.1)
1	<50 mm	1,685	114	1.6(1.1, 2.4)	3.0(2.2, 3.9)	3.7(2.9, 4.8)	6.5(5.3, 8.0)	8.9(7.3, 10.8)	11.7(9.2, 14.8)
2	>= 50mm	10,207	466	1.1(0.9, 1.3)	1.6(1.4, 1.9)	2.1(1.8, 2.4)	3.7(3.3, 4.1)	5.8(5.3, 6.4)	7.7(6.8, 8.7)
FEMALE PATIENTS		2,456	462	1.9(1.4, 2.5)	4.1(3.3, 4.9)	6.4(5.5, 7.4)	14.0(12.7, 15.5)	18.8(17.3, 20.5)	22.0(20.1, 24.0)
3	<50 mm	2075	423	2.2(1.6, 2.9)	4.6(3.7, 5.6)	7.1(6.1, 8.3)	15.3(13.8, 16.9)	20.5(18.8, 22.4)	23.8(21.7, 26.1)
4	>= 50mm	381	39	0.5(0.1, 2.1)	1.3(0.6, 3.2)	2.4(1.3, 4.6)	7.1(4.9, 10.3)	9.6(6.9, 13.2)	
TOTAL		14,348	1,042	*Restricted to prostheses in 2021 Use in Australia.*					

Table 6.1.43 :- ***Tabulation illustrating the Cumulative Revision Rate Percentage of the Primary Resurfacing Hip Arthroplasties on the Australian patient cohort, categorized as per their respective Gender & Resurfacing Femoral Head Sizes utilized.***

- There's been 19,369 registered hip resurfacing arthroplasty cases in Australia, with an additional 555 arthroplasty procedures in 2021 alone. However, in 2021, the annual numbers of the total resurfacing hip arthroplasty procedures performed, decreased by 3.90% than that of the 2020 numbers, and an overall shrinkage by 70.30% since 2005 (when resurfacing arthroplasty was booming globally and was at its peak), is a remarkably good indicator of safer arthroplasty practices for the Australian patients in particular, and regulators, statisticians/researchers concerned worldwide.

- In 2021, almost 93.60% of all the primary resurfacings were done on male patients, with the overall distribution share of 1.10% of all hip arthroplasty procedures that were done in 2021. Further excavation into this regard, revealed, that a major portion of these male patients who have received resurfacing arthroplasties were all young in age, or in other words, as could be said, men with comparatively greater risk enduring capacities, having the strength to withstand the trauma of a revision surgery, if necessary, in short implying the general resurfacing arthroplasty practice scenario in Australia, to be a calculated risk/gamble.

AOANJRR 2022:- Cumulative Revision Percent of Primary Total Resurfacing Arthroplasty by Patient Age Groups & Gender with Primary Diagnosis OA.

SL No.	Age Group & Gender	Total No. of Cases	Total No. of Revisions.	1 Year	3 Years	5 Years	10 Years	15 Years	20 Years
MALE PATIENTS		11,892	580	1.2(1.0, 1.4)	1.8(1.6, 2.1)	2.3(2.1, 2.6)	4.1(3.7, 4.5)	6.2(5.7, 6.8)	8.2(7.4, 9.1)
1	<55 Years	6,210	288	1.0(0.7, 1.2)	1.5(1.2, 1.9)	2.0(1.6, 2.4)	3.8(3.3, 4.4)	6.2(5.5, 7.0)	8.1(7.0, 9.4)
2	55 - 64 Years	4,424	224	1.1(0.8, 1.4)	1.8(1.4, 2.2)	2.4(2.0, 2.9)	4.2(3.6, 4.4)	6.3(5.5, 7.2)	8.4(7.1, 10.0)
3	>= 65 Years	1,258	68	2.5(1.8, 3.5)	3.4(2.5, 4.5)	3.8(2.8, 5.0)	4.8(3.7, 6.3)	6.3(4.9, 8.2)	
FEMALE PATIENTS		2,456	462	1.9(1.4, 2.5)	4.1(3.3, 4.9)	6.4(5.5, 7.4)	14.0(12.7, 15.5)	18.8(17.3, 20.5)	22.0(20.1, 24.0)
1	<55 Years	1,402	261	1.5(1.0, 2.3)	3.5(2.7, 4.6)	5.8(4.6, 7.1)	14.2(12.4, 16.2)	18.9(16.8, 21.1)	22.0(19.5, 24.7)
2	55 - 64 Years	950	188	2.4(1.6, 3.6)	4.8(3.6, 6.4)	7.4(5.9, 9.3)	14.3(12.2, 16.8)	19.3(16.8, 22.0)	22.8(19.9, 26.1)
3	>= 65 Years	104	13	2.9(0.9, 8.7)	4.8(2.0, 11.2)	5.8(2.6, 12.4)	8.8(4.7, 16.3)	13.8(8.2, 22.7)	
TOTAL		14,348	1,042						

Restricted to Prostheses in 2021 use only. Notice the Sharp & Surprisingly Higher RR in Females compared to Males at nearly all points & specially at 3 Years Post-Op mark, therefore leading to TGA(Therapeutics Goods Administration) Restricting Resurfacing Use to Only Selected Large Heads on Male Australian Patients only.

Table 6.1.44 :-***Comparative differences in the Cumulative Revision percent of Primary Total Resurfacing Arthroplasty of Australian Male and Female Patients, who had received a resurfacing arthroplasty due to Primary Diagnosis OA, analyzed as per their Age-Group Categories, of all time.***

- The primary indication for a resurfacing arthroplasty in Australia, was osteoarthritis, that accounted for almost 95.60% of all resurfacing arthroplasty procedures. This is followed by developmental hip dysplasia and osteonecrosis, both having a share of 2.00% and 1.60% of overall resurfacing hip arthroplasty respectively.

AOANJRR 2022 : Cumulative Revision Percent of Primary Total Resurfacing Hip Arthroplasty by Primary Diagnosis of the Australian Patients.

SL No.	Primary Diagnosis	No. of Cases	No. of Revisions.	% of Overall	1 Years	3 Years	5 Years	10 Years	15 Years	20 Years
1	Osteoarthritis	14,348	1,042	95.60%	1.3(1.1, 1.5)	2.2(2.0, 2.5)	3.1(2.8, 3.4)	6.1(5.7, 6.5)	9.0(8.4, 9.5)	11.3(10.6, 12.2)
2	Developmental Dysplasia	294	48	2.00%	3.1(1.6, 5.9)	6.0(3.8, 9.5)	9.8(6.8, 14.0)	13.7(10.1, 18.4)	17.2(13.1, 22.3)	
3	Osteonecrosis	247	34	1.60%	1.2(0.4, 3.7)	3.3(1.7, 6.6)	5.2(3.0, 9.0)	9.1(5.9, 13.7)	15.3(11.0, 21.0)	
4	Other Indications [6]	115	17	0.80%	2.6(0.8, 7.9)	3.5(1.3, 9.1)	6.5(3.1, 13.1)	13.3(7.9, 21.9)	15.9(9.8, 25.2)	
TOTAL		15,004	1,141	Only Primary Diagnoses with >100 procedures have been listed ; Restricted to prostheses in 2021 use.						

Table 6.1.45 :- ***The Most Common Primary Indications, for which a Primary Total Resurfacing Hip Arthroplasty was conducted on Australian Patients, and their relative Cumulative Revision Percent.***

- The categorical use and selection of resurfacing prostheses in majorly osteoarthritic patients, more than any other indications such as a fractured neck of femur, or a dysplasia, can be supported by the fact, that resurfacing which as a whole remains to be largely plagued by the huge revision risk it entails, of which a major gets realized in real life as well, the primary concern should be to use such a procedure only for scenarios, wherein it is expected to have lesser revisions, to control the revision burden as much as practically possible, and this rationale is further consolidated by the facts: -

$$RR_{Resurfacing}[\text{Osteoarthritis}] < RR_{Resurfacing}[\text{Developmental Hip Dysplasia}]$$
$$RR_{Resurfacing}[\text{Osteoarthritis}] < RR_{Resurfacing}[\text{Osteonecrosis}]$$

- Maintaining the consistency with the global scenario, the general revision numbers for resurfacing continues to be alarmingly high compared to conventional THA and Partial Hip Arthroplasties, in Australia.

At 15 Years' time-point, the Australian patients who had undergone a resurfacing arthroplasty due a primary indication for progressively damaging osteoarthritis, had a revision rate of 9.00%, compared 6.30% for similar conditions and time-point for Conventional THA.

Comparative Differences in the Cumulative Revision Percent of the Total Resurfacing Hip Arthroplasty vis-à-vis Conventional Total Hip Arthroplasty performed on Australian Patients with Primary Diagnosis OA, across Different Post-Operative Follow-Up timepoints.

SL No.	Type of Hip Arthroplasty	No. of Cases	No. of Revisions	1 Year	3 Years	5 Years	10 Years	15 Years	20 Years
1	Total Resurfacing Hip Arthroplasty	14,348	1,042	1.3(1.1, 1.5)	2.2(2.0, 2.5)	3.1(2.8, 3.4)	6.1(5.7, 6.5)	9.0(8.4, 9.5)	11.3(10.6, 12.2)
2	Total Hip Arthroplasty[Conventional]	3,97,261	13,098	1.6(1.6, 1.6)	2.3(2.3, 2.4)	2.9(2.8, 2.9)	4.4(4.3, 4.4)	6.3(6.2, 6.5)	8.4(8.1, 8.8)
TOTAL		4,11,609	14,140	Primary THAs with MoM prostheses use has been excluded ; Restricted to Prosthesis in 2021 use.					

Table 6.1.46 :- ***Comparative differences in the Cumulative Revision percent of Primary Total Resurfacing Arthroplasty vis-à-vis Conventional Total Hip Arthroplasty that were performed on the Australian Patients with a Primary Diagnosis of OA, across different Post-Operative Follow-Up Timepoints.***

- While, for indications such as developmental hip dysplasia, osteonecrosis and others indications had a respective share of 17.20%, 15.30% and 15.90%, for the similar post-operative time point.

- For osteoarthritis driven resurfacing arthroplasties, the following inferences were obtained, after careful critical evaluation of the same for the Australian patients: -

  a. The overall cumulative revision percent for resurfacing arthroplasties conducted on patients with primary indication of progressively damaging osteoarthritis, at the time-point of 20 years in the post-operative period, was 11.30%, which is way higher than conventional hip arthroplasties performed for the same indication at similar postoperative timepoints.

  b. The main reasons for primary resurfacing revision in the Australian patient cohort were for Aseptic Loosening, Metal-related pathology/Metallosis, Fracture in decreasing order of their respective impact. Post 7 years, loosening remains as the risk majeure than all other risks combined.

AOANJRR 2022 :- Major Reasons for Revisions of Primary Resurfacing Hip Arthroplasty in Australian Patients with Primary Diagnosis OA.

SL No.	Reason for Revision	Number of Cases	% of Overall.
1	Loosening of Implant	266	25.5
2	Metal Related Pathology	277	21.8
3	Fracture	205	19.7
4	Lysis	111	10.7
5	Infection	68	6.5
6	Pain	61	5.9
7	Prosthesis Dislocation/Instability	26	2.5
8	Osteonecrosis	25	2.4
9	Other Reasons [10]	53	5.1
TOTAL		1,042	100

Table 6.1.47 :- ***Major/Main Reasons which were stated as the Primary Indication for the Australian Patients with Primary Diagnosis OA, to undergo a Revision Arthroplasty.***

  c. Similar to the global scenario, the metal related pathology or the incidences of acute metallosis in the patient's anatomy, causing elevated B[Co], that impairs various other vital organ's functioning, sets in the short-term post-op period itself.

  d. The common revision type is the replacement of both the femoral and acetabular components and converting it into a conventional primary total hip arthroplasty system, with or without bone resection, depending on the failure extent. Such conversion into conventional THAs with the replacement and debridement of both the femoral and acetabular components, accounted for nearly 69.40% of all resurfacing revisions. While, other revision types included the replacement of the femoral component, which is the most villainous component of a resurfacing system, with a conventional stem, that accounted for 24.70% of all resurfacing revisions in Australia. Further revision types are enlisted in the following tabulation as below: -

AOANJRR 2022 : Most Commonly Replaced/Revised Components of a Primary Total Hip Resurfacing Arthroplasty in the Australian Cohort with Primary Diagnosis OA.			
SL No.	**Type of Revision / Component Revised**	**Number of Cases**	**% of Overall.**
1	**Conversion to THA(F+A)**	**723**	**69.40%**
2	**Femoral Component**	**257**	**24.70%**
3	**Acetabular Component**	**30**	**2.90%**
4	**Cement Spacer**	**25**	**2.40%**
5	**Removal Prostheses**	**7**	**0.70%**
TOTAL		**1,042**	**100.00%**

Table 6.1.48 :- ***Most Common Types of Resurfacing Revisions or Commonly Replaced/Revised Components during a Revision of Resurfacing Hip, of Australian Patients, with Primary Diagnosis OA.***

- The age-linked revision rates for resurfacing arthroplasties of the Australian patient cohort, with primary diagnosis OA, is presented summarily as follows: -

AOANJRR 2022 : - Cumulative Revision % of Primary Total Resurfacing Arthroplasty by Patient Age Groups with Primary Diagnosis OA.									
SL No.	Age Groups of Patients	Total No. of Cases	Total No. of Revisions.	1 Year	3 Years	5 Years	10 Years	15 Years	20 Years
1	<55 Years	7,612	549	1.1(0.8, 1.3)	1.9(1.6, 2.2)	2.7(2.4, 3.1)	6.1(5.5, 6.7)	9.1(8.4, 10.0)	11.5(10.4, 12.7)
2	55 - 64 Years	5,374	412	1.3(1.0, 1.7)	2.3(2.0, 2.8)	3.3(2.9, 3.9)	6.3(5.6, 7.0)	9.1(8.3, 10.1)	11.7(10.5, 13.1)
3	>= 65 Years	1,362	81	2.5(1.8, 3.5)	3.5(2.6, 4.6)	3.9(3.0, 5.1)	5.2(4.1, 6.6)	7.1(5.7, 9.0)	
TOTAL		14,348	1,042						

Table 6.1.49 : ***-Age-linked Cumulative Revision Rates for Resurfacing Arthroplasties of the Australian Patient Cohort, with Primary Diagnosis OA.***

- Patient age was not a revision risk factor for the Australian females, who had received a resurfacing arthroplasty due to progressively damaging osteoarthritis, although the general number of such females is miniscule. They also had a significantly greater revision rate than their male counterparts. The maximum revision rate attained for resurfacing hip arthroplasty of the female Australian patients, with a primary diagnosis of progressively damaging osteoarthritis, was a staggering 24.00% at the 20-year time-point with a mean of 22.00% for the same post-op time interval. While, for males under similar conditions, it was a maximum of 9.10% and a mean of 8.20%.

AOANJRR 2022:- Cumulative Revision Percent of Primary Total Resurfacing Arthroplasty by Patient Age Groups & Gender with Primary Diagnosis OA.									
SL No.	Age Group & Gender	Total No. of Cases	Total No. of Revisions.	1 Year	3 Years	5 Years	10 Years	15 Years	20 Years
MALE PATIENTS		11,892	580	1.2(1.0, 1.4)	1.8(1.6, 2.1)	2.3(2.1, 2.6)	4.1(3.7, 4.5)	6.2(5.7, 6.8)	8.2(7.4, 9.1)
1	<55 Years	6,210	288	1.0(0.7, 1.2)	1.5(1.2, 1.9)	2.0(1.6, 2.4)	3.8(3.3, 4.4)	6.2(5.5, 7.0)	8.1(7.0, 9.4)
2	55 - 64 Years	4,424	224	1.1(0.8, 1.4)	1.8(1.4, 2.2)	2.4(2.0, 2.9)	4.2(3.6, 4.4)	6.3(5.5, 7.2)	8.4(7.1, 10.0)
3	>= 65 Years	1,258	68	2.5(1.8, 3.5)	3.4(2.5, 4.5)	3.8(2.8, 5.0)	4.8(3.7, 6.3)	6.3(4.9, 8.2)	
FEMALE PATIENTS		2,456	462	1.9(1.4, 2.5)	4.1(3.3, 4.9)	6.4(5.5, 7.4)	14.0(12.7, 15.5)	18.8(17.3, 20.5)	22.0(20.1, 24.0)
1	<55 Years	1,402	261	1.5(1.0, 2.3)	3.5(2.7, 4.6)	5.8(4.6, 7.1)	14.2(12.4, 16.2)	18.9(16.8, 21.1)	22.0(19.5, 24.7)
2	55 - 64 Years	950	188	2.4(1.6, 3.6)	4.8(3.6, 6.4)	7.4(5.9, 9.3)	14.3(12.2, 16.8)	19.3(16.8, 22.0)	22.8(19.9, 26.1)
3	>= 65 Years	104	13	2.9(0.9, 8.7)	4.8(2.0, 11.2)	5.8(2.6, 12.4)	8.8(4.7, 16.3)	13.8(8.2, 22.7)	
TOTAL		14,348	1,042						
Restricted to Prostheses in 2021 use only. Notice the Sharp & Surprisingly Higher RR in Females compared to Males at nearly all points & specially at 3 Years Post-Op mark, therefore leading to TGA(Therapeutics Goods Administration) Restricting Resurfacing Use to Only Selected Large Heads on Male Australian Patients only.									

Table 6.1.50 : - ***Cumulative Revision Percent of Primary Total Resurfacing Arthroplasty by Gender and Age-Groups of the Australian Patients who received a Resurfacing for Primary Diagnosis OA.***

- The overall age-linked revision scenario for Australian male patients with a resurfacing arthroplasty is presented as follows: -

RR_{Males} [> = 65 Years] > RR_{Males} [55 – 64 Years] …… first post-op 6 Months

RR_{Males} [> = 65 Years] > RR_{Males} [< 55 Years] ……first post-op 1 Year.

- The "Adept" (MatOrtho), "B.H.R" (Smith & Nephew) and "ReCerf" (MatOrtho) were the only TGA approved Resurfacing Hip Prostheses those were in reported circulation and to be utilized for implantation on the Australian patients, in the recent years, while, rest many other globally happening popular resurfacing heads, like many other nations, are banned from human use and totally withdrawn from commercial operations. The following tabulations are presented in succession, herewith that highlights, the relative performance of the above-mentioned resurfacing prostheses in terms of the revision rates observed, and their ODEP Rating Statuses, with Year-Wise Respective implantation on Australian patients, as follows: -

AOANJRR 2022 : Most Used Resurfacing Heads in Primary Total Resurfacing Arthroplasty of Australian Patients.																				
SL No.	Year of Record :- 2003				Year of Record :- 2018				Year of Record :- 2019				Year of Record :- 2020				Year of Record :- 2021			
	Resurfacing Model	ODEP Rating	Mfg.Co.	No. of Cases	Resurfacing Model	ODEP Rating	Mfg.Co.	No. of Cases	Resurfacing Model	ODEP Rating	Mfg.Co.	No. of Cases	Resurfacing Model	ODEP Rating	Mfg.Co.	No. of Cases	Resurfacing Model	ODEP Rating	Mfg.Co.	No. of Cases
1	B.H.R	15A*[Only Males with 48-62mm Heads]	Smith & Nephew	1,359	Adept	13A	MatOrtho	247	Adept	13A	MatOrtho	301	Adept	13A	MatOrtho	318	Adept	13A	MatOrtho	314
2	Durom	Withdrawn / Banned	Zimmer Biomet	58	B.H.R	15A*[Only Males with 48-62mm Heads]	Smith & Nephew	132	B.H.R	15A*[Only Males with 48-62mm Heads]	Smith & Nephew	145	B.H.R	15A*[Only Males with 48-62mm Heads]	Smith & Nephew	156	B.H.R	15A*[Only Males with 48-62mm Heads]	Smith & Nephew	121
3	ASR	Withdrawn / Banned	Depuy Synthes	43	ReCerf	Withdrawn / Banned	MatOrtho	3	ReCerf	Withdrawn / Banned	MatOrtho	81	ReCerf	Withdrawn / Banned	MatOrtho	93	ReCerf	Withdrawn / Banned	MatOrtho	110
4	Cormet	Withdrawn / Banned	Corin Group	42																
5	Cormet 2000 HAP	Withdrawn / Banned	Corin Group	38																
6	Conserve Plus	Withdrawn / Banned	Wright Medical	7																
Most Commonly Used Total [6]				1,547	Most Commonly Used Total [3]			382	Most Commonly Used Total [3]			527	Most Commonly Used Total [3]			567	Most Commonly Used Total [3]			545

Table 6.1.50 :- ***Most Used Resurfacing Femoral Heads for Primary Total Resurfacing Arthroplasty of the Australian Patient Cohort in the Recent Years, vis-à-vis the Most Used Resurfacing Femoral Heads from 2003 (First Year of Operational Record available/accessible from the Australian Registry database).***

Legal Framework of Implant Introduction & Arthroplasty Regulation Policy in Australia: -

- The AOANJRR Annual Reports and the Registry-related Data management, Statistical Work is done and managed by the South Australian Health & Medical Research Institute or 'SAHMRI'.

- SAHMRI is the principal institutional body that collects the arthroplasty data from hospitals and clinical centers from all across Australia, identifies discrepancies, and manages the data flow from all the centers, following which they perform various statistical analyses and other related research work with associated particular investigations(should there be any regarding any prostheses or any Hospital or particular Brand), flags the issue to relevant authorities at the Therapeutic Goods Administration(TGA) body [Australian equivalent of US FDA], and ultimately presents a holistic report during the latter half of every year, that comprises the Arthroplasty Practises & Prostheses Performance's characteristics along with other relevant Data from the past of the registry record to the penultimate year to the year of report in the public domain for research & informational pursuits.

- Now, the TGA is a Governmental Agency that is sponsored and legally enforced for Medical Device Regulation and Monitoring by the Federal Government of Australia. The policies and activities of TGA might appear on an apparent basis to be similar to that of the US FDA but is significantly different in its holistic approach towards real-time after-market watch and monitoring of devices and subsequent handling of any adverse issues pertaining to Medical Devices or Healthcare in General.

- TGA policies are also followed and accepted in the neighboring state of New Zealand which also has a matured Arthroplasty Registry [New Zealand Arthroplasty Registry (NZAR)] comprising of arthroplasty data from the 1990s to date.

- The arthroplasty data reporting to the Registry database in Australia is officially not mandatory, but the existence of the Registry, and its operations are legally mandated with adequate empowerment of

Enforcement capacities, validated through the appropriate legislature in Australia. This is also applicable to the TGA as well.

- The overall outcome from the whole thing is an interesting scenario wherein we find that despite no mandatory compulsions on the hospitals, medical institutes, and clinical centers, there's an astoundingly high rate of reporting coverage, as much as 97% of all the arthroplasty procedures being reported and covered by the Registry and its reports.

- Also, multiple health journals, news blogs, and articles have covered the comparatively sharper and agile response of the TGA as well.

Knee Arthroplasty Practices & Prosthesis Utilization Scenarios on the Australian Patient Cohort.

Overview of Knee Arthroplasty Practices in Australia: -

Total No. of Partial Knee Arthroplasties	= 72,774
Total No. of Total Knee Arthroplasties [T.K.A]	= 8,29,272
Total No. of Revision Knee Arthroplasties	= 78,373
Overall Cumulative Total No. of Knee Arthroplasties	= **9,80,419**

- In 2021, there were 68,466 additional knee arthroplasty procedures on the Australian patient cohort. This marked an increase in knee arthroplasty numbers by 5,141 with an 8.2% YoY rise, compared to the 2020 numbers of knee arthroplasties in Australia.

- Total Knee Arthroplasty (TKA) was the most popular choice of all recognized arthroplasty modalities in Australia accounting for 87.00% of all recorded knee arthroplasties in 2021. Comparatively, other forms of unicondylar knee arthroplasty UKA or partial knee arthroplasty decreased to 5.60% in operational share.

- The proportion of revision knee arthroplasties, out of the total number of arthroplasties performed, reduced to 7.4%, equating to 951 lesser number of revisions in 2021, compared to 2004, had the trend continued since.

General Demography of the Australian Patient Cohort, receiving Knee Arthroplasty: -

- The overall distribution of the Australian patient cohort receiving various forms of knee arthroplasties, categorized as per their co-morbidity status of physical fitness asserted by their respective ASA Grade wise distribution is enclosed through the following tabulation: -

AOANJRR 2022 : - Patient Demographics of Knee Arthroplasty beneficiaries of Australian cohort, based on ASA & BMI scores [Data Since : ASA (2012-2021)].									
SL No.	ASA Score	Partial Knee Arthro.		Total Knee Arthro.		Revision Knee		Total	
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall
1	ASA 1	3,721	12.3	26,318	5.7	1,444	3.5	31,483	5.9
2	ASA 2	18,420	61.1	2,51,372	54.5	17,180	42.1	2,86,972	53.9
3	ASA 3	7,855	26.1	1,78,668	38.7	20,488	50.2	2,07,011	38.9
4	ASA 4	148	0.5	4,975	1.1	1,709	4.2	6,832	1.3
5	ASA 5	1	0	14	0	15	0	30	0
TOTAL		30,145	100	4,61,347	100	40,836	100	5,32,328	100

Table 6.1.51 :- ***Tabulation illustrating the Distribution of Various forms of Knee Arthroplasties [Partial, Total & Revision], of the Australian Patient Cohort, as per their ASA Grade categorization.***

- The overall distribution of the Australian patient cohort receiving various forms of knee arthroplasties categorized as per their respective body mass indices or BMI Index is enclosed through the following tabulation, as follows: -

AOANJRR 2022 : - Patient Demographics of Knee Arthroplasty beneficiaries of Australian cohort, based on ASA & BMI scores [Data Since : BMI (2015 - 2021)].									
SL No.	BMI Category	Partial Knee Arthro.		Total Knee Arthro.		Revision Knee		Total Data Collc.	
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall
1	Underweight	48	0.2	727	0.2	116	0.4	891	0.2
2	Normal Weighed	3,711	14.8	38,463	10.5	3,354	11	45,528	10.8
3	Pre-Obese	10,094	40.3	1,14,379	31.2	9,236	30.2	1,33,709	31.7
4	Obese Class 1	7,647	30.5	1,13,071	30.8	9,305	30.4	1,30,023	30.8
5	Obese Class 2	2,610	10.4	62,100	16.9	5,214	17	69,924	16.6
6	Obese Class 3	948	3.8	37,866	10.3	3,363	11	42,177	10
TOTAL		25,058	100	3,66,606	100	30,588	100	4,22,252	100

Table 6.1.52 :- ***Tabulation illustrating the Distribution of Various forms of Knee Arthroplasties [Partial, Total & Revision], of the Australian Patient Cohort, as per their respective BMI based categorization.***

- On the basis of ASA Grade-based distribution of the patient cohort in Australia, it is found that patients belonging to ASA 1 & ASA 2 categories are more likely to undergo and have undergone partial knee arthroplasty, in greater proportions than total knee arthroplasty.

- About 61.10% of all partial knee arthroplasties were performed on patients belonging to the ASA 2 category, accounting for 18,420 such procedures.

- While, patients belonging to ASA 2 and ASA 3 categories, received a much greater proportion of total knee arthroplasty than any other ASA category. Total Knee Arthroplasty of patients belonging to the above-mentioned ASA category accounted for a combined total of 4,30,040 such arthroplasty procedures, with a percentage distribution of 93.20% of all TKAs performed.

- Based on the BMI-based distribution, it is imminent that the majority of the patients who received a knee arthroplasty of any modality/type, were either of pre-obese or obese class 1 stature, as per the globally acknowledged BMI Indices scale categorization.

Primary Partial Knee Arthroplasty-based Practices on the Australian Patient Cohort: -

- The Australian registry AOANJRR and the prosthesis and healthcare regulatory authority body, the TGA subcategorized partial knee arthroplasty into five distinct subclasses, besides the usual uni-compartmental or unicondylar forms of partial knee arthroplasty. This was not the case in the other nations, those were evaluated for their arthroplasty practises during the course of this research.

- The five sub-categories of partial knee arthroplasty as per Australian conventions are enlisted and defined as follows: -

    - Partial Resurfacing Knee Arthroplasty [PRKA].
    - Bi-Compartmental Partial Knee Arthroplasty [BPKA].
    - Partial Patellar/Trochlear Arthroplasty.
    - Uni-Compartmental / Unicondylar Knee Arthroplasty [UKA].
    - Unispacer based Partial Knee Arthroplasty.

- The overall distribution of the above-mentioned procedures of the overall partial knee arthroplasty case volume based on the obtainable and evaluated data, are illustrated through the following illustration: -

AOANJRR 2022 :- Partial Knee Arthroplasty by Type / Class performed for Australian Patients.			
SL No.	**Partial Knee Arthroplasty Type/Class**	**No. of Cases**	**% of Overall**
1	**Partial Resurfacing**	**245**	**0.3**
2	**Unispacer**	**40**	**0.1**
3	**Bi-Compartmental**	**165**	**0.2**
4	**Patella/Trochlea**	**4,827**	**6.6**
5	**Uni-Compartmental**	**67,497**	**92.7**
TOTAL		**72,774**	**100**

Table 6.1.53 :- ***Tabulation illustrating the Distribution of Various Classes of Partial Knee Arthroplasties of the Australian Patient Cohort.***

- The unispacer-based partial knee arthroplasty, though still one of the recognized forms of partial knee arthroplasty in Australia, has ceased any active usage since 2005, except for customized special rare cases, and has the highest revision rate of any class of partial knee arthroplasty.

- Similar is the case with Bi-Compartmental partial knee arthroplasty, which has not been under active usage since 2012. Partial resurfacing of the knee as a procedure is first publicly acknowledged and discussed in Australian healthcare records and in the registry, which again finds limited usage, and no usage during the latest reporting year of 2021. Hence, these particular specified forms of partial knee arthroplasty are not discussed or evaluated in detail further on.

- There are 4,827 recognized patellar/trochlear replacement procedures in the Australian patient cohort for all primary diagnoses.

- The mean age of the patient cohort undergoing patellar/trochlear specific replacement as a part of knee arthroplasty in Australia, is 58.4 years, with an increased proportion of females taking up such a procedure. Now, this sums up that such forms of surgical intervention are primarily performed on the

younger age of patients, compared to the usual age group of 65-75 years, as is noted globally, during the course of this probe.

- However, the relative revision rate of the said procedure is abnormally and absurdly high in the mid-short-term to long-term post-operative periods. Patellar/trochlear knee replacement on Australian patient cohort presently runs at 37.80% at 15 years of post-op and 24.10% at 10 years of post-op.

- The most common reason for revisions of such procedures is the accelerated worsening of the osteoarthritis leading to bone decay, which in most cases is resolved through converting the same into a total knee replacement procedure, as a part of revising the former failing patellar/trochlear knee arthroplasty.

- Though females undergo patellar knee arthroplasty in greater proportions than males, for revisions it was the reverse wherein males had to undergo a greater number of revisions than females.

- The overall cumulative revision percent scenario of primary patellar/trochlear knee arthroplasty of the Australian patient cohort, with a primary diagnosis of osteoarthritis during varied time-points of postoperative follow-up is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative RR of Primary Patella/Trochlea Partial Knee Arthroplasty for Australian Patient Cohort with Primary Indication OA, highlighting extremely high RRs in longer term.

SL No.	Knee Type	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 7 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op
1	Patellar/Trochlea Replacement Arthroplasty [Partial]	3,589	557	1.7(1.3, 2.2)	7.0(6.2, 8.0)	11.6(10.5, 12.9)	16.8(15.3, 18.4)	24.1(22.1, 26.2)	37.8(33.6, 42.2)
TOTAL		3,589	557						

Table 6.1.54 :- ***Tabulation illustrating the relative cumulative Revision Rate percentages of Patellar/Trochlear Partial Knee Arthroplasty, during various time-points in the Post-Operative window.***

- The age and gender-linked distribution of the patient cohort demography receiving patellar/trochlear forms of partial knee arthroplasty and their respective revision rate during varied time-points of post-operative follow-up is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative RR of Primary Patella/Trochlear Partial Knee Arthroplasty for Australian Patient Cohort with Primary Indication OA, categorized as per Patient Gender & Age Groups. [Re-affirms the Higher Revision Trend in Long Term]

SL No.	Gender of Patients	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 7 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op
Male Patients		814	152	2.9(1.9, 4.3)	9.5(7.5, 11.9)	14.2(11.7, 17.1)	20.6(17.4, 24.4)	29.7(25.3, 34.7)	
1	<65 Years	490	113	3.0(1.8, 5.1)	11.6(8.9, 15.0)	16.0(12.7, 20.0)	24.4(20.0, 29.7)	36.4(30.4, 43.1)	
2	>= 65 Years	324	39	2.6(1.3, 5.1)	6.3(4.0, 9.8)	11.4(8.0, 16.3)	14.7(10.5, 20.4)	18.7(13.4, 25.6)	
Female Patients		2,775	405	1.4(1.0, 1.9)	6.3(5.4, 7.4)	10.9(9.6, 12.3)	15.7(14.0, 17.5)	22.5(20.3, 24.9)	37.0(32.3, 42.1)
3	<65 Years	2,085	318	1.4(0.9, 2.0)	6.2(5.2, 7.4)	11.1(9.6, 12.8)	16.3(14.4, 18.4)	23.8(21.2, 26.7)	38.8(33.5, 44.7)
4	>= 65 Years	690	87	1.4(0.7, 2.6)	6.7(4.9, 9.0)	10.2(8.0, 13.1)	13.9(11.0, 17.4)	18.5(14.8, 23.1)	
TOTAL		3,589	557						

Table 6.1.55 :- ***Tabulation illustrating the relative Patient Gender & Age-Group linked cumulative Revision Rate percentages of Patellar/Trochlear Partial Knee Arthroplasty, during various time-points in the Post-Operative window.***

- The uni-compartmental or Unicondylar knee arthroplasty is one form of partial knee arthroplasty that is globally consistent in the steady usage numbers for the common patient, and not just a niche like the above-discussed, though with its own merits and demerits.

- Progressively worsening osteoarthritis is the prime cause for uni-compartmental or unicondylar knee arthroplasties, though the mean age of its respective patient cohort is higher than the global average, at 65.4 years.

- Amongst the Australian patient cohort, males received a greater number of uni-compartmental procedures at 60.80% than females as of 2021.

- The age-group and gender-linked distribution of unicompartmental knee arthroplasty procedures and their related outcomes with regard to the revision rate percentages is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative Revision Percent of Primary Unicompartmental Knee Arthroplasty by Patient Gender & Age Groups for Patients in Australian cohort with Primary Diagnosis OA.

SL No.	Gender & Age - Group of Patients	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
Male Patients		24,897	2,123	1.9(1.7, 2.1)	4.3(4.1, 4.6)	5.9(5.6, 6.3)	11.1(10.6, 11.7)	17.8(16.9, 18.7)	28.3(26.0, 30.7)
1	<55 Years	2,759	407	3.1(2.5, 3.8)	7.1(6.1, 8.2)	9.3(8.2, 10.6)	18.4(16.4, 20.5)	29.3(26.2, 32.6)	
2	55 - 64 Years	8,248	851	2.0(1.7, 2.4)	4.6(4.1, 5.1)	6.5(6.0, 7.2)	12.1(11.2, 13.1)	20.1(18.6, 21.7)	32.2(28.8, 35.9)
3	65 - 74 Years	9,054	652	1.6(1.3, 1.9)	3.8(3.4, 4.2)	5.3(4.8, 5.8)	9.9(9.0, 10.8)	15.0(13.7, 16.4)	21.3(18.3, 24.6)
4	>= 75 Years	4,836	213	1.6(1.3, 2.0)	3.2(2.7, 3.8)	4.0(3.4, 4.7)	6.9(5.9, 8.0)	8.3(6.9, 10.0)	
Female Patients		20,526	2,326	2.1(1.9, 2.3)	5.0(4.7, 5.3)	7.1(6.8, 7.5)	13(12.4, 13.6)	21.2(20.2, 22.1)	28.8(27.1, 30.6)
5	<55 Years	3,148	559	2.9(2.3, 3.5)	7.9(7, 8.9)	11.0(9.9, 12.3)	19.2(17.5, 21.0)	29.2(26.8, 31.8)	41.9(37.6, 46.6)
6	55 - 64 Years	6,682	842	2.0(1.7, 2.4)	4.9(4.4, 5.5)	7.4(6.7, 8.1)	12.7(11.8, 13.8)	23.1(21.5, 24.9)	32.1(29.1, 35.4)
7	65 - 74 Years	6,849	688	1.9(1.6, 2.2)	4.4(3.9, 5.0)	6.2(5.6, 6.9)	12.7(11.7, 13.8)	19.8(18.3, 21.5)	23.6(21.4, 26.0)
8	>= 75 Years	3,847	237	1.8(1.4, 2.3)	3.7(3.1, 4.3)	5.1(4.4, 5.9)	8.7(7.6, 10.0)	10.3(8.9, 11.8)	
TOTAL		45,423	4,449						

Table 6.1.56 :- ***Tabulation illustrating the relative Patient Gender & Age-Group linked cumulative Revision Rate percentages of Patellar/Trochlear Partial Knee Arthroplasty, during various time-points in the Post-Operative window.***

- The general revision rate of unicompartmental knee arthroplasty across different time points in the respective postoperative period is higher than that of the total knee arthroplasty. At 10 years, the mean revision rate for the Australian patient cohort undergoing such procedure is 12% which further rises to 19.50% and 28.40% at 15 and 20 years respectively in the post-operative period.

- The overall cumulative revision percent for primary unicompartmental knee arthroplasty of the general Australian patient cohort, with a primary diagnosis of progressively worsening osteoarthritis, during different time-points of the post-operative period is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative Revision Percent of Primary U.K.A for Australian Patient Cohort with Primary Indication OA - Highlighting extremely high RRs in longer term.

SL No.	Knee Type	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Unicompartmental Knee Arthroplasty [Partial]	45,423	4,449	2.0(1.8, 2.1)	4.6(4.4, 4.8)	6.5(6.2, 6.7)	12.0(11.6, 12.5)	19.5(18.8, 20.1)	28.4(27.0, 29.8)
TOTAL		45,423	4,449						

Table 6.1.57 :- ***Tabulation illustrating the Overall Cumulative Revision Rate percentages of Unicompartmental or Unicondylar Knee Arthroplasties on the Australian patient cohort, with a primary indication of Progressively Worsening Osteoarthritis, during various time-points of the Post-Operative window.***

- The leading primary reason attributed towards the revision of such failing UKAs is the progressively worsening osteoarthritis, accounting for 36.00% of all the causes leading to the revision of UKAs in Australia.

- Loosening of the prosthesis is the close second reason, accounting for 32.40% of all causes leading to the revision of UKAs.

- The overall distribution of the different primary reasons for the revision of failing primary unicompartmental knee arthroplasty for the Australian patient cohort is presented through the following tabulation: -

Distribution of the Major Reasons for Revision Arthroplasty of Primary Unicompartmental Knee Arthroplasties performed on Australian Patients with Primary Diagnosis OA.			
SL No.	**Reason for Revision Arthroplasty**	**No. of Cases**	**% of Overall**
1	Progression of Osteoarthritis	1,602	36
2	Aseptic Loosening	1,443	32.4
3	Pain	342	7.7
4	Infection	232	5.2
5	Bearing Dislocation	166	3.7
6	Fracture	130	2.9
7	Instability	81	1.8
8	Lysis	81	1.8
9	Wearing of Tibial Insert	67	1.5
10	Mal-alignment of Implant	60	1.3
10	Other Reasons [14]	245	5.5
TOTAL		4,449	100

Table 6.1.58 :- ***Tabulation illustrating the Major Reasons for the Revision Arthroplasty of Primary Unicompartmental Knee Arthroplasty for Australian patients .***

- Maintaining consistency with the global practices regarding the revision of unicompartmental knee arthroplasty, the most common type of revision practice around such revisions in Australia is to convert the failing UKA to a primary TKA, with the replacement of both tibial and femoral components. This was the case for 84.20% of all such UKA revisions.

- The overall scenario regarding prevailing practices in such UKA revisions or the type of revision/replacement performed is illustrated through the following tabulation: -

Distribution of the Major Types of Revision or Replacement Activity performed during the Revision Knee Arthroplasty of the Primary Unicompartmental Knee Arthroplasty of the Australian Patient Cohort, with a Progressively Worsening OA.			
SL No.	**Type of Revision Arthroplasty/Items Revised**	**No. of Cases**	**% of Overall**
1	Conversion to TKA [Tibial/Femoral]	3,744	84.2
2	Uni. Articular Bearing Insert Only	458	10.3
3	Uni. Tibial Component Only	98	2.2
4	Uni. Femoral Component Only	49	1.1
5	Cement Spacer	37	0.8
6	UKA(Uni Tibial/Uni Femoral)	33	0.7
7	Patella Resurfacing	15	0.3
8	Prosthesis/Implant Removal	5	0.1
9	Re-insertion of Components.	4	0.1
10	Bi-Compartmental Femoral Component	3	0.1
11	Tibial Component Change	2	0
12	Patella Only	1	0
TOTAL		4,449	100

Table 6.1.59 :- ***Tabulation illustrating the Major Types of Revision Activity, performed during the Revision Knee Arthroplasty of the Primary Unicompartmental Knee Arthroplasty of the Australian patient cohort, with a progressively worsening osteoarthritis.***

- The age of the patient is a major factor influencing the overall outcome of primary unicondylar knee arthroplasty in Australia, with the revision rate decreasing with increasing age. This is an interesting scenario considering the physical vulnerabilities rise with increasing age, but this research infers that the general rationale is the degree of mobility and activity performance that is the integral determining factor in this case.

- Younger patients with a UKA are likely to be in comparatively more hyper-activity than the older ones, while the general life-style pattern of Australians with senior age might be of limited mobility/physically active than the usual US or European standards, thereby causing UKAs due to

osteoarthritis faring better with rising age, since the troubling source of pain or instability and the chances of the prosthesis loosening out are slime or decreased due to limited activity, in turn decreasing the revision rate with increasing age.

- The age-linked distribution of primary and revision UKA of the Australian patient cohort, across multiple time points in the post-operative follow-up period is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative Revision Percent of Primary Unicompartmental Knee Arthroplasty by Age-Groups for Patients with Primary Indication OA.

SL No.	Patient Age-Group	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	<55 Years	5,907	966	3.0(2.6, 3.5)	7.5(6.9, 8.3)	10.3(9.4, 11.2)	18.8(17.5, 20.2)	29.2(27.2, 31.2)	43.5(39.8, 47.4)
2	55 - 64 Years	14,930	1,693	2.0(1.8, 2.3)	4.7(4.4, 5.1)	6.9(6.5, 7.4)	12.4(11.7, 13.1)	21.6(20.5, 22.8)	32.1(29.8, 34.6)
3	65 - 74 Years	15,903	1,340	1.7(1.5, 1.9)	4.1(3.8, 4.4)	5.7(5.3, 6.1)	11.2(10.5, 11.9)	17.3(16.2, 18.4)	22.2(20.4, 24.2)
4	>= 75 Years	8,683	450	1.7(1.4, 2.0)	3.4(3.0, 3.9)	4.5(4.0, 5.0)	7.8(7.0, 8.6)	9.3(8.3, 10.4)	
TOTAL		45,423	4,449						

Table 6.1.60 :- ***Tabulation illustrating the Distribution of the prevalent cumulative Revision Rate percentages of Primary Unicompartmental Knee Arthroplasty, as per Patient Age-Groups(irrespective of Gender), with the primary diagnosis of Progressively Worsening OA.***

Note: **-** The above-mentioned transient in the revision incidence cases decreasing with rising age is evident from the tabulation and the mean revision rates calculated from the data accessed by this research.

Prostheses Specific & Prosthesis Characteristics based Outcomes of UKAs of the Australian Patient Cohort: -

- With regards to the prosthesis-specific scenario for unicompartmental or unicondylar knee arthroplasties, the top 10 most utilized prosthesis combinations accounted for 99.4% of all unicompartmental procedures in Australia.

- The data obtained from the Australian registry revealed that the majority of the UKAs performed on the Australian patient cohort, utilized a fixed bearing, with a distribution share of 51.10%, while the remainder of the UKA procedures were performed using a mobile bearing articulating polymer insert.

- Fixed bearings in UKAs have proven to be superior to mobile bearings in UKAs since the former have a much lower vis-à-vis revision rate than the latter. The distribution of fixed vis-à-vis mobile unicondylar knee prosthesis, utilized during the primary unicompartmental knee arthroplasty of the Australian patients, and their relative outcomes in terms of the cumulative revision rate percentages, across various post-operative follow-up timepoints is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative RR of Primary Unicompartmental Knee Arthroplasty by Knee Prosthesis Mobility Type for Patients with Primary Diagnosis OA.

SL No.	Mobility of Knee Prosthesis	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Fixed	23,193	1,291	1.5(1.4, 1.7)	3.8(3.5, 4.0)	5.2(4.9, 5.6)	9.3(8.7, 9.9)	14.9(13.7, 16.2)	
2	Mobile	22,229	3,157	2.4(2.2, 2.6)	5.4(5.1, 5.7)	7.6(7.2, 8.0)	13.8(13.3, 14.4)	21.6(20.8, 22.4)	30.6(29.1, 32.0)
TOTAL		45,422	4,448						

Table 6.1.61 :- ***Tabulation illustrating the Distribution of the prevalent Utilization scenarios of Fixed vis-à-vis Mobile Unicondylar Knee Prostheses for Primary Unicompartmental Knee Arthroplasty of the Australian patients with a progressively worsening osteoarthritis.***

Note: **-** The abrupt and huge rise in the cumulative revision rate percent post 10-years into the post-operative window, provening the rationale that UKAs are primarily short-termed solutions, when quicker recovery is essential for the respective patient, irrespective of the Prosthesis type being utilized.

- UKAs using robotic and other computer-assisted or guided approaches had better outcomes in terms of the involving revision rate for the respective patients on whom these were performed, though many clinicians and publications doubt the extent of infection control during such robotic or computer navigated/guided UKAs.

- Such beneficial effect of robotic assistance and computer navigate arthroplasty on the post-operative revision aspects, is not observed if it is compared on the basis of the bearing mobility of the polyethylene insert between the tibial and femoral ends of the prosthesis unit.

- The most reasonable rationale as inferred by this probe is that the exact benefit angle through robotic assistance based UKA is through the computer-guided high-precision alignment and accuracy of the overall procedure. This aspect minimizes the scope of loosening of the prosthesis and therefore has a lower category-specific revision rate and also lower incidences of a revision due to the usual cause of aseptic loosening of the prosthesis.

- The overall differences between the cumulative revision rate percentages of the primary unicompartmental knee arthroplasty procedures performed on the Australian patient cohort, based on whether robotic assistance was used or not is presented through the 'Inclusion of Modern Technologies' segment of this chapter.

- The most utilized prosthesis combinations for the Unicompartmental Knee Arthroplasty of the Australian patient cohort, and their relative outcomes in terms of the revision rate percentages across various post-operative window timepoints is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative RR of Primary Unicompartmental Knee Arthroplasty Popular Prosthesis Combinations with Minimum 200 Procedures in the Australian Cohort of all Indications/Diagnoses.														
SL No.	Unicompartmental Femoral Comp.	Manufacturer/Supplier of Prosthesis	ODEP Rating	Unicompartmental Tibial Comp.	Mfg.Co.	ODEP Rating	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 7 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op
1	Allegretto Uni	Sulzer Orthopedics	Unrated	ZUK	Lima Corporate	10A* / 13A*	283	23	0.7(0.2, 2.8)	4.6(2.6, 7.9)	7.2(4.5, 11.4)			
2	BalanSys	Mathys Medical	7A*	BalanSys Uni Fixed	Mathys Medical	7A*	1,085	52	1.8(1.1, 2.8)	3.6(2.6, 5.1)	4.4(3.1, 6.1)	7.9(5.7, 11.0)	13.0(8.9, 18.8)	
3	Endo-Model Sled	Waldemar LINK	10B	Endo-Model Sled	Waldemar LINK	10B	1,330	217	1.3(0.8, 2.1)	5.2(4.1, 6.5)	8.0(6.7, 9.7)	14.7(12.7, 16.9)	22.2(19.5, 25.3)	
4	Genus	Adler Ortho	Uni Version Unrated	Genus	Adler Ortho	Uni Version Unrated	395	14	3.0(1.6, 5.4)	4.6(2.7, 7.8)				
5	Journey Uni	Smith & Nephew	5A*	Journey Uni v2.0	Smith & Nephew	5A*	1,205	59	2.3(1.6, 3.3)	4.7(3.6, 6.3)	6.0(4.6, 7.9)			
6		Smith & Nephew	5A*	Journey Uni All Poly	Smith & Nephew	5A*	340	40	1.5(0.6, 3.6)	6.9(4.6, 10.3)	9.2(6.4, 13.0)	15.0(11.0, 20.3)		
7	Oxford(cless) [Cless = Cementless]	Zimmer Biomet	13A*	Oxford (cless)	Zimmer Biomet	13A*	8,274	569	2.7(2.4, 3.1)	4.7(4.2, 5.2)	6.0(5.5, 6.6)	11.1(10.0, 12.2)	20.4(16.7, 24.7)	
8		Zimmer Biomet	13A*	Oxford (ctd)	Zimmer Biomet	3A / 15A / Withdrawn [All variants]	468	49	3.5(2.1, 5.6)	6.4(4.5, 9.1)	9.3(6.9, 12.4)	15.3(10.9, 21.3)		
9	Oxford (ctd) [Ctd = Cemented]	Zimmer Biomet	3A / 15A / Withdrawn [All variants]	Oxford (ctd)	Zimmer Biomet	3A / 15A / Withdrawn [All variants]	13,545	2,552	2.2(1.9, 2.4)	5.7(5.3, 6.1)	8.2(7.7, 8.6)	14.6(14.0, 15.3)	22.2(21.4, 23.1)	31.1(29.7, 32.6)
10	Persona	Zimmer Biomet	5A	Persona	Zimmer Biomet	5A	593	6	2.2(0.9, 5.2)					
11	Restoris MCK	Stryker	Lapsed/3A	Restoris MCK	Stryker	Lapsed/3A	6,349	172	1.3(1.0, 1.6)	3.2(2.7, 3.7)	4.1(3.5, 4.8)			
12	Sigma HP [HP = High Performance]	DePuy Synthes	13A	Sigma HP [HP = High Performance]	DePuy Synthes	13A	1,643	77	1.0(0.6, 1.6)	2.8(2.0, 3.8)	4.8(3.7, 6.2)	8.4(6.4, 10.9)		
13	Triathlon PKR	Stryker	10A	Triathlon PKR	Stryker	10A	375	31	3.0(1.7, 5.3)	6.4(4.3, 9.5)	7.5(5.1, 10.8)	12.2(8.0, 18.5)		
13	ZUK	Lima Corporate	10A* / 13A*	ZUK	Lima Corporate	10A* / 13A*	9,579	577	1.5(1.3, 1.7)	3.4(3.1, 3.8)	4.6(4.2, 5.1)	7.9(7.2, 8.7)	12.7(11.2, 14.3)	
14	Others [5]					NA	345	57	5.7(3.7, 8.8)	12.5(9.3, 16.7)	17.2(13.4, 22.0)			
TOTAL							45,809	4,495						

Table 6.1.62 :- ***Tabulation illustrating the various Unicondylar Knee Prosthesis combinations utilized for the Primary Unicompartmental Knee Arthroplasty of the Australian patient cohort and their relative Cumulative Revision Rate percentages across multiple Post-Operative follow-up timepoints, alongside their respective Manufacturing/Supplier firm details and ODEP Rating Statuses***

General Primary Total Knee Arthroplasty-based Practices on the Australian Patient Cohort: -

- There were 8,29,272 primary total knee arthroplasty or TKAs procedures recognized within the Australian registry, including an additional 59,474 arthroplasty cases since 2020, with an YoY increase of 9.00% in 2021, compared to 2020, for primary TKAs of the Australian patient cohort in Australia.

- Primary total knee arthroplasty in Australia increased its relative proportion of all knee arthroplasty procedures to 87.00% of all in 2021.

- In line with the globally noted scenario, the leading cause of a total knee replacement in Australia, is progressively worsening osteoarthritis and is more prevalent in female patients compared to male

patients. The domination of females over males in the relative distribution of the TKA procedures in Australia is noted to be in effect since 2003 and

- The mean age of the patient cohort receiving total knee arthroplasty in Australia is 68.5 years.

- The gender-wise distribution of the TKA procedures in Australia is presented through the following tabulation: -

AOANJRR 2022 :- Age & Gender of Primary Total Knee Arthroplasty [TKA] Patients in the Australian Cohort.

SL No.	Gender of Patients.	No. of Cases	% of Overall	Minimum	Maximum	Median	Mean	Standard Deviation
1	Male	3,64,431	43.90%	8	101	68	68.1	9.1
2	Female	4,64,841	56.10%	8	103	69	68.7	9.3
TOTAL		8,29,272	100	8	103	69	68.5	9.2

Table 6.1.63 :- ***Tabulation illustrating the Patient Gender wise distribution of Primary Total Knee Arthroplasties performed on the Australian patient cohort, along with the Mean-Median-Maximum & Minimum Ages of the Patients.***

- On the aspect of the debated issue of the patellar resurfacing vs no patella, post a total knee arthroplasty, the major practice in Australian arthroplasty practices is to resurface the patella at the time of the primary total knee arthroplasty surgery. The relative proportion percent of a patella resurfaced during a primary TKA, of all TKAs has increased to 76.10% in 2021, while the complete sacrifice of the patella/ no patella approaches continued to steadily decline since 2008 in Australia.

- The most common method of fixation utilized for total knee arthroplasty of the Australian patient cohort is cementing both the tibial and femoral components at the time of surgery. Such cemented procedures are the majority practices in Australia and hence account for 62.50% of all TKAs in 2021.
- Unlike the existent practises of cementless fixation during a significant proportion of TKAs in some other nations evaluated during the course of this research, the whole idea of non-cemented fixation of knee prosthesis during a total knee arthroplasty of the Australian patient cohort is utilized on a very limited scale.

- The use of non-cemented fixation as of 2021 in Australia accounted for 18.60% of all such total knee arthroplasties.

- While, hybrid fixation methods were utilized for 18.90% of the procedures in 2021.

- Regarding the polyethylene type of the bearing material insert, highly cross-linked polyethylene/cross-linked polyethylene (HXLPE/XLPE) has made significant inroads into mainstream total knee arthroplasty practices in Australia.

- The adoption of XLPE as the articulating surface bearing material significantly grew from less than 10% in 2006 to 75.80% in 2021, posting a sharp and consistent growth over the years, replacing non-XLPE-based conventional polyethylene material based bearing material inserts from main-stream total knee arthroplasty practices in Australia.

- The relative patient reported satisfaction levels and the revision rate linked outcomes with regards to XLPE and non-XLPE prosthesis units is discussed in detail in the later relevant sections.

Majorly utilized Individual Prostheses for the Primary Total Knee Arthroplasties of the Australian Patient Cohort: -

- The most commonly utilized femoral and tibial prostheses as of 2021 for TKA of the Australian patient cohort is enlisted as follows: -

    - Most Commonly Utilized Femoral Prostheses as of 2021-
        a. Triathlon CR (Stryker).
        b. Persona CR (Zimmer Biomet).
        c. Attune CR (DePuy Synthes).

    - Most Commonly Utilized Tibial Prostheses as of 2021 –
        a. Triathlon (Stryker).
        b. Persona (Zimmer Biomet).
        c. Genesis II (Smith & Nephew).

- The top 10 most commonly utilized prostheses for primary total knee arthroplasty, accounted for the more than the majority proportion numbers of all the TKAs performed on the Australian patient cohort since 2003.

- The overall most commonly utilized top 10 femoral & tibial prostheses for primary total knee arthroplasty, irrespective of the fixation method applied segregation of the Australian patient cohort is enclosed through the following tabulation: -

Distribution of The Top 10 Most Used Femoral Prostheses in Primary Total Knee Replacement of the Australian Patient Cohort. [All Fixation Methods Covered]

SL No.	2003			2018			2019			2020			2021		
	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases
1	LCS CR	Depuy Synthes	3,183	Triathlon CR	Stryker	12,328	Triathlon CR	Stryker	13,405	Triathlon CR	Stryker	13,772	Triathlon CR	Stryker	16,268
2	Duracon	Stryker	2,846	Nexgen CR Flex	Zimmer Biomet	5,796	Persona CR	Zimmer Biomet	5,665	Persona CR	Zimmer Biomet	8,439	Persona CR	Zimmer Biomet	11,462
3	Nexgen CR	Zimmer Biomet	2,150	Persona CR	Zimmer Biomet	3,588	Nexgen CR Flex	Zimmer Biomet	4,305	GMK Sphere Primary [ODEP Lapsed]	Medacta International	3,250	Attune CR	Depuy Synthes	4,135
4	PFC Sigma CR	Depuy Synthes	1,419	Attune CR	Depuy Synthes	3,246	Attune CR	Depuy Synthes	3,404	Attune CR	Depuy Synthes	3,149	GMK Sphere Primary [ODEP Lapsed]	Medacta International	3,646
5	Scorpio CR	Stryker	1,354	Nexgen LPS Flex	Zimmer Biomet	2,190	GMK Sphere Primary [ODEP Lapsed]	Medacta International	2,747	Nexgen CR Flex	Zimmer Biomet	2,391	Attune PS	Depuy Synthes	2,206
6	Genesis II CR	Smith & Nephew	1,059	GMK Sphere Primary	Medacta International	2,147	LCS CR	Depuy Synthes	1,842	Attune PS	Depuy Synthes	1,781	Nexgen CR Flex	Zimmer Biomet	1,665
7	Natural Knee II	Zimmer Biomet	1,002	LCS CR	Depuy Synthes	2,090	Attune PS	Depuy Synthes	1,795	Apex Knee CR	Corin Group	1,608	Apex Knee CR	Corin Group	1,601
8	Natural LPS	Zimmer Biomet	902	Vanguard CR	Zimmer Biomet	1,956	Vanguard CR	Zimmer Biomet	1,567	LCS CR	Depuy Synthes	1,407	Legion Oxinium CR	Smith & Nephew	1,587
9	Profix	Smith & Nephew	883	Evolution	MicroPort Orthopedics	1,660	Evolution	MicroPort Orthopedics	1,541	Legion Oxinium CR	Smith & Nephew	1,364	Legion Oxinium PS	Smith & Nephew	1,206
10	Scorpio PS	Stryker	751	Apex Knee CR	Corin Group	1,408	Apex Knee CR	Corin Group	1,477	Evolution	MicroPort Orthopedics	1,218	Legion CR	Smith & Nephew	1,099
Most Used [10]		71.5% of Overall	15,549	Most Used [10]	64.8% of Overall	36,409	Most Used [10]	66.1% of Overall	37,748	Most Used [10]	71% of Overall	38,379	Most Used [10]	76.2% of Overall	44,875
Remainder Implants [47]		28.5% of Overall	6,185	Remainder Implants [74]	35.2% of Overall	19,776	Remainder Implants [67]	33.9% of Overall	19,347	Remainder Implants [65]	29% of Overall	15,692	Remainder Implants [65]	23.8% of Overall	14,053
TOTAL [57 Implants]			21,734	TOTAL [84 Implants]		56,185	TOTAL [77 Implants]		57,095	TOTAL [75 Implants]		54,071	TOTAL [75 Implants]		58,928

Table 6.1.64 :- ***Tabulation illustrating the Overall Top 10 Femoral Prostheses along with their respective Manufacturer/Supplier firm details, which have been in popular utilization for Primary Total Knee Arthroplasty of the Australian Patient Cohort, irrespective of the Fixation Method applied.***

Distribution of The Top 10 Most Used Tibial Prostheses in Primary Total Knee Replacement of the Australian Patient Cohort. [All Fixation Methods Covered].															
SL No.	2003			2018			2019			2020			2021		
	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases
1	Nexgen	Zimmer Biomet	3,755	Triathlon	Stryker	13,221	Triathlon	Stryker	14,348	Triathlon	Stryker	14,547	Triathlon	Stryker	16,955
2	Duracon	Stryker	2,843	Nexgen	Zimmer Biomet	7,929	Genesis II	Smith & Nephew	7,456	Persona	Zimmer Biomet	9,064	Persona	Zimmer Biomet	12,024
3	Genesis II	Smith & Nephew	2,040	Genesis II	Smith & Nephew	7,698	Persona	Zimmer Biomet	6,334	Genesis II	Smith & Nephew	6,325	Genesis II	Smith & Nephew	6,879
4	MBT	Depuy Synthes	1,364	Attune	Depuy Synthes	4,622	Nexgen	Zimmer Biomet	5,646	Attune	Depuy Synthes	4,983	Attune	Depuy Synthes	6,387
5	LCS	Depuy Synthes	1,362	Persona	Zimmer Biomet	4,040	Attune	Depuy Synthes	5,250	Nexgen	Zimmer Biomet	3,144	GMK Primary[ODEP Lapsed]	Medacta International	3,490
6	Series 7000 [Now Known as	Stryker	1,360	Apex Knee	Corin Group	2,123	GMK Primary [ODEP Lapsed]	Medacta International	2,556	GMK Primary[ODEP Lapsed]	Medacta International	2,951	Apex Knee	Corin Group	2,319
7	PFC Sigma	Depuy Synthes	1,168	GMK Primary [ODEP Lapsed]	Medacta International	2,106	Apex Knee	Corin Group	2,330	Apex Knee	Corin Group	2,376	Nexgen	Zimmer Biomet	2,179
8	MBT Duofix	Depuy Synthes	1,060	Vanguard	Zimmer Biomet	2,046	Vanguard	Zimmer Biomet	1,740	MBT	Depuy Synthes	1,257	Columbus	Bbraun	1,089
9	Natural Knee II	Zimmer Biomet	1,002	MBT	Depuy Synthes	1,928	MBT	Depuy Synthes	1,670	Evolution[ODEP Lapsed]	MicroPort Orthopedics	1,205	Evolution[ODEP Lapsed]	MicroPort Orthopedics	996
10	Profix	Smith & Nephew	894	Evolution[ODEP Lapsed]	MicroPort Orthopedics	1,660	Evolution[ODEP Lapsed]	MicroPort Orthopedics	1,537	Columbus	Bbraun	1,111	MBT	Depuy Synthes	931
Most Used [10]		77.5% of Overall	16,848	Most Used [10]	84.5% of Overall	47,473	Most Used [10]	85.6% of Overall	48,867	Most Used [10]	86.9% of Overall	46,963	Most Used [10]	90.4% of Overall	53,249
Remainder Implants [38]		22.5% of Overall	4,886	Remainder Implants [51]	15.5% of Overall	8,712	Remainder Implants [49]	14.4% of Overall	8,228	Remainder Implants [47]	13.1% of Overall	7,108	Remainder Implants [47]	9.6% of Overall	5,679
TOTAL [48 Implants]			21,734	TOTAL [61 Implants]		56,185	TOTAL [59 Implants]		57,095	TOTAL [57 Implants]		54,071	TOTAL [57 Implants]		58,928

Table 6.1.65 :- ***Tabulation illustrating the Overall Top 10 Tibial Prostheses along with their respective Manufacturer/Supplier firm details, which have been in popular utilization for Primary Total Knee Arthroplasty of the Australian Patient Cohort, irrespective of the Fixation Method applied.***

- The prostheses marked in red indicate either a lapsed or unrated ODEP status. In some specific cases, might bear other detrimental indications, unless specified other than the rating scenario.

- The above tabulation is further refined and re-tabulated by filtering the most commonly utilized top ten femoral and tibial prostheses, as per fixation methods deployed to implant them on the Australian patient cohort, during a TKA procedure.

- The most commonly utilized top 10 femoral prostheses for the primary TKA, using a cemented, non-cemented and hybrid fixation method, are presented in the following tabulations: -

AOANJRR 2022 :- The Top 10 Most Used Cemented Femoral Prostheses in Primary Total Knee Replacement of the Australian Patient Cohort.															
SL No.	2003			2018			2019			2020			2021		
	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases
1	Duracon	Stryker	1,222	Triathlon CR	Stryker	6,673	Triathlon CR	Stryker	6,645	Triathlon CR	Stryker	6,247	Triathlon CR	Stryker	7,115
2	LCS CR	Depuy Synthes	942	Attune CR	Zimmer Biomet	3,158	Persona CR	Zimmer Biomet	3,415	Persona CR	Zimmer Biomet	4,920	Persona CR	Zimmer Biomet	6,303
3	Nexgen LPS	Zimmer Biomet	827	Nexgen CR Flex	Zimmer Biomet	2,931	Attune CR	Depuy Synthes	3,283	GMK Sphere Primary [ODEP Lapsed]	Medacta International	3,250	GMK Sphere Primary[ODEP Lapsed]	Medacta International	3,646
4	Nexgen CR	Zimmer Biomet	765	Persona CR	Zimmer Biomet	2,363	GMK Sphere Primary [ODEP Lapsed]	Medacta International	2,747	Attune CR	Depuy Synthes	2,876	Attune CR	Depuy Synthes	2,275
5	Nexgen LPS Flex	Zimmer Biomet	693	GMK Sphere Primary	Medacta International	2,147	Nexgen CR Flex	Zimmer Biomet	2,316	Attune PS	Depuy Synthes	1,694	Attune PS	Depuy Synthes	2,107
6	Genesis II CR	Smith & Nephew	645	Nexgen CR Flex	Zimmer Biomet	1,927	Attune PS	Depuy Synthes	1,777	Legion Oxinium CR	Smith & Nephew	1,364	Legion Oxinium CR	Smith & Nephew	1,587
7	PFC Sigma PS	Depuy Synthes	515	Evolution	MicroPort Orthopedics	1,620	Evolution	Medacta International	1,513	Nexgen CR Flex	Zimmer Biomet	1,225	Legion Oxinium PS	Smith & Nephew	1,206
8	Profix	Smith & Nephew	497	Legion Oxinium PS	Smith & Nephew	1,393	Legion Oxinium CR	Smith & Nephew	1,379	Evolution	MicroPort Orthopedics	1,140	Columbus	Bbraun	1,089
9	Genesis II Oxinium CR	Smith & Nephew	479	Attune PS	Depuy Synthes	1,365	Legion Oxinium PS	Smith & Nephew	1,272	Columbus	Bbraun	1,111	Evolution	MicroPort Orthopedics	989
10	Genesis II PS	Smith & Nephew	419	Genesis II Oxinium PS	Smith & Nephew	1,344	Genesis II Oxinium PS	Smith & Nephew	1,268	Genesis II Oxinium PS	Smith & Nephew	1,074	Genesis II Oxinium PS	Smith & Nephew	876
Most Used [10]		71.6% of Overall	7,004	Most Used [10]	64.4% of Overall	24,921	Most Used [10]	65.3% of Overall	25,615	Most Used [10]	68.6% of Overall	24,901	Most Used [10]	72.3% of Overall	27,193
Remainder Implants [38]		28.4% of Overall	2,778	Remainder Implants [71]	35.6% of Overall	13,785	Remainder Implants [67]	34.7% of Overall	13,600	Remainder Implants [63]	31.4% of Overall	11,415	Remainder Implants [65]	27.7% of Overall	10,441
TOTAL [48 Implants]			9,782	TOTAL [81 Implants]		38,706	TOTAL [76 Implants]		39,215	TOTAL [73 Implants]		36,316	TOTAL [73 Implants]		37,634

Table 6.1.66 :- ***Tabulation illustrating the Overall Top 10 Cemented Femoral Prostheses along with their respective Manufacturer/Supplier firm details, which have been in popular utilization for Primary Total Knee Arthroplasty of the Australian Patient Cohort.***

The Top 10 Most Used Cementless Femoral Prostheses in Primary Total Knee Replacement of the Australian Patient Cohort.

SL No.	2003			2018			2019			2020			2021		
	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases
1	LCS CR	Depuy Synthes	2,241	Triathlon CR	Stryker	5,655	Triathlon CR	Stryker	6,760	Triathlon CR	Stryker	7,525	Triathlon CR	Stryker	9,153
2	Duracon	Stryker	1,624	Nexgen CR Flex	Zimmer Biomet	2,865	Persona CR	Zimmer Biomet	2,250	Persona CR	Zimmer Biomet	3,519	Persona CR	Zimmer Biomet	5,159
3	Nexgen CR	Zimmer Biomet	1,385	LCS CR	Depuy Synthes	1,445	Nexgen CR Flex	Zimmer Biomet	1,989	Nexgen CR Flex	Zimmer Biomet	1,166	Attune CR	Depuy Synthes	1,860
4	PFC Sigma CR	Depuy Synthes	1,075	Persona CR	Zimmer Biomet	1,225	LCS CR	Depuy Synthes	1,297	LCS CR	Depuy Synthes	992	Nexgen CR Flex	Zimmer Biomet	798
5	Scorpio CR	Stryker	1,059	Vanguard CR	Zimmer Biomet	1,042	Vanguard CR	Zimmer Biomet	797	Apex Knee CR	Corin Group	773	Apex Knee CR	Corin Group	765
6	Natural Knee II	Zimmer Biomet	746	Apex Knee CR	Corin Group	648	Apex Knee CR	Corin Group	664	PFC Sigma CR	Depuy Synthes	449	LCS CR	Depuy Synthes	583
7	Active Knee	Allegra Orthopedics	633	Legion CR	Smith & Nephew	566	PFC Sigma CR	Depuy Synthes	549	Legion CR	Smith & Nephew	413	Legion CR	Smith & Nephew	510
8	Maxim	Zimmer Biomet	425	PFC Sigma CR	Depuy Synthes	532	Legion CR	Smith & Nephew	503	Vanguard CR	Zimmer Biomet	381	Score [ODEP Lapsed]	Amplitude	381
9	Genesis II CR	Smith & Nephew	414	BalanSys	Mathys Medical	367	BalanSys	Mathys Medical	390	Score [ODEP Lapsed]	Amplitude	365	GMK Primary[ODEP Lapsed]	Medacta International	291
10	Profix	Smith & Nephew	386	Genesis II CR	Smith & Nephew	367	Score [ODEP Lapsed]	Amplitude	356	Attune CR	Depuy Synthes	273	Genesis II CR	Smith & Nephew	242
Most Used [10]		83.6% of Overall	9,988	Most Used [10]	84.2% of Overall	14,712	Most Used [10]	87% of Overall	15,555	Most Used [10]	89.3% of Overall	15,856	Most Used [10]	92.7% of Overall	19,742
Remainder Implants [28]		16.4% of Overall	1,964	Remainder Implants [26]	15.8% of Overall	2,767	Remainder Implants [22]	13% of Overall	2,325	Remainder Implants [24]	10.7% of Overall	1,899	Remainder Implants [24]	7.3% of Overall	1,552
TOTAL [38 Implants]			11,952	TOTAL [36 Implants]		17,479	TOTAL [32 Implants]		17,880	TOTAL [34 Implants]		17,755	TOTAL [34 Implants]		21,294

Table 6.1.67 :- ***Tabulation illustrating the Overall Top 10 Non-Cemented Femoral Prostheses along with their respective Manufacturer/Supplier firm details, which have been in popular utilization for Primary Total Knee Arthroplasty of the Australian Patient Cohort.***

The Top 10 Most Used Cemented Tibial Prostheses in Primary Total Knee Replacement of the Australian Patient Cohort.

SL No.	2003			2018			2019			2020			2021		
	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases
1	Nexgen	Zimmer Biomet	3,010	Triathlon	Stryker	11,640	Triathlon	Stryker	10,825	Triathlon	Stryker	9,456	Triathlon	Stryker	10,614
2	Duracon	Stryker	2,348	Genesis II	Smith & Nephew	7,631	Genesis II	Smith & Nephew	7,404	Persona	Zimmer Biomet	7,577	Persona	Zimmer Biomet	9,893
3	Genesis II	Smith & Nephew	1,993	Nexgen	Zimmer Biomet	7,125	Persona	Zimmer Biomet	5,955	Genesis II	Smith & Nephew	6,305	Genesis II	Smith & Nephew	6,877
4	PFC Sigma	Depuy Synthes	1,168	Attune	Depuy Synthes	4,534	Attune	Depuy Synthes	5,168	Attune	Depuy Synthes	4,689	Attune	Depuy Synthes	4,458
5	MBT	Depuy Synthes	1,067	Persona	Zimmer Biomet	4,028	Nexgen	Zimmer Biomet	5,036	Nexgen	Zimmer Biomet	2,860	GMK Primary [ODEP Lapsed]	Medacta International	3,295
6	LCS	Depuy Synthes	1,033	Apex Knee	Corin Group	2,094	GMK Primary [ODEP Lapsed]	Medacta International	2,419	GMK Primary [ODEP Lapsed]	Medacta International	2,844	Apex Knee	Corin Group	2297
7	Series 7000 [Now Known as Scorpio / Scorpio+]	Stryker	1,007	Vanguard	Zimmer Biomet	2,023	Apex Knee	Corin Group	2,277	Apex Knee	Corin Group	2,369	Nexgen	Zimmer Biomet	2,052
8	Profix	Smith & Nephew	719	GMK Primary[ODEP	Medacta International	1,939	Vanguard	Zimmer Biomet	1,717	Evolution[ODEP Lapsed]	MicroPort Orthopedics	1,205	Columbus	Bbraun	1,089
9	Natural Knee II	Zimmer Biomet	587	Evolution[ODEP Lapsed]	MicroPort Orthopedics	1,660	Evolution[ODEP Lapsed]	MicroPort Orthopedics	1,537	Columbus	Bbraun	1,111	Evolution [ODEP Lapsed]	MicroPort Orthopedics	996
10	AGC	Zimmer Biomet	478	MBT	Depuy Synthes	1,496	MBT	Depuy Synthes	1,267	Vanguard	Zimmer Biomet	1,029	MBT	Depuy Synthes	786
Most Used [10]		84.9% of Overall	13,410	Most Used [10]	87.8% of Overall	44,170	Most Used [10]	85.6% of Overall	43,605	Most Used [10]	87.6% of Overall	39,445	Most Used [10]	90.3% of Overall	42,357
Remainder Implants [31]		15.1% of Overall	2,382	Remainder Implants [45]	12.2% of Overall	6,152	Remainder Implants [43]	14.4% of Overall	6,267	Remainder Implants [41]	12.4% of Overall	5,592	Remainder Implants [40]	9.7% of Overall	4,533
TOTAL [41 Implants]			15,792	TOTAL [55 Implants]		50,322	TOTAL [53 Implants]		49,872	TOTAL [51 Implants]		45,037	TOTAL [50 Implants]		46,890

Table 6.1.68 :- ***Tabulation illustrating the Overall Top 10 Cemented Tibial Prostheses along with their respective Manufacturer/Supplier firm details, which have been in popular utilization for Primary Total Knee Arthroplasty of the Australian Patient Cohort.***

AOANJRR 2022 :- The Top 10 Most Used Cementless Tibial Prostheses in Primary Total Knee Replacement of the Australian Patient Cohort.

SL No.	2003			2018			2019			2020			2021		
	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases	Total Knee Implant Model	Mfg.Co.	No. of Cases
1	MBT Duofix	Depuy Synthes	1,060	Triathlon	Stryker	1,681	Triathlon	Stryker	3,523	Triathlon	Stryker	5,091	Triathlon	Stryker	6,341
2	Nexgen	Zimmer Biomet	745	Nexgen	Zimmer Biomet	804	Nexgen TM CR	Zimmer Biomet	625	Persona	Zimmer Biomet	1,487	Persona	Zimmer Biomet	2,131
3	Natural Knee II	Zimmer Biomet	524	MBT Duofix	Depuy Synthes	797	Nexgen	Zimmer Biomet	610	MBT Duofix	Depuy Synthes	430	Attune	Depuy Synthes	1,929
4	Duracon	Stryker	495	Nexgen TM CR	Zimmer Biomet	724	MBT Duofix	Depuy Synthes	570	Nexgen TM CR	Zimmer Biomet	418	Nexgen TM CR	Zimmer Biomet	362
5	Active Knee	Allegra Orthopedics	487	MBT	Depuy Synthes	432	MBT	Depuy Synthes	403	MBT	Depuy Synthes	304	Score [ODEP Lapsed]	Amplitude	288
6	Series 7000 [Now Known as Scorpio / Scorpio+]	Stryker	353	Score [ODEP Lapsed]	Amplitude	180	Persona	Zimmer Biomet	379	Attune	Depuy Synthes	294	GMK Primary [ODEP Lapsed]	Medacta International	195
7	LCS	Depuy Synthes	329	Regenerex	Zimmer Biomet	177	ACS Fixed	ImplantCast GmbH	192	Nexgen	Zimmer Biomet	284	MBT	Depuy Synthes	145
8	RBK [ODEP Withdrawn]	Exactech	305	GMK Primary [ODEP Lapsed]	Medacta International	167	GMK Primary [ODEP Lapsed]	Medacta International	137	Score [ODEP Lapsed]	Amplitude	184	Nexgen	Zimmer Biomet	127
9	MBT	Depuy Synthes	297	RBK [ODEP Withdrawn]	Exactech	145	Score [ODEP Lapsed]	Amplitude	131	GMK Primary [ODEP Lapsed]	Medacta International	107	Legion	Smith & Nephew	95
10	Profix Mobile	Smith & Nephew	242	Nexgen TM LPS	Zimmer Biomet	130	Nexgen TM LPS	Zimmer Biomet	119	RBK [ODEP Withdrawn]	Exactech	100	Natural Knee II	Zimmer Biomet	86
Most Used [10]		81.4% of Overall	4,837	Most Used [10]	89.3% of Overall	5,237	Most Used [10]	92.6% of Overall	6,689	Most Used [10]	96.3% of Overall	8,699	Most Used [10]	97.2% of Overall	11,699
Remainder Implants [18]		18.6% of Overall	1,105	Remainder Implants [16]	10.7% of Overall	626	Remainder Implants [14]	7.4% of Overall	534	Remainder Implants [13]	3.7% of Overall	335	Remainder Implants [14]	2.8% of Overall	339
TOTAL [28 Implants]			5,942	TOTAL [26 Implants]		5,863	TOTAL [24 Implants]		7,223	TOTAL [23 Implants]		9,034	TOTAL [24 Implants]		12,038

Table 6.1.69 :- ***Tabulation illustrating the Overall Top 10 Non-Cemented Tibial Prostheses along with their respective Manufacturer/Supplier firm details, which have been in popular utilization for Primary Total Knee Arthroplasty of the Australian Patient Cohort.***

Fixation Method based Most Commonly Utilized Prosthesis Combinations for Primary Total Knee Arthroplasty & their Outcomes: -

- Besides the most utilized top ten individual femoral and tibial prostheses units for the TKA of the Australian patient cohort, the prosthesis combination-based outcomes in terms of respective revision rate percentages, across various timepoints in the postoperative window, plays a crucial factor to ascertain the prosthesis usage behaviour and extent of success/failures.

- This is due to the reason that, individual prostheses cannot exactly indicate the combination they are used in, and as a result, a particular component femoral or tibial, despite being excellently designed and optimized as per prevailing patient requirements, could raise alertness for triggering higher number of revisions, when it is utilized in combination with some particular prosthesis, that denigrates its otherwise pristine and blemish-free record.

- Hence, prosthesis combinations those were implemented on the Australian patient cohort, during their knee arthroplasties, irrespective of primary or revision nature, along with it's present ODEP rating statuses, and relative outcome in the form of cumulative revision rate percentages across varied post-operative timepoints, categorized as per the fixation method deployed to implant them is tabulated and presented hereon.

- The data is refined to only those prosthesis combinations those are either on present commercial circulation or is being actively implanted as of the modern present day, are included, excluding the old data. The respective cumulative mean revision rate percentages against the lowest and highest reported rates, across different time-points in the post-operative period, involving both the short- and long-term aspects are subsequently tabulated, alongside the respective ODEP Rating statuses for each of these combinations are included to establish the general performance standards of the particular prosthesis against an established benchmarking and rating platform.

- Though most of the global implant makers ideally are against a heterogenous combination of implants, involving components from different makers, often such combinations generate some of the most interestingly favourable results, barring a few obvious practical situations.

- The most commonly utilized cemented fixation-based prostheses combinations that were utilized for at least 400 primary TKAs of the Australian patient cohort, along with their ODEP rating statuses and respective maker details are presented as follows: -

Distribution of the Cumulative Revision Rate Percentage of Cemented Modern Prosthesis Combinations(in Current Circulation & Use) used in Primary Total Knee Arthroplasty of the Australian Patient Cohort with atleast >400 Procedures [Data Period : 1st September, 1999 to 31st December, 2021], alongside it's ODEP Rating Status & Manufacturer/Supplier Details.

SL No.	Femoral Component	Tibial Component	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	ACS	ACS Fixed	ImplantCast GmbH	10A	735	23	1.5(0.9, 2.8)	2.8(1.8, 4.3)	3.6(2.4, 5.4)			
2		ACS Mobile			1,310	30	0.8(0.4, 1.5)	1.9(1.2, 2.9)	3.1(2.1, 4.6)			
3	Active Knee	Active Knee	Allegra Orthopedics	Unrated	3,280	121	0.9(0.6, 1.3)	2.7(2.2, 3.4)	3.7(3, 4.5)	5.4(4.5, 6.6)	7.9(5.3, 11.6)	
4	Advance	Advance II	MicroPort Orthopedics	15A /ODEP Lapsed/Unrated	850	63	1.5(0.9, 2.6)	4.3(3.1, 5.9)	5.1(3.8, 6.8)	7.1(5.5, 9.1)	8(6.2, 10.4)	
5	Anatomic	Anatomic	Amplitude	Unrated	1,263	29	1.2(0.7, 1.9)	2.8(1.9, 4)	2.8(1.9, 4)			
6	Apex Knee CR	Apex Knee	Corin Group	Unrated	4,926	56	0.5(0.4, 0.8)	1.2(0.9, 1.6)	1.8(1.3, 2.4)			
7	Apex Knee PS	Apex Knee			5,548	133	0.8(0.6, 1)	2.3(1.9, 2.8)	3.1(2.6, 3.8)			
8	Attune CR	Attune	Depuy Synthes	7A / 7A*	20,427	473	0.9(0.8, 1)	2.3(2.1, 2.5)	3.1(2.8, 3.4)			
9	Attune PS	Attune		7A / 7A* / 5A	10,431	206	0.9(0.7,1.1)	2.1(1.8, 2.4)	2.6(2.3, 3)			
10	BalanSys	BalanSys	Mathys Medical	7A	2,141	61	0.4(0.2, 0.8)	1.6(1.1, 2.2)	2.1(1.5, 2.8)	3.7(2.8, 4.9)		
11	Columbus	Columbus	Bbraun	10A / 13A / 7A	4,460	72	0.9(0.7, 1.3)	2.2(1.7, 2.9)	2.4(1.9, 3.1)	3.9(2.3, 6.6)	5.1(3.5, 7.5)	
12	E.Motion	E.Motion	Bbraun	Unrated	583	25	1.9(1.1, 3.4)	3.7(2.4, 5.6)	3.9(2.6, 5.9)			
13	Evolis	Evolis	Medacta International	Unrated	1,104	24	0.4(0.1, 1)	1.1(0.6, 1.9)	1.7(1, 2.7)	3.1(2, 4.8)		
14	Evolution	Evolution	MicroPort Orthopedics	ODEP Lapsed	10,085	251	0.8(0.7, 1)	2.4(2.1, 2.7)	3.1(2.7, 3.5)			
15	GMK Primary	GMK Primary	Medacta International	ODEP Lapsed	738	26	1.1(0.6, 2.2)	2.6(1.7, 4.2)	3.3(2.2, 5)	4.3(2.9, 6.3)		
16	GMK Sphere Primary	GMK Primary		7A [GMK Sphere]	14,314	325	1.3(1.1, 1.5)	2.8(2.5, 3.1)	3.2(2.8, 3.6)			
17		GMK Sphere Primary			2,404	64	0.8(0.5, 1.3)	2.8(2.1, 3.7)	4.4(3.3, 5.8)			
18	Genesis II CR	Genesis II	Smith & Nephew	ODEP Lapsed	16,521	666	0.9(0.8, 1.1)	2.3(2.1, 2.6)	3(2.7, 3.3)	4.4(4.1, 4.8)	5.6(5.1, 6.1)	7(6.1, 7.9)
19	Genesis II Oxinium CR			Multiple Ratings Status across all Variants[15A* to Lapsed]	10,108	546	1.1(0.9, 1.3)	2.7(2.4, 3)	3.4(3.1, 3.8)	5.9(5.4, 6.5)	8.5(7.7, 9.3)	10.4(9.1, 11.8)
20	Genesis II Oxinium PS				21,819	1,321	1.4(1.3, 1.6)	3.6(3.3, 3.8)	4.9(4.6, 5.2)	7.2(6.8, 7.7)	9.7(9, 10.3)	
21	Genesis II PS				19,825	822	1.1(1, 1.3)	2.7(2.5, 2.9)	3.6(3.3, 3.9)	4.9(4.5, 5.2)	6(5.5, 6.5)	6.4(5.8, 7.1)
22	LCS CR	LCS	Depuy Synthes	15A/15A*/ 13A/7A	3,941	335	1(0.7, 1.4)	3.7(3.2, 4.4)	5.1(4.4, 5.8)	7.3(6.5, 8.2)	9.4(8.5, 10.5)	10.7(9.6, 12)
23		MBT		15A/15A*/ 13A/7A ; Unrated[MBT]	13,293	580	0.8(0.7, 1)	2.6(2.3, 2.9)	3.6(3.2, 3.9)	5.2(4.8, 5.7)	6.1(5.6, 6.8)	
24	Legion CR	Genesis II	Smith & Nephew	Multiple Ratings Status across all Variants[15A* to Lapsed]	3,807	93	1.1(0.8, 1.5)	2.3(1.8, 2.9)	3.2(2.6, 4)	4.3(3.2, 5.9)		
25	Legion Oxinium CR				8,902	224	0.8(0.6, 1)		3.6(3.1, 4.1)	4.5(3.9, 5.2)		
26	Legion Oxinium PS				16,287	648	1.1(0.9, 1.2)		4(3.7, 4.4)	5.7(5.2, 6.3)		
27	Legion PS				5,929	189	1.3(1, 1.6)	2.5(2.1, 2.9)	3.1(2.7, 3.7)	4.3(3.6, 5)		
28	MRK	MRK	MatOrtho	15A / 13A	659	21	0.8(0.3, 1.9)	2.3(1.3, 3.9)	2.5(1.5, 4.2)	4.2(2.6, 6.6)		
29	Natural Knee Flex	Natural Knee II	Zimmer Biomet	Unrated	2,595	84	1.2(0.9, 1.8)	2.7(2.1, 3.4)	3.1(2.4, 3.9)	4.3(3.4, 5.5)		
30	Nexgen CR	Nexgen		15A*	4,174	161	0.7(0.5, 1)	1.6(1.3, 2)	2.1(1.7, 2.6)	3.1(2.6, 3.7)	5(4.2, 5.9)	6.1(5.1, 7.3)
31	Nexgen CR Flex	Natural Knee II*		Unrated	806	16	0.4(0.1, 1.2)	1(0.5, 2)	1.3(0.7, 2.4)	2.2(1.3, 3.6)		
32		Nexgen			30,252	689	0.7(0.6, 0.8)	1.6(1.4, 1.7)	2.1(1.9, 2.3)	2.9(2.7, 3.2)	3.9(3.5, 4.4)	
33	Nexgen LCCK	Nexgen		Unrated	1,086	57	2.1(1.4, 3.1)	3.7(2.7, 5)	5(3.8, 6.7)	6.3(4.7, 8.4)		
34	Nexgen LPS	Nexgen		15A* / 15A	6,158	320	1.1(0.9, 1.4)	2.4(2, 2.8)	3.1(2.7, 3.6)	4.7(4.1, 5.3)	6.4(5.7, 7.2)	8.8(7.5, 10.4)
35	Nexgen LPS Flex	Nexgen		ODEP Rating Withdrawn / 15A	36,453	1,574	0.9(0.8, 1)	2.3(2.1, 2.4)	3.1(2.9, 3.3)	5(4.7, 5.3)	6.8(6.4, 7.2)	
36	Nexgen RII	Nexgen		Unrated	685	36	2.1(1.3, 3.6)	4.2(2.8, 6.1)	5.3(3.7, 7.6)	8.4(5.9, 11.9)		
37	Optetrak Logic CR	Optetrak Logic	Exactech	5A	705	18	0.9(0.4,2)	2.4(1.4, 4)	2.9(1.7, 4.7)			
38	Optetrak Logic PS	Optetrak Logic		7A	635	24	1.9(1.1, 3.3)	3.4(2.2, 5.2)	4.4(2.9, 6.7)			
39		Optetrak Logic RBK		7A/ODEP Rating Withdrawn	934	20	1.5(0.9, 2.6)	2.4(1.5, 3.8)	3.2(1.9, 5.2)			
40	PFC Sigma CR	MBT	Depuy Synthes	15A / 15A*/ Unrated[MBT]	1190	42	0.8(0.5, 1.6)	1.9(1.2, 2.8)	2.3(1.6, 3.3)	3.4(2.5, 4.6)	3.8(2.8, 5.3)	
41		PFC Sigma		15A	13507	492	0.8(0.7, 1)	2.1(1.8, 2.3)	2.6(2.4, 2.9)	3.6(3.3, 4)	5.2(4.7, 5.8)	7(5.8, 8.5)
42	PFC Sigma PS	MBT		7A / 10A / Unrated[MBT]	6153	346	1(0.8, 1.3)	2.9(2.5, 3.4)	3.9(3.4, 4.4)	5.4(4.8, 6)	7.2(6.4, 8.1)	
43		PFC Sigma		7A / 10A / 15A[PFC Sigma]	8352	393	1.2(1, 1.4)	2.6(2.3, 2.9)	3.3(2.9, 3.7)	4.7(4.2, 5.2)	6.4(5.8, 7.2)	
44	Persona CR	Nexgen	Zimmer Biomet	7A / 5A* / 15A*[Nexgen]	508	9	1(0.4, 2.4)	1.9(1, 3.7)				
45		Persona		7A	17927	212	0.8(0.7, 1)	1.8(1.6, 2.1)	2.3(2, 2.8)			
46	Persona PS	Persona		7A / 5A /	4102	67	0.8(0.6, 1.2)	1.8(1.4, 2.3)	2.5(1.9, 3.3)			
47	RBK	RBK	Exactech	ODEP Rating Withdrawn	2665	120	1(0.7, 1.4)	2.5(2, 3.2)	3.3(2.6, 4.0)	4.9(4.1, 5.9)	6.1(4.9, 7.5)	
48	SAIPH	SAIPH	MatOrtho	7A	4778	77	0.5(0.3, 0.8)	1.7(1.3, 2.2)	2.2(1.7, 2.8)			
49	Score	Score	Amplitude	ODEP Lapsed	1048	42	1.7(1, 2.7)	3(2.1, 4.3)	4.2(3, 5.7)	5.5(3.9, 7.6)		
50	Triathlon CR	Triathlon	Stryker	15A*/13A*/	63,667	1,497	0.8(0.7, 0.9)	1.9(1.8, 2)	2.4(2.3, 2.6)	3.7(3.5, 4.0)	5.1(4.5, 5.7)	
51	Triathlon FS	Triathlon		Unrated	411	29	3.5(2.1, 5.9)	6.6(4.5, 9.7)	8(5.5, 11.6)			
52	Triathlon PS	Triathlon		13A	9,799	424	1.5(1.2, 1.7)	3(2.7, 3.4)	3.8(3.4, 4.3)	5.7(5.2, 6.3)	7.8(6.5, 9.2)	
53	Unity Knee	Unity Knee	Corin Group	5A	613	2	0.3(0.1, 1.3)	0.3(0.1, 1.3)				
54	Vanguard CR	Vanguard	Zimmer Biomet	ODEP Lapsed	12,293	433	0.8(0.6, 0.9)	2.1(1.9, 2.4)	2.7(2.5, 3.1)	4.6(4.1, 5.1)	8.3(6, 11.3)	
55	Vanguard PS	Vanguard		10A	4,625	299	1.9(1.6, 2.4)	4.4(3.9, 5.1)	5.4(4.8, 6.2)	7.7(6.8, 8.6)	8.1(7.2, 9.2)	
56	Other [80]				4,895	378	3.1(2.6, 3.6)	6.4(5.7, 7.3)	8.6(7.7, 9.7)	13.2(11.7, 14.8)	20.2(16.3, 24.7)	
Cumulative Total No. of Primary & Revisions					4,46,706	15,288	*denotes the prothesis combinations that haven't reported any implementation/use on Australian Patients in 2021. ; blank cells indicate either no data could be accessed or incomplete data.					

Table 6.1.70 :- ***Tabulation illustrating the Overall Cumulative Revision Rate percentages of the Most Commonly Cemented Prostheses Combinations [Femoral + Tibial], which have been in Popular Utilization for Primary Total Knee Arthroplasty of the Australian Patient Cohort, along with their respective ODEP Rating Statuses and Manufacturer/Supplier firm details.***

- The most commonly utilized non-cemented fixation-based prostheses combinations that were utilized for at least 400 primary TKAs of the Australian patient cohort, along with their ODEP rating statuses and respective maker details are presented as follows: -

Distribution of the Cumulative Revision Rate Percentage of Non-Cemented Modern Prosthesis Combinations(in Current Circulation & Use) used in Primary Total Knee Arthroplasty of the Australian Patient Cohort with atleast >400 Procedures [Data Period : 1st September, 1999 to 31st December, 2021], alongside it's ODEP Rating Status & Manufacturer/Supplier Details.

SL No.	Femoral Component	Tibial Component	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	ACS	ACS Fixed	ImplantCast GmbH	10A	1,095	52	1.5(0.9, 2.5)	4(2.9, 5.4)	4.8(3.6, 6.4)			
2	Active Knee	Active Knee	Allegra Orthopedics	Unrated	4,899	565	1.3(1.1, 1.7)	4(3.4, 4.5)	5.6(5, 6.3)	9.6(8.8, 10.5)	13.3(12.2, 14.4)	
3	Apex Knee CR	Apex Knee	Corin Group	Unrated	468	27	2.4(1.3, 4.3)	5.4(3.7, 8)	5.7(3.9, 8.3)			
4	Attune CR	Attune	Depuy Synthes	7A / 7A*	1,632	10	0.8(0.4, 1.7)	1.2(0.5, 2.8)				
5	Columbus	Columbus	Bbraun	10A / 13A / 7A	500	66	3.2(2, 5.2)	7.7(5.6, 10.4)	9.7(7.4, 12.7)	13.1(10.4, 16.5)		
6	GMK Primary	GMK Primary	Medacta International	ODEP Lapsed	1,493	52	1.2(0.7, 1.9)	3.2(2.3, 4.3)	3.9(2.9, 5.2)			
7	Genesis II CR	Genesis II	Smith & Nephew	ODEP Lapsed	747	44	1.5(0.8, 2.6)	3.9(2.7, 5.5)	4.7(3.3, 6.5)	7.1(5.3, 9.6)		
8	Genesis II PS			13A* / ODEP Lapsed	420	31	1.7(0.8, 3.5)	3.3(2, 5.6)	4.1(2.5, 6.5)	6.6(4.5, 9.6)		
9	LCS CR	LCS	Depuy Synthes	15A/15A*/ 13A/7A	2,379	171	1.4(1, 2)	3.4(2.7, 4.2)	4.3(3.5, 5.2)	6.1(5.2, 7.2)	7.3(6.2, 8.5)	8.8(7.6, 10.2)
10		MBT		15A/15A*/ 13A/7A ; Unrated[MBT]	9,391	483	1.1(0.9, 1.3)	3.4(3, 3.8)	4.1(3.7, 4.6)	5.5(5, 6)	7.8(6.9, 8.8)	
11		MBT Duofix		15A/15A*/ 13A/7A ; Unrated[MBT Duofix]	14,555	832	1.3(1.1, 1.5)	3.3(3, 3.6)	4.1(3.8, 4.5)	5.4(5, 5.8)	7.4(6.8, 8)	9.8(8.6, 11.1)
12	Natural Knee Flex	Natural Knee II	Zimmer Biomet	Unrated	1,721	42	0.7(0.4, 1.3)	1.6(1.1, 2.4)	2.1(1.5, 2.9)	3(2.2, 4.1)		
13	Nexgen CR	Nexgen		Multiple Ratings Status across all Variants[15A* to Lapsed]	3,446	130	0.6(0.4, 0.9)	1.7(1.3, 2.2)	2.1(1.7, 2.7)	3(2.5, 3.7)	4(3.3, 4.8)	5.7(4.7, 7.1)
14		Nexgen TM CR			746	50	1.4(0.7, 2.5)	4.3(3, 6.1)	6.1(4.6, 8.2)	6.9(5.2, 9.1)	8.1(6, 10.8)	
15	Nexgen CR Flex	Nexgen			8,681	326	1.1(0.9, 1.4)	2.7(2.4, 3.1)	3.3(2.9, 3.7)	4.2(3.7, 4.7)	5(4.4, 5.7)	
16		Nexgen TM CR			11,400	324	0.5(0.4, 0.7)	1.8(1.5, 2)	2.3(2.9, 3.7)	3.3(2.9, 3.7)	4.6(3.9, 5.5)	
17	Nexgen LPS	Nexgen TM LPS		ODEP Rating Withdrawn / 15A	1,446	34	0.6(0.3, 1.2)	1.2(0.7, 1.9)	2.1(1.4, 3.1)	2.7(1.9, 3.9)	3.7(2.5, 5.6)	
18	Nexgen LPS Flex	Nexgen			1,196	50	2.6(1.8, 3.7)	4(3, 5.3)	4.1(3.1, 5.5)			
19		Nexgen TM LPS			1,062	51	1.3(0.8, 2.2)	3.1(2.2, 4.3)	4.2(3.2, 5.7)	5.3(4, 7)		
20	PFC Sigma CR	MBT	Depuy Synthes	15A / 15A*/ Unrated[MBT]	995	70	2.3(1.5, 3.5)	4.9(3.7, 6.4)	5.6(4.3, 7.2)	6.7(5.3, 8.5)	8.5(6.5, 11)	
21		MBT Duofix*		15A / 15A*/ Unrated[MBT Duofix]	3,327	165	1(0.7, 1.4)	2.7(2.2, 3.3)	3.4(2.9, 4.1)	4.8(4, 5.7)		
22	Persona CR	Persona	Zimmer Biomet	7A	3,436	46	1.3(0.9, 1.8)	2.3(1.7, 3.3)				
23	RBK	RBK	Exactech	ODEP Rating Withdrawn	6,907	371	1.3(1.1, 1.6)	3.1(2.7, 3.6)	4.2(3.7, 4.7)	5.5(5, 6.1)	6.8(6, 7.6)	
24	Score	Score	Amplitude	ODEP Lapsed	2,970	223	1.6(1.2, 2.1)	5(4.2, 6)	6.9(5.9, 8)	11.1(9.6, 12.7)		
25	Triathlon CR	Triathlon	Stryker	15A*/13A*/	30,575	789	1(0.9, 1.2)	2.3(2.1, 2.5)	3(2.7, 3.2)	4.3(4.0, 4.6)	6.2(5.2, 7.3)	
26	Triathlon PS			13A	1,343	67	1.9(1.3, 2.8)	3.5(2.6, 4.7)	4.6(3.6, 6)	5.8(4.6, 7.4)		
27	Vanguard CR	Regenerex	Zimmer Biomet	Multiple Ratings Status across all Variants[15A* to Lapsed] ; Regenerex Unrated	1,697	88	1.2(0.8, 1.8)	3.3(2.6, 4.3)	4(3.1, 5)	6.7(5.3, 8.4)		
28		Vanguard		ODEP Lapsed	1,695	107	1.4(1, 2.1)	4.1(3.3, 5.2)	4.8(3.9, 5.9)	6.5(5.4, 7.9)		
29	Other [32]				2,826	207	2.6(2.1, 3.3)	6.1(5.3, 7.1)	7.2(6.3, 83)	8.8(7.7, 10.1)	9.6(8.3, 11.2)	
Cumulative Total No. of Primary & Revisions					1,23,048	5,473	*denotes the prothesis combinations that haven't reported any implementation/use on Australian Patients in 2021.					

Table 6.1.71 :- ***Tabulation illustrating the Overall Cumulative Revision Rate percentages of the Most Commonly Non-Cemented Prostheses Combinations [Femoral + Tibial], which have been in Popular Utilization for Primary Total Knee Arthroplasty of the Australian Patient Cohort, along with their respective ODEP Rating Statuses and Manufacturer/Supplier firm details.***

- The most commonly utilized hybrid fixation-based prostheses combinations that were utilized for at least 400 primary TKAs of the Australian patient cohort, along with their ODEP rating statuses and respective maker details are presented as follows: -

AOANJRR 2022 :- Cumulative Revision Percent of Hybrid Modern Prosthesis Combinations(in Current Circulation & Use) used in Primary Total Knee Arthroplasty of the Australian Patient Cohort with atleast >400 Procedures [Data Period : 1st September, 1999 to 31st December, 2021].

SL No.	Femoral Component	Tibial Component	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	ACS	ACS Fixed	ImplantCast GmbH	10A	1,478	66	1.3(0.8. 2.1)	4.1(3.1, 5.3)	5(3.8, 6.4)			
2	Active Knee	Active Knee	Allegra Orthopedics	Unrated	2,323	159	0.7(0.4, 1.1)	2.8(2.2, 3.5)	3.8(3.1, 4.7)	6.9(5.8, 8.2)	10.7(9, 12.8)	
	Advance	Advance II	MicroPort Orthopedics	15A	428	23	0.7(0.2, 2.2)	2.4(1.3, 4.4)	3.4(2, 5.7)	5.4(3.5, 8.3)	6.5(4.2, 10.1)	
3	Apex Knee CR	Apex Knee	Corin Group	Unrated	4,208	66	0.9(0.7, 1.3)	1.6(1.2, 2.1)	2.2(1.7, 2.8)			
4	Attune CR	Attune	Depuy Synthes	7A / 7A*	778	6	1.1(0.5, 2.5)					
5	Attune PS			7A / 7A* / 5A	601	5	1(0.4, 2.6)					
6	BalanSys	BalanSys	Mathys Medical	7A	2,157	47	1(0.7, 1.6)	2.1(1.6, 2.9)	2.5(1.9, 3.4)			
7	GMK Primary	GMK Primary	Medacta International	ODEP Lapsed	790	30	1.2(0.6, 2.3)	3.8(2.6, 5.5)	4.1(2.9, 6)			
8	Genesis II CR	Genesis II	Smith & Nephew	ODEP Lapsed	8,615	473	1(0.8, 1.2)	3.2(2.9, 3.6)	4.3(3.9, 4.8)	6(5.5, 6.6)	7.2(6.5, 7.9)	8.1(7.2, 9.1)
9	Genesis II PS			13A* / ODEP Lapsed	707	68	1.7(1, 3)	4.4(3.1, 6.2)	5.6(4.1, 7.6)	8.7(6.8, 11.1)	10.7(8.5, 13.6)	
10	LCS	LCS	Depuy Synthes	15A/15A*/ 13A/7A	2,364	152	1(0.7, 1.5)	2.7(2.1, 3.5)	3.8(3.1, 4.7)	5.5(4.6, 6.6)	6.9(5.8, 8.1)	8.5(7.1, 10.2)
11		MBT		15A/15A*/ 13A/7A ; Unrated[MBT]	11,061	367	0.7(0.6, 0.9)	2.1(1.9, 2.4)	2.8(2.5, 3.1)	4(3.6, 4.4)	4.5(4, 5.1)	
12		MBT Duofix		15A/15A*/ 13A/7A ; Unrated[MBT Duofix]	1,000	37	1.3(0.8, 2.2)	3.2(2.3, 4.5)	3.3(2.4, 4.7)	4.1(3, 5.7)		
13	Legion CR	Genesis II	Smith & Nephew	Multiple Ratings Status across all Variants[15A* to Lapsed]	3,810	141	1.4(1.1, 1.8)	3.5(2.9, 4.2)	4.3(3.6, 5.1)	6.1(5, 7.5)		
14	Natural Knee Flex	Natural Knee II	Zimmer Biomet	Unrated	1,971	41	0.4(0.2, 0.8)	1.3(0.8, 1.9)	1.8(1.3, 2.5)	2.5(1.8, 3.4)		
15	Nexgen CR	Nexgen		Multiple Ratings Status across all Variants[15A* to Lapsed]	4,361	159	0.6(0.4, 0.9)	1.7(1.4, 2.2)	2.2(1.8, 2.7)	3.1(2.6, 3.8)		
16	Nexgen CR Flex	Nexgen			22,072	563	0.7(0.6, 0.8)	1.8(1.6, 2)	2.3(2.1, 2.5)	3.1(2.8, 3.3)	3.8(3.4, 4.4)	
17		Nexgen TM CR			879	24	0.7(0.3, 1.5)	1.5(0.9, 2.6)	1.7(1, 2.8)	2.4(1.5, 3.7)	3.7(2.4, 5.8)	
18	Nexgen LPS	Nexgen		ODEP Rating Withdrawn / 15A	1,048	57	0.5(0.2, 1.2)	2.7(1.9, 3.9)	4.1(3, 5.6)	5.4(4.1, 7)	6.3(4.8, 8.2)	
19	Nexgen LPS Flex	Nexgen			1,065	660	2.1(1.4, 3.1)	4.3(3.3, 5.8)	5.5(4.2, 7.1)	6.8(5.1, 9.1)		
20		Nexgen TM LPS			511	20	0.6(0.2, 1.8)	1.8(0.9, 3.4)	2(1.1, 3.7)	3.1(1.9, 5.1)	5.4(3.2, 9.2)	
21	Optetrak Logic CR	Optetrak Logic	Medacta International	ODEP Lapsed	1,067	29	1.1(0.6, 2)	2.5(1.7, 3.8)	4(2.6, 6.1)			
22	PFC Sigma CR	MBT	Depuy Synthes	15A / 15A*/ Unrated[MBT]	4,171	224	1.3(1, 1.6)	3.1(2.6, 3.7)	4(3.4, 4.7)	5.1(4.5, 5.9)	7(6, 8.1)	9(7.1, 11.3)
23		PFC Sigma		Multiple Ratings Status across all Variants[15A* to Lapsed]	11,854	410	0.6(0.5, 0.8)	1.9(1.6, 2.1)	2.4(2.1, 2.7)	3.4(3.1, 3.8)	5.1(4.5, 5.8)	6.3(5.4, 7.4)
24	PFC Sigma PS	MBT Duofix*		15A / 15A*/ Unrated[MBT Duofix]	2,252	178	1.8(1.3, 2.5)	4.4(3.7, 5.4)	5.9(5, 7)	7.9(6.8, 9.2)	10.1(8.6, 11.8)	
25	Persona CR	Persona	Zimmer Biomet	7A	9,113	114	1(0.8, 1.3)	2(1.6, 2.5)	2.2(1.7, 2.9)			
26	RBK	RBK	Exactech	ODEP Rating Withdrawn	1,612	76	1.1(0.7, 1.7)	2.9(2.2, 3.9)	3.7(2.9, 4.8)	4.9(3.8, 6.2)	7.5(5.5, 10.2)	
27	Score	Score	Amplitude	ODEP Lapsed	1,724	99	1.5(1, 2.2)	3.9(3.1, 5)	6.3(5.1, 7.7)			
28	Trekking	Trekking	Samo Biomedica	7B / Lapsed / Pre-Entry	560	20	1.1(0.5, 2.4)	2.8(1.7, 4.6)	3.5(2.1, 5.7)			
29	Triathlon CR	Triathlon	Stryker	15A*/13A*/	33,066	687	0.7(0.6, 0.8)	1.6(1.5, 1.8)	2.1(2, 2.3)	3.2(3, 3.6)	4.3(3.5, 5.3)	
30	Triathlon PS			13A	2,970	119	1.7(1.3, 2.3)	2.7(2.2, 3.4)	3.6(3, 4.4)	4.9(4.1, 6)		
31	Vanguard CR	Vanguard	Zimmer Biomet	Multiple Ratings Status across all Variants[15A* to Lapsed]	13,404	490	0.8(0.7, 1)	2.2(2, 2.5)	3(2.7, 3.3)	5(4.5, 5.5)	6.4(5.6, 7.3)	
32	Vanguard PS	Vanguard			709	34	1.4(0.8, 2.6)	3.2(2.1, 4.9)	4.2(2.9, 6)	5.8(4.1, 8.2)		
33	Other [68]				3,212	256	2.9(2.3, 3.5)	6.1(5.3, 7)	7.3(6.4, 8.3)	9.2(8.1, 10.4)	11.6(10, 13.6)	
Cumulative Total No. of Primary & Revisions					1,57,941	5,300	*denotes the prothesis combinations that haven't reported any implementation/use on Australian Patients in 2021. ; blank cells indicate either no data could be accessed or incomplete data.					

Table 6.1.72 :- ***Tabulation illustrating the Overall Cumulative Revision Rate percentages of the Most Commonly Hybrid fixation based Prostheses Combinations [Femoral + Tibial], which have been in Popular Utilization for Primary Total Knee Arthroplasty of the Australian Patient Cohort, along with their respective ODEP Rating Statuses and Manufacturer/Supplier firm details.***

Primary Diagnoses based Influences & Outcomes of Total Knee Arthroplasty in Australia: -

- The most commonly stated cause or reason for a primary total knee arthroplasty of the Australian patient cohort has historically been consistent with osteoarthritis.

- The overall distribution of the primary total knee arthroplasty procedures performed on the Australian patient cohort, as per their indicated primary diagnosis or the prime driving reason to undergo an arthroplasty, along with their relative revision rate percentage during different time-points in the post-operative follow-up period is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative Revision Percent of Primary Total Knee Arthroplasty of the Australian Patient Cohort by Primary Diagnosis Type.

SL No.	Primary Diagnosis	Total Cases	Total Revised	Primary % of Overall	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Osteoarthritis [OA]	7,11,978	25,251	97.80%	1.0(1.0, 1.0)	2.5(2.4, 2.5)	3.2(3.2, 3.3)	4.7(4.7, 4.8)	6.4(6.3, 6.5)	8.0(7.8, 8.3)
2	Rheumatoid Arthritis [RA]	8,091	331	1.10%	1.1(0.9, 1.4)	2.3(2.0, 2.7)	3.0(2.7, 3.5)	4.7(4.2, 5.3)	6.5(5.7, 7.5)	10.4(8.3, 13.1)
3	Other Inflammatory Arthritis	3,697	161	0.50%	1.6(1.2, 2.0)	3.1(2.6, 3.8)	4.2(3.5, 5.0)	5.8(4.9, 6.9)	6.9(5.6, 8.5)	
4	Osteonecrosis	2,185	98	0.30%	1.1(0.7, 1.6)	3.2(2.5, 4.1)	4.3(3.4, 5.3)	5.5(4.4, 6.8)	7.7(5.9, 10.0)	
5	Other Diagnoses [4]	1,744	220	0.20%	4.5(3.6, 5.6)	9.7(8.3, 11.4)	13.2(11.4, 15.3)	21.0(18.1, 24.3)	31.0(25.5, 37.3)	
TOTAL		7,27,695	26,061	100.00%						

Table 6.1.73 :- ***Tabulation illustrating the existent cumulative Revision Rate percentage of the Primary Total Knee Arthroplasty of the Australian Patient Cohort, against the most commonly cited reasons for Primary Arthroplasty / Primary Diagnosis Types.***

- Considering osteoarthritis as the leading most primary diagnosis indication, primary total knee arthroplasty standouts as the best modality of knee arthroplasty compared to all other modalities, as far as the involving revision rate is concerned. The maximum obtainable revision rate scenario for primary TKA in long-term is at 8.00% in Australia, as presented through the following tabulation, based on the evaluated Australian TKA practices facts & figures: -

The Overall Revision Rate scenario of the Primary Total Knee Arthroplasty (TKA) on Australian Patient Cohort with Primary Indication OA.

SL No.	Knee Type	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Total Knee Arthroplasty	7,11,978	25,251	1(1, 1)	2.5(2.4, 2.5)	3.2(3.2, 3.3)	4.7(4.7, 4.8)	6.4(6.3, 6.5)	8(7.8, 8.3)
TOTAL		7,11,978	25,251						

Table 6.1.74 :- ***Tabulation illustrating the Overall Revision Rate scenario of the Primary Total Knee Arthroplasties performed on the Australian patient cohort, with a primary diagnosis of osteoarthritis. [Broad Numbers, which doesn't comprise macro & micro details].***

Revision Knee Arthroplasty Practices and Related Scenarios in Australia: -

- Post-operative incidences of infection in and around the arthroplasty site on the patients, is the most reported cause for a revision knee arthroplasty in Australia, which is closely followed by loosening of the implant modules, general instability and pain/patella-femoral pain as some of the common reasons for the revision of a TKA.

- The most common form of revision activity during such revision knee arthroplasty procedures on the Australian patient cohort involves the revision or replacement of only the articulating surface bearing insert. Incidences of replacing the entire prosthetic combination arrangement with a new one involving both the tibial and femoral knee prosthesis components is the close second most commonly noted revision activity on Australian patients with a primary diagnosis of osteoarthritis.

- The majorly revised prosthesis components or the most common forms of revision activities, performed during the revision knee arthroplasty of the primary TKAs of the patients with primary diagnosis OA is presented through the following tabulation: -

Table 6.1.75 :- ***Tabulation illustrating the Most Commonly Replaced/Revised Prosthesis Components of a Total Knee Prosthesis, during a Revision Knee Arthroplasty of a primary TKA, of the Australian Patient Cohort.***

AOANJRR 2022 :- Major Types of Revision Arthroplasty & Items Revised of Primary Total Knee Arthroplasty for Patients with Primary Diagnosis OA.			
SL No.	**Type of Revision Arthroplasty/Items Revised**	**No. of Cases**	**% of Overall**
1	Insert Only	6,901	27.3
2	TKA (Tibial/Femoral)	6,226	24.7
3	Patella Only	4,670	18.5
4	Articular Bearing Insert / Patella	2,651	10.5
5	Tibial Component	2,040	8.1
6	Cement Spacer	1,309	5.2
7	Femoral Component	1,230	4.9
8	Removal of Prostheses	139	0.6
9	Minor Components	49	0.2
10	Total Femoral	13	0.1
11	Cement Only	12	0
12	Re-Insertion of Components	11	0
TOTAL		**25,251**	**100.00%**

- The overall distribution of the various reasons stated to be as the primary reason for the revision of failing primary TKAs performed on the Australian patient cohort is illustrated through the following tabulation: -

Table 6.1.76 :- ***Tabulation illustrating the prevailing Most Commonly cited Reasons for Revision of a Primary Total Knee Arthroplasty of an Australian patient.***

AOANJRR 2022 :- Major Reasons for Revision Arthroplasty of Primary Total Knee Arthroplasty for Patients with Primary Diagnosis OA in Australia.			
SL No.	**Reason for Revision Arthroplasty**	**No. of Cases**	**% of Overall**
1	Infection	6,724	26.6
2	Aseptic Loosening	5,667	22.4
3	Instability	2,427	9.6
4	Pain	2,020	8
5	Patellofemoral Pain	1,994	7.9
6	Patella Erosion	1,655	6.6
7	Arthrofibrosis	989	3.9
8	Fracture	893	3.5
9	Mal-alignment of Implant	584	2.3
10	Wearing of Tibial Insert	351	1.4
11	Lysis	340	1.3
12	Incorrect Sizing	253	1
13	Metal Related Pathology	113	0.4
14	Other Reasons	1,241	4.9
TOTAL		**25,251**	**100.00%**

- An interesting insight was found from the reported data of the Australian registry, wherein it was stated that male patients tend to have a higher rate of revision of their TKAs, mostly “due to an increased incidence of infection”. However, for female patients in Australia it was the usual cause of loosening off the prosthesis that leads to their greatest number of revision knee arthroplasties. Such gender-specific incidences of infections and gender-specific infections topping the reported data charts as the leading cause for revisions in males are quite weird and is not noted anywhere else across the nations, which were evaluated for their respective arthroplasty and prosthesis utilization practices during the span of this research probe.

- Similarly, the trends of male patients having greater incidences of requiring a revision knee arthroplasty than females, is also a first among the other nations evaluated and studied in great detail, during the process of this research. The most plausible inference that could be hypothesized based on such findings may indicate the possibilities of Australian females being more physically active than their male counter-parts during varied ages of their lives. Though such hypothesis can only be ascertained if some degree of the Australian livelihood and general lifestyle could be studied in corollary with the various joint-replacement scenarios observed.

- The overall rate of revision for total knee arthroplasty of the Australian patient cohort is noted to be decreasing with increasing age as stated and discussed earlier. Patients aging less than 55 years are noted to be having close to 3 times the revision rate percentages than that of the patients belonging to the senior patients aging greater than 75 years, during the immediate short-term post-op period within 6 months to 1 years since the primary. This difference further widens with progressing time in the postoperative window.

- The patient age-group wise distribution of the prevalent revision rate percentages of the primary TKAs performed on the Australian patient cohort, is presented as follows: -

Distribution of Number of Primary & Revision Total Knee Arthroplasty by Age-Groups of the Australian Patients with Primary Indication OA, alongwith their Cumulative Revision Rate percentages across varied Post-Operative follow-up timepoints.

SL No.	Patient Age-Group	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	<55 Years	46,794	3,334	1.6(1.5, 1.7)	4.4(4.2, 4.6)	5.9(5.6, 6.1)	8.9(8.6, 9.3)	12.9(12.3, 13.4)	16.6(15.6, 17.7)
2	55 - 64 Years	1,90,748	8,782	1.1(1.1, 1.2)	3(2.9, 3)	3.9(3.8, 4)	5.9(5.8, 6.1)	8.3(8.1, 8.5)	10.5(10.1, 11)
3	65 - 74 Years	2,85,504	9,068	0.9(0.9, 1)	2.3(2.2, 2.4)	3(2.9, 3)	4.3(4.2, 4.4)	5.4(5.2, 5.5)	6.2(6, 6.5)
4	>= 75 Years	1,88,932	4,067	0.8(0.8, 0.9)	1.7(1.7, 1.8)	2.2(2.1, 2.2)	2.9(2.8, 3)	3.4(3.3, 3.6)	3.5(3.3, 3.7)
TOTAL		7,11,978	25,251						

Table 6.1.77 :- ***Tabulation illustrating the Patient Age-Group wise distribution of Primary & Revision Knee Arthroplasties of the Australian cohort, with a Primary Indication of OA, alongside their Cumulative Revision Rate percentage s across varied Post-Operative follow-up timepoints..***

- While, the age-group linked distribution of the prevalent revision rate percentages of the primary TKAs on the Australian patient cohort, against the patient gender, categorized against the patient gender groups, is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative RR % of Primary Total Knee Arthroplasty for Australian Patient Cohort with Primary Indication OA, categorized as per Patient Gender & Age Groups. [Restricted to Modern Prosthesis - Prosthesis in Current Circulation/Use in Australia)]

SL No.	Gender of Patients	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
Male Patients		3,16,008	12,026	1.2(1.2, 1.2)	2.8(2.7, 2.8)	3.5(3.5, 3.6)	5.1(5, 5.2)	7(6.8, 7.1)	8.8(8.4, 9.2)
1	<55 Years	20,206	1,518	1.9(1.7, 2.1)	4.8(4.5, 5.1)	6.2(5.8, 6.6)	9.3(8.8, 9.8)	13.6(12.8, 14.5)	17.5(16, 19.2)
2	55 - 64 Years	89,262	4,277	1.3(1.2, 1.4)	3.2(3.1, 3.4)	4.2(4.1, 4.3)	6.3(6.1, 6.5)	8.7(8.4, 9)	11(10.3, 11.8)
3	65 - 74 Years	1,29,197	4,410	1.1(1.1, 1.2)	2.5(2.4, 2.6)	3.3(3.2, 3.4)	4.6(4.5, 4.8)	5.8(5.6, 6.1)	6.7(6.3, 7.1)
4	>= 75 Years	77,343	1,821	1(0.9, 1.1)	2(1.9, 2.1)	2.4(2.3, 2.6)	3.2(3, 3.3)	3.7(3.5, 4)	3.8(3.5, 4.1)
Female Patients		3,95,970	13,225	0.8(0.8, 0.9)	2.2(2.2, 2.3)	3(2.9, 3)	4.4(4.3, 4.5)	6(5.8, 6.1)	7.5(7.2, 7.8)
5	<55 Years	26,588	1,816	1.3(1.2, 1.5)	4(3.8, 4.3)	5.6(5.3, 5.9)	8.7(8.2, 9.1)	12.3(11.6, 13)	15.9(14.6, 17.3)
6	55 - 64 Years	1,01,486	4,505	0.9(0.9, 1)	2.7(2.6, 2.8)	3.7(3.6, 3.8)	5.7(5.5, 5.9)	8(7.7, 8.3)	10.1(9.5, 10.8)
7	65 - 74 Years	1,56,307	4,658	0.7(0.7, 0.8)	2.1(2, 2.2)	2.8(2.7, 2.8)	4(3.9, 4.1)	5(4.8, 5.2)	5.9(5.5, 6.3)
8	>= 75 Years	1,11,589	2,246	0.7(0.7, 0.8)	1.6(1.5, 1.6)	2(1.9, 2.1)	2.7(2.6, 2.8)	3.2(3, 3.4)	3.3(3.1, 3.6)
TOTAL		7,11,978	25,251						

Table 6.1.78 :- ***Tabulation illustrating the Patient Age-Group & Gender linked distribution of the Primary & Revision Knee Arthroplasties of the Australian cohort, with a Primary Indication of OA, alongside their Cumulative Revision Rate percentage s across varied Post-Operative follow-up timepoints..***

<u>Fixation Method-Based Knee Arthroplasty Practices on the Australian Patient Cohort: -</u>

- The fixation method utilized during the arthroplasty procedure to augment and aid the internal fixation of the prosthesis unit with the bone, is very integral towards the general stability of the prosthesis.

- Cementing the tibial component of the total knee joint prosthesis unit, during minimally stabilized or cruciate retaining procedures of knee arthroplasties provides for the best outcomes in the Australian patient cohort.

- The various scenarios of revision rates for the respective fixation methods deployed, and their related inter-comparison is presented as follows: -

  For Minimally Stabilized/Cruciate Retaining Knee Prosthesis,

  - RR [Hybrid Fixation] < RR [Cemented Fixation].
  - RR [Hybrid Fixation] < RR [Non-Cemented Fixation].
  - RR [Non-Cemented Fixation] > RR [Cemented] (during initial 6months post-op.)
  - RR [Non-Cemented Fixation] < RR [Hybrid] & RR [Cemented]. (At 2year-3½ year post-op)

  For Posterior Stabilized/Cruciate Sacrificing Knee Prosthesis,

- RR [Cemented] < RR [Hybrid].
- RR [Non-Cemented] < RR [Cemented].
- RR [Non-Cemented] < RR [Hybrid].

For Medial Pivot Design Knee Prosthesis,

- RR [Cemented] = RR [Non-Cemented].

- The above-stated scenarios of revision rate percentages of the primary TKAs performed on the general Australian cohort, across multiple follow-up points in the post-operative window is presented through the following tabulations: -

Distribution of the Cumulative Revision Rate Percentages of Minimally Stabilized / Cruciate Retaining[C.R] Knee Prosthesis used for Primary Total Knee Arthroplasty by Knee Prosthesis Fixation Methods Applied on Australian Patients with Primary Indication OA.

SL No.	Knee Prosthesis Fixation Method	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Cemented	2,42,582	6,965	0.8(0.8, 0.9)	2.1(2, 2.1)	2.7(2.7, 2.8)	4.1(4, 4.2)	5.7(5.5, 5.9)	7.1(6.7, 7.5)
2	Cement-less	1,14,394	5,027	1.1(1.1, 1.2)	2.9(2.8, 3)	3.7(3.6, 3.9)	5.3(5.1, 5.5)	7.2(6.9, 7.4)	9.3(8.8, 9.8)
3	Hybrid	1,43,849	4,483	0.8(0.8, 0.9)	2.2(2.1, 2.2)	2.8(2.7, 2.9)	4.1(3.9, 4.2)	5.4(5.2, 5.7)	6.7(6.2, 7.2)
TOTAL		*5,00,825*	*16,475*	Data for only Modern Prosthesis [Prosthesis in Current Circulation & Use in Australia]			Excluding Non-Cemented 'Genesis Oxinium' (Smith&Nephew) Femoral Prostheses - Metallosis/Mfg. Issue/Re-Call		

Table 6.1.79 :- ***Tabulation illustrating the Distribution of Cumulative Revision Rate percentages of Minimally Stabilized / Cruciate Retaining[C.R] Knee Prosthesis, used for the Primary Total Knee Arthroplasty of the Australian patient cohort, as per the Fixation Method applied during the procedure.***

AOANJRR 2022 :- Cumulative Revision Percent of Posterior Stabilized [P.S] Knee Prosthesis used for Primary Total Knee Arthroplasty by Knee Prosthesis Fixation Methods Applied on Australian Patients with Primary Indication OA.

SL No.	Knee Prosthesis Fixation Method	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Cemented	1,55,992	6,717	1.1(1.1, 1.2)	2.7(2.7. 2.8)	3.6(3.5, 3.7)	5.4(5.3, 5.6)	7.2(7, 7.4)	9.2(8.4, 10.2)
2	Cement-less	6,202	279	1.8(1.5. 2.2)	3.2(2.8, 3.7)	4(3.6, 4.6)	5.3(4.7, 6)	6.7(5.5, 8.1)	
3	Hybrid	10,641	607	1.7(1.5, 2)	3.8(3.4, 4.2)	4.9(4.5, 5.4)	6.4(5.9, 7)	8.2(7.4, 9)	
TOTAL		1,72,835	7,603	Data for only Modern Prosthesis [Prosthesis in Current Circulation & Use in Australia]					

Table 6.1.80 :- ***Tabulation illustrating the Distribution of Cumulative Revision Rate percentages of Posterior Stabilized [P.S] / Cruciate Sacrificing Knee Prosthesis, used for the Primary Total Knee Arthroplasty of the Australian patient cohort, as per the Fixation Method applied during the procedure.***

AOANJRR 2022 :- Cumulative Revision Percent of Medial Pivot Design Knee Prosthesis used for Primary Total Knee Arthroplasty by Knee Prosthesis Fixation Methods Applied on Australian Patients with Primary Indication OA.

SL No.	Knee Prosthesis Fixation Method	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Cemented	32,550	782	1(0.9, 1.1)	2.5(2.3, 2.7)	3.1(2.9, 3.4)	4.9(4.2, 5.6)	6.9(5.3, 8.9)	
2	Cement-less	594	43	2.8(1.7, 4.5)	5.6(4, 7.8)	6.5(4.8, 8.9)	7.5(5.5, 10)	7.5(5.5, 10)	
3	Hybrid	679	33	0.8(0.3, 1.8)	2.8(1.8, 4.5)	3.9(2.6, 6)	5.9(4.1, 8.4)	7.5(5.1, 10.8)	
TOTAL		*33,823*	*858*	Data for only Modern Prosthesis [Prosthesis in Current Circulation & Use in Australia]					

Table 6.1.81 :- ***Tabulation illustrating the Distribution of Cumulative Revision Rate percentages of Medial Pivot [M.P] design based Knee Prosthesis, used for the Primary Total Knee Arthroplasty of the Australian patient cohort, as per the Fixation Method applied during the procedure.***

Patient Reported Outcome Measures (PROMs) for Total Knee Arthroplasty of the Australian Patient Cohort: -

- The prevalent modalities to capture patient reported outcome measure responses from the patients in Australia, is largely centered around the EuroQoL Visual Analogue Score (EQ-VAS), the EuroQoL-5D-5L (EuroQoL 5 Dimensions and 5 Levels) and the Oxford Knee Score (OKS) for knee arthroplasties.

- The practice of capturing patient reported outcomes and their stated satisfaction levels with their respective life standards compared pre and post operatively, alongside their own experience and relative satisfaction from the prosthesis and arthroplasty undergone, kicked off much later in Australia, than most other nations which were evaluated during the course of this research.

- As of present day, the general practice of PROMs capturing is still in a pilot-rollout status in Australia, and has not been completely integrated with the arthroplasty reporting protocol through its own MDS at the hospital and clinic level. Rather, as it stands on the basis of evaluated relevant healthcare regulatory documents, registry publications and other related investigation, if would be practical to

state that as far patient reported outcomes of their undergone arthroplasty procedure is concerned, the onus is on the patient to get their opinions and statements reported on their own initiative, through a separate portal, other than the regular MDS portals.

- As a result, the relative number of patients reported outcomes captured vis-à-vis the overall number of knee arthroplasties recorded in the registry database or being performed as of the latest reported year, is far less, than the latter.

- Nevertheless, multiple interesting and intriguing insights with critical observations were inferred by this research probe, during the evaluation process of such patient-reported outcome measures.

EQ-VAS-based PROMS on Primary Total Knee Arthroplasty by Australian Patients: -

- The total number of pre-operative EQ-VAS-based PROMs captured for primary TKA is 21,087. The respective linked post-operative EQ-VAS-based PROMs data was available for 13,321 individual patients in Australia.

- The mean and standard deviation and the overall pre-operative vis-à-vis post-operative change in the net EQ-VAS scores, indicated by the patients highlighting their general health status pre and post the trauma of a knee arthroplasty is calculated and is presented through the following tabulation: -

AOANJRR 2022 :- Mean Pre-Op vis-à-vis Post-Op EQ-VAS[EuroQoL Visual Analogue Score] Health Score in Primary Total Knee Arthroplasty (TKA) for Australian Patient Cohort with Primary Indication OA.

SL No.	Type/Class of Arthroplasty	Pre-Operative EQ-VAS Score			Post - Operative EQ-VAS Score		
		No. of Case Reportings	Mean EQ-VAS Score +/- S.D	Median	No. of Case Reportings	Mean EQ-VAS Score +/- S.D	Median
1	Total Knee Arthroplasty	21,087	69.82 +/- 18.46	75	13,321	79.59 +/- 15.80	82

Table 6.1.82 :- ***Tabulation illustrating the Mean Pre-Operative & Post-Operative EuroQoL Visual Analogue Scale (EQ-VAS), with the Median points, as reported by the Australian patient recipients of Primary Total Knee Arthroplasty.***

- The mean EQ-VAS score for post-operative PROM responses by the TKA recipient patients, increased by 10 points, compared to its respective pre-operative EQ-VAS score, highlighting the general consensus of the Australian patient cohort regarding the overall health status and across multiple other parameters to have improved for better, post-operatively and not degraded, which would otherwise be the case, had the net postop score decreased compared to the respective linked preop score.

- The pre-operative EQ-VAS score of the patients decreases with an increasing ASA Grade i.e., with increasing general co-morbidity levels. However, irrespective of their pre-operative condition with respect to their co-morbidity levels, the post-operative improvement margins were all positive and the relative magnitude of change after the arthroplasty is similar for each patient group.

- Whereas, the margin of post-operative growth in the EQ-VAS scores increases equivocally with the rise in the respective patient's BMI category and therefore the trend of maintaining the 10-point score basis pre- vs post-improvement margin doesn't prevail.

- The overall mean pre-operative vis-à-vis post-operative EQ-VAS scores as reported by the respective primary TKA undergoing patients, with their net change in the reported scores compared preoperatively and postoperatively, linked with their gender and age-group is presented through the following tabulation: - (Age is segregated as below or higher 65, since 65-75 formulates the core patient group in line or the existing recipient for a TKA, and also close to the mean age-group level).

AOANJRR 2022 :- Mean Pre-Op vis-à-vis Post-Op EQ-VAS[EuroQoL Visual Analogue Score] Health Score in Primary Total Knee Arthroplasty (TKA) for Australian Patient Cohort with Primary Indication OA.

SL No.	Gender of the Patients	Age Group of Patients	Pre-Operative EQ-VAS Health		Pre-Operative EQ-VAS Health		Change in EQ-VAS Health Score [Pre-Op vis-à-vis Post-Op]
			No. of Case Reportings	Mean EQ-VAS Health Score	No. of Case Reportings	Mean EQ-VAS Health Score	
1	Male	<65	3,593	67.78	2,284	78	10.22
2		>=65	5,879	71.59	3,648	79.5	7.91
3	Female	<65	4,101	65.23	2,582	76.83	11.59
4		>=65	7,514	68.71	4,807	78.55	9.83
Data for only Modern Prosthesis [Prosthesis in Current Circulation & Use in Australia]					Adjusted for ASA Score & BMI Category		

Table 6.1.83 :- ***Tabulation illustrating the Mean Pre-Operative & Post-Operative EQ-VAS, with the Median points, as reported by the Australian patient recipients of Primary Total Knee Arthroplasty, categorized as per Patient Gender & Age-Group along-with their Net Change in the Scores on a Pre-Op vis-à-vis Post-Op basis.***

Oxford Knee Score (OKS) based PROMS on Primary Total Knee Arthroplasty by the Australian Patients: -

- The Oxford Knee Score is a globally recognized form of capturing patient-reported outcome measures, which are primarily focused on specific assessment of the general functional status or ability and pain levels of the patient, through specific questions that could be answered through responses each on a 5-level scale of 0 being the worst possible score to 4 as the best possible score.

- The mean pre-operative OKS was 22.42, based on 21,012 individual patient reportings amongst the Australian patient cohort, undergoing primary total knee arthroplasty.

- The mean post-operative OKS during the immediate short-term period, post 6 months of the primary TKA, improved further to 37.59, based on 13,354 individual patient reportings amongst the Australian patient cohort, undergoing primary total knee arthroplasty, indicating a net overall change in the pre-op-vis-à-vis-post-op OKS by 15.17 points.

- The mean pre-operative vis-à-vis post-operative Oxford Knee Scores, as reported by the respective primary TKA recipient Australian patient cohort, along with the median values is presented as follows: -

AOANJRR 2022 :- Mean Pre-Op vis-à-vis Post-Op Oxford Knee Score[OKS] Health Score in Primary Total Knee Arthroplasty (TKA) for Australian Patient Cohort with Primary Indication OA.

SL No.	Type/Class of Arthroplasty	Pre-Operative Oxford Knee Score Score			Post - Operative Oxford Knee Score Score		
		No. of Case Reportings	Mean Oxford Knee Score +/- S.D	Median	No. of Case Reportings	Mean Oxford Knee Score +/- S.D	Median
1	Total Knee Arthroplasty	21,087	22.42+/- 8.34	22	13,354	37.59 +/- 7.97	39

Table 6.1.84 :- ***Tabulation illustrating the Mean Pre-Operative & Post-Operative Oxford Knee Score (O.K.S), with the Median points, as reported by the Australian patient recipients of Primary Total Knee Arthroplasty.***

- The biggest margin of preoperative to post-operative change observed for Oxford Knee Scores reported by the Australian patient cohort undergoing primary total knee arthroplasty was that of the female patients below 65 years of age of all of the patient group. Comparatively, less than 65 years old male patients posted the greatest margin of positive change in the pre-vis-à-vis post operative scores, when only the male patient cohort in Australia is considered.

- The age-group and gender-linked distribution of the pre-operative and post-operative Oxford Knee Scores, undergoing primary total knee arthroplasty is presented through the following tabulation: -

AOANJRR 2022 :- Mean Pre-Op vis-à-vis Post-Op Oxford Knee Score[OKS] Health Score in Primary Total Knee Arthroplasty (TKA) for Australian Patient Cohort with Primary Indication OA.							
SL No.	Gender of the Patients	Age Group of Patients	Pre-Operative Oxford Knee Score Health Score		Post-Operative Oxford Knee Score Health Score		Change in Oxford Knee Score Health Score [Pre-Op vis-à-vis Post-Op]
			No. of Case Reportings	Mean Oxford Knee Score Health Score	No. of Case Reportings	Mean Oxford Knee Score Health Score	
1	Male	<65	3,571	22.06	2,279	37.43	15.37
2		>=65	5,847	24.31	3,656	37.9	13.59
3	Female	<65	4,090	20.16	2,596	36.4	16.25
4		>=65	7,504	21.35	4,823	37.05	15.7
Data for only Modern Prosthesis [Prosthesis in Current Circulation & Use in Australia]					Adjusted for ASA Score & BMI Category		

Table 6.1.85 :- ***Tabulation illustrating the Mean Pre-Operative & Post-Operative OKS, with the Median points, as reported by the Australian patient recipients of Primary Total Knee Arthroplasty, categorized as per Patient Gender & Age-Group along-with their Net Change in the Scores on a Pre-Op vis-à-vis Post-Op basis.***

- The net mean changes in the pre-operative vis-à-vis post-operative Oxford Knee Scores increase with the increase in the respective patient ASA Grade category, with the ASA Grade 4 patients posting the biggest overall pre- vs post-change in their reported Oxford Knee Scores, as much as by 17.45 score points on an average basis.

- Similar trends are noted for BMI-based segregations of Oxford Knee Scores of the reporting Australian patient cohort, wherein the group with the greatest BMI indices value (>= 40.00), belonging to the 'Obese Class 3', as per the universal convention standards, posting the biggest margin of their functional ability status and pain relief improvement post-operatively, compared to their pre-operative conditions, by as much as 16.86 score points, on an average basis.

- The ASA Grade linked distribution of the Oxford Knee Score of the reporting patients whom were the recipients of primary total knee arthroplasty are presented through the following tabulation: -

AOANJRR 2022 :- ASA Grade linked Distribution of the Mean Pre-Op vis-à-vis Post-Op Oxford Knee Score[OKS] Health Score in Primary Total Knee Arthroplasty (TKA) for Australian Patient Cohort with Primary Indication OA.						
SL No.	Patient's Respective ASA-Grade	Pre-Operative Oxford Knee Score Health Score		Post-Operative Oxford Knee Score Health Score		Change in Oxford Knee Score Health Score [Pre-Op vis-à-vis Post-Op]
		No. of Case Reportings	Mean Oxford Knee Score Health Score	No. of Case Reportings	Mean Oxford Knee Score Health Score	
1	ASA 1	1,025	24.44 (23.94, 24.94)	690	39.45 (38.45 - 40.04)	15.00 (14.34 - 15.67)
2	ASA 2	11,262	23.20 (23.04 - 23.37)	7,182	38.07 (37.88 - 38.27)	14.87 (14.66 - 15.08)
3	ASA 3	8,500	21.34 (21.16 - 21.52)	5,337	36.88 (36.67 - 37.10)	15.54 (15.30 - 15.78)
4	ASA 4	183	18.87 (17.71 - 20.03)	109	36.32 (34.86 - 37.77)	17.45 (15.79 - 19.10)
Cumulative Total / Mean		20,970	21.96 (21.46 - 22.46)	13,318	37.68 (36.96 - 38.29)	15.71 (15.02 - 16.40)

Table 6.1.86 :- ***Tabulation illustrating the Mean Pre-Operative & Post-Operative OKS, as reported by the Australian patient recipients of Primary Total Knee Arthroplasty, categorized as per Patient's ASA Grade along-with their Net Change in the Scores on a Pre-Op vis-à-vis Post-Op basis.***

- The BMI Indices category of the patient-linked distribution of the Oxford Knee Score of the reporting patient cohort who were the recipients of a primary total knee arthroplasty are presented through the following tabulation: -

AOANJRR 2022 :- BMI Category linked Distribution of the Mean Pre-Op vis-à-vis Post-Op Oxford Knee Score[OKS] Health Score in Primary Total Knee Arthroplasty (TKA) for Australian Patient Cohort with Primary Indication OA.						
SL No.	Patient's Respective BMI Category	Pre-Operative OKS		Post-Operative OKS		Change in Oxford Knee Score Health Score [Pre-Op vis-à-vis Post-Op]
		No. of Case Reportings	Mean Oxford Knee Score Health Score	No. of Case Reportings	Mean Oxford Knee Score Health Score	
1	Normal (18.50 - 24.99)	2,043	24.67 (24.24 - 25.10)	1,272	38.30 (37.80 - 38.80)	13.63 (13.14 - 14.11)
2	Pre-Obese (25.00-29.99)	6,300	23.38 (23.06 - 23.71)	3,979	37.96 (37.61 - 38.31)	14.58 (14.30 - 14.85)
3	Obese Class 1 (30.00 - 34.99)	6,385	22.07 (21.75 - 22.40)	4,032	37.12 (36.76 - 37.47)	15.04 (14.77 - 15.32)
4	Obese Class 2 (35.00 - 39.99)	3,619	20.79 (20.42 - 21.16)	2,315	36.88 (36.47 - 37.29)	16.09 (15.73 - 16.45)
5	Obese Class 3 (>= 40.00)	2,462	19.74 (19.33 - 20.15)	1,624	36.60 (36.14 - 37.06)	16.86 (16.43 - 17.29)
Cumulative Total / Mean		20,809	22.13 (21.76 - 22.50)	13,222	37.37 (36.95 - 37.78)	15.24 (18.59 - 15.60)

Table 6.1.87 :- ***Tabulation illustrating the Mean Pre-Operative & Post-Operative OKS, as reported by the Australian patient recipients of Primary Total Knee Arthroplasty, categorized as per Patient's BMI Grade along-with their Net Change in the Scores on a Pre-Op vis-à-vis Post-Op basis.***

Prosthesis Characteristics Specific Outcome scenarios for Primary Total Knee Arthroplasty in Australia: -

- The prosthesis/implant characteristics specific based outcomes for primary total knee arthroplasty in Australia is discussed in this segment.

- Relevant data on the implant characteristics and design specifications with their related influence on the outcomes of the primary TKA of the general Australian patient cohort, was available in great detail across Australian health databases, the registry and the TGA documentary archives.

- These data were studied and examined to great lengths during the course of this research, and often 'interesting' facts / inferences are co-related to the practices or scenarios in other nations, and doubly verified to obtain a final well validated inference of the implant characteristic specific performance attributes with the related influence on the outcomes.

- It is the bearing surface and its degree of mobility with respect to the femoral and tibial counterpart prosthesis components, that has possibly seen the greatest deal of innovation and developmental upgrades over the recent years. One such innovation came through the tibial insert being provided with the ability to move against the tibial baseplate, or being mobile in nature, compared to the usual fixed ones.

- Besides the mobile bearings, there are fixed bearings with fixed inserts without any mobility action in their design specifications.

- Another scope of innovation was through the modularity of the overall knee prostheses construct. Non-modular prostheses are either an all polyethylene or a polyethylene insert that is moulded to a metal baseplate. While, modular prostheses came with a metal tibial baseplate with options for both mobile and fixed articulating surface inserts.

- Based on the above prosthesis design or characteristic specific attributes regarding bearing surface mobility and modularity, the general outcome of their respective performance from a total knee arthroplasty, is measured against the cumulative revision rate percentage. Though there are other parameters reasonable enough to adjudge the prosthesis outcomes with, but globally the general approach and rationale is adjudged through the revision rate numbers or percent, since it is possibly the worst-case scenario that a primary can reach.

- Total knee arthroplasties performed using fixed bearing surfaces including a non-modular tibial prosthesis unit, have a lower revision rate in moderate short term to long term in the post-operative window of the Australian patient cohorts with primary diagnosis of osteoarthritis.

- When fixed prostheses are compared, moulded non-modular tibial prosthesis have a lower revision rate than the fixed modular components.

- The cumulative revision rate percentage of primary total knee arthroplasty procedures performed on the Australian patient cohort, with a primary diagnosis of osteoarthritis categorized as per the bearing mobility of respective implant utilized during the primary procedure, across various time-points in the post-operative period is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative Revision Rate Percentage of the Primary Total Knee Arthroplasties performed on Australian Patients with a Primary Diagnosis of Osteoarthritis, as per the Bearing Mobility Type of their utilized Knee Prosthesis unit.

SL No.	Bearing Mobility Type	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Fixed Bearing	5,82,551	19,151	1(0.9, 1)	2.3(2.3, 2.4)	3.1(3, 3.1)	4.6(4.5, 4.6)	6.2(6.1, 6.4)	7.9(7.6, 8.2)
2	Mobile Bearing	1,29,255	6,094	1.1(1.1, 1.2)	3(2.9, 3.1)	3.9(3.8, 4)	5.4(5.3, 5.6)	7.1(6.9, 7.3)	8.7(8.3, 9.1)
TOTAL		7,11,806	25,245	Data for only Modern Prosthesis [Prosthesis in Current Circulation & Use in Australia]					

Table 6.1.88 :- ***Tabulation illustrating the Overall Revision Rate percentages of the Primary Total Knee Arthroplasties performed on the Australian Patients with a primary diagnosis of Osteoarthritis, as per the Bearing Mobility statuses of their respective utilized Knee Prostheses units.***

- The rate of revisions of various forms of fixed bearing knee prostheses, in present clinical use on the Australian patients, is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative RR of Primary Total Knee Arthroplasty by Fixed Bearing Type for Patients with Primary Indication OA.

SL No.	Fixed Bearing Type	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	All Polyethylene	990	23	0.6(0.3, 1.4)	1.6(1, 2.7)	2.3(1.4, 3.6)	3.5(2.2, 5.4)	3.5(2.2, 5.4)	
2	Moulded Non-Modular	18,721	576	0.6(0.5, 0.7)	1.8(1.6, 2)	2.4(2.2, 2.6)	3.4(3.2, 3.8)	3.4(3.2, 3.8)	
3	Fixed Modular	5,62,840	18,552	1(0.9, 1)	2.4(2.3, 2.4)	3.1(3, 3.1)	4.6(4.5, 4.7)	4.6(4.5, 4.7)	8(7.6, 8.3)
TOTAL		*5,82,551*	*19,151*	Data for only Modern Prosthesis [Prosthesis in Current Circulation & Use in Australia]					

Table 6.1.89 :- ***Tabulation illustrating the prevalent revision rate percentages of the various fixed mobility prostheses types in presented clinical utilization for Primary TKA of the Australian patient cohort with primary diagnosis of OA, during various time-points in their respective post-operative period.***

- On the aspect of prosthesis stability, certain features of the implant intended to be implanted to replace the worn-out joint capsule, are directly linked to substitute for the intrinsic stability structure and load distribution mechanism of the knee ligaments, during various sets of articulation and motion.

- Primarily based on this aspect, knee implants are generally classified as:
    - Cruciate Retaining or Minimally Stabilized. (CR)
    - Cruciate Sacrificing or Posterior Stabilized. (PS)
    - Fully Constraint
    - Hinged Prosthesis.
- The rationale behind the above classification is the general level of constraint applied on the artificial prosthesis, based on the ligamentous stability and laxity. However, besides the above three most common types of knee prostheses, two more variants were found to be in regular utilization and is recognized and due defined by the Australian registry as well.

- These two are the Medial Pivot design and Fully Stabilized designs. The Australian registry defined medial pivot design prostheses as those with a “ball and socket” based mechanism of articulation.

- The Medial Pivot or (MP) designs of knee prosthesis to be granted with a separate inclusion mentioning by the Australian registry, may be due to the budding nascent interest upon the design by the global clinicians and biomechanical researchers to evaluate and observe, how the deep dished bearing

providing embedded separate articulation groove channels for both the condyles with improved congruency and stress distribution behaves in real life scenarios.

- The medial pivot design in the simplest terms can be explained as a posterior stabilized implant, with deep dished articulating bearing surfaces, with separate groove channels for the both condyles in an improved congruency conformity.

- The utilization of minimally stabilized or cruciate retaining knee prostheses for the total knee arthroplasty of the Australian patient cohort has remained largely stable and the majorly prevalent popular choice of usage, since 2011. As of 2021, CR knee prostheses alone accounted for 76.10% of all primary procedures.

- Comparatively, the utilization of posterior stabilized or cruciate sacrificing knee prostheses for the total knee arthroplasty of the Australian patient cohort is on the declining trend and it was used for only 14.70% of all primary TKA procedures in 2021.

- Medial pivot designed knee prostheses though at present implemented on the Australian patient cohort in smaller numbers, but the overall numbers indicate an increasing utilization trend, at the cost of a declining posterior-stabilized knee prosthesis usage.

- The involved rates of revision of posterior stabilized and specially the medial pivot design knee prostheses despite all the design innovations are noted to be higher than that of the cruciate retaining designs of knee prosthesis. However, the revision rate percent of medial pivot designed knee prosthesis is lower than that of the cruciate sacrificing or the posterior stabilized ones.

- The revision rate scenarios of the various designs and configurations of knee prosthesis available for active implementation during total knee arthroplasty of the Australian patient cohort, when compared against each other are: -

    - RR [Posterior. Stabilized & Medial. Pivot] > RR [Minimally. Stabilized (M.S)]
    - RR [Medial Pivot (M.P)] < RR [Posterior Stabilized (P.S)]
    - RR [P.S] $_{\text{Infection}}$ > RR [M.S && M.P] $_{\text{Loosening.}}$
    - RR [P.S] $_{\text{Loosening.}}$ > RR [M.S && M.P] $_{\text{Loosening.}}$
    - RR [M.P] $_{\text{Pain \& Instability Issues.}}$ > RR [M.S] $_{\text{Pain \& Instability.}}$

- Fully Stabilized and Hinged (Constraint) knee prostheses, with large peg and box designs are rarely utilized on the general Australian patient cohort during primary arthroplasty procedures. Though, it remains as a reliable choice in revision knee arthroplasty conditions, especially when the patient is subjected to multiple revisions involving moderate to severe bone loss, or in revisions due severe bone decay and compromised bone-ligamentous strength capabilities, which is mitigated and substituted through the constraint and hinged design mechanism of the prosthesis, with long stems at both the ends.

- Posterior Stabilized, Cruciate Retaining designs of knee prosthesis formulate for the majority of the total knee arthroplasties, performed due to a primary diagnosis of gradually worsening osteoarthritis, the fully stabilized find its usage in total knee arthroplasties arising due to rheumatoid arthritis and fracture. Similarly, as discussed in the previous point, hinged knee prostheses were utilized in greater proportions for tumour, knee and associated fracture incidences, besides some of complex rheumatoid arthritis conditions.

- The most common reasons for the failure and subsequent revision of both fully stabilized and hinged knee prostheses is post-operative infection, followed by implant loosening for fully stabilized designs and additional fracture for hinged knee implants.

- The overall cumulative revision rate percentage of primary total knee arthroplasties performed on the Australian patients performed on the basis of a primary diagnosis of osteoarthritis as per knee implant design type is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative Revision Percent of Primary Total Knee Arthroplasty by Knee Stability Design for Patients with Primary Indication OA.

SL No.	Type of Knee Stability Design	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Minimally Stabilized / CR	5,00,931	16,521	0.9(0.9, 0.9)	2.3(2.3, 2.4)	3(2.9, 3.1)	4.4(4.3, 4.5)	6(5.9, 6.2)	7.6(7.4, 7.9)
2	Posterior Stabilized [P.S]	1,72,835	7,603	1.2(1.1, 1.2)	2.8(2.7, 2.9)	3.7(3.6, 3.8)	5.5(5.3, 5.6)	7.2(7, 7.5)	9.2(8.4, 10)
3	Medial Pivot Design [M.P]	33,823	858	1(0.9, 1.2)	2.6(2.4, 2.8)	3.2(3, 3.5)	4.9(4.4, 5.5)	6.2(5.2, 7.3)	
4	Fully Stabilized	2,786	164	2.7(2.2, 3.4)	5.1(4.3, 6)	6.4(5.4, 7.5)	8.6(7.2, 10.3)		
5	Hinged [Full Constraint]	1,436	99	2.9(2.2, 4)	6.2(4.9, 7.7)	8(6.4, 10)	12.1(9.6, 15.2)		
TOTAL		7,11,811	25,245						

Table 6.1.90 :- ***Tabulation illustrating the prevailing cumulative Revision Rate percentages of the Primary Total Knee Arthroplasties performed on the Australian patient cohort, with an Primary Indication of Osteoarthritis, as per the Knee Stability Design of the respective Prosthesis utilized during the TKA procedure.***

General Patient-Reported Satisfaction Levels from their Total Knee Arthroplasty

- Besides the usual metrics for analyzing and capturing patient reported outcomes of their respective knee arthroplasties, to assess their opinion about how the procedure and the prosthesis implanted during the procedure has alleviated their overall functional status and quality of life, the general satisfaction levels were also captured for the respective Australian patient cohort who received a primary total knee arthroplasty.

- The satisfaction level status data was accessed by this research from the Australian registry, wherein it was found that the respective patients were asked about their self-assessed satisfaction levels from the procedure they had undergone, during the post-operative period follow-up at 6 months from the original primary arthroplasty procedure date, to capture the best plausible and undiluted responses from the patients.

- The satisfaction level of the respective patient cohort is the simplest way to assess the patient's sensing of him/herself and such responses for prosthesis characteristics specific parameters are also evaluated during the course of this research, which are discussed, tabulated and statistically evaluated / plotted subsequently in this segment.

- Based on a total input stream of 13,332 patients, 58.50% had opined to have been "Very Satisfied", from their primary total knee arthroplasty procedure. While, 25.20% felt themselves to be just "Satisfied" with their undergone procedure and their present post-operative conditions, compared to their state pre-operatively.

- Combined the general state turns out as 83.70% of the reporting patients to be under a very positive to a positive impression with their procedure and implant performance, during the immediate short-term.

- The overall primary total knee arthroplasty procedure satisfaction levels of the Australian patients with primary diagnosis osteoarthritis (single-largest diagnoses group), is presented through the following tabulation: -

AOANJRR 2022 : Patient expressed Procedure satisfaction for Primary TKA in Australian Cohort with Primary Diagnosis Osteoarthritis.

SL No.	Type of Arthroplasty	Very Satisfied		Satisfied		Neutral		Dis-satisfied		Very Dis-satisfied		TOTAL	
		No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall	No. of Cases [N]	% of Overall
1	Total Knee Arthroplasty	7,795	58.50%	3,363	25.20%	1,158	8.70%	512	3.80%	504	3.80%	13,332	100%

Data compiled only for prostheses used for TKA in 2021 for the Australian cohort ; PROMs Reporting is still on roll-out stages in AUS & therefore is not mandatory for all patients to fill in ; Interested parties / Institutes participating can encourage PROMs coverage by allowing patients to register their feedback on a separate Registry governed portal for PROMs capture.

Table 6.1.91 :- ***Tabulation illustrating the Patient's Satisfaction Levels from their undergone Total Knee Arthroplasty Procedure.***

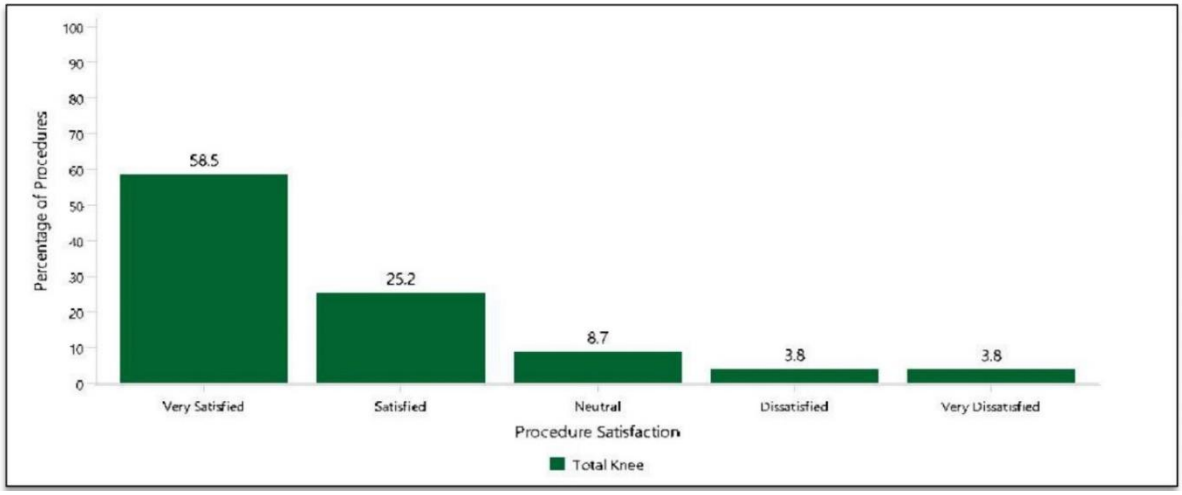


Figure 6.1.8 :- A ***Procedure % vs Patient Satisfaction Plot illustrating the Patient's Satisfaction Levels from their undergone Total Knee Arthroplasty Procedures, in Australian practices.***

- Further refining the above satisfaction level tabulation of the primary total knee arthroplasty patient cohort in Australia, as per the respective patient cohort and age-group is formulated and illustrated through the following tabulation: -

AOANJRR 2022 : Procedure Satisfaction in Primary TKA by Gender & Age by Patients with Primary Diagnosis Osteoarthritis																				
SL No.	Gender	Age	Very Satisfied			Satisfied			Neutral			Dissatisfied			Very Dis-satisfied			TOTAL		
			No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category
1	MALE	<65	1,325	58.2	17	610	26.8	18.1	187	8.2	16.1	68	3	13.3	88	3.9	17.5	2,278	100	17.1
		>= 65	2,098	58.2	26.9	942	25.8	28	332	9.1	28.7	136	3.7	26.6	142	3.9	28.2	3,650	100	27.4
2	FEMALE	<65	1,490	57.4	19.1	648	25	19.3	242	9.3	20.9	123	4.7	24	91	3.5	18.1	2,594	100	19.5
		>= 65	2,882	59.9	37	1,163	24.2	34.6	397	8.3	34.3	185	3.8	36.1	183	3.8	36.3	4,810	100	36.1
TOTAL			7,795	58.5	100	3,363	25.2	100	1,158	8.7	100	512	3.8	100	504	3.8	100	13,332	100	100

Table 6.1.92 :- ***Tabulation illustrating the Patient's Satisfaction Levels from their undergone Total Knee Arthroplasty Procedure, segregated as per their respective Age-Group & Gender.***

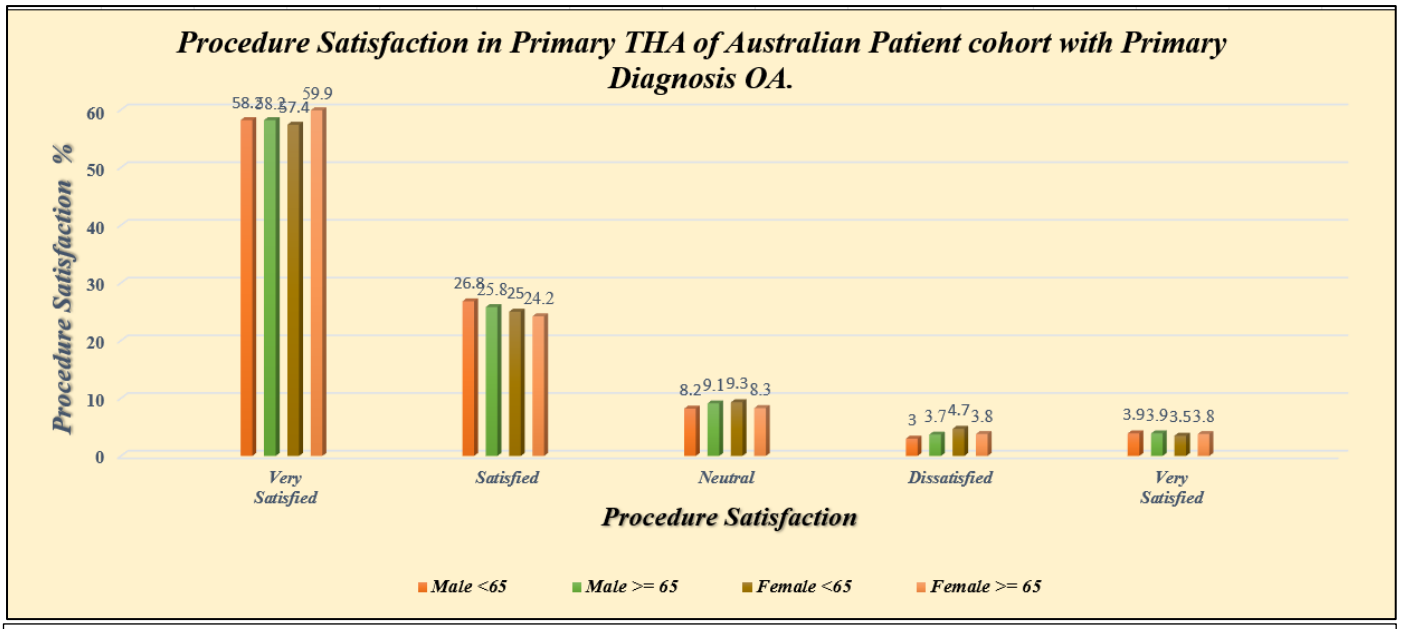


Figure 6.1.9 :- A ***Procedure Satisfaction % vs Patient Satisfaction Plot illustrating the Patient's Satisfaction Levels from their undergone Total Knee Arthroplasty Procedures, in Australian practices, categorized as per Patient Age-Group & Gender.***

- The distribution of the general satisfaction level of the respective patient cohort with respect to their respective total knee implant's stability design plan is presented through the following tabulation & graph plot: -

AOANJRR 2022 :- Procedure Satisfaction in Primary Total Knee Arthroplasty by Knee Stability Design Types of Australian Patients with Primary Indication OA.																			
SL No.	Type of Knee Stability Design	Very Satisfied			Satisfied			Neutral			Dissatisfied			Very Dis-satisfied			TOTAL		
		No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category
1	Medial Pivot Design [M.P]	426	58.71	5.5	198	27.3	5.9	54	7.4	4.7	26	3.6	5.1	22	3	4.4	726	100	5.5
2	Minimally Stabilized / CR	6,146	58.4	79.7	2,661	25.3	79.6	925	8.8	80.5	393	3.7	77.1	396	3.8	79.4	10,521	100	79.7
3	Posterior Stabilized [P.S]	1,136	57.9	14.7	483	24.6	14.5	170	8.7	14.8	91	4.6	17.8	81	4.1	16.2	1,961	100	14.8
TOTAL		7,708	58.4	100	3,342	25.3	100	1,149	8.7	100	510	3.9	100	499	3.8	100	13,208	100	100

Table 6.1.93 :- ***Tabulation illustrating the Patient's Satisfaction Levels from their undergone Total Knee Arthroplasty Procedure, segregated as per their respective Knee Implant's Stability Design.***

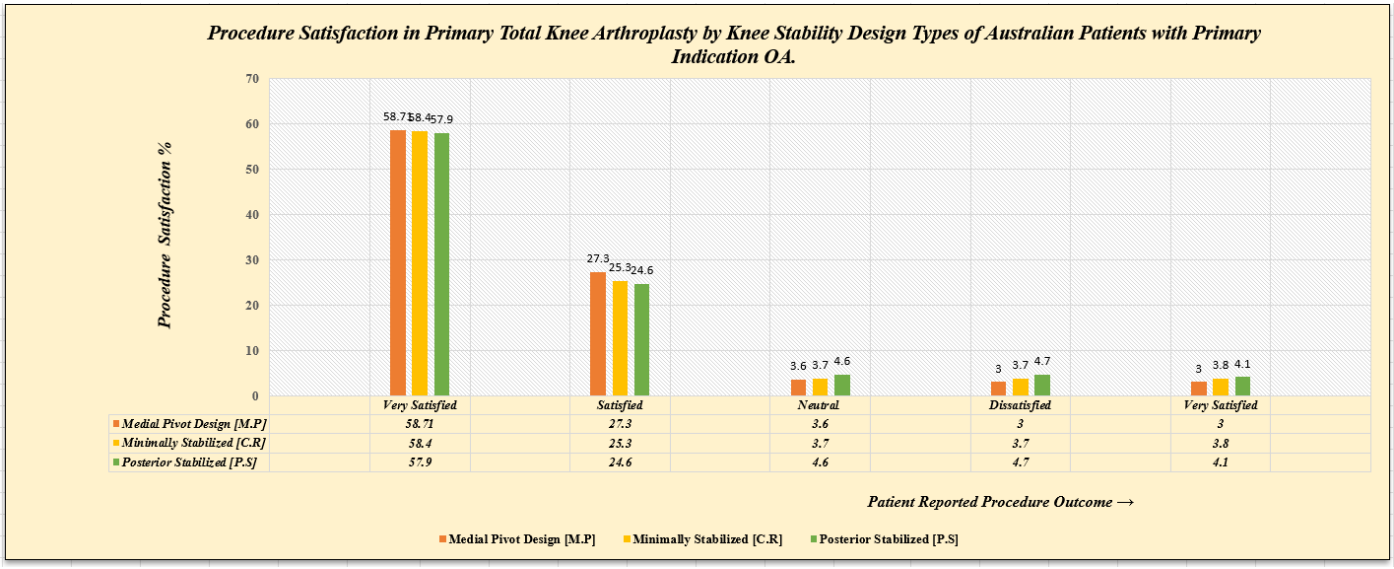


Figure 6.1.10 :- A ***Procedure Satisfaction % vs Patient Reported Satisfaction Plot illustrating the Patient's Satisfaction Levels from their undergone Total Knee Arthroplasty Procedures, in Australian practices, categorized as per their utilized Knee Implant's Stability Design type.***

Patellar Resurfacing vs. No Patella Scenario in Australian Knee Arthroplasty Practices: -

- The revision rate percentage of the Australian patient cohort undergoing patellar resurfacing are comparatively lower in the longer-term perspective, vis-à-vis to that of the condition without a patella, irrespective of the stability design (whether CR, PS, MP, constraint/hinged) of the utilized knee prosthesis.

- The cumulative revision rate percentage of the operated patients is the highest when a posterior stabilized total knee implant is implanted without a patella/patellar resurfacing, more abrupt. While, it is the lowest, when a combination of medial pivot design knee prosthesis or a cruciate retaining knee prosthesis is utilized with a patella / patellar resurfacing.

- The overall scenario in the prevalent revision rate percentages of primary TKAs performed on the Australian patient cohort, based on the stability design and patellar usage parameters, is presented through the following tabulation: -

Distribution of the prevalent Revision Rate Percentages of the Primary Total Knee Arthroplasties performed on the Australian Patient Cohort, with Primary Diagnosis of OA, as per their respective Prosthetic Characteristics specific attributes of Stability Design & Patellar Usage Policy Adopted.

SL No.	Stability Design Type of the Knee Prosthesis	Patellar Usage	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Minimally Stabilized / Cruciate Retaining [C.R]	Patella Used	2,71,492	6,925	0.8 (0.8, 0.9)	1.9 (1.9, 2.0)	2.5 (2.5, 2.6)	3.7 (3.6, 3.8)	5.3 (5.1, 5.5)	6.6 (6.2, 7.0)
2		No Patella	2,29,439	9,526	1 (0.9, 1.0)	2.7 (2.6, 2.8)	3.5 (3.4, 3.5)	5.0(4.9, 5.1)	6.7 (6.5, 6.9)	8.5 (8.1, 8.8)
3	Posterior Stabilized [P.S]	Patella Used	1,33,855	4,800	1.1 (1.0, 1.1)	2.4 (2.3, 2.5)	3.2 (3.1, 3.3)	4.7 (4.5, 4.8)	6.2 (6.0, 6.5)	8.8 (7.5, 10.4)
4		No Patella	38,980	2,803	1.6 (1.5, 1.8)	4.2 (4.0, 4.4)	5.5 (5.2, 5.7)	7.7 (7.4, 8.0)	9.9 (9.5, 10.3)	10.9 (10.3, 11.5)
5	Medial-Pivot [M.P] Design	Patella Used	21,593	394	0.9 (0.8, 1.0)	2.0(1.8, 2.3)	2.5 (2.3, 2.8)	3.5 (2.9, 4.2)	6.1 (3.7, 10.0)	
6		No Patella	12,230	464	1.3 (1.1, 1.5)	3.5(3.1, 3.8)	4.2 (3.8, 4.7)	6.3 (5.6, 7.2)	7.3 (6.3, 8.6)	
Cumulative Total			7,07,589	24,982						

Table 6.1.94 :- ***Tabulation illustrating the prevailing revision rate percentage of Primary TKAs based on respective Patellar Usage Policy adopted during the Arthroplasty procedure [Retention/Sacrifice].***

- While the comparative scenario for a patellar usage vs no patellar usage / resurfacing in terms of the revision rates of the knee prostheses used during primary TKA of the Australian patient cohort is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative Revision Percent of Primary Total Knee Arthroplasty by Patellar Usage[Resurfacing or Retention / Non-Resurfacing or Sacrifice] of Australian Patients with Primary Diagnosis OA.

SL No.	Patella Usage Policy Adopted	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Patella Used / Resurfaced	4,30,124	12,294	0.9(0.9, 0.9)	2.1(2.1, 2.2)	2.8(2.7, 2.8)	4.1(4, 4.2)	5.7(5.5, 5.8)	7.2(6.8, 7.6)
2	No Patella / Sacrificed	2,81,854	12,957	1.1(1.1, 1.1)	3(2.9, 3)	3.8(3.7, 3.9)	5.5(5.4, 5.6)	7.3(7.1, 7.4)	9(8.6, 9.3)
TOTAL		7,11,978	25,251						

Table 6.1.95 :- ***Tabulation illustrating the prevailing revision rate percentage of Primary TKAs based on respective Patellar Usage Policy adopted during the Arthroplasty procedure [Retention/Sacrifice].***

- The post-operative satisfaction levels of the patients with respect to whether their respective TKA, involved a patellar resurfacing vs no patella, is presented through the following tabulation: -

AOANJRR 2022 :- Procedure Satisfaction of Australian Patients with Primary Indication OA through Primary Total Knee Arthroplasty by Patella Usage Policy Adopted.

SL No.	Patella Usage Policy Adopted	Very Satisfied			Satisfied			Neutral			Dissatisfied			Very Dis-satisfied			TOTAL		
		No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category
1	Patella Used / Resurfaced	6,046	58.9	77.6	2,615	25.5	77.8	878	8.5	75.8	381	3.7	74.4	353	3.4	70	10,273	100	77.1
2	No Patella / Sacrificed	1,749	57.2	22.4	748	24.5	22.2	280	9.2	24.2	131	4.3	25.6	151	4.9	30	3,079	100	22.9
TOTAL		7,795	58.5	100	3,363	25.2	100	1,158	8.7	100	512	3.8	100	504	3.8	100	13,332	100	100

Table 6.1.96 :- ***Tabulation illustrating the Patient's Satisfaction Levels from their undergone Total Knee Arthroplasty Procedures, with respect to the Patellar Usage scenario for the Australia patient cohort.***

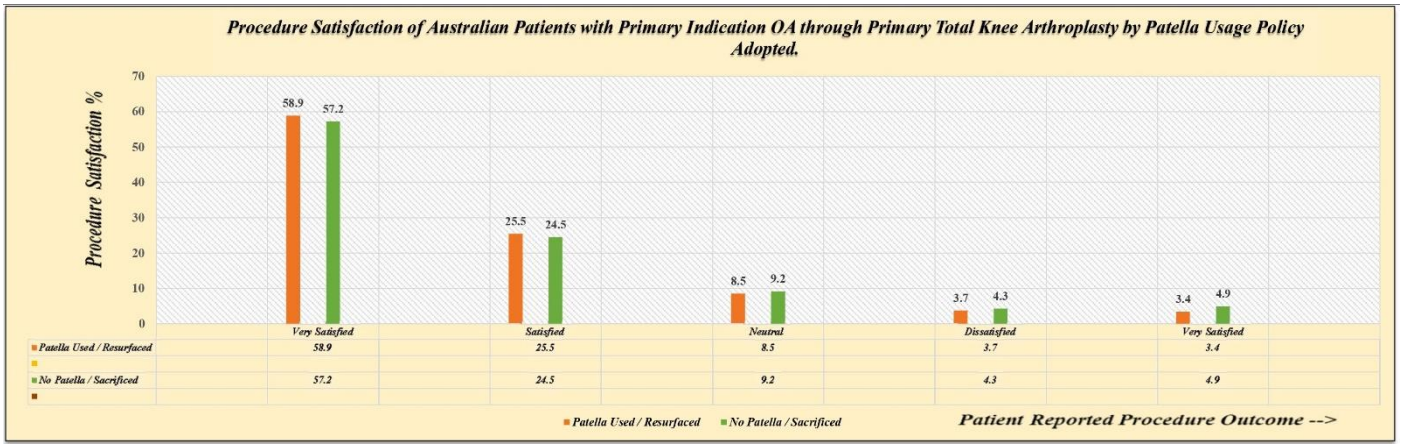


Figure 6.1.11 :- ***Plot illustrating the Comparative Patient's Satisfaction Levels from their undergone Total Knee Arthroplasty Procedures, with respect to the Patellar Usage scenario for the Australia patient cohort in Procedure Satisfaction % vs Patient Satisfaction..***

XLPE vs Non-XLPE Based Articulating Bearing Surface Scenarios & Outcomes for Total Knee Arthroplasty on the Australian Patient Cohort: -

- The utilization of cross-linked polyethylene or highly cross-linked polyethylene as the optimal choice material for the designing and development of the tibial bearing surface for the easy articulation of the femoral ends, has steamed pace possibly faster than how other major nations with a reputed health-care system had.

- Despite claims of added benefits and performance enhancements, various real-life on ground data showed anti-oxidant and vitamin-E infused/enriched into XLPE based articulating bearing surface liner inserts to perform the same as the XLPE based ones, if not for the worse, hence such groups of prosthesis components are merged into the XLPE category, since the parent material is what at present proven to be worth an actual on-ground difference. The relative similarity in their respective performances in terms of the revision rate percentage across multiple time-points in the postoperative window is presented through the following tabulation: -

Distribution of the Cumulative Revision Percents of XLPE vis-à-vis XLPE with Anti-Oxidant based Polyethylene Articular Bearing Surfaces when used for Primary Total Knee Arthroplasty of the Australian Patient Cohort with Primary Indication OA.
[Highlights there is No Remarkable Difference in terms of RR observed over the Two Variants of XLPE Bearing Offerings from Prosthesis Mfg. Brands, quashing the 'marketed' narrative of improved Revision Resistance with XLPE+Anti-Oxidant, as observed for the Australian Cohort].

SL No.	Polyethylene Type	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	XLPE	2,68,711	7,096	0.9(0.8, 1)	2.1(2.1, 2.2)	2.7(2.7, 2.8)	4(3.9, 4.1)	5(4.8, 5.2)	
2	XLPE + Anti-Oxidant	69,893	1,192	0.9(0.8, 1)	2.1(2, 2.3)	2.8(2.6, 3)	3.9(3.3, 4.7)		
TOTAL		3,38,604	8,288	Data for only Modern Prosthesis [Prosthesis in Current Circulation & Use in Australia]					

Table 6.1.97 :- ***Tabulation illustrating the prevailing revision rate percentages of Primary TKAs based on respective articulation bearing surface polyethylene type for XLPE variants and with those with XLPE +Anti-Oxidant combinations, highlighting no Significant differences in the post-operative revision rates across any point of time, in the Australian patients.***

- In consistency with the global scenario, XLPE based prostheses used in primary total knee procedures on the Australian patient cohort, posted better revision rate percentages than those, using conventional forms of polyethylene or non-XLPE (UHMWPE, HDPE) based bearing surface liners.

- XLPE based prostheses were utilized in 3,38,604 recognized primary TKAs of the Australian patient cohort, as per the Australian registry.

- The major improvement against the conventional material-based knee prosthesis units, as stated by the Australian registry, was the overall reduced incidences of post-operative implant loosening.

- In longer term postoperative window aspects, the relative differences in the prosthesis character specific outcome differences between XLPE and non-XLPE units is more prominent, irrespective of the age group of the patient group concerned. The cumulative revision rate of primaries conducted on patients aging less than 65 years of age, using XLPE and non-XLPE based prosthesis units were 7.00% and 10.10% respectively, at the end of 15-year post-operative window. The difference margin of 3.10% is quite some margin to ponder about, considering the global numbers.

- Similarly for the aged citizens, with more than 65 years of age, the difference at the same post-operative follow-up timepoint was 3.80% and 5.00% for XLPE vis-à-vis non-XLPE based units deployed. The age-linked comparative distribution of XLPE & non-XLPE primary total knee arthroplasty procedures, with their relative revision rate percentages, during various time-points in the postoperative follow-up window is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative Revision Percent of Primary Total Knee Arthroplasty for Australian Patient Cohort with Primary Indication OA, categorized as per Polyethylene Type used & Respective Patient Age Groups. [Restricted to Modern Prosthesis - Prosthesis in Current Circulation/Use in Australia)]									
SL No.	Polyethylene Type & Patient Age Group	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
Non-XLPE Articular Surface Bearings		3,73,040	16,956	1(1, 1.1)	2.7(2.7, 2.8)	3.6(3.5, 3.6)	5.2(5.1, 5.3)	6.9(6.8, 7.1)	8.7(8.4, 8.9)
1	<65 Years Old Patient Group	1,23,543	8,362	1.3(1.2, 1.4)	3.6(3.5, 3.8)	4.8(4.7, 5)	7.3(7.1, 7.4)	10.1(9.9, 10.4)	12.9(12.4, 13.4)
2	>= 65 Years Old Patient Group	2,49,497	8,594	0.9(0.9, 1)	2.3(2.2, 2.3)	2.9(2.9, 3)	4.1(4, 4.2)	5(4.9, 5.2)	5.8(5.5, 6)
XLPE Articular Surface Bearings		3,38,604	8,288	0.9(0.9, 1)	2.1(2.1, 2.2)	2.7(2.7, 2.8)	4(3.9, 4.1)	5(4.8, 5.2)	
5	<65 Years Old Patient Group	1,13,851	3,749	1.1(1, 1.1)	2.7(2.6, 2.8)	3.6(3.5, 3.7)	5.3(5.1, 5.5)	7(6.6, 7.5)	
6	>= 65 Years Old Patient Group	2,24,753	4,539	0.8(0.8, 0.9)	1.8(1.8, 1.9)	2.3(2.2, 2.4)	3.2(3.1, 3.3)	3.8(3.6, 4)	
TOTAL		7,11,644	25,244	Including 69,893 Arthroplasty Procedures using XLPE with Infused Anti-Oxidant Variants ; Excluding 334 Arthroplasty Procedures with Unknown P.E.					

Table 6.1.98 :- ***Tabulation illustrating the prevailing cumulative Revision Rate percentages of the Primary TKAs performed on the Australian patient cohort, based on the type of polyethylene utilized in Knee Prosthesis units, categorized as per respective patient's age-groups.***

- The detailed comparative differences in the overall cumulative rate of revisions of the primaries based on the polyethylene material type utilized for the articulating bearing surface of the artificial total knee prosthesis unit, as far as the Australian patient cohort is concerned, is presented through the following tabulation: -

AOANJRR 2022 :- Cumulative Revision Percents of XLPE vis-à-vis Non-XLPE based Polyethylene Articular Bearing Surfaces when used for Primary Total Knee Arthroplasty of the Australian Patient Cohort with Primary Indication OA.									
SL No.	Polyethylene Type	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Non-XLPE	3,73,040	16,956	1.0 (1.0, 1.1)	2.7 (2.7, 2.8)	3.6 (3.5, 3.6)	5.2(5.1, 5.3)	6.9 (6.8, 7.1)	8.7(8.4, 8.9)
2	XLPE	3,38,604	8,288	0.9 (0.9, 1.0)	2.1 (2.1, 2.2)	2.7 (2.7, 2.8)	4.0(3.9, 4.1)	5.0(4.8, 5.2)	
TOTAL		7,11,644	25,244	*Data for only Modern Prosthesis [Prosthesis in Current Circulation & Use in Australia]*					

Table 6.1.99 :- ***Tabulation illustrating the prevailing cumulative Revision Rate percentages of the Primary Total Knee Arthroplasties performed on the Australian patient cohort, based on the type of polyethylene utilized in Knee Prosthesis units.***

Influences of Modern Biomedical Technology on General Knee Arthroplasty Practices & Related Outcomes in Australia: -

- Based on the inferences, inferred from the resources across multiple documents and archived data from various Australian healthcare sources, it is clearly evident that the scale and adoption of technology aided advancements for arthroplasty practices is quite high and on the steady rise in Australia.

- It is inferred that the general Australian arthroplasty practices has been greatly futuristic, and not exactly an orthodox or old-school one like that of the Swedish practices. The overall arthroplasty scenario for all modalities and institutions performing them is constantly keeping up with the modern biomedical technologies to improve the prevailing health standards for attaining a higher precision and more reliable benchmark in pace with the modern world.

- There's been a steady decline on the non-technology or conventional forms of total knee arthroplasty in Australia. Unlike most other nations which were evaluated and critically examined for their respective arthroplasty practices and other scenarios, whom in general terms belong to the Global North, with an understandable healthcare system of repute, in Australia, as of 2021, only 37.60% of primary total knee arthroplasties, were performed without using any modern-day technology assistance.

- These ‘modern-day technology assistance’ include Robotic Surgeries or Robotic Assisted Knee Arthroplasty, Computer based Surgical Navigation System (CNS), Image derived Instrumentation (IDI) methods as the most prominent ones.

- The number of primary total knee arthroplasties performed utilizing the above-mentioned forms of available modern-day technology guided assistance on the Australian patient cohort is presented as follows: -
    - Computer Navigation Surgical Systems = 1,77,448 & [28.5% of All TKAs in 2021].
    - Image Derived Instrumentation Assistance Systems = 56,677 & [11.30% of All TKAs in 2021].
    - Robotic Assistance Guided Surgical System = 30,469 & [22.50% of All TKAs in 2021].
- On the aspect of outcomes of such arthroplasty procedures using the above-mentioned technological advancements, it is noted and inferred that the paramount and prime target of arthroplasties performed using such methodologies, are aimed at high precision positioning and alignment during the implantation process of a knee prosthesis, during complex primary and revision procedures. However, based on the reasons of revisions of procedures performed using such modalities, it can be safely said that these techniques and methods attain their primary targets and therefore successful, since revisions due to prosthesis loosening and instability are much lower, and what plagues the otherwise a great blessing is the scope of infections, which often is the cited reason for the revision of primaries performed using such technologies on the Australian patient cohort.

- The various revision rate scenarios for the technology assistance mediums/modalities available compared against each other as follows: -
    - RR [CNS] < RR [Manual TKA (m. TKA)]. At 6-Months Post-Op.
    - RR [CNS] $_{<65\ Years}$ < RR [m. TKA].
    - RR [CNS] $_{>=65\ Years}$ < RR [m. TKA].
    - RR [IDI] > RR [m.TKA].
- The patient centric assessment of their respective knee replacement procedures and post-operative prosthesis performance in terms of their general satisfaction levels which were implemented using the above-mentioned modern-day technologies compared vis-à-vis to the manually performed ones are presented as follows: -

AOANJRR 2022 :- Procedure Satisfaction in Primary Total Knee Arthroplasty by Mode of Arthroplasty Utilized / Levels of Technology Assistance used for Australian Patients with Primary Indication OA.

SL No.	Mode of Arthroplasty Utilized	Very Satisfied			Satisfied			Neutral			Dissatisfied			Very Dis-satisfied			TOTAL		
		No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category	No. of Cases	% of Overall	% of this Category
1	Robotically Assisted	1,050	60.6	13.5	421	24.3	12.5	146	8.4	12.6	49	2.8	9.6	68	3.9	13.5	1,734	100	13
2	Computer Navigated System	2,465	59.1	31.6	1,017	24.4	30.2	368	8.8	31.8	162	3.9	31.6	157	3.8	31.2	4,169	100	31.3
3	Image-Derived Instrumentation [I.D.I]	695	63.2	8.9	266	24.2	7.9	64	5.8	5.5	37	3.4	7.2	37	3.4	7.3	1,099	100	8.2
4	Manual / Non-Technology Assisted	3,585	56.6	46	1,659	26.2	49.3	580	9.2	50.1	264	4.2	51.6	242	3.8	48	6,330	100	47.5
TOTAL		7,708	58.5	100	3,363	25.2	100	1,158	8.7	100	512	3.8	100	504	3.8	100	13,332	100	100

Table 6.1.100 :- ***Tabulation illustrating the Patient’s Satisfaction Levels from their undergone Total Knee Arthroplasty Procedures, with respect to the Degree of Modern-Technology Guided Assistance in Australia.***

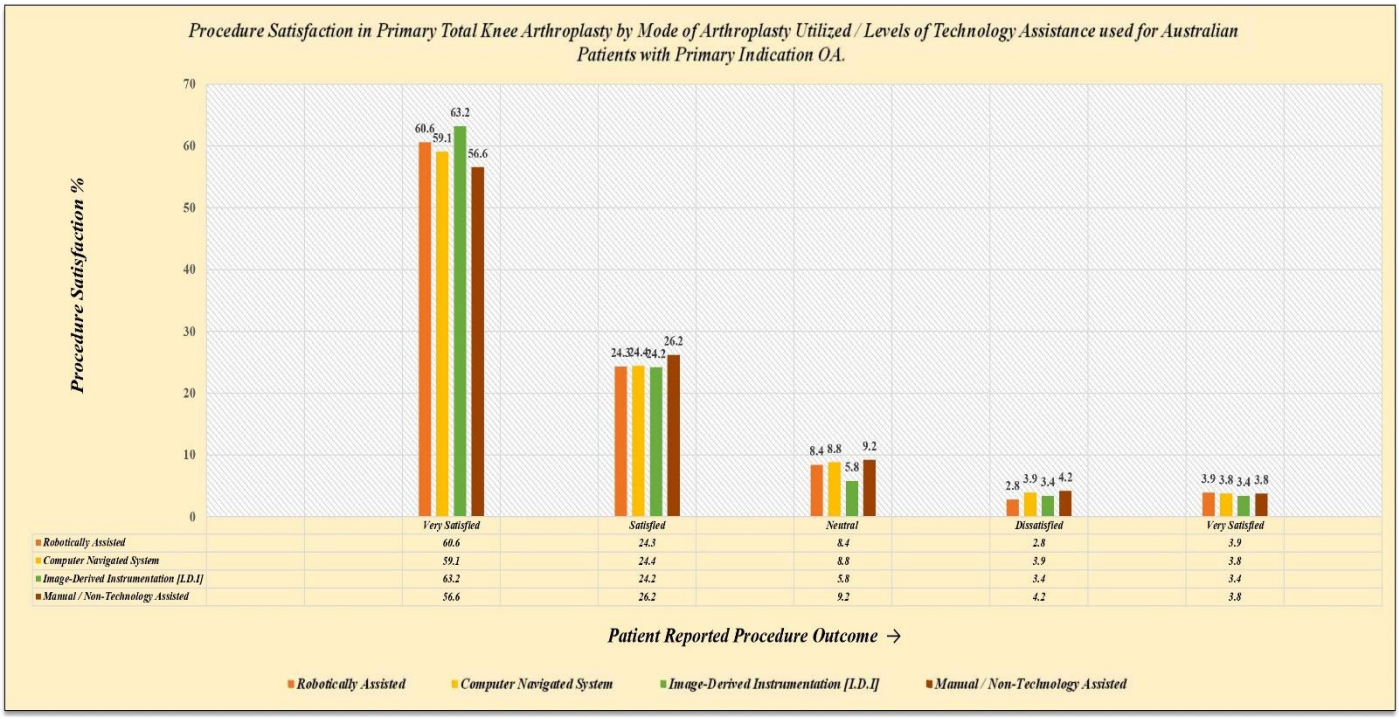


Figure 6.1.12 :- ***Procedure Satisfaction % vs Patient Reported Procedure Outcome based Histogram Chart for the Degree of Technical Guided Assistance or Inclusion for Total Knee Arthroplasty of the Australian Patient Cohort.***

- The distribution and utilization of modern-day technology assistance, in the form of Robotic assisted with manual forms of arthroplasty, for Primary Unicompartmental Knee Arthroplasty, and their relative outcome in terms of the cumulative revision rate percentages across various time points in their respective post-operative window is presented as follows: -

AOANJRR 2022 :- Cumulative RR of Primary Unicompartmental Knee Arthroplasty since 2015 which were either Manual performed / Performed under Robotic Assistance for Primary Indication OA.

SL No.	Mode of UKA	Total Cases	Total Revised	Cumulative RR @ 1 Year Post-Op	Cumulative RR @ 3 Years Post-Op	Cumulative RR @ 5 Years Post-Op	Cumulative RR @ 10 Years Post-Op	Cumulative RR @ 15 Years Post-Op	Cumulative RR @ 20 Years Post-Op
1	Robotic Assisted UKA	6,751	194	1.3(1.1, 1.6)	2.4(2.0, 2.8)	3.4(2.9, 3.9)	4.2(3.6, 4.9)	4.4(3.8, 5.1)	4.4(3.8, 5.1)
2	Manual UKA	16,468	687	2.0(1.8, 2.3)	3.3(3.0, 3.6)	4.1(3.8, 4.5)	4.8(4.4, 5.2)	5.5(5.1, 5.9)	6.2(5.7, 6.7)
TOTAL		23,219	881						

Table 6.1.101 :- ***Tabulation illustrating the Distribution of Technology Guided Primary Unicompartmental Knee Arthroplasty Procedures performed on the Australian Patient Cohort, alongside their relative Revision Rate percentages across different post-operative timepoints.***

MODULE – VI

"Results & Discussion"

CHAPTER – 2

United States of American
Hip Arthroplasty Practices
and
Patient Related Outcome Scenarios

United States of American
Arthroplasty Practices
&
Related Outcome Scenarios.

(Primary Results & Related Observations with Inferences)

- ***Overall American Arthroplasty Numbers at a Glance:***

General USA Based Arthroplasty Numbers: -

Total No. of Arthroplasties Recorded [All Hip+Knee] = **25,12,153.**
Total No. of Hip Arthroplasties Recorded [Total + Hemi] = **9,16,739** [**2012 – 2021**].
Total No. of Knee Arthroplasties Recorded [TKA + UKA] = **13,73,113** [**2012 – 2021**].
Total No. of Revision Arthroplasties [Hip + Knee] = **2,16,366.**
Total No. of Revision Hip Arthroplasties = **1,03,514.**
Total No. of Revision Knee Arthroplasties = **1,12,852.**

Preface of the American Arthroplasty Practices: -

- The United States of America, the world's biggest economy, is a multi-dimensional powerhouse of excellence, across many domains, healthcare and related biomedical infrastructure being one of them. This is further emboldened by the fact that three out the globally relevant quadropoly implant manufacturer firms, are based out of the USA.

- The benchmark of a first world nation, with a healthcare of general repute all across the world, attracting a major populace for medical tourism, for those who can afford, and also those, with technical expertise on this domain for various opportunities in the nation, otherwise known as the, 'Land of Opportunities'.

- The US drug and medical device regulatory authority, US FDA (United States Food & Drug Administration), is one of the most commonly cited and globally revered regulatory body.

- Based on primary literature survey, on the basics of the arthroplasty commerce, it is also noted that US, is perhaps the biggest arthroplasty market, in terms of the overall revenue involved, if not the procedural volume.

- Considering the above-mentioned facts, this research felt it to be critically necessary to involve US based hip and knee arthroplasty practices, and patient related outcomes into the evaluation and research work mainframe, otherwise, the overall work might not be of adequate relevance to have been missed out on both the biggest arthroplasty markets in terms of revenue and by procedural volume (India / China), though the latter couldn't be accessed due to multi-factorial reasons.

General Hip and Knee Arthroplasty Practices in the USA: -

- The primary source of hip and knee arthroplasty data, for the American patient cohort, is obtained from the "*American Joint Replacement Registry*" or the AJRR. Besides, other secondary sources such as US FDA declassified documents, company document archives and scientific publications were also utilized as much was possible within the time-bound limitations of this research.

- Unlike most other national registries in present active operation, the '*AJRR*' is noted to be operated by a non-public association of orthopaedic surgeons, known as the "*American Academy of Orthropedic Surgeons*" (AAOS). Now, the AAOS is a globally renowned organization with the participation of a wide spectrum of professionals, and undoubtedly is of general positive repute, but the research felt, certain activities required more transparency, which could've been plausible, had it been governed differently, involving persons, with a greater no conflict backgrounds. Details on this shall be discussed as appropriate in end segment of this chapter.

- There are no prevalent norm or regulation, for a mandatory arthroplasty and implant usage reporting to any of the healthcare sources or the registry database in place or circulatory effect as of date in the US, though this research doesn't completely write off the possibilities of any newer or older regulation that affirms the collection and reporting of arthroplasty data, in some parts of the nation.

- The overall procedures reflected in the AJRR database are primarily from its network and 'member' hospitals and clinics. Besides, the US registry is also found to be very innovatively and smartly utilize the large-scale insurance data from sources such as CMS ('Centre for Medicare & Medic-aid Services) to obtain crucial patient demographic data and other procedural details to completely bridge missed out or incompletely reported arthroplasty procedural data. This also allows for the cross-verify the hospital/clinic reported data, with the insurance data of the common general patient cohorts, thereby, eliminating any possibilities of mis-representation or data alteration.

- The data volume that formulates the primary base on which this chapter is being devised, comprises of 2.5 million hip and knee arthroplasty procedures, a breakdown of which is presented through the following tabulation: -

AJRR 2022 :- Cumulative Annual Procedural Volume of the US Patient Cohort during the Period of 2012 - 2021.

SL No.	Arthroplasty Procedure Type	Cumulative Annual Procedure Volume	% of Overall
1	Total Knee Arthroplasty	13,06,719	51.20%
2	Total Hip Arthroplasty	8,21,640	33.30%
3	Revision Knee Arthroplasty	1,12,852	4.80%
4	Hemi-Arthroplasty	95,099	3.70%
5	Revision Hip Arthroplasty	1,03,514	4.20%
6	Partial Knee Arthroplasty	66,394	2.60%
7	Hip Resurfacing Arthroplasty	5,935	0.20%
TOTAL		25,12,153	100.00%

Table 6.2.1 :- ***Tabulation illustrating the Overall Breakdown of the Various forms of Hip and Knee Arthroplasty Procedures that were performed on the American patient cohorts, during the years of 2012 – 2021, for whom relevant data could be accessed from the American Registry Database.***

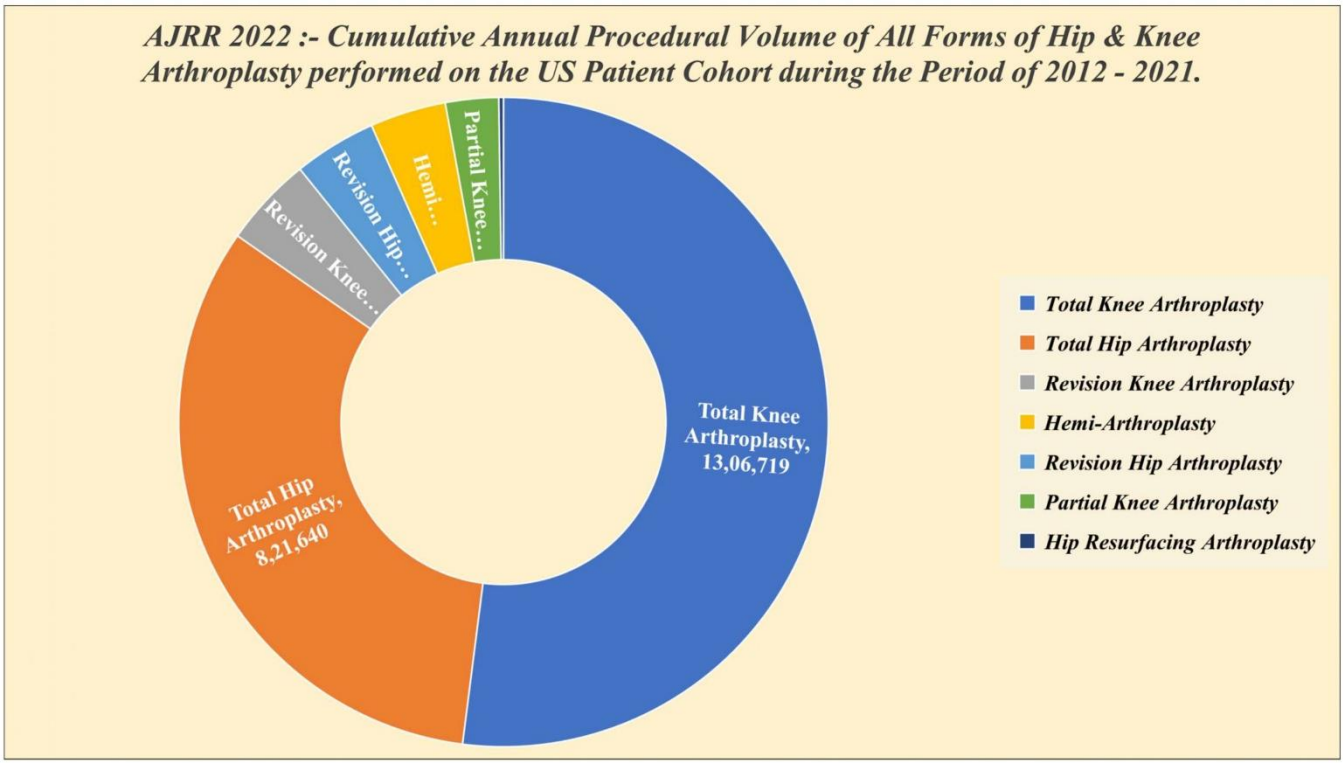


Figure 6.2.1 :- ***A Pie-Chart illustration of the Cumulative Annual Procedural Volume of All Recognized forms of Hip and Knee Arthroplasty, that are performed on the American Patient Cohort, during the period of 2012 – 2021 .***

- On the aspect of patient demographics of the arthroplasty recipient cohort in the USA, Female patients are leading the charts for elective THA and TKA in both the reports, about the US and UK population, with most of them leading in the youngest (<50 Years) and young (>55 Years) age groups.

- MoM hip constructs along with MoM Resurfacing implants continue to have a drastically higher revision rate for all groups of patients. When examined for revision rates excluding MoM and resurfacing cases, the numbers or graphs show up a different story for implant failures and revision rates.

- The AJRR 2022 reports that whatever MoM implants are being circulated and implanted in its cohort of patients, CoCr-based implants bear the worst performance records, and the numbers stated by AJRR 2022 show a marked decrease in CoCr operations in the US, due to its extensive surface wear, trunnion and taper corrosion action concerns.

- The fall of MoM hip constructs in the US has directly benefitted ceramic head implants, whose usage as in the case of CoP continues to rise with every passing year. While a major portion of the remaining MoM usage is linked to titanium alloy-based implants, nevertheless, the overall failure rates and revision numbers for CoP are far less than those of MoM, and this enhanced performance encourages its usage all over.

- The AJRR 2022 also highlights the advent of Dual Mobility (DM) hips and its rising numbers, although still “statistically insignificant”, and its rising popularity amongst a certain group of patients.

- With regards to DM hips, the AJRR 2022 finds it to be of good use in implantation for the oldest patient group 90 years and higher, or in older aged persons who had been a subject of multiple revisions in his/her lifetime. Apart from the oldest aged group of patients, the AJRR 2022 finds DM hips to be in use for extremely young patients (less than 50 years or even young) promising them extended ROM,

greater flex, and support for the hyperactive lifestyle. The basic idea of supplementing for increased hyperactivity and load-bearing capabilities, DM hips seems to benefit only either extreme sections of the patient groups – either the youngest or the oldest, however, DM hips don't seem to be very commonly deployed for the most common or prime age group who make up the bulk of the elective THA patients, i.e., in the 60 – 75 years age bracket.

- This pattern was mainly attributed to the significantly higher revision numbers of DM hips, due to its new mode of failure – intra-prosthetic dislocation (IPD), which discourages surgeons to go for DM hips in the prime-aged arthroplasty patient groups. Similar facts were also reported in the NJR 2022, wherein DM hips are shown to have almost 2x failure rates than most of the unipolar hip combinations barring MoM implants.

- Extensive research and thoughts on the usage patterns of DM hips, indicate that the choice of DM hips was mostly seen in young males and females, and the specific comment by the NJR 2022 report page 28, in the executive summary section wherein DM hip patients are attributed to an "*entirely different demographic than the generic arthroplasty patient group*", re-affirms the investigated idea, that DM hips might be used not just for helping multiple re-revision or hyperactive lifestyle as its indications for use, but also to supplement for an entirely different cohort of patient requirements from their hip arthroplasties. Certain scientific literature examined by this research, implored the angle of a hip arthroplasty driven improved sexual life after THA in both males and females. [*Meiri, R., Rosenbaum, T. Y., & Kalichman, L. (2014). Sexual Function before and after Total Hip Replacement: Narrative Review. Sexual medicine, 2(4), 159–167. https://doi.org/10.1002/sm2.35*]

- It is therefore self-explanatory that despite its involving risks of intra-prosthetic dislocation and pre-mature wearing, dual mobility hips continue to finds its place amongst the lower and higher age-linked extremities of the global patient cohort.

- In terms of data reporting and collection mechanisms for the AJRR, the AJRR does not yet have 100% coverage of its entire clinical institutions conducting THAs & TKAs in the US, nor does it have any sort of mandatory reporting criteria for its partner institutions.

- The American registry instead of better partnering with Governmental and other agencies, chose to go for a payment model system for data capture for its registry database and capturing vital insurance data (Medicare & Medicaid) for pre-op, surgical, and post-op data. The American registry also reportedly utilized a systematic payment incentive-based model to capture PROMs data for its registry. This however remains to be checked for ethical concerns and as a crucial point to consider, while adjudging the patient related outcomes, since most of the data are "purchased" or arranged on a quid pro quo basis, and not voluntarily reported.

- While comparing the American registry database with the other similar national registry databases that have been evaluated and included within the analyses and evaluation procedure of this research, a basic pattern was observed that the data reported it the American registry was more of a blemish-free fairy-tale story in the US Arthroplasty domain, with lots of exclusions and statistically significant data categorized as "Others" across several sections of its report. The registry database and its reports though had plenty of 'useful' data, but practically very less of information and negligible insights or derivable knowledge, and what extent of it was practically a camouflage to the actual realities behind, remains to be seen.

- These facts and findings further fuel the possibilities of under-reporting or data suppression or as the NJR says "systematically coordinated agreement", when it is observed that the AJRR is the only report

of major repute and of a major arthroplasty market in the world, wherein the registry report "thanks" major implant MNC brands as its "supporters and partners". The rationale behind this to be the active participation by the MNC brands in supplying the registry with its implant data as a part of "partner" ing, didn't fit the rational sense, since the brand logos of the major MNCs changed every year, with some of them missed out or changed in their positioning on their respective "thanking" note by the registry database, with the fact that those particular MNCs missed out on being featured on AJRR reports were not due to any reason that they weren't functional or operational on those particular years, rather they continued their respective business operations like the usual times in those particular years as well, fuels the doubt on the exact definition of being the "supporter" of the registry.

- The afore-mentioned phenomenon is exhibited through the following figures, which are excerpts from the official registry report for the last 3 consecutive years. The changing number of "supporters" over the years, may be fruit of what is explained by the British registry as "systematically coordinated agreement".

- The story of the American Registry and its "Supporters" & "Partners" illustratively explained over the years: -



Figure 6.2.2 :- ***Excerpts from the Official American Arthroplasty Registry – "AJRR"'s report of 2020, wherein they have "Thanked" their "Supporters and Founding " – Exhibit 1.***

Note :- 9 Implant Manufacturing Corporations including the Quadropoly – DePuy Synthes ; Stryker ; Zimmer Biomet and Smith & Nephew.



Figure 6.2.3 :- ***Excerpts from the Official American Arthroplasty Registry – "AJRR"'s report of 2021, wherein they have "Thanked" their "Supporters and Founding " – Exhibit 2.***
Note :- 6 Implant Manufacturing Corporations including the Quadropoly – DePuy Synthes ; Stryker ; Zimmer Biomet and Smith & Nephew.



Figure 6.2.4 :- ***Excerpts from the Official American Arthroplasty Registry – "AJRR"'s report of 2022, wherein they have "Thanked" their "Supporters and Founding " – Exhibit 3.***
Note :- 7 Implant Manufacturing Corporations including the Quadropoly – DePuy Synthes ; Stryker ; Zimmer Biomet and Smith & Nephew.



Figure 6.2.5 :- ***Excerpts from the Official American Arthroplasty Registry – "AJRR"'s report of 2023, wherein they have "Thanked" their "Supporters and Founding " – Exhibit 4.***
Note :- 8 Implant Manufacturing Corporations including the Quadropoly – DePuy Synthes ; Stryker ; Zimmer Biomet and Smith & Nephew.

- No other registry databases or their official reports were found to specifically "thank" their "supporters", that involves the major implant manufacturers, who are explicitly mentioned by their respective branding logos. It was also not the case that products only belonging to these companies are mentioned or included within the database or its report, rather implant utilization scenarios for those made by relatively smaller firms such as the Corin Group, are also found to be included within the relevant arenas of the database and its reports.

- An interesting fact that came out of the comparative analysis of NJR and AJRR showed that conventional UHMWPE almost faded out on market share and active operation in the case of THA, which has directly propelled the sharp rise of Highly Cross-linked Polyethylene (HXLPE), Cross-Linked Polyethylene (XLPE) and Anti-Oxidant Coated/Infused Polyethylene(A-PE) articular surfaces.

- The decline of UHMWPE was attributed to decreased abrasive resistance and promotion of the accumulation of granular mass near the articular surface further leading to increased chemical activity t in-turn promotes free ionic radical release from the implant into the anatomy thereby causing a chain of anatomical hazardous mess.

- A-PE articular surfaces though peaking at some point, lost out majorly to HXLPE and XLPE in elective THA cases in recent years. Though in revision cases, A-PE has some stable use where the revision was due to infection, in elective cases, HXLPE is the prime choice of surgeons/patients.

- Patient gender linked influences on the outcome scenarios, specifically the involving revision rate percentages across multiple timepoints in the post-operative window when examined for the cumulative revision rate percent of the cementless vs cemented femoral fixation of patients, aged >= 65 years; - the cemented femoral components had a statistically increased cumulative revision rate percentage in males, while the cemented femoral components had a lower revision rate percentage in case of female patients. Though no explanation was presented in the report behind this reported fact, this requires some separate exploration.

- Nevertheless, the American patient cohort continues to receive hip and knee arthroplasty-based interventions for their failing hip and knees, for a variety of indications, over the years, and most interestingly, the impact of the pandemic in the years of 2020 and partially in 2021, doesn't seem to have troubled or reduced much of the procedural volume in the US, rather the recovery to normal proportions of occupancies was more rapid than that was for other nations.

- The following line-graph plot illustrates the cumulative growth in the annual procedural volume of hip and knee arthroplasties that are performed on the general American patient cohort over the years since 2012 to 2021: -

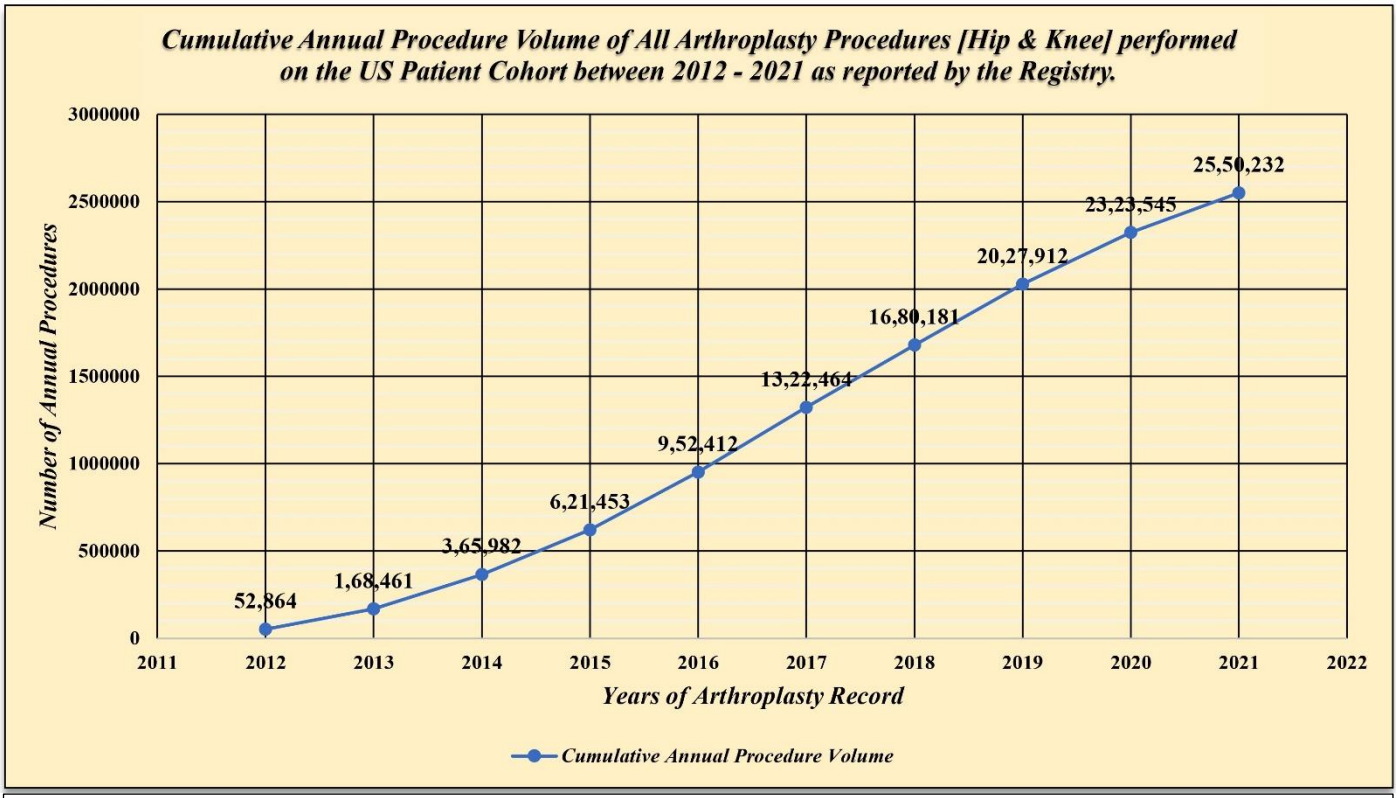


Figure 6.2.6 :- ***Line Graph Plot illustrating the Cumulative Rise in the Annual Procedural Volume of All Arthroplasty Procedures, performed on the American Patient Cohort, during the years of 2012 – 2021.***

- On an overall basis, maintaining consistency with the global finding, female patient cohorts in the US, were the majority recipients for hip and knee arthroplasty-based interventions for their prevailing conditions, irrespective of any micro-level filtering or segregation of the data.

- Female patient cohorts in the US, received 14,91,839 uniquely reported individual hip and knee arthroplasty procedures, that was 58.50% of the entire 2.5 million number of cumulative arthroplasty data, that this research could access. While, the equivalent male patients, received 10,49,170 uniquely reported individual hip and knee arthroplasty procedures, that made up for 41.10% of the overall numbers tallied. The overall scenario is easier interpretation, is presented through the following tabulation and pie-chart plot: -

AJRR 2022 :- Patient Gender Wise Distribution of All Arthroplasty Procedures both Hip & Knee performed on the US Patient Cohort between 2012 - 2021.			
SL No.	**Gender of Patients**	**No. of Cases**	**% of Overall**
1	Male	10,49,170	41.10%
2	Female	14,91,839	58.50%
3	Not Reported	9,223	0.40%
Total		**25,50,232**	**100.00%**

Table 6.2.2 :- ***Tabulation illustrating the Overall Patient Gender-linked Distribution of the Overall Number of Hip and Knee Arthroplasties, that are performed on the American Patient Cohort, during the years of 2012 – 2021.***

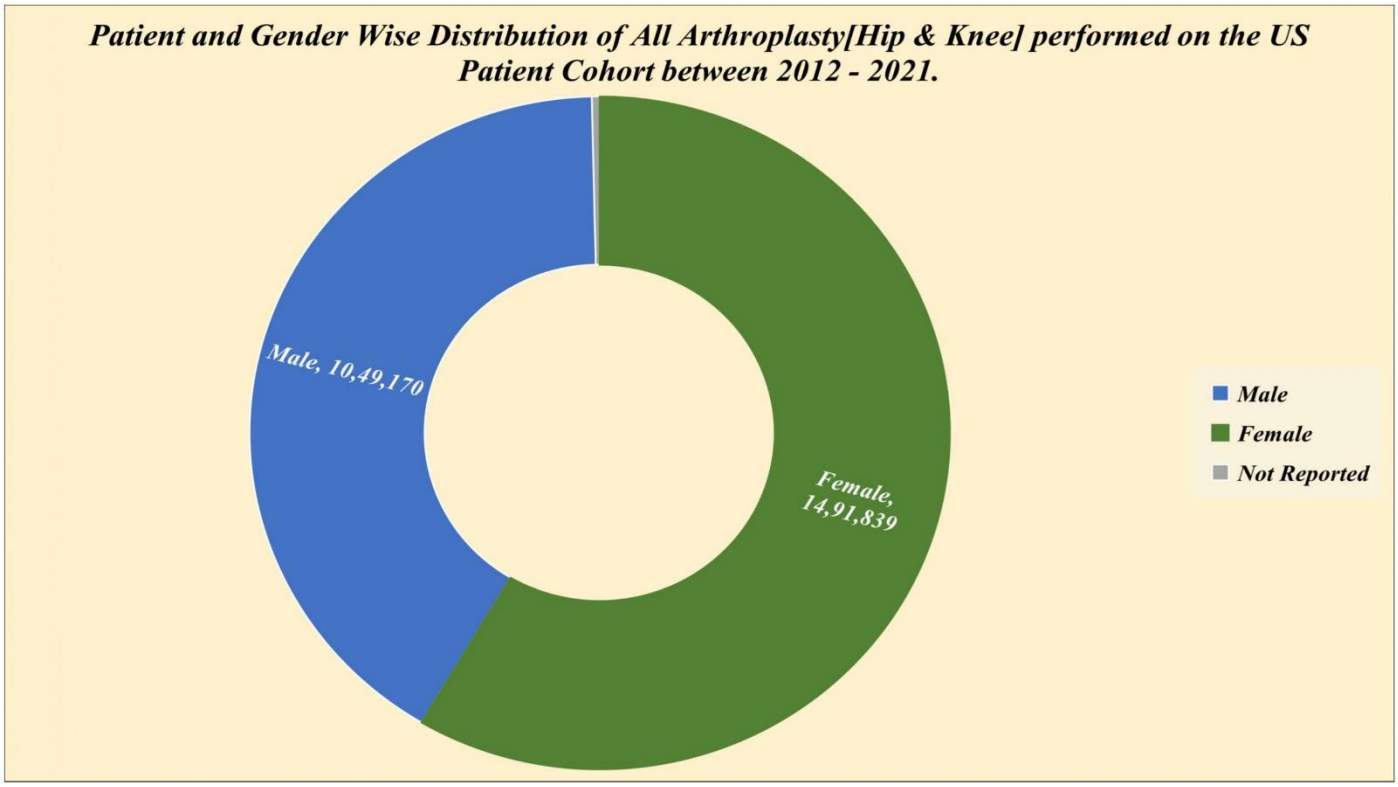


Figure 6.2.7 :- ***A Pie-Chart Plot illustration of the Overall Patient Gender-linked Distribution of the Overall Number of Hip and Knee Arthroplasties, that are performed on the American Patient Cohort, during the years of 2012 – 2021.***

Hip Arthroplasty Practices & Prostheses Utilization Scenarios with Relative Outcomes on the Patient Cohort in USA.

- There was a total of 10,64,750 uniquely reported individual hip arthroplasty procedures that were performed on the American patient cohort, during the years of 2012 – 2021, in the US, across all the recognized modalities of hip arthroplasties. However, an exact logically conclusive figure for the hip arthroplasties performed in 2021, couldn't be obtained.

- While Elective THAs, dominate the overall numbers and percentages, for the cumulative number of hip arthroplasties performed, the revision hip arthroplasties, was the second most commonly performed procedure, in connection to hip arthroplasties in the US.

- There were 8,21,640 uniquely reported individual elective THAs, which made up 77.17% of the overall hip arthroplasty numbers, whereas, the second-best revision hip arthroplasty as an uniquely reported procedure, was performed on 1,03,514 individuals, that was 9.72% of the overall hip arthroplasty volume.

- Unlike the case for British arthroplasty procedures, the American registry did report on the partial hip arthroplasties or hemi-arthroplasties performed on its respective cohort of patients, which was 95,099 and 8.93% by the overall numbers and respective distribution share percent against the cumulative number of hip procedures performed.

- The overall distribution of all forms of hip arthroplasties performed on the American patient cohort, between the period of 2012 – 2021, is presented through the following tabulation: -

AJRR 2022 :- Overall Distribution of All forms of Hip Arthroplasty performed on the US Patient Cohort between the Period of 2012 - 2021, as per reported by the Registry.			
SL No.	**Arthroplasty Procedure Type**	**Respective Number of Cases**	**% of Overall**
1	**Elective Primary Total Hip Arthroplasty**	**8,21,640**	**77.17%**
2	**Revision Hip Arthroplasty**	**1,03,514**	**9.72%**
3	**Hemi-arthroplasty**	**95,099**	**8.93%**
4	**Total Hip Arthroplasty for Fracture**	**28,079**	**2.64%**
5	**Other Arthroplasty Procedures**	**10,483**	**0.98%**
6	**Hip Resurfacing Arthroplasty**	**5,935**	**0.56%**
TOTAL		**10,64,750**	**100.00%**

Table 6.2.3 :- ***Tabulation illustrating the Overall Distribution of the Various forms of Hip Arthroplasties that are performed on the American Patient Cohort, during the years of 2012 – 2021.***

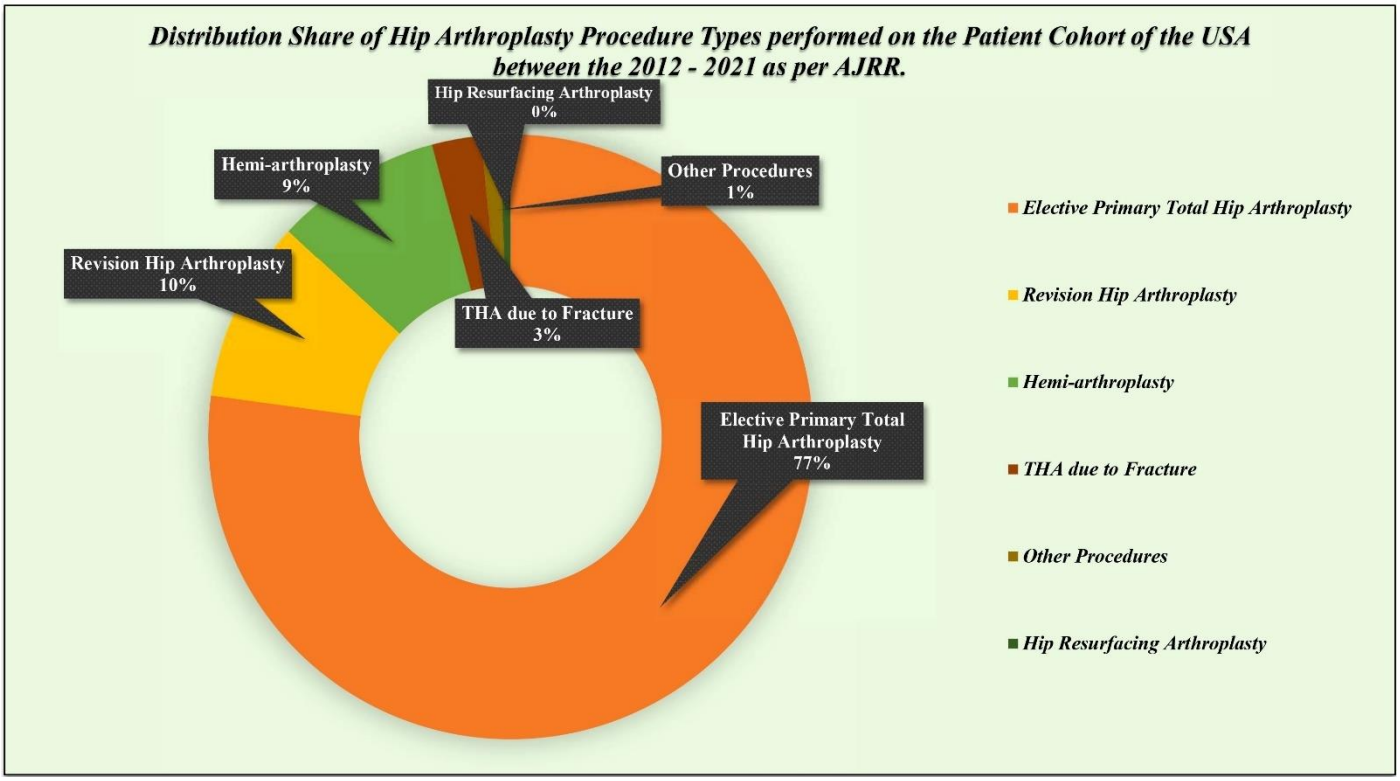


Figure 6.2.8 :- ***A Pie-Chart Plot illustration of the Overall Distribution of the Various forms of Hip Arthroplasties that are performed on the American Patient Cohort, during the years of 2012 – 2021, based on their relative distribution share percentages of the Overall Numbers of Hip Arthroplasty.***

General Patient Demographics of the Hip Arthroplasty Recipient Patient Cohort in USA: -

- When compared for the mean age-group of the hip arthroplasty recipient patient cohorts in the US, it is noted that yet again the mean age for non-emergency based THAs, correspond to the prime age-group bracket for hip arthroplasties, that this research noted globally, and theorized in the earlier segments of this theses work. The mean age of the elective THA recipient patient cohorts in the US is 65.7 years.

- The mean age of the American patient cohorts, who received a revision hip arthroplasty, was also in the same age bracket, was 67.4 years.

- However, the mean-age of the patients undergoing a partial hip or hemi-arthroplasty procedure, was significantly higher than what it is, across most other nations, whose arthroplasty practices were probed and discussed by this research. The mean age of hemi-arthroplasty recipients in the US, is noted as 82.4 years.

- While, globally partial forms of arthroplasties, for both failing hip and knees are generally utilized on those sets of patient cohorts, who are younger than the usual core-age group, with an average of either less than 50 years or in those aging between 50 to 60 years of age, primarily due to the reason of a comparatively better bone quality and the inherent age-linked ability to withstand or to undergo a single or multiple revision hip arthroplasties, further down their respective lives, alongside the general level of trauma associated with it.

- The mean age-linked distribution of the overall hip arthroplasty procedures that are performed on the general patient cohort in the US is presented through the following tabulation: -

Mean Age-Group of the Respective Patient Cohort linked Distribution of the Overall Hip Arthroplasty Numbers in the USA, involving procedures performed between 2012 - 2021.				
SL No.	**Arthroplasty Procedure**	**No. of Cases**	**Mean Age of Patient (in Years)**	**S.D**
1	Elective Primary Total Hip Arthroplasty	8,21,640	65.7	11.3
2	Revision Hip Arthroplasty	1,03,514	67.4	12.6
3	Hemi-arthroplasty	95,099	82.4	9.7
4	THA due to Fracture	28,079	72.2	11.8
5	Other Procedures	10,483	65.4	21.8
6	Hip Resurfacing Arthroplasty	5,935	53.7	9.3
Total Number of Arthroplasty Cases		10,64,750		

Table 6.2.5 :- ***Tabulation illustrating the Overall Distribution of the Various forms of Hip Arthroplasties that are performed on the American Patient Cohort, during the years of 2012 – 2021.***

- On the aspect of the patient age-group linked distribution of the elective THA recipient patient cohorts in the US segregated by their respective genders, it is noted that for the young age-group of the patient cohort, it was the male patients who dominated in their relative proportions of receiving comparatively more number of the arthroplasties performed for the same age-group, than their female counterparts.

- The youngest patient group essentially refers to those aged less than 50 years of age, where male patients made up for the 55.20% of the overall procedural volume for the said age-group, while females had the remaining 44.90%.

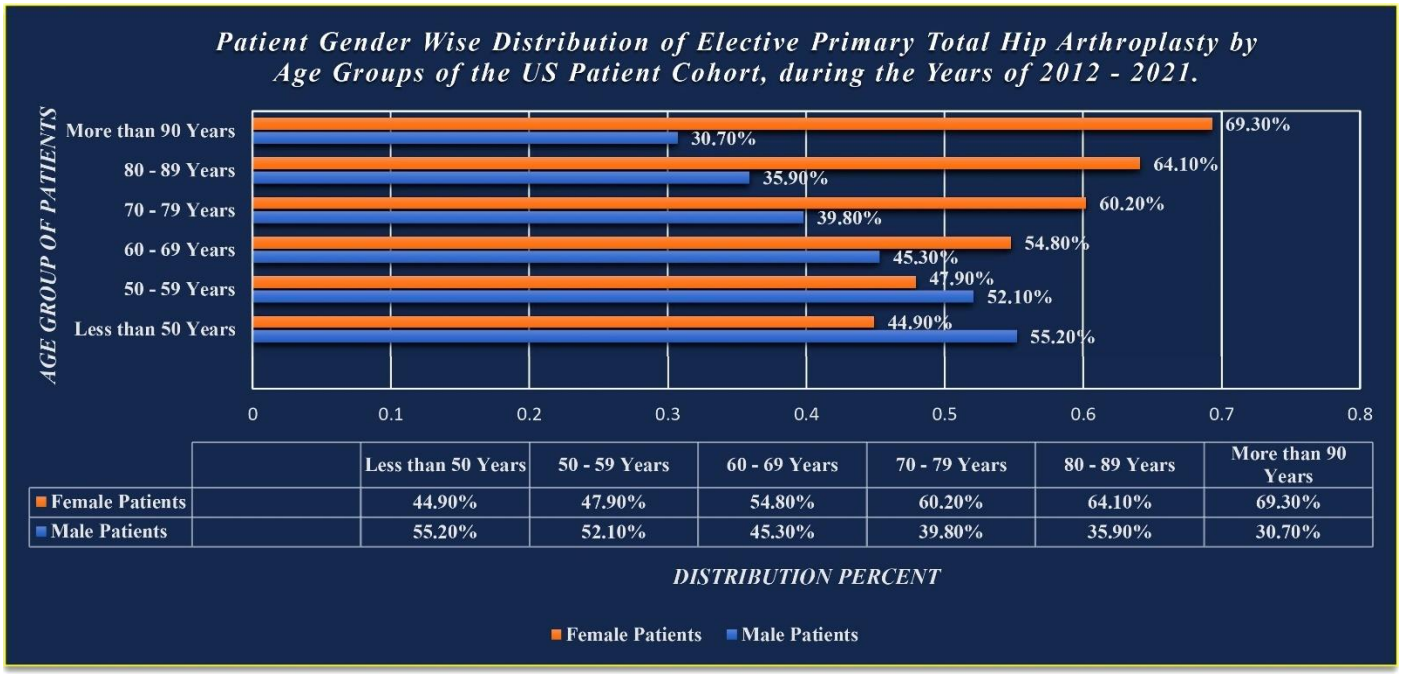
- However, the scenario changes rapidly as the age-group criterion rises, wherein it is seen the female patient led dominance in the relative proportion for the number of respective elective THA procedures received, becomes more prominent.

- From 60 – 69 years of age onwards, the dominance in the overall share of the elective THAs performed increases, with the greatest margin of dominance noted for the senior-most age-group involving patients aged 90 years or more, wherein 69.30% of all the elective THAs performed in the US, were received by patients of female gender.

- The overall age-group and gender linked distribution of the elective THA procedures that are performed on the general patient cohort in the US, across the period of 2012 – 2021, is presented through the following tabulation and graph plot, for easier reference: -

AJRR 2022 :- Patient Gender Wise Distribution of Elective Primary Total Hip Arthroplasty Procedures by Age Groups of the US Patient Cohort, during the Years of 2012-2021.				
SL No.	**Patient Age-Group**	**Male Patients**	**Female Patients**	**Total %**
1	Less than 50 Years	55.20%	44.90%	100.10%
2	50 - 59 Years	52.10%	47.90%	100.00%
3	60 - 69 Years	45.30%	54.80%	100.10%
4	70 - 79 Years	39.80%	60.20%	100.00%
5	80 - 89 Years	35.90%	64.10%	100.00%
6	More than 90 Years	30.70%	69.30%	100.00%

Table 6.2.6 :- ***Tabulation illustrating the Overall Patient Age-Group and Gender linked Distribution of the Elective Non-Emergency Total Hip Arthroplasties (THA)s that are performed on the American Patient Cohort, during the years of 2012 – 2021.***



	Less than 50 Years	50 - 59 Years	60 - 69 Years	70 - 79 Years	80 - 89 Years	More than 90 Years
Female Patients	44.90%	47.90%	54.80%	60.20%	64.10%	69.30%
Male Patients	55.20%	52.10%	45.30%	39.80%	35.90%	30.70%

Figure :- ***A Bar-Graph Plot of the Age-Group of US Patients vs Distribution Percentage Occupied, illustrating the Overall Patient Age-Group and Gender linked Distribution of the Elective Non-Emergency Total Hip Arthroplasties (THA)s that are performed on the American Patient Cohort, during the years of 2012 – 2021.***

Leading Causes/Indications for Primary Total Hip Arthroplasty of the American Patients: -

- Given by the general pattern of distribution of the THA procedures performed on the American patients, it is understandable that the leading number of THAs are attributed for the "Elective THAs", i.e., those which doesn't involve any general complication or any scenario for fatal injury or accident driven case, for which the American registry is noted to have a separate classification header termed as " Hip Arthroplasty due to Fracture", it could therefore be fairly stated that the leading cause or indication for primary 'elective' total hip arthroplasty of the American patients, is due to a progressively worsening osteoarthritis of their hips.

- However, a detailed indication summary and distribution number for the hip arthroplasty procedures, irrespective of them being a primary total or hemi, was not available across the American registry sources and few other options availed.

- Therefore, incidences of relatively complicated case scenarios such as hip dysplasia and limb shortening, could not be discussed in this detail, and sources from the scientific literature might not be practically relevant or may involve underlying biases.

- Fractured Neck of Femur (NOF), which is a commonly reported indication globally, though not as much as the progressively worsening osteoarthritis scenario, is discussed.

Fractured Neck of Femur (NOF) driven Primary THA scenarios of the American Patients: -

- The exact number of fractured NOF cases in the US, couldn't be ascertained by this research, since there were multiple cumulative number figures for the fractured NOF cases, on the registry database

alone, but the general idea is that the numbers of primary THAs performed due to a primary indication of a fractured NOF will be no less than 35,000.

- For a primary indication of a fractured NOF, the general arthroplasty practice in the US seems to involve a hemi-arthroplasty-based intervention than a THA to rectify the condition of the patient suffering from it.

- On a historical basis, it is noted that primary Hemi-Arthroplasty procedures are performed in much greater proportions, than primary total hip arthroplasty procedures, for the overall number of procedures performed due to a NOF fracture condition. However, the general practice is noted to post a micro-level swing, wherein a steady decline in the relative proportional percentages of the hemi-arthroplasty procedures for fractured NOF is noted, that directly is benefits the THA proportions, and thereby contributing for its steady rise on a YoY basis.

- In 2012, of all the hip arthroplasty procedures that were performed on the US patient cohort, for a fractured NOF diagnoses, 83.10% of them were performed utilizing a partial hip or hemi-arthroplasty-based approach, while, only a 16.90% of them were a primary THA.

- The scenario for 2021, was that 26.80% of all the primary hip procedures performed due to a fractured NOF diagnoses were primary THAs, while the remnant 73.20% were performed through a hemi-arthroplasty-based approach. The hemi-arthroplasty proportional percentages though still remain as the leading choice, but the overall scenario of comparative decline and rise of both the arthroplasty modalities is presented through the following tabulation, which is self-explanatory.

AJRR 2022 :- Distribution of Hip Arthroplasty Procedure types Performed for Neck of Femur Fracture over the Years of Record 2012 - 2021 of the US Patient Cohort.

SL No.	Year of Record	Total Hip Arthroplasty for Neck of Femur Fracture	Hemi-Arthroplasty	Total %
1	2012	16.90%	83.10%	100.00%
2	2013	18.20%	81.80%	100.00%
3	2014	20.40%	79.70%	100.10%
4	2015	19.90%	80.10%	100.00%
5	2016	21.90%	78.10%	100.00%
6	2017	22.30%	77.70%	100.00%
7	2018	22.20%	77.80%	100.00%
8	2019	23.70%	76.30%	100.00%
9	2020	24.80%	75.20%	100.00%
10	2021	26.80%	73.20%	100.00%

Table 6.2.7 :- ***Tabulation illustrating the Distribution of Primary Hip Arthroplasty Procedures performed due to a Fractured NOF primary diagnoses, segregated as per the Modality of Hip Arthroplasty adopted (THA vs Hemi-A), on the American Patient Cohort.***

- On the aspect of the demographics of the patient cohort undergoing a fractured NOF primary diagnosis based primary hip arthroplasty in the US, the intricate details are again couldn't be accessed or obtained from totally reliable sources.

- Again, similar to the elective THA scenario, it is noted that male patients who were less than 50 years of age, received the majority proportion of the primary hip arthroplasties performed for a fractured NOF cause. The male patient cohort of age less than 50 years are attributed to have undergone 54.10%

of all the primary hip arthroplasties performed due to fractured NOF scenario, while the remnant 45.90% is attributed for the female patient cohort, belonging to the similar age-group.

- This scenario changes with the increasing age-groups, wherein for the senior-most age-group involving patient cohorts aging 90 years or more, showed 70.07% of all the fractured NOF led primary hip arthroplasty procedures, being performed on the female patients, while, the remnant 29.93% is performed on the male patients.

- The overall patient age-group and gender linked distribution of the primary hip arthroplasties performed due a fractured NOF led primary diagnosis, is presented through the following tabulation: -

AJRR 2022 :- Patient Age & Patient Gender Wise Distribution of Neck of Femur (NOF) Fracture in the US Patient Cohort, as reported by the Registry.

SL No.	Patient Age-Group	Male Patients	Female Patients	Total %
1	Less than 50 Years	54.10%	45.90%	100.00%
2	50 - 59 Years	42.16%	57.84%	100.00%
3	60 - 69 Years	34.76%	65.24%	100.00%
4	70 - 79 Years	32.38%	67.62%	100.00%
5	80 - 89 Years	32.36%	67.64%	100.00%
6	More than 90 Years	29.93%	70.07%	100.00%

Table 6.2.8 :- ***Tabulation illustrating the Overall Patient Age-Group and Gender linked Distribution of the Primary Hip Arthroplasties that are performed on the American Patient Cohort, due to a Primary Indication of a Fractured Neck of Femur(NOF), during the years of 2012 – 2021.***

***Prosthesis-Characteristics Specific Aspect of Hip Arthroplasty Practices and Patient Related Outcome Scenarios for the American Patient Cohort*: -**

- Femoral head sizes are an intricate parameter that are capable of influencing the end-results and long-term outcomes of a hip arthroplasty, if utilized inappropriately.

- For elective primary THAs performed on the general American patient cohort, an increased utilization of 36 mm femoral heads is noted since 2012, which is more or less stable since 2018, with no particular signs of decrease or increase, as far as the data from the registry is concerned.

- The general trend towards larger femoral head sizes >= 40 mm continues to rise, while on a comparative basis 32 mm and 28 mm or less decreased in relative proportions, though the 28 mm sized femoral heads is noted to be more or less stabilized in terms of utilization scenarios.

- The cumulative revision rate percentage of the patients aging >= 65 years is noted to be comparatively higher, when a femoral head of sizes 28 mm or less and those sized 40 mm or higher are utilized. For this particular age-group of the American patients, femoral head sizes of 32 mm and 36 mm seems to be optimally best choice, unless bounded by other case-specific requirements & limitations.

- Dual Mobility (DM) hip prostheses continues to rise, with a steadily growing populace of the recipient patient cohort for both primary and revision hip arthroplasty applications on the American patient cohort since 2012.

- Similar to the utilization scenarios noted for the other nations evaluated and discussed in great detail within this theses work, dual mobility hip prostheses only find the favorably comparatively best results when they are utilized for patients who belong to the either extremity of the age-groups concerned, i.e., to either youngest and oldest age-group scenarios.

- The best plausible explanation for this prevalent scenario, as inferred by this research is that considering the involving risks of pre-mature failure of a DM hip prostheses due to a IPD or intra-prosthetic dislocation based failure, the oldest age-group seems to be the safest group to receive such a hyper-mobile bearing hip prostheses, since patients of those ages are not particularly expected to be as hyper-active and mobile than those who are in their 50s/60s or younger. Similarly, for the youngest age-group, who might particularly require to adapt for a hyper-active life-style regime post their hip arthroplasty either due to a livelihood based requirement or for a personal choice, such prosthesis with a hyper and doubly mobile bearing surface could just be the perfect selection, notwithstanding the fact that these 'youngest' or younger age-groups are expected to be able to withstand a single or multiple revision hip arthroplasty in their remaining course of lifespan, should be a requirement for it.

- DM hips despite of its benevolent promises, continues to face the risks of a pre-mature failure owing to an intra-prosthetic dislocation, which is diagrammatically explained in the relevant section of the Australian Arthroplasty practices chapter of this thesis, yet the following two figures are affixed to illustrate the condition: -

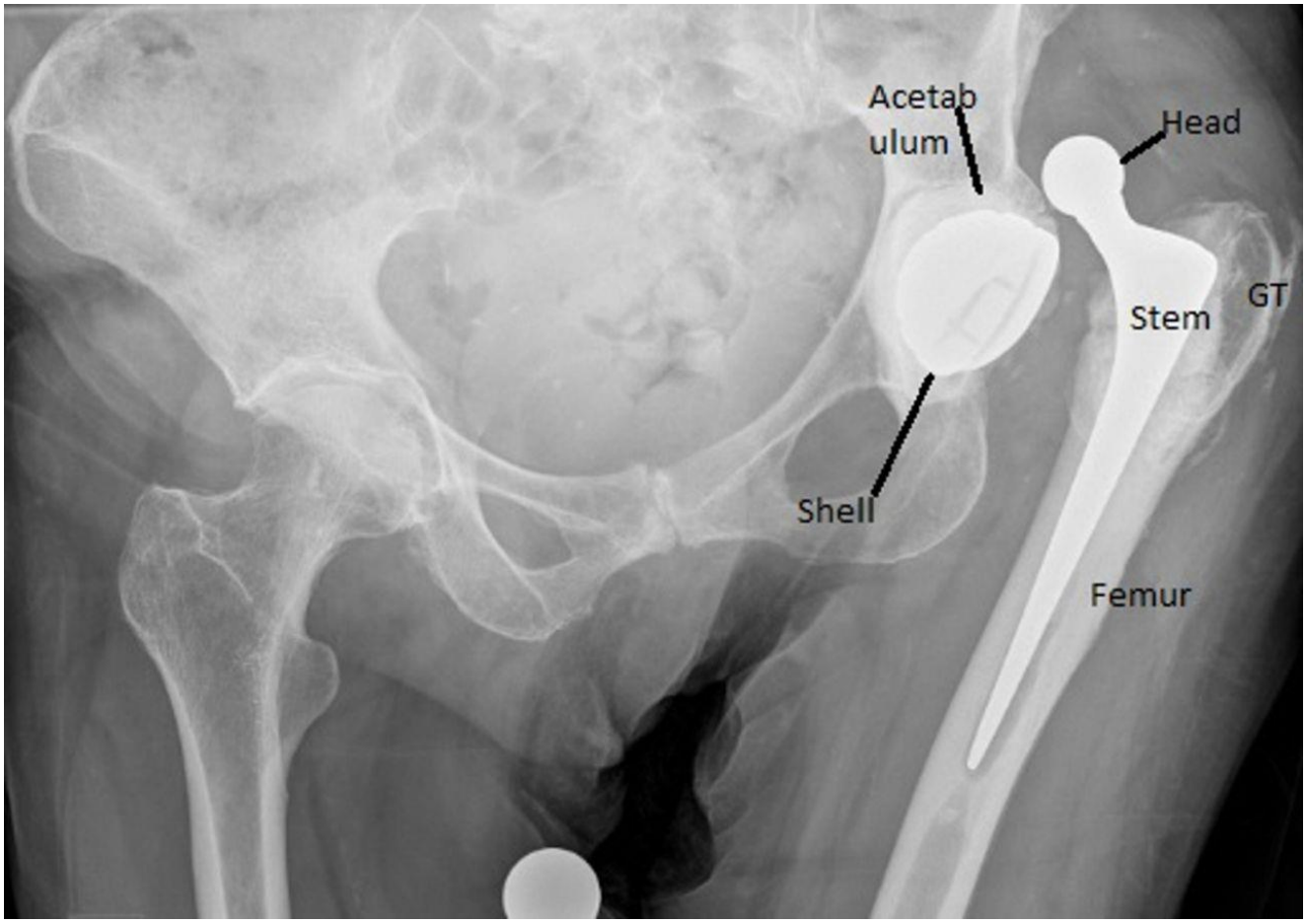


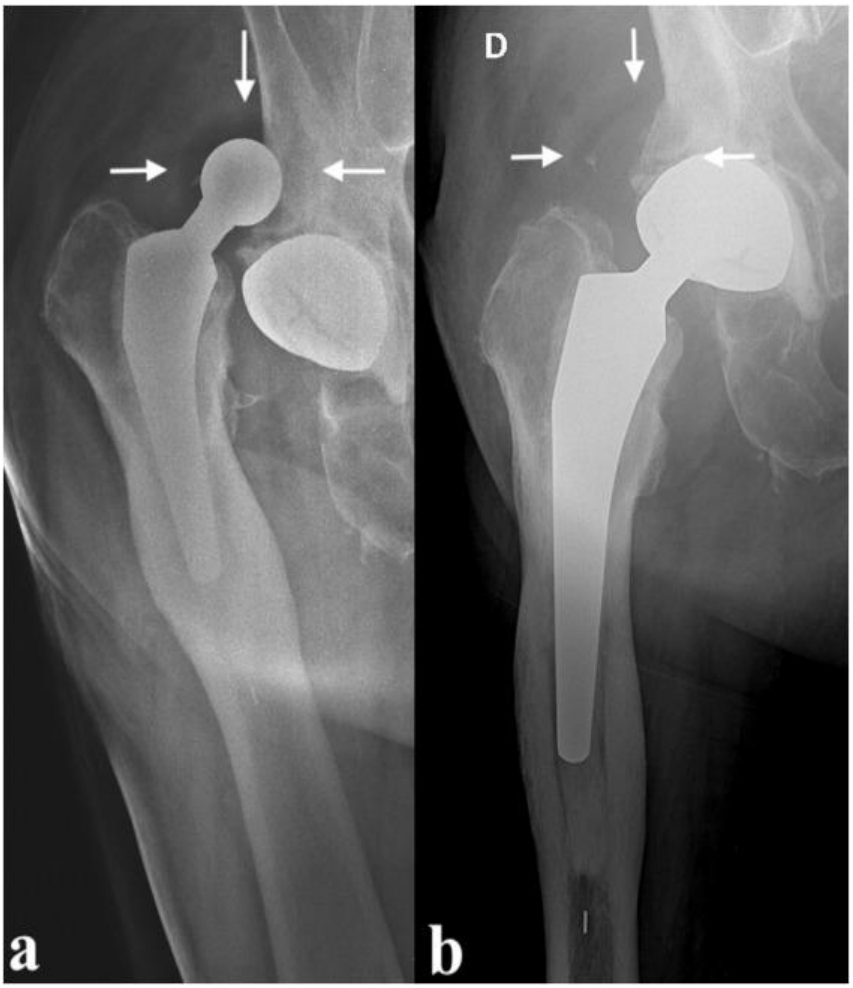
Figure 6.2.9 :- ***Radiographic illustration of an Intra-Prosthetic Dislocation incidence of a Dual Mobility Hip Prostheses on the Left Hip of a patient. – Exhibit 1.***

Image Source: - Zabaglo M, Merchant H, Haggis P, *et al* Dual mobility hip arthroplasty: iatrogenic intraprosthetic dislocation of a 22 mm head. *BMJ Case Reports CP* 2022;**15:**e245859.

Figure 6.2.10 :- ***Radiographic illustration of an Intra-Prosthetic Dislocation incidence of a Dual Mobility Hip Prostheses on the Right Hip of a patient. – Exhibit 2A.***

Note ***: - Image 'a' denotes the primary X-Ray image of the hip, confirming an IPD incidence.***
Image 'b' denotes the secondary X-Ray image of the same hip, post an attempted Closed Reduction of the Hip, though the Femoral Head alignment is not perfectly attained and the Femoral Neck not Centered in the Acetabular Cup.

Image Source: - Rotini, Marco et al. "Iatrogenic intraprosthetic dislocation after closed reduction of dual mobility total hip arthroplasty: Report of two cases." *International journal of surgery case reports* vol. 71 (2020): 225-229. doi:10.1016/j.ijscr.2020.04.085.



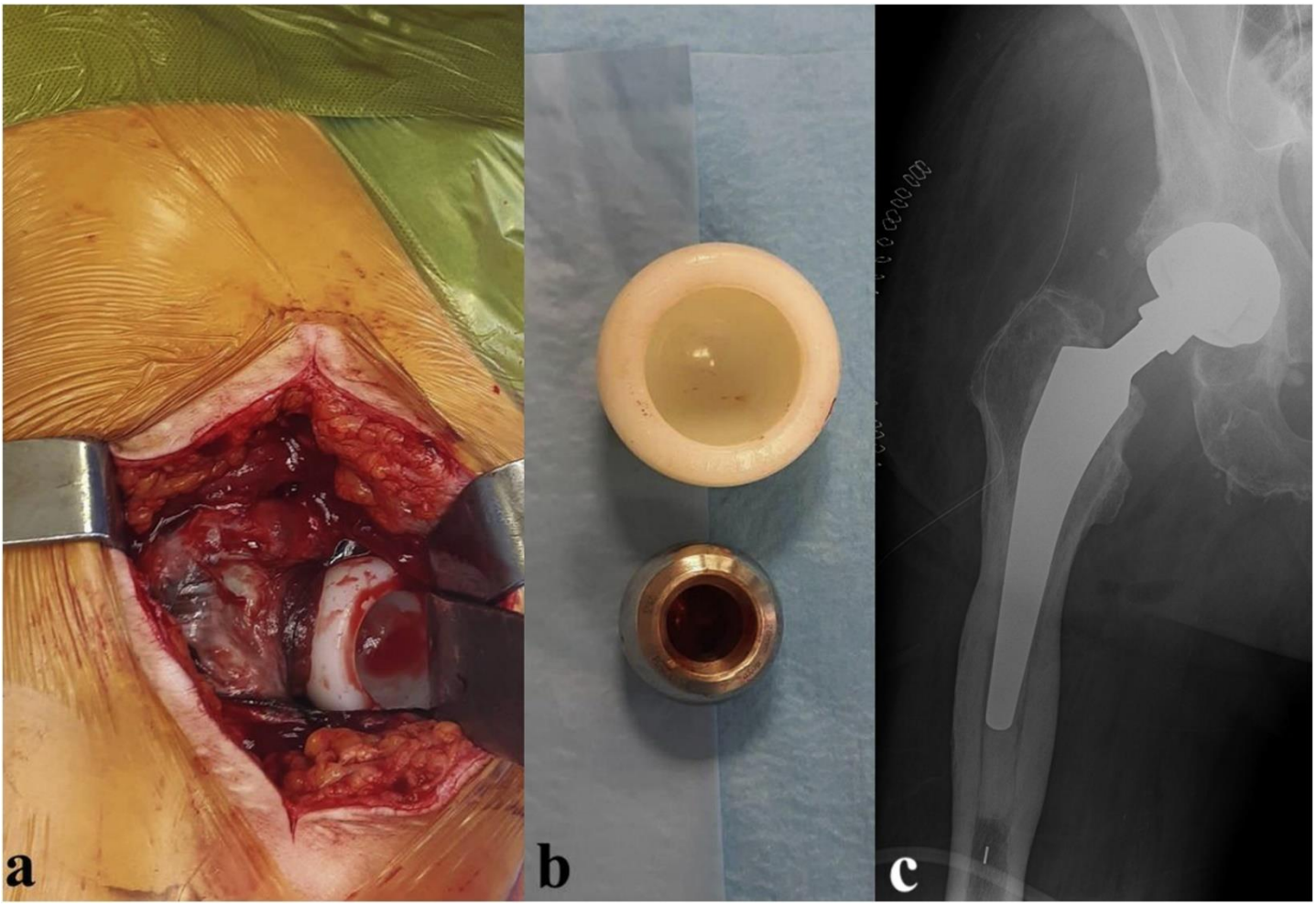


Figure 6.2.11 :- ***Radiographic illustration of an Intra-Prosthetic Dislocation incidence of a Dual Mobility Hip Prostheses on the Right Hip of a patient. – Exhibit 2B.***

Note ***: - Image 'a' denotes the Dislocated Polyethylene Liner to be Retrieved from the Adjoining Soft Tissues. Image 'b' denotes the Dislocated Polyethylene Liner, itself was having No Remarkable signs of Wear. Image 'c' denotes the Rectified Alignment of the Hip Prosthesis Module, post the Revision Hip Surgery.***

Image Source: - Rotini, Marco et al. "Iatrogenic intraprosthetic dislocation after closed reduction of dual mobility total hip arthroplasty: Report of two cases." *International journal of surgery case reports* vol. 71 (2020): 225-229. doi:10.1016/j.ijscr.2020.04.085.

- The overall utilization scenario for conventional hip prostheses compared vis-à-vis the Dual Mobility hip prostheses, in terms of relative usage proportions, implanted on the general American patient cohort during the period of 2012 – 2021, is presented through the following tabulation: -

AJRR 2022 :- Distribution of Relative Utilization Proportion Percentage scenarios for Dual Mobility Usage and Conventional Hip Prostheses, categorized as per their Femoral Head Sizes Implanted during Elective Primary Total Hip Arthroplasty for the US Patient Cohort, during the Period of 2012 - 2021.

SL No.	Year of Record	Dual Mobility	Less than Equal to 28 mm	32mm	36mm	Larger than Equal to 40 mm	Total %
1	2012	6.30%	4.60%	33.10%	47.90%	8.20%	100.10%
2	2013	6.10%	4.90%	32%	51.50%	5.60%	100.10%
3	2014	6.80%	3.40%	28.70%	55.40%	5.70%	100.00%
4	2015	6.80%	3.10%	27.50%	57.40%	5.30%	100.10%
5	2016	7.20%	2.80%	26.40%	58.40%	5.20%	100.00%
6	2017	7.20%	2.30%	24.60%	60.10%	5.80%	100.00%
7	2018	8.00%	1.90%	22.10%	61.90%	6.20%	100.10%
8	2019	9.30%	1.60%	20.50%	62.20%	6.50%	100.10%
9	2020	9.90%	2.60%	19.10%	60.80%	7.70%	100.10%
10	2021	9.70%	3.50%	18.60%	59.90%	8.30%	100.00%

Table 6.2.9 :- ***Tabulation illustrating the Distribution of the Relative Utilization Proportion Percentage scenarios compared for Dual Mobility Usage vis-à-vis Conventional Hip Prostheses, categorized as per their Femoral Head Sizes Implanted during the Elective Primary THA of the American Patient Cohort, during the operative period of 2012 - 2021.***

- On a comparative overall basis as well, the afore-mentioned theory by this research of selective utilization of DM Hip prostheses, specifically in greater proportions for the youngest and oldest age-groups, can be evidently proven by the following utilization distribution scenario tabulation, wherein the respective utilization proportions of the Standard Bearing based hip prostheses vis-à-vis the DM hip prostheses proportion percentages are tabulated, for all the age-groups of the patient cohort in the US.

AJRR 2022:- Distribution of Bearing Mobility Type usage in Prostheses implanted during Elective Primary Total Hip Arthroplasty by Patient Age-Group of the US Patient Cohort, from the period 2012 - 2021.

SL No.	Patient Age-Group	Standard Bearing Prostheses	Dual Mobility Prostheses	Total
1	Less than 50 Years	90.80%	9.20%	100.00%
2	50 - 59 Years	92.00%	8.00%	100.00%
3	60 - 69 Years	92.50%	7.50%	100.00%
4	70 - 79 Years	92.10%	7.90%	100.00%
5	80 - 89 Years	91.30%	8.70%	100.00%
6	More than 90 Years	89.40%	10.60%	100.00%

Table 6.2.10 :- ***Tabulation illustrating the Distribution of the Bearing Mobility Type usage in Hip Prostheses implanted during the Elective Primary THA of the American Patient Cohort across all Age-Groups, during the period of 2012 – 2021.***

- For Elective THAs that are performed on the American patient cohort, the utilization of Ceramic femoral heads continues to rise, while there's a "statistically significant decrease" in the metallic femoral heads that are made of CoCr alloy, attributing to its excessive trunionosis and taper corrosion activity, leading to a pre-mature failure of the implant procedure.

- While, trunnion is the junction of the femoral stem and femoral head contact points in a total hip prostheses module, trunionosis refers to a specific type of implant wearing, that happens locally at this very junction called the trunnion. Even though these two component parts are fixed together in a very compact and tight adhesion, there's always a micro-motile activity that keeps happening at the bearing surface contact points, which ideally after a specific cycle of repetitions, is expected to release minute metallic wear debris into the joint capsule and to the adjoining soft tissues, which is totally undesirous by any given standards.

- These ejected or released metallic wear debris are responsible for triggering an inflammatory and immune-response action in the otherwise stable hip joint site, causing severe pain and agony to the patient, leading to the loosening of the implant, snowballing into a much bigger hip joint catastrophe, that could be only rectified through a complex revision hip arthroplasty, adding further on to patient already over-burdened with the trauma arising out of it.

- The following images are affixed to illustrate the afore-mentioned scenario in the best way possible: -

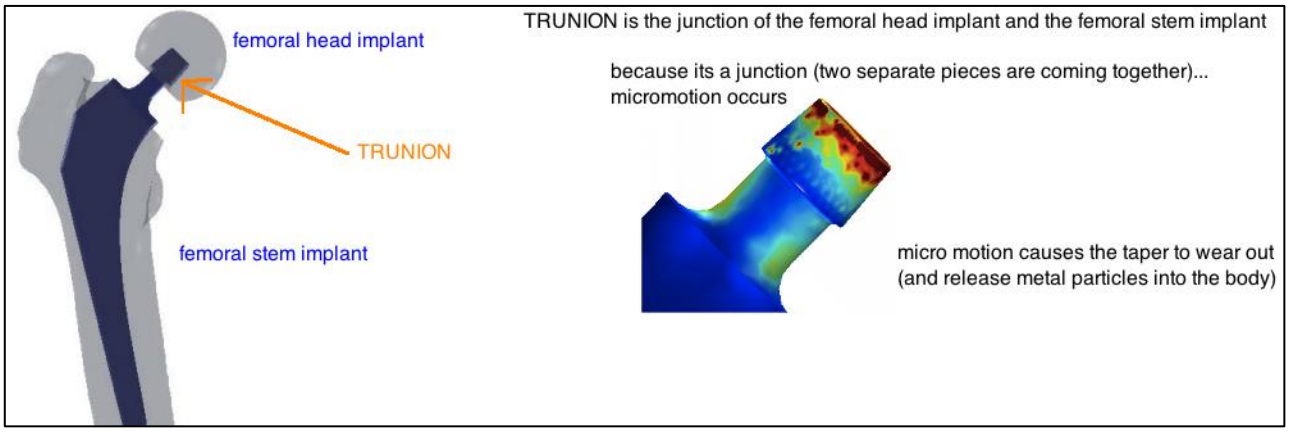


Figure 6.2.12 :- ***Illustrative image of the Femoral Head and Stem Trunnion and the Trunionosis of the Contact Point site.***
Image Source:- Bone Talks - https://www.bonetalks.com/new-blog/2016/5/30/what-is-trunionosis-orthopedic-surgeons-review-the-major-concepts

- Such surface layer degradation to metallic wearing at the trunnion junction point of the femoral head and stem, erases and causes the protective outer surface layer to get depleted, as a result of such frictional micro-motion, thereby increasing the metallic exposure to the anatomic environment, that further accelerates the corrosive activity as well as the inflammatory immune response action. The surface layers are placed strategically to prevent the core metallic surface from coming in direct contact with the body tissues and environment, since the surface layer is usually composed of protective ions that acts as an inert membrane partition separating the two reactive zones away.
  This kind of protective surface layer erosion leading to the exposure of the underlying reactive metallic surface is known as fretting corrosion.

- This is more evidently noticed when dis-similar metallic components are being held at the trunnion junction point, say a CoCr stem with a Titanium head. The following image is for the illustrative purpose, for the above discussed phenomenon.: -

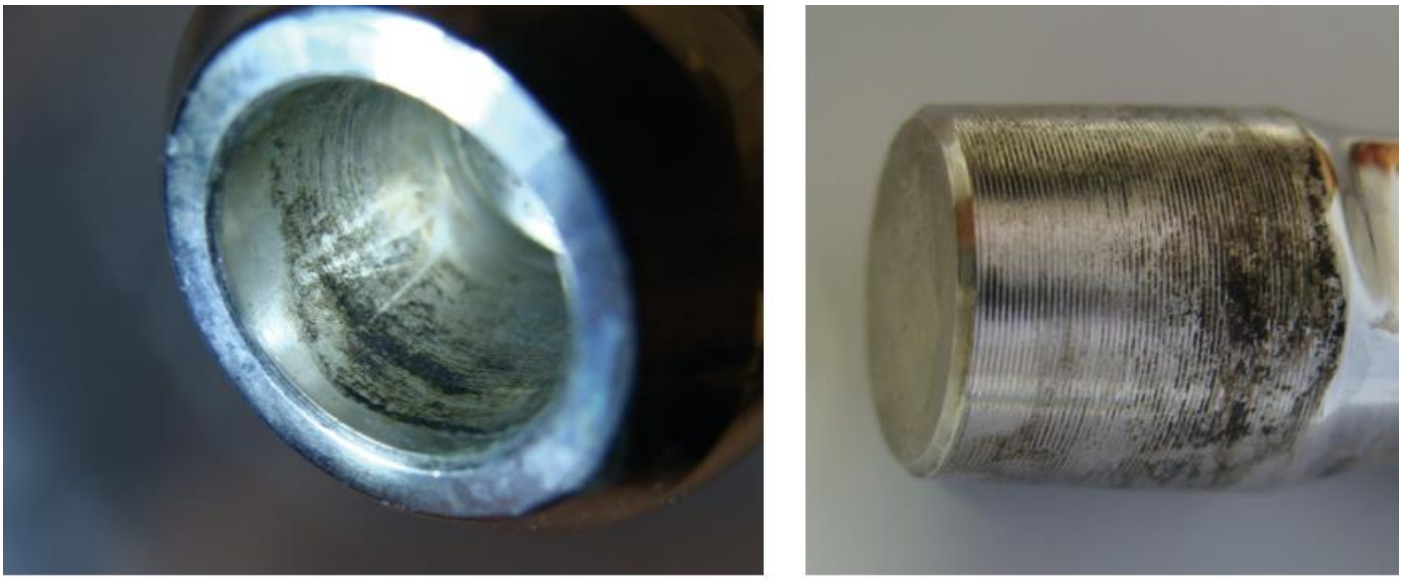


Figure 6.2.13 :- ***Illustrative image of the Fretting Corrosion led Implant damage activity involving the CoCr Femoral Head bore, indicated by 'a', while, a Trunionosis of the Titanium Alloy Femoral Stem from a failed Hip Prosthesis Unit, indicated by 'b'.***

Image Source: - Hussenbocus, S.M., Kosuge, D.D., Solomon, L.B., Howie, D.W., & Oskouei, R.H. (2015). Head-Neck Taper Corrosion in Hip Arthroplasty. *BioMed Research International, 2015*.



Figure 6.2.14 :- ***Illustrative image of Highlighting a Closer Look upon the Trunionosis of a Metallic Femoral Stem, retrieved from a Failed Hip Prosthesis Unit.***

Image Source: - Orthobullets - https://www.orthobullets.com/recon/422821/tha-trunnionosis

- Notwithstanding the fact there were several shortcomings and possible 'suppressions' of intricate data, particularly with the American registry, they recognized such a crucial implant failure activity, that is potentially causing immense trouble to the clinicians handling them and patients having to withstand them, requires a commendable appreciation for their approach.

- The afore-mentioned instances of implant failures which are usually accompanied with an elevated B[Co] level, indicating a metallosis event, is therefore self-explanatory for the gradual and steady decline of the CoCr based MoM bearing utilization for the primary THA of the general American patient cohort. The following tabulation presents the distribution percentages of the femoral head material utilized in an elective primary THA in the US: -

AJRR 2022:- Distribution of Femoral Head Prostheses Material utilized for implanting during the Elective Primary Total Hip Arthroplasty by Year Wise Record of Arthroplasty Procedure of the US Patient Cohort, from the period 2012 - 2021.

SL No.	Year of Arthroplasty Procedure Record	Ceramicized Metal	Cobalt-Chromium [CoCr]	Ceramic	Total
1	2012	38.00%	55.90%	6.10%	100.00%
2	2013	43.80%	51.20%	5.00%	100.00%
3	2014	50.00%	43.90%	6.10%	100.00%
4	2015	54.80%	38.50%	6.80%	100.10%
5	2016	58.40%	34.20%	7.50%	100.10%
6	2017	62.10%	30.10%	7.80%	100.00%
7	2018	69.00%	24.10%	7.00%	100.10%
8	2019	71.70%	19.60%	8.80%	100.10%
9	2020	73.30%	16.90%	9.90%	100.10%
10	2021	76.30%	13.80%	9.90%	100.00%

Table 6.2.11 :- ***Tabulation illustrating the Distribution of Femoral Head Material Utilization Scenarios for the Elective Primary THA of the general American Patient Cohort, during the period of 2012 – 2021.***

- Analysing the data for femoral head material utilization, in accordance to the patient age-group receiving them, it is noted that the senior-most aged group of patients, received the greatest proportion of CoCr based femoral heads, that might be driven due to economic limitations, considering the fact that CoCr implants are usually cheaper than the Ceramic and Titanium based ones, also notwithstanding the fact that these group of people, are not particularly expected to perform high extents of mobility actions and the hip arthroplasty in all probabilities for them, was primarily performed to relieve them from the severe pain arising out of failing hip and alleviate their QoL.

- The following tabulation presents the patient age-group linked distribution of the femoral head material utilization scenarios, for the American patient cohort: -

AJRR 2022:- Distribution of Femoral Head Prostheses Material utilized for implanting during the Elective Primary Total Hip Arthroplasty by Patient Age-Group of the US Patient Cohort, from the period 2012 - 2021.

SL No.	Patient Age-Group	Ceramicized Metal	Cobalt-Chromium [CoCr]	Ceramic	Total
1	Less than 50 Years	11.00%	3.10%	85.90%	100.00%
2	50 - 59 Years	11.20%	5.10%	83.70%	100.00%
3	60 - 69 Years	10.30%	9.90%	79.80%	100.00%
4	70 - 79 Years	9.30%	19.10%	71.60%	100.00%
5	80 - 89 Years	7.60%	30.30%	62.10%	100.00%
6	More than 90 Years	9.30%	33.80%	56.90%	100.00%

Table 6.2.12 :- ***Tabulation illustrating the Patient's Age-Group wise linked Distribution of the Femoral Head Materials of the Hip Prostheses Utilization Scenarios for the Elective Primary THA of the general American Patient Cohort, during the period of 2012 – 2021.***

- Therefore, on similar notes, the once leading femoral-acetabular articulating bearing surface choice of MoP, is steadily declining on the basis of their annual utilization proportions, that is directly attributed to the rise of other comparatively well tolerated and safer bearing surface options of CoP, CMoP (Ceramicised Metal on Poly) and Dual Mobility. The following tabulation presents the overall scenario of the distribution of femoral-acetabular bearing surfaces as per their respective materials utilized for the elective primary THA of the American patient cohort: -

AJRR 2022 :- Distribution of Femoral-Acetabular Bearing Surfaces Utilization as per composing Materials used in the Elective Primary Total Hip Arthroplasty for the US Patient Cohort during the Years of 2012 - 2021.

SL No.	Year of Arthroplasty Procedure Record	CoP	MoP	Dual Mobility	CMoP	Total
1	2012	34.40%	54.30%	5.70%	5.60%	100.00%
2	2013	41.40%	49.10%	4.80%	4.70%	100.00%
3	2014	47.20%	41.60%	5.50%	5.80%	100.10%
4	2015	51.30%	36.90%	5.40%	6.40%	100.00%
5	2016	54.90%	32.20%	5.90%	7%	100.00%
6	2017	57.90%	28.10%	6.60%	7.40%	100.00%
7	2018	63.40%	22.70%	7.50%	6.40%	100.00%
8	2019	65.10%	18.40%	8.40%	8.20%	100.10%
9	2020	64.60%	15.10%	10.40%	9.90%	100.00%
10	2021	62.60%	12.80%	13.40%	11.20%	100.00%

Table 6.2.13 :- ***Tabulation illustrating the Overall Distribution of the Various Femoral-Acetabular Bearing Surfaces, categorized as per their respective Materials utilized for the Elective Primary THA of the American Patient Cohort, during the years of 2012-2021.***

- The utilization scenario of conventional polyethylene-based liners such as UHMWPE and HDPE are completely marginalized and diminished in their utilization for the primary THAs of the general American patient cohort, leaving out only a miniscule portion of procedures wherein a conventional UHMWPE polyethylene acetabular liner is used. Such procedures are reported to be "less than 1.00%" of the entire American arthroplasty registry database.

- The decline of the conventional UHMWPE has met with the rise of other modern polyethylene liners with better abrasive control properties, such as the Highly Cross-linked Polyethylene or HXLPE, and the Anti-Oxidant infused Polyethylene (A-PE). The acetabular liners that are made of HXLPE/A-PE are noted to be on the increased utilization trends compared to the conventional UMHWPE and HDPE options, fuelled by the comparatively better revision rate percentage scenarios in the long-term aspect of HXLPE liners.

- Since 2012, a brief period of A-PE rise is noted, but the rise was not at all a meteoric one, and remained fairly stable at around 12 – 14% utilization numbers, before dropping down to a drastic 4.90% in 2021, directly benefitting HXLPE that peaks in 2021, with an overall utilization proportional percentage of 94.70%.

- The following tabulation presents the overall distribution scenario of the various polyethylene types utilized as the articular surface insert liners, for the elective primary THA of the general American patient cohort: -

AJRR 2022 :- Distribution of Polyethylene Type Usage for Anti-Oxidant Polyethylene vis-à-vis Highly Cross Linked Polyethylene (HXLPE) utilization as Polyethylene Bearing Insert for Articular Surface of the Prostheses, used during Elective Primary Total Hip Arthroplasty of the US Patient Cohort during the Period of 2012 - 2021.					
SL No.	**Year of Arthroplasty Procedure Record**	**Highly CrossLinked Polyethylene [HXLPE]**	**Anti-Oxidant Polyethylene**	**Total**	**Difference**
1	**2012**	**92.50%**	**6.90%**	**99.40%**	**The 0.30 - 0.10% Possibly belongst to HDPE, UHMWPE & Other Forms of Polyethylene Bearing Inserts.**
2	**2013**	**89.90%**	**9.70%**	**99.60%**	
3	**2014**	**89.00%**	**10.70%**	**99.70%**	
4	**2015**	**87.20%**	**12.60%**	**99.80%**	
5	**2016**	**85.60%**	**14%**	**99.60%**	
6	**2017**	**86.30%**	**13.20%**	**99.50%**	
7	**2018**	**86.10%**	**13.50%**	**99.60%**	
8	**2019**	**86.40%**	**13.40%**	**99.80%**	
9	**2020**	**91.90%**	**7.70%**	**99.60%**	
10	**2021**	**94.70%**	**4.90%**	**99.60%**	
No Specific Mentions with Data regarding the Usage of HDPE, UHMWPE as Arthroplasty Prostheses in the US Patient Cohort and their Related Outcomes in the Immediate Short Term vis-à-vis Long Term, Compared to HXLPE & AO infused PE.					
AJRR was the Only Registry probed & evaluated during the Course of this Investigation that Compared & Highlighted the Broad Utilization/Usage Details of HXLPE & AO infused PE for Arthroplasty Implants, wherein the Actual Real Life Difference in Outcome or QoL or in any other Results is very meagre to negligible and is disputed across multiple Other Regions of the World. In short the descriptions are very "Corporate Friendly" /"Supporter-Friendly", rather than being Patient or Clinico-Mechanical Oriented					

Table 6.2.14 :- ***Tabulation illustrating the Overall Distribution of the Various Polyethylene Types Utilized as the Polyethylene Bearing Insert for the Femoral-Acetabular articulation, used in the Elective Primary THA of the American Patient Cohort during the period of 2012 – 2021.***

Fixation Method Utilization and Related Outcomes Scenarios for the Primary THA of the American Patients: -

- On the aspect of the respective fixation method followed, cementless fixation of the hip prostheses is the most commonly adopted practice in the United States.

- The overall ratio of cemented vis-à-vis non-cemented fixation is such that the latter fixation method dramatically outweighs the cemented elective THA fixation procedures that are performed on the general American patient cohort between the years of 2012 – 2021, with only '2.70%' of them being a cemented one on an average basis, while the remaining fixations were non-cemented fixated.

- With increasing patient age-group, the relative proportion of cemented fixations compared vis-à-vis to that of the non-cemented fixations increases, with the biggest proportion of cemented fixations being performed on the most senior age group of the patient cohort, i.e., on those aged 90 years or more, may be due to their naturally weakened bone quality and strength.

- The overall age-group wise categorized distribution of the Cemented vis-à-vis Non-Cemented procedures are presented through the following tabulation: -

AJRR 2022 :- Cemented & Cementless Femoral Stem Fixation Distribution of the US Patient Cohort, in Elective Primary Total Hip Arthroplasty Procedures by Age Group of Patients.				
SL No.	**Patient Age-Group**	**Cementless**	**Cemented**	**Total**
1	**Less than 50 Years**	**99.30%**	**0.70%**	**100.00%**
2	**50 - 59 Years**	**99.10%**	**0.90%**	**100.00%**
3	**60 - 69 Years**	**98.10%**	**1.90%**	**100.00%**
4	**70 - 79 Years**	**94.00%**	**6.00%**	**100.00%**
5	**80 - 89 Years**	**83.40%**	**16.60%**	**100.00%**
6	**More than 90 Years**	**69.20%**	**30.80%**	**100.00%**

Table 6.2.15 :- ***Tabulation illustrating the Overall Distribution of the Cemented vis-à-vis Non-Cemented based Distribution of the Fixation Methodology, used in the Elective Primary THA of the American Patient Cohort during the period of 2012 – 2021.***

- Based on the overall hip arthroplasty data availed for the evaluation and analyses purposes of this research it is noted that the "Summit" femoral stem by DePuy Synthes, was the femoral stem with the greatest number of respective implantations, followed by a close second of "Accolade C" femoral stem by Stryker.

- While, the "Summit" is presently rated 15A / 7A by the ODEP, the "Accolade C" is unrated by the ODEP.

- However, fixation methodology-based prostheses combinations could not be obtained for the cemented fixations, that were utilized for the general American patient cohort, albeit no rationale reasons for the suppression of cemented prostheses data could be inferred by this research.

- The overall cumulative revision rate percentage of the cemented femoral stems utilized for the primary THA of the general American patient cohort is presented through the following tabulation: -

AJRR 2022 :- Cumulative Revision Percent of Cemented Femoral Stems utilized for Primary Hip Arthroplasty of the Patient Cohort of the USA aged >= 65 Years with Primary OA, between 2012 - 2020.

SL No.	Femoral Stem	Manufacturer / Supplier of the Prosthesis	ODEP Rating	No. of Reported Cases	No. of Revised Cases	Time Since Primary Hip Arthroplasty			
						1 Year	3 Years	5 Years	7 Years
1	Summit	Depuy Synthes	15A / 7A	2,024	33	0.97(0.61 - 1.49)	1.57(1.07 - 2.25)	2.32(1.51 - 3.42)	2.57(1.66 - 3.79)
2	Accolade C	Stryker	Unrated	1,721	20	0.74(0.4 - 1.26)	1.23(0.75 - 1.91)	1.71(0.96 - 2.83)	1.71(0.96 - 2.83)
3	Exeter	Stryker	15A*	1,319	18	0.93(0.51 - 1.58)	1.36(0.8 - 2.16)	1.73(1.03 - 2.74)	1.73(1.03 - 2.74)
4	VerSys Advocate	Zimmer Biomet	Unrated	1,312	19	0.93(0.51 - 1.58)	1.39(0.84 - 2.18)	1.63(1.01 - 2.5)	1.63(1.01 - 2.5)
5	Avenir		7A / Pre-Entry A*	1,311	10	0.56(0.25 - 1.12)	1.06(0.52 - 1.97)	1.06 (0.52 - 1.97)	
6	VerSys		15A* / 15A	1,277	24	1.37(0.83 - 2.14)	1.57(0.98 - 2.39)	2.50(1.57 - 3.77)	2.5(1.57 - 3.77)
7	Synergy	Smith & Nephew	15A*	1,194	18	1.18(0.67 - 1.97)	1.62(0.98 - 2.53)	1.84(1.11 - 2.89)	1.84(1.11 - 2.89)
8	Omnifit	Stryker	Unrated	918	12	0.79(0.35 - 1.56)	1.09(0.54 - 2.01)	1.65(0.89 - 2.84)	1.65(0.89 - 2.84)
9	C-Stem	Depuy Synthes		649	5	0.83(0.32 - 1.84)	0.83(0.32 - 1.84)	2.62(1.29 - 4.74)	
10	Spectron	Smith & Nephew		541	11	1.51(0.71 - 2.85)	2.04(1.04 - 3.63)	1.57(0.33 - 4.93)	1.57(0.33 - 4.93)
11	Echo FX	Zimmer Biomet		406	3	0.25(0.02 - 1.33)	0.59(0.12 - 1.99)	1.82(1.54 - 2.14)	1.86(1.57 - 2.19)
Cumulative Total				12,672	173				

Table 6.2.16 :- ***Tabulation illustrating the Cumulative Revision Rate percentage of the Most Commonly Deployed Femoral Stem, that is fixated Cement during the Elective Primary THA of the American Patient Cohort during the period of 2012 – 2021, along with their respective ODEP Rating Statuses and Manufacturer/Supplier firm details.***

- The overall cumulative revision rate percentage of the cementless hip prostheses combinations utilized for the primary THA of the general American patient cohort is presented through the following tabulation: -

AJRR 2022 :- Cumulative Revision Percent of Cementless Prostheses Combinations utilized for Primary THA of the American Patient Cohort of the USA aged >= 65 Years with Primary Indication of a Progressively Worsening Osteoarthritis, between 2012 - 2020.

SL No.	Acctabular Shell	Femoral Stem	Manufacturer / Supplier of the Prosthesis	ODEP Rating	No. of Reported Cases	No. of Revised Cases	Time Since Primary Hip Arthroplasty			
							1 Year	3 Years	5 Years	7 Years
1	Trident	Accolade II	Stryker	15A*/7A[Trident] ; 10A[Accolade II]	37,367	787	1.47(1.35 - 1.59)	2.05(1.9 - 2.2)	2.32(2.16 - 2.5)	2.43(2.25 - 2.62)
2	Pinnacle	Corail	Depuy Synthes	15A*/10A*[Pinnacle] ; 15A*/10A[Corail]	35,617	363	0.71(0.63 - 0.8)	1.01(0.91 - 1.12)	1.16(1.04 - 1.29)	1.21(1.08 - 1.35)
3		Summit		15A*/10A*[Pinnacle] ; 15A/7A[Summit]	25,350	365	1.17(1.04 - 1.31)	1.43(1.28 - 1.59)	1.58(1.42 - 1.76)	1.71(1.5 - 1.94)
4		Actis Duofix		3B [Actis Total Hip System/Actis Duofix]	17,265	76	0.45(0.35 - 0.56)	0.52(0.41 - 0.65)		
5		Tri-Lock		10A*[Tri-Lock]	16,653	224	0.95(0.81 - 1.1)	1.30(1.13 - 1.49)	1.54(1.34 - 1.76)	1.72(1.43 - 2.05)
6	Trident II	Accolade II	Stryker	Pre-Entry A* / 3A*[Trident II] ; 10A[Accolade II]	15,182	107	0.75(0.62 - 0.91)	0.81(0.66 - 0.99)		
7	R3	Anthology	Smith & Nephew	13A* [Both R3 & Anthology]	12,655	203	1.34(1.15 - 1.56)	1.65(1.43 - 1.89)	1.77(1.53 - 2.03)	1.87(1.6 - 2.19)
8	Continuum	M/L Taper	Zimmer Biomet	13A[Continuum] ; 15A*[M/L Taper]	11,618	280	1.77(1.54 - 2.03)	2.30(2.03 - 2.6)	2.70(2.39 - 3.04)	2.79(2.46 - 3.14)
9	G7	Taperloc 133		15A[Taperloc Hip System/133]	11,080	140	1.12(0.93 - 1.33)	1.39(1.17 - 1.65)	1.5(1.23 - 1.81)	1.50(1.23 - 1.81)
10		Taperloc 133 Microplasty		7A[G7] ; 10A[Taperloc Microplasty]	6,798	98	1.30(1.04 - 1.59)(	1.51(1.24 - 1.84)	1.56(1.27 - 1.9)	1.56(1.27 - 1.9)
11	R3	Synergy	Smith & Nephew	13A*[R3] ; 15A*[Synergy]	6,437	145	1.92(1.61 - 2.29)	2.33(1.97 - 2.73)	2.5(2.11 - 2.95)	2.5(2.11 - 2.95)
12	R3	PolarStem		13A*[R3] ; 10A*/5A[PolarStem]	5,565	51	0.84(0.61 - 1.12)	1.10(0.82 - 1.45)	1.10(0.82 - 1.45)	1.10(0.82 - 1.45)
13	Trilogy	M/L Taper	Zimmer Biomet	15A*[Both Trilogy & M/L Taper]	4,365	102	1.42(1.1 - 1.8)	2.03(1.63 - 2.5)	2.49(2.02 - 3.04)	3.11(2.43 - 3.92)
14	Pinnacle	S-ROM	Depuy Synthes	15A*/10A*[Pinnacle] ; 15A[S-ROM]	3,746	79	1.24(0.92 - 1.64)	2.07(1.62 - 2.6)	2.39(1.87 - 3.01)	3.48(2.45 - 4.78)
15	Trident	Secur-Fit Max	Stryker ; Depuy Synthes	15A*/7A[Trident] ; Unrated[Secur-Fit Max]	3,304	79	1.40(1.04 - 1.85)	2.19(1.73 - 2.75)	2.43(1.92 - 3.02)	2.81(2.16 - 3.59)
16	Trident	Accolade TMZF	Stryker	15A*/7A[Trident] ; Unrated[Accolade TMZF]	2,954	66	1.22(0.87 - 1.67)	1.56(1.16 - 2.06)	2.07(1.59 - 2.65)	2.43(1.88 - 3.09)
17	G7	Echo Bi-Metric	Zimmer Biomet	7A[G7] ; 7A*[Echo Bi-Metric]	2,809	29	0.79(0.51 - 1.18)	1.10(0.75 - 1.58)	1.20(0.81 - 1.72)	1.2(0.81 - 1.72)
18	Continuum	Trabecular Metal		13A[Continuum] ; 15A*[Trabecular Metal]	2,773	63	1.85(1.39 - 2.4)	2.26(1.74 - 2.87)	2.42(1.87 - 3.09)	2.42(1.87 - 3.09)
19	FMP	Linear	DJO Surgical /Global	Unrated[Both FMP & Linear]	2,431	24	0.83(0.53 - 1.26)	0.99(0.64 - 1.46)	1.18(0.72 - 1.85)	1.18(0.72 - 1.85)
20	Trident	Secur-Fit	Stryker ; Depuy Synthes	15A*/7A[Trident] ; Unrated[Secur-Fit]	2,380	71	1.94(1.44 - 2.56)	2.82(2.2 - 3.57)	3.28(2.58 - 4.1)	3.28(2.58 - 4.1)
21	R3	Synergy HA	Smith & Nephew	13A*[R3] ; Unrated[Synergy HA]	2,212	50	1.65(1.17 - 2.25)	2.10(1.55 - 2.78)	2.44(1.82 - 3.22)	2.68(1.94 - 3.6)
22	Trident	Secur-Fit Plus Max	Stryker ; Depuy Synthes	15A*/7A[Trident] ; Unrated[Secur-Fit Plus Max]	1,956	39	1.43(0.98 - 2.04)	1.94(1.39 - 2.64)	1.94(1.39 - 2.64)	2.68(1.94 - 3.6)
23	G7	M/L Taper	Zimmer Biomet	7A[G7] ; 15A*[M/L Taper]	1,730	22	1.23(0.77 - 1.86)	1.41(0.91 - 2.11)	1.41(0.91 - 2.11)	
24	Trabecular Metal			15A*[Trabecular Metal] ; 15A*[M/L Taper]	1,628	41	1.91(1.33 - 2.67)	2.32(1.66 - 3.15)	2.51(1.78 - 3.44)	3.96(2.35 - 6.19)
25	Mallory Head	Taperloc 133		ODEP Rating Withdrawn[Mallory Head] / 15A[Taperloc 133]	1,541	17	0.86(0.48 - 1.44)	1.10(0.66 - 1.75)	1.22(0.74 - 1.93)	1.22(0.74 - 1.93)
26	G7	Avenir-Muller		7A[G7] ; 10A*[Avenir-Muller]	1,438	14	0.78(0.42 - 1.36)	0.99(0.55 - 1.66)		
27	Continuum			13A[Continuum] ; 15A*/15A[VerSys]	1,392	32	1.94(1.31 - 2.78)	2.36(1.65 - 3.28)	2.36(1.65 - 3.28)	2.36(1.65 - 3.28)
28		VerSys		15A*[Trilogy] ; 15A*/15A[VerSys]	1,290	25	1.11(0.64 - 1.82)	1.96(1.27 - 2.88)	2.22(1.47 - 3.23)	2.22(1.47 - 3.23)
29	Trilogy				1,287	28	1.33(0.81 - 2.09)	1.78(1.15 - 2.65)	2.47(1.67 - 3.52)	2.47(1.67 - 3.52)
30	Continuum	Fitmore		13A[Continuum] ; 15A*/10A*[Fitmore]	1,282	37	2.27(1.56 - 3.2)	2.68(1.89 - 3.68)	2.95(2.09 - 4.03)	3.21(2.25 - 4.43)
31	FMP	TaperFill	DJO Surgical /Global	Unrated[Both FMP &TaperFill]	1,244	16	0.97(0.54 - 1.66)	1.42(0.84 - 2.26)	1.42(0.84 - 2.26)	
32	Trident	Citation	Stryker	15A*/7A[Trident] ; Citation Femoral Stem Device Recalled by USFDA didn't met Material Specifications for Tensile Bond Strength & Crystallinity.	1,175	45	2.64(1.84 - 3.68)	3.36(2.43 - 4.51)	3.57(2.6 - 4.76)	4.17(3.02 - 5.59)
33	Continuum	Accolade II	Zimmer Biomet	13A[Continuum] ; 10A[Accolade II]	1,101	20	1.78(1.11 - 2.72)	1.90(0.77 - 2.2)	1.90(1.2 - 2.87)	1.90(1.2 - 2.87)
34		Taperloc 133		13A[Continuum] ; 15A[Taperloc 133]	1,086	16	1.03(0.55 - 1.78)	1.34(0.77 - 2.2)	1.76(1.01 - 2.87)	
35	Trident II	Corail	Stryker ; Depuy Synthes	Pre-Entry A* / 3A*[Trident II] ; 15A*/10A[Corail]	1,005	6	0.63(0.26 - 1.31)			
36	Trident	ABG II	Stryker	15A*/7A[Trident] ; ODEP Rating Withdrawn[ABG II]	941	23	2.35(1.52 - 3.47)	2.35(1.52 - 3.47)	2.52(1.64 - 3.7)	2.52(1.64 - 3.7)
37	Novation	Alteon	Exactech	ODEP Rating Withdrawn[Novation] ; Unrated [Alteon]	919	19	1.64(0.96 - 2.64)	2.22(1.38 - 3.4)	2.22(1.38 - 3.4)	
38	Restoration ADM	Accolade II	Stryker	Unrated[Restoration ADM] ; 10A[Accolade II]	871	10	0.94(0.45 - 1.79)	1.24(0.64 - 2.22)	1.24(0.64 - 2.22)	1.24(0.64 - 2.22)
39	Trinity	TriFit TS	Corin Group	10A*[Trinity] ; 7A[TriFit TS]	834	16	1.41(0.75 - 2.44)	2.42(1.41 - 3.87)	2.42(1.41 - 3.87)	2.42(1.41 - 3.87)
40	G7	Corail	Zimmer Biomet ; Depuy Synthes	7A[G7] ; 15A*/10A[Corail]	796	7	0.76(0.32 - 1.58)	0.76(0.32 - 1.58)	1.21(0.45 - 2.69)	
41	RingLoc+	Taperloc 133	Zimmer Biomet	Unrated[RingLoc+] ; 15A[Taperloc HipSystem/Taperloc133]	755	20	1.59(0.87 - 2.69)	2.44(1.5 - 3.74)	2.61(1.63 - 3.98)	2.61(1.63 - 3.98)
42	R3	Corail	Smith & Nephew ; Depuy Synthes	13A*[R3] ; 15A*/10A[Corail]	706	3	0.28(0.06 - 0.97)	0.43(0.12 - 1.18)	0.43(0.12 - 1.18)	
43		Echelon	Smith & Nephew	13A*[R3] ; Unrated[Echelon - Found to be in use in Venezuela/Hispanic Population of US]	695	17	1.31(0.65 - 2.4)	2.25(1.28 - 3.68)	3.50(1.91-5.86)	3.50(1.91-5.86)
44	Escalade Acctabular System	Ovation Hip Stem	Ortho Development Corporation	Unrated[Both Escalade & Ovation]	688	8	1.02(0.46 - 2.02)	1.18(0.56 - 2.24)	1.18(0.56 - 2.24)	1.18(0.56 - 2.24)
45	Continuum	M/L Taper Kinectiv	Zimmer Biomet	13A[Continuum] ; 10A*[M/L Taper Kinectiv]	672	18	1.80(0.98 - 3.04)	2.48(1.48 - 3.91)	2.72(1.64 - 4.24)	3.12(1.86 - 4.89)
46	Versafit Cup DM	AMIStem-II	Medacta International	Unrated[VersafitCup DM] ; 10A[AMIStem-II]	670	13	1.64(0.87 - 2.84)	1.94(1.09 - 3.21)	1.94(1.09 - 3.21)	1.94(1.09 - 3.21)
47	Pinnacle	AML	Depuy Synthes	15A*/10A*[Pinnacle] ; Unrated[AML]	668	15	0.91(0.38 - 1.89)	2.05(1.15 - 3.39)	2.43(1.42 - 3.89)	2.43(1.42 - 3.89)
48	Trident II	Secur-Fit	Stryker ; Depuy Synthes	Pre-Entry A* / 3A*[Trident II] ; Unrated[Secur-Fit]	600	10	1.77(0.91 - 3.13)	1.77(0.91 - 3.13)		
49	Restoration ADM	Novation	Stryker	Unrated[Restoration ADM] ; Unrated[Novation]	589	5	0.68(0.23 - 1.65)	0.68(0.23 - 1.65)	0.86(0.33 - 1.91)	0.86(0.33 - 1.91)
50	Trabecular Metal	Trabecular Metal	Zimmer Biomet	15A*[Trabecular Metal]	582	12	1.58(0.78 - 2.88)	2.02(1.07 - 3.5)	2.3(1.25 - 3.9)	2.3(1.25 - 3.9)
51		VerSys		15A*[Trabecular Metal] ; 15A*/15A[VerSys]	579	11	1.56(0.77 - 2.84)	1.92(1.02 - 3.31)	1.92(1.02 - 3.31)	1.92(1.02 - 3.31)
52	Regenerex RingLoc+	Taperloc 133		Unrated[RingLoc+] ; 15A[Taperloc HipSystem/Taperloc133]	569	15	2.33(1.3 - 3.84)	2.56(1.47 - 4.16)	2.98(1.7 - 4.85)	2.98(1.7 - 4.85)
53	Consensus	TaperSet	Shalby Advanced Technology Inc.[formerly Consensus Orthopedics]	Unrated[Both Consensus & Taperset]	528	12	1.52(0.72 - 2.86)	2.49(1.35 - 4.2)	2.49(1.35 - 4.2)	2.49(1.35 - 4.2)
54	Dynasty BioFoam	ProFemur Gladiator	MicroPort Orthopedics	Unrated[Dynasty Biofoam] ; 7A[ProFemur Gladiator]	517	11	1.77(0.72 - 2.86)	2.07(1.05 - 3.67)	2.59(1.3 - 4.63)	2.59(1.3 - 4.63)

55	Provident	Provident	Globus Medical	Unrated	512	10	1.57(0.74 - 2.97)	1.79(0.88 - 3.25)	2.11(1.07 - 3.75)	2.11(1.07 - 3.75)
56	Mpact	MasterLoc	MatOrtho	7A*[Mpact] ; Pre-Entry A*	509	7	1.39(0.62 - 2.73)	1.39(0.62 - 2.73)		
57	G7	Fitmore	Zimmer Biomet	7A[G7] ; 15A*/10A*[Fitmore]	508	5	1.10(0.42 - 2.44)	1.10(0.42 - 2.44)	1.10(0.42 - 2.44)	
58	Restoration ADM	Secur-Fit Plus Max	Stryker ; Depuy Synthes	Unrated[Both Restoration ADM & Secur-Fit Plus Max]	505	22	2.97(1.74 - 4.73)	4.37(2.82 - 6.42)	4.37(2.82 - 6.42)	
59	Trident II	Secur-Fit Max		Pre-Entry A* / 3A*[Trident II] ; Unrated[Secur-Fit Max]	474	7	1.31(0.55 - 2.71)			
60		Actis Duofix		Pre-Entry A* / 3A*[Trident II] ; 3B [Actis Total IIip System/Actis Duofix]	428	1	0.24(0.02 - 1.26)	0.24(0.02-1.26)		
61	Continuum	Taperloc 133 Microplasty	Zimmer Biomet	13A[Continuum] ; 10A[Taperloc Microplasty]	425	5	0.98(0.33 - 2.37)	1.27(0.48 - 2.81)	1.27(0.48 - 2.81)	
62	Dynasty BioFoam	ProFemur Z	MicroPort Orthopedics	Unrated[Dynasty Biofoam] ; 10A[Profoam Z]	419	27	4.31(2.65 - 6.57)	6.02(4.01 - 8.6)	6.65(4.49 - 9.38)	6.65(4.49 - 9.38)
63	G7	Trabecular Metal	Zimmer Biomet	7A[G7] ; 15A*[Trabecular Metal]	405	4	0.77(0.22 - 2.11)	1.47(0.42 - 3.87)	1.47(0.42 - 3.87)	
64	RingLoc+	Echo Bi-Metric		Unrated[RingLoc+] ; 7A*[Echo Bi-Metric]	402	9	1.99(0.94 - 3.74)	1.99(0.94 - 3.74)	2.26(1.11 - 4.09)	2.26(1.11 - 4.09)
TOTAL CEMENTLESS REVISION PERCENT CASES					2,66,295	4,112				

Table 6.2.17 :- ***Tabulation illustrating the Cumulative Revision Rate percentage of the Most Commonly Deployed Femoral Stem, that is Non-Cemented during the Elective Primary THA of the American Patient Cohort during the period of 2012 – 2021, along with their respective ODEP Rating Statuses and Manufacturer/Supplier firm details.***

Revision Hip Arthroplasty Practices in the US and Patient Related Outcomes of the American Patient Cohorts: -

- Post-Operative Infection and Inflammatory Reaction is cited in greatest proportion numbers of revision hip arthroplasties of the general American patient cohort. An incidence of a post-op infection and inflammatory reaction was reported as the primary indication or reason to undergo a revision hip surgery for 21.20% of all the revision hip arthroplasties recorded between 2012 – 2021.

- While post-operative instability related complications were attributed to be the second-most commonly reported reason for a revision hip arthroplasty of the American patient cohort, which was 18.00% of all the revision hip arthroplasties recorded between 2012 – 2021.

- The overall scenario of the various reasons cited for the revision hip arthroplasties performed on the American patient cohort is presented through the following tabulation: -

AJRR 2022 :- Distribution of Primary Indications for Revision Hip Arthroplasty of the US Patient Cohort, between the period of 2012 - 2021.		
SL No.	*Primary Indications for Revision Arthroplasty*	*% of Overall*
1	Infection & Inflammatory Reaction	21.20%
2	Instability Related Complications	18%
3	Aseptic Loosening	16.30%
4	Mechanical Complications	13.80%
5	Peri-Prosthetic Fracture	10.30%
6	Other Complications	9.30%
7	Implant Wear or Osteolysis	7.50%
8	Pain	3.10%
9	Hematoma or Wound Complication	0.20%
TOTAL		100.00%

Table 6.2.18 :- ***Tabulation illustrating the Overall Distribution of the Most Commonly attributed Reasons or Primary Indications for the Revision Hip Arthroplasty of the American Patient Cohort, during the period of 2012 – 2021.***

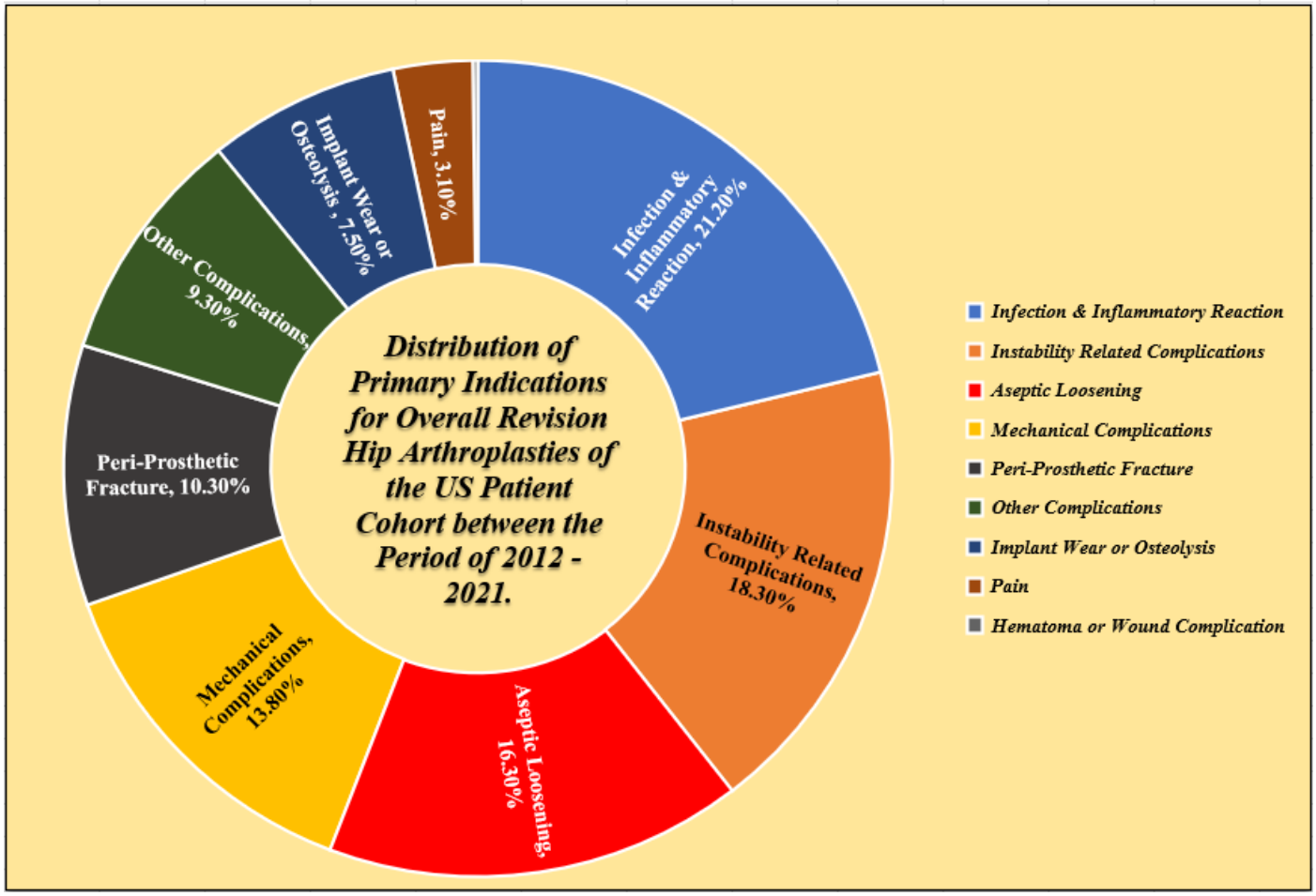


Figure 6.2.15 :- ***A Pie-Chart Plot illustrating the Distribution of the Major Primary Indications for Overall Revision Hip Arthroplasties of the American Patient Cohort, during the period of 2012 – 2021.***

- Regarding the type of hip prostheses utilized during the revision hip arthroplasty procedures of the American patient cohort, it is noted that conventional standard bearing based hip prostheses are utilized in the maximal proportions, compared to DM and constrained forms of hips. The primary inference from this phenomenon that this research obtained is that, unless there's a scenario, wherein there is a patient-specific requirement or the primary failure has further complicated the hip joint, standard bearing hip prostheses, as per the degree of bearing mobility are the general preference of the American arthroplasty surgeons.

- While, for the revision hip procedures, HXLPE based polyethylene liners for the femoral-acetabular articular bearing surface, are the most commonly utilized, maybe to keep further liner abrasion wear-based revision risks at bay. However, in the recent years, a slight decline in the HXLPE and A-PE liner utilization proportions are noted, which maybe fulfilled by the conventional UHMWPE/HDPE based liner surfaces, but the exact reasons behind this phenomenon was neither revealed by the registry nor was it plausible for this research to excavate.

- The only rational theory that this theory could possibly infer is the involvement of economic liabilities associated with a revision hip arthroplasty, and the general trauma of the common class of patients in America, with an expensive healthcare system.

- The overall scenarios pertaining to the Polyethylene material usage and the Hip Prostheses Bearing mobility utilization scenarios are presented through the following two tabulations: -

AJRR 2022 :- Distribution of Hip Prostheses Bearing Type as per Degree of Mobility used in Revision Hip Arthroplasty of the US Patient Cohort, used during the Period of 2012 - 2021.					
SL No.	**Year of Record**	**Standard Bearing Hip**	**Dual Mobility(DM) Hip**	**Constrained Hip**	**Total**
1	2012	55.80%	17.30%	26.90%	100.00%
2	2013	55%	15.80%	29.30%	100%
3	2014	54.20%	17%	28.80%	100.00%
4	2015	53.90%	19.50%	26.60%	100.00%
5	2016	52.30%	21.00%	26.70%	100.00%
6	2017	49.10%	22.90%	28%	100.00%
7	2018	49.70%	26.50%	23.90%	100.10%
8	2019	48.30%	28.70%	23%	100.00%
9	2020	47.30%	31.60%	21.20%	100.10%
10	2021	55.20%	25.90%	18.90%	100.00%

Table 6.2.19 :- ***Tabulation illustrating the Overall Distribution of the Most Commonly attributed Reasons or Primary Indications for the Revision Hip Arthroplasty of the American Patient Cohort, during the period of 2012 – 2021.***

Distribution of Polyethylene Articular Bearing Surface utilization proportions, categorized as per their respective Material of Origin, implanted during the Revision Hip Arthroplasty of the American Patient Cohort, during the period of 2012 - 2021.					
SL No.	**Year of Record**	**Utilization Distribution Share in TKA of the US Patient Cohort**			
		HXLPE[Highly Cross-Linked Polyethylene]	**Anti-Oxidant Polyethylene**	**Total**	**The Remaining % of Overall might Comprise of Conventional Polyethylene(HDPE, UHMWPE) or Anyother Types of Polyethyelene Bearing Inserts for Articular Surface of the Hip Prostheses, which is not Reported by the Registry for Reasons Best Known to Them.**
1	2012	94.60%	3.10%	97.70%	
2	2013	88.90%	8.90%	97.80%	
3	2014	87.40%	10.30%	97.70%	
4	2015	87.00%	10.70%	97.70%	
5	2016	85.60%	10.50%	96.10%	
6	2017	85.80%	10.50%	96.30%	
7	2018	84.90%	12.00%	96.90%	
8	2019	84.00%	12.60%	96.60%	
9	2020	86.90%	9.80%	96.70%	
10	2021	87.00%	8.50%	95.50%	

Table 6.2.20 :- ***Tabulation illustrating the Overall Distribution of the Most Commonly attributed Reasons or Primary Indications for the Revision Hip Arthroplasty of the American Patient Cohort, during the period of 2012 – 2021.***

<u>Patient Reported Outcome Measures (PROMs) Scenarios for the Hip Arthroplasties performed on the American Patient Cohort: -</u>

- Unlike the PROMs related practices in the other nations evaluated and discussed within this thesis, there are no standardized protocol or norm in place for the capturing of the patient reported outcome measures, or the patient's self-reflected opinions about their arthroplasty procedure, respective implant performance and their overall post-operative life.

- This phenomenon was glaringly noticed by this research during the primary probe and evaluation of the American arthroplasty practices, wherein multiple PROMs scales were being seen in active circulation and practices, which are also quoted in multiple scientific literature as well.

- Albeit, there are no written binding rule, to stay limited within a couple of PROMs tools, but generally the arthroplasty monitoring body, which is generally the registry authority in collaboration with

multiple other health regulatory agencies, pushes for the utilization of a standardized formulae of collecting patient responses on their undergone procedure, implant performance and overall life post-operatively. The 'push' is generally done through the merger of the PROMs component to the usual MDS dataset, for arthroplasty procedure reporting, so as to ensure an adequate level of PROMs capturing from the patient cohort.

- However, since the general practice of the American registry is to technically purchase data, through their "payment model system", it is understandable that it is purely under their discretion to 'buy' the specific data as a commodity, worthy of their 'payment', based on their liking and disliking, which is thereby amplified through the representation of selective and in some cases incomplete data with regards to arthroplasty numbers and related outcome scenarios, camouflaging the shortcomings or intentional suppressions, by bombarding with a variety of irrelevant data such as patient discharge, treatment environment data, to anyone outside of their circles, evaluating their scheme of operations and the general practice scenario in the USA.

- Therefore, detailed data pertaining only to the following PROMs components were available to be retrieved from official registry database sources: -

    - HOOS JR. [Hip Disability & Osteoarthritis Outcome Score].
    - PROMIS-10 [Patient Reported Outcomes Measurement Information System 10].
    - VR-12 [The Veterans RAND 12 Item Health Survey].

- The above-mentioned PROMs parameters on its basic rational does the same thing, that an Oxford score does, but on a functional basis, these are quite different than the other PROMs parameters that have been discussed about in great lengths across this thesis.

- The PROMIS-10 parameter comprises of a dual scoring paradigm that involve both the mental and physical health components of the arthroplasty recipient patients. This was also the case for VR-12 as well.

- Prospective and recipient patients participating in the VR-12 and PROMIS-10 based PROMs mechanism, report not just about their general physical health and functionality pre and post to an arthroplasty procedure, but also, about their respective mental health with regards to the overall trauma and agony undergone throughout their journey of getting their troubled hip and knees replaced.

- This research infers the inclusion of the mental health component with the mainframe of patient reported outcome analyses is definitely a positive and appreciable approach

- Besides the aforementioned metrics of PROMs capturing, other metrics such as the WOMAC and Oxford Hip/Knee Scores are noted in the present active circulation and utilization, though data on these couldn't be availed from verifiable sources.

- A sample PROMs capturing form/sheet of the above-mentioned and discussed metrics of patient reported outcome measures are affixed as below, for ready reference of the captured data-points: -

Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR.)

English version 1.0

Instructions

This survey asks for your view about your hip. This information will help us keep track of how you feel about your hip and how well you are able to do your usual activities.

Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Pain

What amount of hip pain have you experienced the **last week** during the following activities?

1. Going up or down stairs

   None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

2. Walking on an uneven surface

   None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your hip.

3. Rising from sitting

   None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

4. Bending to floor/pick up an object

   None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

5. Lying in bed (turning over, maintaining hip position)

   None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

6. Sitting

   None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

Figure 6.2.16 :- ***Sample HOOS JR. based PROMs Questionnaire form for the General Patient Arthroplasty recipient Patient Cohort.***

PATIENT NAME	DOB

WESTERN ONTARIO AND MCMASTER OSTEOARTHRITIS INDEX (WOMAC)

Please circle the appropriate rating for each item.

RATE YOUR PAIN WHEN...	NONE	SLIGHT	MODERATE	SEVERE	EXTREME	HOSPITAL USE ONLY
Walking	0	1	2	3	4	
Climbing stairs	0	1	2	3	4	
Sleeping at night	0	1	2	3	4	
Resting	0	1	2	3	4	
Standing	0	1	2	3	4	TOTAL

RATE YOUR STIFFNESS IN THE...	NONE	SLIGHT	MODERATE	SEVERE	EXTREME	HOSPITAL USE ONLY
Morning	0	1	2	3	4	
Evening	0	1	2	3	4	TOTAL

RATE YOUR DIFFICULTY WHEN...	NONE	SLIGHT	MODERATE	SEVERE	EXTREME	HOSPITAL USE ONLY
Descending stairs	0	1	2	3	4	
Ascending stairs	0	1	2	3	4	
Rising from sitting	0	1	2	3	4	
Standing	0	1	2	3	4	
Bending to floor	0	1	2	3	4	
Walking on even floor	0	1	2	3	4	
Getting in/out of car	0	1	2	3	4	
Going shopping	0	1	2	3	4	
Putting on socks	0	1	2	3	4	
Rising from bed	0	1	2	3	4	
Taking off socks	0	1	2	3	4	
Lying in bed	0	1	2	3	4	
Getting in/out of bath	0	1	2	3	4	
Sitting	0	1	2	3	4	
Getting on/off toilet	0	1	2	3	4	
Doing light domestic duties (cooking, dusting)	0	1	2	3	4	
Doing heavy domestic duties (moving furniture)	0	1	2	3	4	TOTAL

PATIENT SIGNATURE	DATE

REVIEWED BY PHYSICAL THERAPIST	DATE	WOMAC TOTAL SCORE /96

YAVAPAI REGIONAL MEDICAL CENTER
PHYSICAL REHABILITATION SERVICES

WOMAC OSTEOARTHRITIS INDEX QUESTIONNAIRE

REHABILITATION SERVICES
PT THA/TKA WOMAC QUESTIONNAIRE
MR-1433 (11/15)

Figure 6.2.17 :- ***Sample WOMAC [Western Ontario and McMaster Osteoarthritis Index] based PROMs Questionnaire form for the General Arthroplasty recipient Patient Cohort in the United States of America.***

THE VETERANS RAND 12 ITEM HEALTH SURVEY (VR-12)

Instructions: This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure how to answer a question, please give the best answer you can.

(Circle one number on each line)

1. In general, would you say your health is:

EXCELLENT	VERY GOOD	GOOD	FAIR	POOR
1	2	3	4	5

2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?	YES, LIMITED A LOT	YES, LIMITED A LITTLE	NO, NOT LIMITED AT ALL
a. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	1	2	3
b. Climbing **several** flights of stairs?	1	2	3

3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

	NO, NONE OF THE TIME	YES, A LITTLE OF THE TIME	YES, SOME OF THE TIME	YES, MOST OF THE TIME	YES, ALL OF THE TIME
a. **Accomplished less** than you would like.	1	2	3	4	5
b. Were limited in the **kind** of work or other activities.	1	2	3	4	5

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	NO, NONE OF THE TIME	YES, A LITTLE OF THE TIME	YES, SOME OF THE TIME	YES, MOST OF THE TIME	YES, ALL OF THE TIME
a. **Accomplished less** than you would like.	1	2	3	4	5
b. Didn't do work or other activities as **carefully** as usual.	1	2	3	4	5

Figure 6.2.18 :- ***Sample VR-12 based PROMs Questionnaire form for the General Arthroplasty recipient Patient Cohort in the United States of America. – Exhibit 1A***

5. During the past 4 weeks, how much did **pain** interfere with your normal work (including both work outside the home and house work)?

NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMELY
1	2	3	4	5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

6. How much of the time during the past 4 weeks:

	ALL OF THE TIME	MOST OF THE TIME	A GOOD BIT OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
a. Have you felt **calm and peaceful**?	1	2	3	4	5	6
b. Did you have **a lot of energy**?	1	2	3	4	5	6
c. Have you felt **downhearted and blue**?	1	2	3	4	5	6

Figure 6.2.19 :- ***Sample VR-12 based PROMs Questionnaire form for the General Arthroplasty recipient Patient Cohort in the United States of America. – Exhibit 1B.***

7. During the past 4 weeks, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
1	2	3	4	5

Now, we'd like to ask you some questions about how your health may have changed.

8. Compared to one year ago, how would you rate your **physical health** in general now?

MUCH BETTER	SLIGHTLY BETTER	ABOUT THE SAME	SLIGHTLY WORSE	MUCH WORSE
1	2	3	4	5

9. Compared to one year ago, how would you rate your **emotional problems** (such as feeling anxious, depressed or irritable) **now**?

MUCH BETTER	SLIGHTLY BETTER	ABOUT THE SAME	SLIGHTLY WORSE	MUCH WORSE
1	2	3	4	5

PROMIS Global-10 Score

Patient Name: _____ Patient MRN: _____

Date: _____

Please respond to each question or statement by marking on box per row.

	Excellent	Very Good	Good	Fair	Poor
1. In general, would you say your health is:	☐ +5	☐ +4	☐ +3	☐ +2	☐ +1
2. In general, would you say your quality of life is:	☐ +5	☐ +4	☐ +3	☐ +2	☐ +1
3. In general, how would you rate your physical health?	☐ +5	☐ +4	☐ +3	☐ +2	☐ +1
4. In general, how would you rate your mental health, including your mood and your ability to think?	☐ +5	☐ +4	☐ +3	☐ +2	☐ +1
5. In general, how would you rate your satisfaction with your social activities and relationships?	☐ +5	☐ +4	☐ +3	☐ +2	☐ +1
9r. In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	☐ +5	☐ +4	☐ +3	☐ +2	☐ +1

	Completely	Mostly	Moderately	A little	Not at all
6. To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	☐ +5	☐ +4	☐ +3	☐ +2	☐ +1

	Never	Rarely	Sometimes	Often	Always
10r. How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ +5	☐ +4	☐ +3	☐ +2	☐ +1

	None	Mild	Moderate	Severe	Very Severe
8r. How would you rate your fatigue on average?	☐ +5	☐ +4	☐ +3	☐ +2	☐ +1

	No pain										Worst pain imaginable
7rc. How would you rate your pain on average?	☐ +0	☐ +1	☐ +2	☐ +3	☐ +4	☐ +5	☐ +6	☐ +7	☐ +8	☐ +9	☐ +10

Figure 6.2.20 :- ***Sample PROMIS-10 based PROMs Questionnaire form for the General Arthroplasty recipient Patient Cohort in the United States of America. – Exhibit 1A.***

Figure 6.2.21 :- ***Sample PROMIS-10 based PROMs Questionnaire form for the General Arthroplasty recipient Patient Cohort in the United States of America. – Exhibit 1B.***

Global Physical Health raw score:

1. Recalculate Question 7r

"0: No pain": +5 "1", "2" or "3": +4 "4", "5" or "6": +3

"7", "8" or "9": +2 "10: Worst pain imaginable: +1

Q7rc recorded score: ____ Q7rc recalculated score: ____

2. Sum the responses for questions Q3, Q6, Q7r (recalculated), and Q8r

Q3: ____ + Q6: ____ + Q7r: ____ + Q8r: ____ = ____ points

Global Mental Health raw score:

1. Sum the responses for questions Q3, Q6, Q7r (recalculated), and Q8r

Q2: ____ + Q4: ____ + Q5: ____ + 10r: ____ = ____ points

Global Physical Health T-score and Global Mental Health T-score:

1. Use the below raw sum to T-score tables for physical health and mental health.

Global Physical Health T-score: ____ points

PROMIS Global Physical Health v1.2 Short Form Conversion Table		
Raw Summed Score	T-Score	SE*
4	16.2	4.8
5	19.9	4.7
6	23.5	4.5
7	26.7	4.3
8	29.6	4.2
9	32.4	4.2
10	34.9	4.1
11	37.4	4.1
12	39.8	4.1
13	42.3	4.2
14	44.9	4.3
15	47.7	4.4
16	50.8	4.6
17	54.1	4.7
18	57.7	4.9
19	61.9	5.2
20	67.7	5.9
*SE = Standard Error on T-score metric		

Global Mental Health T-score: ____ points

PROMIS Global Mental Health v1.2 Short Form Conversion Table		
Raw Summed Score	T-Score	SE*
4	21.2	4.6
5	25.1	4.1
6	28.4	3.9
7	31.3	3.7
8	33.8	3.7
9	36.3	3.7
10	38.8	3.6
11	41.1	3.6
12	43.5	3.6
13	45.8	3.6
14	48.3	3.7
15	50.8	3.7
16	53.3	3.7
17	56.0	3.8
18	59.0	3.9
19	62.5	4.2
20	67.6	5.3
*SE = Standard Error on T-score metric		

- The obtained PROMs scenario for the elective THA recipient patient cohort in the US, who participated in the patient reported outcome measuring program, since this is not mandatory, for the metrics of HOOS JR, PROMIS-10 and VR-12 obtained pre-operative vis-à-vis post-operatively within a span of 1 year since the primary hip arthroplasty procedure is presented through the following tabulation: -

AJRR 2022 :- Pre-Operative vis-à-vis Post-Operative PROMs Mean Scores for Elective Primary Hip Arthroplasty By Different PROMs Parameters within 1 Year of Pre-Post Time Interval, of the US Patient Cohort, during 2012 - 2021.						
SL No.	**PROMs Parameter**	**PROMs Component**	**Pre-Op vis-à-vis Post-Op [1 Year]**	**No. of Cases**	**Mean**	**Standard Deviation[S.D]**
1	HOOS JR. [Hip Disability & Osteoarthritis Outcome Score]	Score	Pre-Operative	45,059	47.9	16.5
			Post-Operative	17,422	85.6	15.5
2	PROMIS-10 [Patient Reported Outcomes Measurement Information System 10]	Mental T	Pre-Operative	31,811	48.4	9.7
			Post-Operative	13,138	52.4	8.9
		Physical T	Pre-Operative	31,813	39.3	7.6
			Post-Operative	13,137	49.7	9.1
3	VR-12 [The Veterans RAND 12 Item Health Survey]	Mental Health Component	Pre-Operative	15,088	51.2	12.6
			Post-Operative	5,613	56.1	9.8
		Physical Health Component	Pre-Operative	14,955	30.9	9.7
			Post-Operative	5,621	45.5	10.9
Total Number of Cases Tracked under PROMs Reporting by AJRR				**1,93,657**		

Table 6.2.21 :- ***Tabulation illustrating the Overall Mean Pre-Operative vis-à-vis Post-Operative PROMs Scores for Elective Primary THAs of the American Patient Cohort, within a Year into the Post-Operative Window, reflected for respective procedures performed during 2012 – 2021.***

- The age-linked variance in the overall responses filed by the elective THA recipient patient cohort in the US, and their general statement in terms of a "Meaningful Improvement", in their respective lives, post the replacement of their failing/ailing hips, with an artificial hip prosthesis, is presented through the following tabulation: -

AJRR 2022 :- Age-Wise Change in Pre-Operative and 1 Year Post-Operative PROMs Scores after Elective Primary Hip Arthroplasty for the US Patient Cohort aged 55 Years and Higher, between 2012 - 2021.							
SL No.	**PROMs Parameter**	**PROMs Component**	**Age-Group of Patient (in Years)**	**Patients with Pre-Operative Score**	**Patients with Linked Post-Operative Score**	**% of PROMs coverage/ Compliance by Pre-Op 1 Year Score Patients for Post-Op PROMs Score**	**Patients Describing Having "Meaningful Improvement"**
1	HOOS JR. [Hip Disability & Osteoarthritis Outcome Score]	Score	55 - 64	12,575	2,734	21.70%	91.70%
			65 - 74	16,665	4,295	25.80%	91.50%
			75 - 84	8,585	2,160	25.20%	89.70%
			>85 Years	1,482	323	21.80%	86.70%
2	PROMIS-10 [Patient Reported Outcomes Measurement Information System 10]	Mental T	56 - 64	8,541	1,791	21%	39.60%
			66 - 74	11,937	3,182	26.70%	37.40%
			76 - 84	6,220	1,649	26.50%	32.90%
			>85 Years	1,048	249	23.80%	26.90%
		Physical T	57 - 64	8,542	1,791	21%	76.40%
			67 - 74	11,937	3,179	26.60%	75.20%
			77 - 84	6,223	1,649	26.50%	68.70%
			>85 Years	1,048	249	23.80%	58.60%
TOTAL				**94,803**	**23,251**		

Table 6.2.22 :- ***Tabulation illustrating the Patient Age-Group linked Overall Pre-Operative vis-à-vis Post-Operative participation numbers of the American Elective Primary THA recipient Patient Cohort, and their relative responses for a 'Meaningful Improvement', reflected for respective procedures performed during 2012 – 2021.***

MODULE – VI

"Results & Discussion"

CHAPTER – 3

United Kingdom
Hip and Knee Arthroplasty Practices
and
Patient Related Outcome Scenarios.

United Kingdom's
Hip & Knee Arthroplasty Practices
&
Related Outcome Scenarios.

(Primary Results & Related Observations with Inferences)

- ***Overall British Arthroplasty Numbers at a Glance:***

General Number of United Kingdom Arthroplasty Numbers: -

Total No. of Arthroplasties Recorded [Hip + Knee] = **18,53,452.**
Total No. of Hip Arthroplasties Recorded [Total + Hemi] = **7,13,480** [**1999 – 2021**].
Total No. of Knee Arthroplasties Recorded [TKA + UKA] = **9,02,016** [**1999 – 2021**].
Total No. of Revision Knee Arthroplasties [Hip + Knee] = **1,61,579.**
Total No. of Revision Hip Arthroplasties = **83,206.**
Total No. of Revision Knee Arthroplasties = **78,373.**

Number of United Kingdom Hip & Knee Arthroplasties in 2021: -

Total No. of Hip Arthroplasties = **52,787.**
Total No. of Knee Arthroplasties = **68,466.**

Preface of the British Arthroplasty Practices: -

- United Kingdom is a nation with an immensely rich history of science cultivation, ranging from physics, mathematics to clinical sciences. While clinical sciences involving orthopaedics, coupled with the biomedical principles of biomechanics, biomaterials, implant design and regulation is what this research is primarily interested.

- The primary source of the data regarding arthroplasty practices on patients from UK, is the esteemed 'National Joint Registry' or the NJR. This database is of particular global repute and is revered as one of most complete and intricate databases for historical and current arthroplasty practices, patient specific trends and implant performance behaviours to multifarious conditions and stimuli.

- Besides, other relevant healthcare sources pertaining to operations in the region of UK, such as the MHRA, British Orthopaedic Association (BOA), the NHS were of incredibly useful to this research, not just for minute detailing for patient or implant certification data, but also for enriching the foundations of this research in many integral and intrinsic ways.

- Crucial inputs from prosthesis certification and market surveillance agencies such as the United Kingdom Conformity Assessed (UKCA) portal and 'Beyond Compliance' coupled with ODEP are valuable to ascertain various behind-the-scenes rationales for a multitude of issues ranging from prostheses to individual practices, which are discussed in great detail hereon.

- Interestingly, across the span of 18.75 years of available arthroplasty practice and related outcome data, Metal on Metal (MoM) and Metal on Polymer (MoP) based bearing surfaces, along-with cemented fixation, still dominates the utilization numbers across all the databases in UK. However, in 2021, Ceramic on Polymer (CoP) based bearing surfaces were the most implanted ones with a hybrid fixation method.

- Dual Mobility (DM) hip prostheses continues to increase in utilization numbers across the patient cohort spread through-out the United Kingdom, with 2021 showing the biggest utilization numbers. However, the general 'commentary' by the UK Registry itself for DM hips with a MoPoM bearing are way higher than most cemented and non-cemented unipolar combinations at 5 years post-operatively, except MoM bearings.

- The general inference of this research was to some extent confirmed by the UK Registry – the NJR, wherein it affirmed about a different patient demographic who have been receiving DM prostheses, than the usual demography of arthroplasty recipient patients undergoing THA.

- CoP bearing surfaces outperformed conventional MoP bearing surfaces in all the recognized forms of fixation methods, i.e., cemented, non-cemented and hybrid, for the patient cohort in UK. Some of the improved performance could be attributed to the increased utilizations of HXLPE based articulating surface liners.

- While for the knee arthroplasty-based practices and related outcome scenarios aspects for the UK patient cohort, it was unconstrained cemented fixed bearing total knee replacements which dominated the overall knee arthroplasty numbers in UK, by a staggering 58%, followed by a distant second of posterior stabilized knees at 20%.

- On a comparative aspect, the posterior stabilized knees are found to be gradually dropping in their relative utilization numbers, while unicondylar knees of both fixed & mobile nature are directly benefiting from the former's drop, with a sharp increase since 2013 onwards, accelerated by the COVID. The general rationale behind such phenomenon, inferred by this research is that the tremendous impact of the hospitalization burden due to the pandemic, caused clinicians, hospitals and to some extent aware patients to reconsider their plans of hospital stay, leading to switching from THA to unicondylar or partial knee arthroplasty, which involved comparatively shorter hospital stay and faster recovery window.

General Arthroplasty Monitoring and Regulatory Framework in United Kingdom: -

- On the regulatory legal framework and reporting policy aspect, the thorough and active collaborative action of the NJR along with NHS, MHRA, BESS, BOA, and various other orthopaedic and health monitoring/regulatory agencies, it was possible to them make arthroplasty reporting and implant usage/utilization declaration reported to either of the agency databases, preferably the NJR, to be as 'Mandatorily' compulsory for all public, private and joint-venture institutes performing such clinical activities, involving hip, knee, shoulder, elbow and ankle. Though, the gamut of this research is focused around hip and knee arthroplasties only.

- Such a measure of mandatory reporting and subsequent counter audit to capture any under-reported or carefully suppressed procedures, with or without a favourable result into the database and for the analysis mainframe for the scientific and clinical community, worldwide for relevant and practical research on the same, is severely critical to ensure a fair practice scenario in an ideal scenario condition, and to

promptly identify any rising or small undesirous incidences that are bound to compromise the QoL of the patient community in general, and for devising quicker effective measures to answer them.

- Pro-active measures such as monthly or quarterly audit of all the reported and happening arthroplasty procedures across the member institutions and clinics, and the data reported to other British registries / databases, including some of the patient database management software platforms of certain institutes are regularly conducted, to bring up missed out and suppressed data, into the main frame of analyses and reporting, along-with the updating of individual database strengths, so as to maintain contemporary relevance.

- Such activities have led to the inclusion and identification of several such hip, knee and ankle arthroplasty procedures performed across the UK, besides the rectification of erroneous/mismatched data, thereby improving the data quality and general reliability of the entire mechanism. This is particularly commendable, given all the non-ideal set of practices in existence, to fulfil certain agendas, best kept in darkness, spanning globally, for an uniform and transparent widespread health-consciousness.

- Some of the benefits of auditing arthroplasty data, to identify and reduce the percentage of missed out data are given as follows: -

    - Missing Primary Hip Arthroplasty = 4.30% [2014-2015].

      ↓

      2.86% [2019 – 2020].

    - Missing Primary Knee Arthroplasty = 3.50% [2014 – 2015].

      ↓

      1.94% [2019 – 2020].

    - Missing Revision Knee Arthroplasty = 8.80% [2014 -2015].

      ↓

      4.81% [2019 – 2020].

- Through such repeated audits and back-tracking for missed-out data on hip/knee arthroplasties, the UK health authorities and the registry have managed to bring a sizeably significant portion of missed out or suppressed cases into the main frame. It was for first and only time, during the entire course of this research, wherein a public statement from a registry database was found that acknowledged the tendencies of mal-practices regarding data under-reporting, through a very significantly worded phrase '***systematic co-ordinated agreement***', which has been very crucial in formulating the foundation of analysis the various practices around the world, in a more practical fashion, rather than a textbook idealistic one.

- The phrase is indicated to imply an unholy and undesirous nexus between the implant designers, manufacturer/supplier firms, clinicians, institutes and unfortunately a section of the patients(also the victim class – losing big, for initial compromises made), to keep un-warranted data to be intentionally out-of-bounds from the purview of registry and other healthcare databases, in particular cases to either bias or influence the outcome scenarios pertaining to their beneficiary concerns, thereby completely violating the basic pillars of the operations of a registry database, and further endangering patient welfare and health to an abysmal danger.

- Consistent with other nations as well, for arthroplasty practices based in UK, general revision procedures were uniquely defined as, 'any operation where one or more components are added into, or removed from, or modified, in an existent joint replacement', or 'if a Debridement and Implant Retention (DAIR) with or without modular exchanges are performed'.

- Now, the situation pertaining to DAIR procedures, the scenario is not uniform globally, as for example in Swedish arthroplasty practices, such procedures are not uniquely counted as an individual revision procedure, with further entailing issues.

Hip Arthroplasty Practices & Prostheses Utilization Scenarios with Relative Outcomes on the Patient Cohort in UK.

- Excluding legacy arthroplasty procedures and implant utilizations, and factoring in the contemporarily relevant data on modern arthroplasty practices and commercial/clinical operations of various hip prostheses, there were 13,44,357 primary total hip arthroplasty records accessible for due scrutinization and evaluation of this research, which were performed on UK's patient cohort.

- The above quoted figure of hip arthroplasty data, spans from 1st of April, 2003 to 31st of December, 2021.

- On the aspect of gender specific distribution of primary hip arthroplasty procedures for the patient cohort in UK, the majority recipients were females, having 59.80% of all recorded primary hip procedures, while male patients accounted for remaining 40.20%.

- Maintaining consistency with the global scenario, progressively worsening osteoarthritis, or sometimes cited just as 'osteoarthritis', was the single most majority primary indication, for primary hip arthroplasties in UK. Osteoarthritis was cited among other concern/pressing issues for 12,66,690 individual hip arthroplasties in UK accounting for 91.20% of all recorded primary hip arthroplasty procedures.

- The distribution of the total hip arthroplasty procedures performed on the British patient cohort based on 'osteoarthritis' as either a sole indication or one of the many indications, segregated as per patient gender is given through the following tabulation: -

NJR 2022 :- Impact of Osteoarthritis as a Primary or One of the Major Indication for Primary Hip Arthroplasty of the UK Patient Cohort.							
SL No.	Indication Trends	Male Patients		Female Patients		Overall	
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall
1	Osteoarthritis as the Sole Reason for Primary Hip Arthroplasty	4,83,427	89.50%	7,00,033	87.00%	11,83,460	88.00%
2	Osteoarthritis as One of Many Reasons for Primary Hip Arthroplasty	4,99,720	92.50%	7,26,970	90.40%	12,26,690	91.20%
Category Total		9,83,147	40.79%	14,27,003	59.20%	24,10,150	100.00%

Table 6.2.23 :- ***Tabulation illustrating the Distribution of Osteoarthritis linked Primary Hip Arthroplasty of the British Patient Cohort, segregated as per their respective gender.***

- On the fixation method applied aspect, it was noted for hip arthroplasty it was noted: -
    - Cemented Fixation = Decreasing [Stable since Last few Years].
    - Cementless Fixation = Increasing.
    - Hybrid Fixation = Increasing [Consistent Growth / Increasing].
    - Reverse Hybrid Fix. = Small Increase.
    - Resurfacing Hip = Closing Down.

- Since 2003, a gradual transient change in the overall approach design to primary total arthroplasty of the patient cohort from UK, is noted, wherein a series of changes in multiple aspects were introduced, while some faded away, some of the changes became an integral component of the overall general arthroplasty approach and practices for hip arthroplasty later on, or as of the recent period.

- While in 2003, majority of the implants utilized during a primary THA, were cemented and most of them utilized smaller femoral heads sized around 28mm or less (22.25mm – 26mm). However, the shift was noticed through a gradual shift towards the utilization of larger femoral heads, which were sized atleast 28mm, and most of them being larger than 28mm heads. This change in the selection of femoral head sizes from shorter to comparatively larger sized heads, was accompanied with the gradual shift towards non-cemented and hybrid modes of internal prostheses fixation methods, drifting away from the orthodox conventional cemented approaches.

- The new wave of preferences in terms of femoral head sizes have settled in and firmly established itself as the modern-day standard practice in mainstream arthroplasty practices. Based on prevailing conditions of femoral head utilizations the following are the top three ranked choices in UK: -
    - 32 mm Femoral Heads – 1st
    - 36 mm Femoral Heads – 2nd .
    - 28 mm Femoral Heads – 3rd.

- While CoP bearings rose in relative proportions for their respective number of implants on the general patient cohort, CoC bearings with notably the 36mm femoral head, declined drastically since 2011, which directly benefitted to the rise of 32 mm CoP and Dual Mobility or DM hips.

- When comparing the gender linked distribution of the revision hip arthroplasties in UK, it is noted that the female patients under 55 years of age had a higher comparative revision rate than their equivalently aged male patients, though the general numbers for both the categories are highest amongst all age-groups for the same patient cohort.

- However, this scenario changes abruptly when the patient age-group rises to the senior-most levels, as females ageing 80 or more, had far lesser number of revisions, compared to the males in the same age-group in UK.

- The infamous and much talked about resurfacing hip arthroplasty procedures maintain a steady revision rate that is twice as higher than other alternatives.

General Demography of the Hip Arthroplasty recipient British Patient Cohort: -

- The general demography background of the primary hip arthroplasty recipient patient cohort in the United Kingdom is presented in this segment. The demography for primary hip arthroplasty recipients is primarily segregated and categorized as per their respective patient gender, mean/median age-groups and their respective ASA grade wise categorization.

- The ASA Grade of a patient highlights the general level of co-morbidity status of the respective patient, while ASA Grade 1 highlights the best plausible gradation, indication no underlying or existent diseases of the said patient, while ASA 5 being the worst possible gradation, a particular patient can be categorized into, indicating a seriously moribund patient who is not expected to survive without a surgical intervention.

- Patients belonging to the ASA Grade 2 have undergone the greatest number of primary total hip arthroplasties, amounting to 9,08,907 individual arthroplasty procedures, accounting to 67.50% of all the recognized hip arthroplasties performed on the British patient cohort.

- The overall distribution of the gender linked number of primary total hip arthroplasties performed on the British patient cohort, as per their respective ASA-grade wise categorization is presented through the following tabulation: -

General Demographics of the British Patient Cohort, receiving Primary Total Hip Arthroplasty, as per the respective ASA-Grade wise Categorization of the Patients.							
SL No.	ASA Category	Male Patients		Female Patients		Overall	
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall
1	ASA 1	95,495	17.70%	1,10,435	13.70%	2,05,930	15.30%
2	ASA 2	3,51,284	65.00%	5,57,623	69.30%	9,08,907	67.60%
3	ASA 3	89,629	16.60%	1,31,972	16.40%	2,21,601	16.50%
4	ASA 4	3,551	0.70%	4,209	0.50%	7,760	0.60%
5	ASA 5	66	<0.1%	93	<0.1%	159	<0.1%
Category Total		5,40,025	40.17%	8,04,332	59.83%	13,44,357	100.00%

Table 6.2.24 :- ***Tabulation illustrating the ASA-Grade wise Patient Gender linked Distribution of the general Patient Demography who have undergone a Primary Total Hip Arthroplasties performed in the United Kingdom, and their relative percentage of the overall numbers.***

- The mean and median age-group of the primary total hip arthroplasty recipient patient cohort in the United Kingdom, segregated as per their respective gender is presented through the following tabulation: -

Distribution of the Mean and Median Age-Group of the Male & Female British Patient Cohort, receiving Primary Hip Arthroplasty.							
SL No.	Criteria	Male Patients		Female Patients		Overall Patients	
		Mean Age [S.D]	Median	Mean Age [S.D]	Median	Mean Age [S.D]	Median
1	Mean Age of the Patients receiving Hip Arthroplasty	66.6 [11.6]	68	69.2 [11.1]	70	68.1 [11.4]	69

Table 6.2.25 :- ***Tabulation illustrating the Mean and Median Age Group of the Primary Total Hip Arthroplasty recipient patient cohort in the United Kingdom, segregated as per their respective gender.***

Clinician specific Practices and Preferences and their related Outcomes of the UK Patient Cohort: -

- Based various inputs and archived documents that were accessed by this research from various health authorities of the UK, the theory rationale primarily conceived by this research, which was to some extent consolidated by the ODEP's statements, that revision rates alone shouldn't be the adjudging parameter to determine the relative outcomes and successes of a particular arthroplasty procedure or any particular prosthesis combination or an individual one.

- Now this theory is justifiable on the fact that many times clinicians and performing surgeons improvise the surgical methods and implant implementation techniques, besides utilization of customized or assembled prostheses combinations, against the manufacturer/supplier company guided/issued guidelines. Such activities generate both favourable and non-favourable results, and not always a catastrophic as some makers indicate.

- Though, such improvised forms of prosthesis utilization for the general patient cohort, is usually termed as 'off-label' usage by the parent prosthesis maker, through which they shred off their share of involving responsibilities invested along with the prosthesis unit, such improvised implementations of prostheses are widespread, albeit not in majority performances, and usually generate favourable outcomes as indicated by some of UK health authorities and the registry itself citing 'best performance and outcomes' arising out of heterogeneous mix of prostheses usage, though a the UK public agency of MHRA has a non-recommendation policy / stance in this regard, for reasons difficult to infer by this research, and best known to them.

- Also, a section of arthroplasty performing clinician surgeons, prefer to re-modify the textbook approach for non-complex cases, which either bear very promising results or may cause some seriously deterring faults. Such personal choice-based preferences could possibly put up for their convenience or due any anatomical compulsion of the patient.

- However, still revision rate continues to be an essentially critical tool for assessing the relative success or failure of an arthroplasty procedure or the general performance of a particular implant, since despite all limitations and troubles a faulty implant can plague the patient with, from a patient point-of-view, undergoing a revision arthroplasty, involving the re-opening of the site and exchange/replacement of the implants is the worst possible scenario to face. Therefore, through-out the course of this research apart from discussing many other factors responsible for the relative success/failure of an implant or an arthroplasty procedure, the prime focus is on the involved revision rate and the cause associated.

- There are ample incidences of improvised and mixed utilization of prostheses for primary and revision hip/knee arthroplasties resulting in superior and positive outcomes / end-results, that are documented

across this thesis, specifically in Swedish practices, wherein majority proportions of the primaries are conducted using such mixed combination of prostheses.

- An example of a clinician preferences-based improvisation from UK based arthroplasty practices, without a positive result, is presented hereon, based on archived documents and registry data from UK:

    - Press-fit acetabular cups in a non-cemented implementation arrangement for primary hip arthroplasty were or possibly are still on clinical use for end-patients as on date for the patient cohort in UK, however these particular designs of acetabular cups and arrangement methodologies despite all the theoretical benefits, didn't exactly reap the appropriate amount of the positive results, that it initially promised.

    - Hence these particular designs of implants were tested with great zeal on cadavers and select group of patients, to demonstrate that during the press based fitting mechanism of the acetabular cup is in place during the arthroplasty procedure, due to the difference on the proprioception capabilities / differences, the manual pressing pressure may turn out to of excess magnitude, causing the cup to undergo an over-embedded impact into the acetabulum bone shaft. This also involves a certain degree of subtrochanteric denting causing an impaired primary component stability, arising from erroneous alignment of the prosthesis module.

    - This denture causes an uneven stress distribution on the bone shaft and over the course of repeated loading during post-operative recovery window, there were incidences of severely complicated periprosthetic fracture or further bone fractures, rendering the implant totally unsuccessful in its primary target.

    - Unintended shear forces during the manual press-fit can lead to an in-homogenous cavity and incongruent contact site between the implant and the bone, with a diminished contact space area.

    - Sometimes these may cause minute calcar fractures, which progressively worsens with time to formulate a large fracture incidence, causing immense trauma and pain to the respective patient.

- Direct anterior approach for primary hip arthroplasty for surgical access of the site is most common approach adopted for the primary hip arthroplasty procedure of the UK patient cohort.

<u>Revision Hip Arthroplasty Practices and Scenarios in UK</u>

- The necessity of evolving the arthroplasty and prosthesis usage data capturing process, and its relative essence in identifying previously unknown failure designs and causes are highly instrumental towards devising active and prompt responses to any sudden uprising potentially fatal health hazard.

- The primary tool to report an arthroplasty procedure with prosthesis usage detailing to the registry database is facilitated through the MDS or the Minimum Data Set pre-set forms/data-entry portals. Now through the evolution of these portals/forms, the capturing of vital issues causing prosthesis and arthroplasty failure, leading to complex revision hip arthroplasties, such as 'Adverse Reaction due to Particulate Debris', has become plausible to trace and track, which was not possible previously.

- The capturing of 'adverse reaction to particulate debris' or ARPD started off from 2008 through the operational launch of the MDSv3, whereon it has been due recorded whenever applicable, otherwise previously such incidences were passed off as, 'others'/miscellaneous. With the evolution of the MDS forms, conditions such as ARPDs are receiving increasingly more attention than ever, and it is

therefore now possible to note and track the strikingly high revision rate percentages involved with the incidences of ARPDs on the general patient cohort, especially those with MoM bearings.

- The analysis of the stemmed MoM bearings by femoral head sizes revealed that the shortest and the previously go-to conventional choice of the many surgeons across the world, i.e., the 28mm heads have the best survivorship, but again this 'best', still happens to be the comparative worst of all other available respective alternate options.

- The UK arthroplasty registry has utilized a specific statistical methodology to categorize a particular prosthesis's failure rate, which is used vastly across scientific literature and related clinico-engineering analyses in UK, but the reliability is questioned by clinicians and researchers based on other nations, including those which were evaluated in the course of this research. This particular statistical parameter is known as, the 'Prosthesis Time Incidence Rate' or 'PTIR'.

- Prosthesis Time Incidence Rates or PTIR, are a measure of the general rate at which a prosthesis fails and requires a revision arthroplasty surgery. PTIR is calculated as the number of revision surgeries per 1,000 prosthesis years of follow-up. The UK registry and some of the British academic institutes find PTIR to be a valuable tool for assessing the performance of the different prosthesis designs and materials. It can also be applied for tracking the changes in the incidences of revision surgeries and related changes in the approach patterns over time.

- A PTIR of 4.5 indicates that for every 1,000 prosthesis implantations, there are 4.5 revision surgeries performed each year. This tool can therefore be utilized for calculating the revision risk and implant failure rates for individual prosthesis units, models and brands, even any particular implant component. PTIR is an important parameter for clinicians to choose/recommend the best plausible prosthesis for their patients and can help the patients make informed decisions about their surgery.

- The patient community may help themselves through getting hold of another statistical metric for filtering their choices to decide a prosthesis combination for themselves. While, the research community may utilize the PTIR to identify key scopes to improve prosthesis design and materials.

- For the primary hip arthroplasty recipient patient cohort in UK, there were three prime leading causes or reasons for revision hip arthroplasties – Aseptic Loosening of the Prostheses in the post-operative window, post-operative Pain/Instability issues and subluxation/dislocation of the prosthesis components.

- The entailing scenarios for some of the prime causes, besides the leading three causes of revision hip arthroplasties as noted for the UK patient cohort, is presented as follows: -

    - Aseptic Loosening – In the case of an aseptic loosening of the prostheses or any of its comprising components, the general cumulative mean revision rate is fairly steady and constant up to 5 years into the post-operative period, post which they steadily rise. The PTIR for aseptic loosening of the prosthesis starts to rise immediately post the surgery for cemented hip arthroplasty fixations, and similarly in non-cemented MoP bearings.

    - Post-Operative Pain – For post-operative pain as the primary indication for the first revision cases, it was fairly constant at all points, except that of the beginning/immediate post-operative stages, wherein the patient is at a maximal vulnerability to pain and other related issues from a patient's point-of-view. The observation of PTIR for pain indicated for revisions, supports the idea that the patient is at the stage of maximal discomfort during the immediate short-term post-operative period, and the patient is either relieved through some physio-therapeutic or through

normal healing/recovery processes of the surgical trauma later on, as the patient adapts to the implant functioning.

- Subluxation/Dislocation – In case of subluxation and dislocation incidences for the prosthesis revision, all such incidences are generally higher in the first year itself, owing to the fact that a prosthesis placed incorrectly aligned is bound to falter from the initial stages of post-operative recovery itself.

- Periprosthetic Fracture – For periprosthetic fractures, the highest revision rate is observed within a year of the primary arthroplasty surgery, post which it declines markedly, only to rise again post 7 years into the post-operative window.

- Adverse Reaction to Particulate Debris (ARPD) – The revisions caused due to ARPD incidences continues to rise upto 15 years post-operatively, before subsiding. The rise is consistent with the passing time into the post-op window since the primary and this was more prominently observed for resurfacing hip arthroplasties, which are globally infamous for its metallosis problem and non-cemented MoM bearing total hip prostheses.

- Post-Operative Infection – The revision rate is initially high till 3 years post-op, and then it falls for all groups, as the general window for a bacterial or fungal infection to kick in, is closed.

- However, despite sounding very promising from a theoretical or mathematical/statistical perspective, hard reality-based ground facts don't always oblige the fundamentals and principles of mathematics and statistics, and hence, the utilization of PTIR for the general quality and performance assessment is not found or rather observed in practice anywhere outside of UK, based on reliability concerns.

- The detailed hip revision arthroplasty scenarios and the prosthesis specific linked revision rates for primary total hip arthroplasties of the recipient patient cohort in the UK are presented hereon through appropriate tabulations, figures.

- The distribution of the number of revision hip arthroplasties performed on the patient cohort of UK, based on the type of the revision procedure or the stage-wise demarcation of the performed revision procedure and their relative proportion percent of the overall recorded revisions in that year, is presented through the following tabulation: -

- Based on the data presented on the above tabulation it can be seen that the highest year-wise revision hip arthroplasty procedures were in 2012. The plausible inference that this research could infer is that the peaking of the revision hip arthroplasty procedures in 2012, coincides with the boom of the resurfacing hip arthroplasty techniques in 2008-2009s that promised to answer all the prevailing constraints, only to fail big-time, causing a series of inorganic revision load burden on the performing clinicians and institutes, as well as the patients and regulatory authorities, following its debacle, until its complete banning and withdrawal from 2013 – 2014 onwards.

- The respective leading indication or causes linked distribution and break-up of the single and dual-stage revision hip arthroplasties performed on the patient cohort of the UK, of all time, and during the last five years is illustrated through the following two tabulations: -

NJR 2022:- Overall Hip Revision Arthroplasty Numbers & Percentage of Revision by Indications and Type or Stages of Revision Arthroplasty performed on the NJR Patient Cohort of All Time. [2003 - 2021]					
SL No.	Prime Indication for Revision Surgery	Type of Revision Procedure			All Revision Procedures
		No. of Single Stage Procedures (%)	Stage One of Dual Stage (%)	Stage Two of Dual Stage (%)	
1	Aseptic Loosening	53,562(46.1)	995(11.6)	2,338(21.4)	56,895
2	Dislocation/Subluxation	19,244(16.6)	350(4.1)	552(5.0)	20,146
3	Pain	18,366(15.8)	824(9.6)	926(8.5)	20,116
4	Lysis	17,026(14.7)	761(8.9)	711(6.5)	18,498
5	Implant Wear	16,148(13.9)	345(4.0)	421(3.8)	16,914
6	Periprosthetic Fracture	14,444(12.4)	341(4.0)	488(4.5)	15,273
7	Other Indications	7,936(6.8)	284(3.3)	856(7.8)	9,076
8	Mis-alignment of Implant	6,248(5.4)	116(1.4)	116(1.1)	6,480
9	Infection	5,974(5.1)	7,061(82.2)	6,760(61.8)	19,795
10	Implant Fracture	4,290(3.7)	89(1.0)	169(1.5)	4,548
11	Head-to-Socket Size Mismatch	782(0.7)	22(0.3)	27(0.2)	831
12	Adverse Reaction to Particulate Debris*	10,677(10.7)	253(3.3)	173(2.3)	11,103
TOTAL		1,74,697	11,441	13,537	1,99,675
**The parameters(Adverse Reaction to Particulate Debris) were not recorded in the initial phase of the registry ; only since MDSv3, MDSv6 & MDSv7 Revisions due to Adverse Reaction to Particulate Debris data has been captured and presented / Real nos. could be higher.*					

Table 6.2.26 :- ***Tabulation illustrating the Overall Distribution of Revision Hip Arthroplasty procedures, performed on the British Patient Cohort, categorized as per the respective Prime Indication cited as the Reason for the Revision Surgery, segregated by the Respective Stage-Wise Revision Intervention adopted, during 2003-2021 .***

NJR 2022:- Overall Hip Revision Arthroplasty Numbers & Percentage of Revision by Indications & Type or Stages of Revision Arthroplasty performed on the NJR Patient Cohort Since Last 5 Years [2016 - 2021].					
SL No.	Prime Indication for Revision Surgery	Type of Revision Procedure			All Revision Procedures
		No. of Single Stage Procedures (%)	Stage One of Dual Stage (%)	Stage Two of Dual Stage (%)	
1	Aseptic Loosening	11,920(37.7)	196(7.7)	158(7.6)	12,274
2	Dislocation/Subluxation	6,128(19.4)	106(4.2)	65(3.1)	6,299
3	Periprosthetic Fracture	5,794(18.3)	115(4.5)	115(5.5)	6,024
4	Implant Wear	4,150(13.1)	75(2.9)	33(1.6)	4,258
5	Lysis	3,988(12.6)	190(7.5)	83(4.0)	4,261
6	Adverse Reaction to Particulate Debris*	3,213(10.2)	93(3.6)	49(2.4)	3,355
7	Infection	2,712(8.6)	2,225(87.3)	1,695(81.3)	6,632
8	Mis-alignment of Implant	1,486(4.7)	26(1.0)	9(0.4)	1,521
9	Other Indications	1,400(4.4)	68(2.7)	124(5.9)	1,592
10	Implant Fracture	1,250(4.0)	21(0.8)	15(0.7)	1,286
11	Pain	1,241(3.9)	38(1.5)	24(1.2)	1,303
12	Head-to-Socket Size Mismatch	121(0.4)	<4(0.1)	<4(0.0)	127
TOTAL		43,403	3,155	2,374	48,932
**The parameters(Adverse Reaction to Particulate Debris) were not recorded in the initial phase of the registry ; only since MDSv3, MDSv6 & MDSv7 Revisions due to Adverse Reaction to Particulate Debris data has been captured and presented / Real nos. could be higher.*					

Table 6.2.27 :- ***Tabulation illustrating the Overall Distribution of Revision Hip Arthroplasty procedures, performed on the British Patient Cohort, categorized as per the respective Prime Indication cited as the Reason for the Revision Surgery, segregated by the Respective Stage-Wise Revision Intervention adopted, during the last few years of the available recorded data for the span of [2016-2021] .***

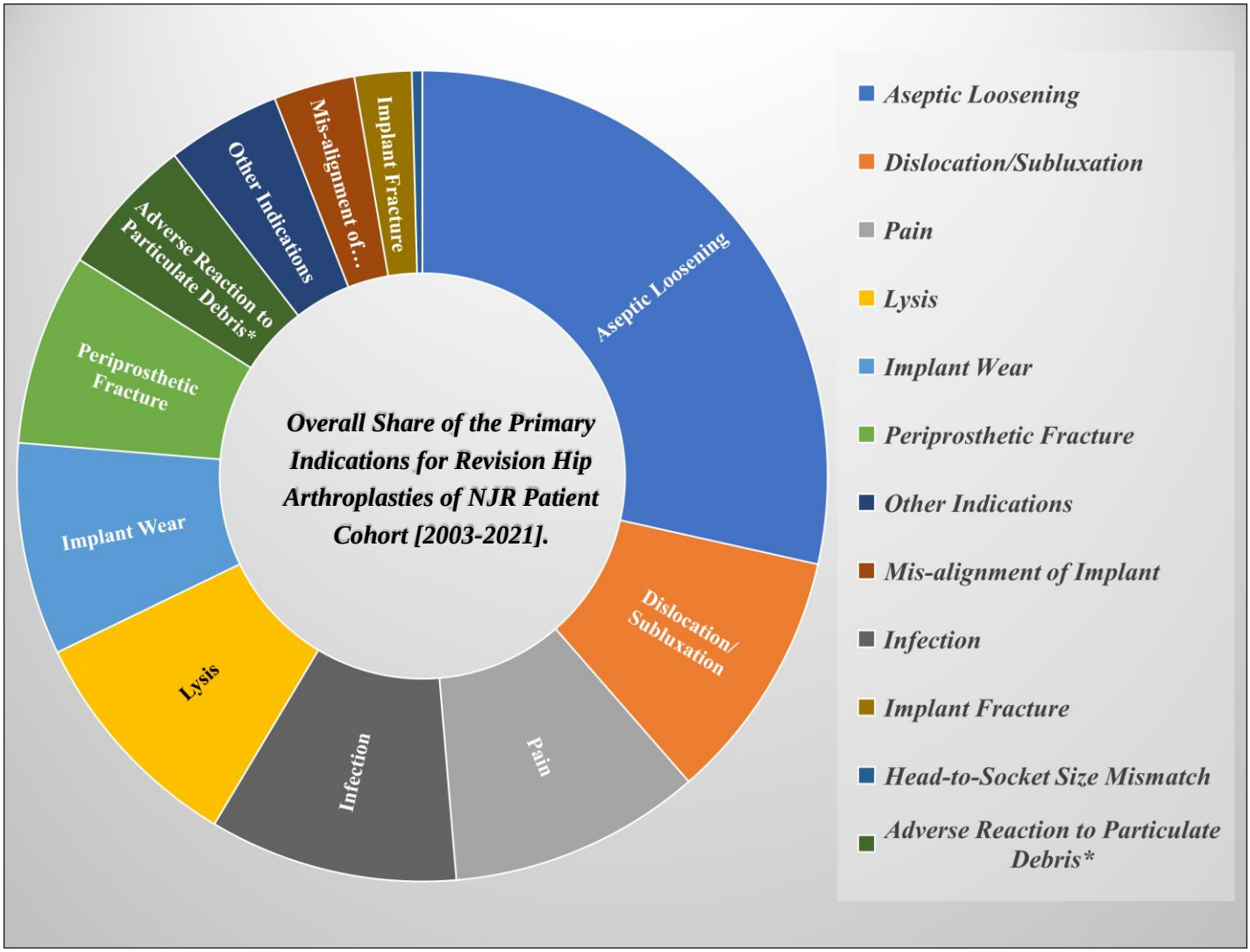


Figure 6.2.22 :- ***A Pie-Chart plot to illustrate the distribution share of the Various Majorly Reported Primary Indications, based on which the Greatest Number of Revision Hip Arthroplasties were performed on the British Patient Cohort, for the entire span of Available Arthroplasty Record during the years of 2003 - 2021.***

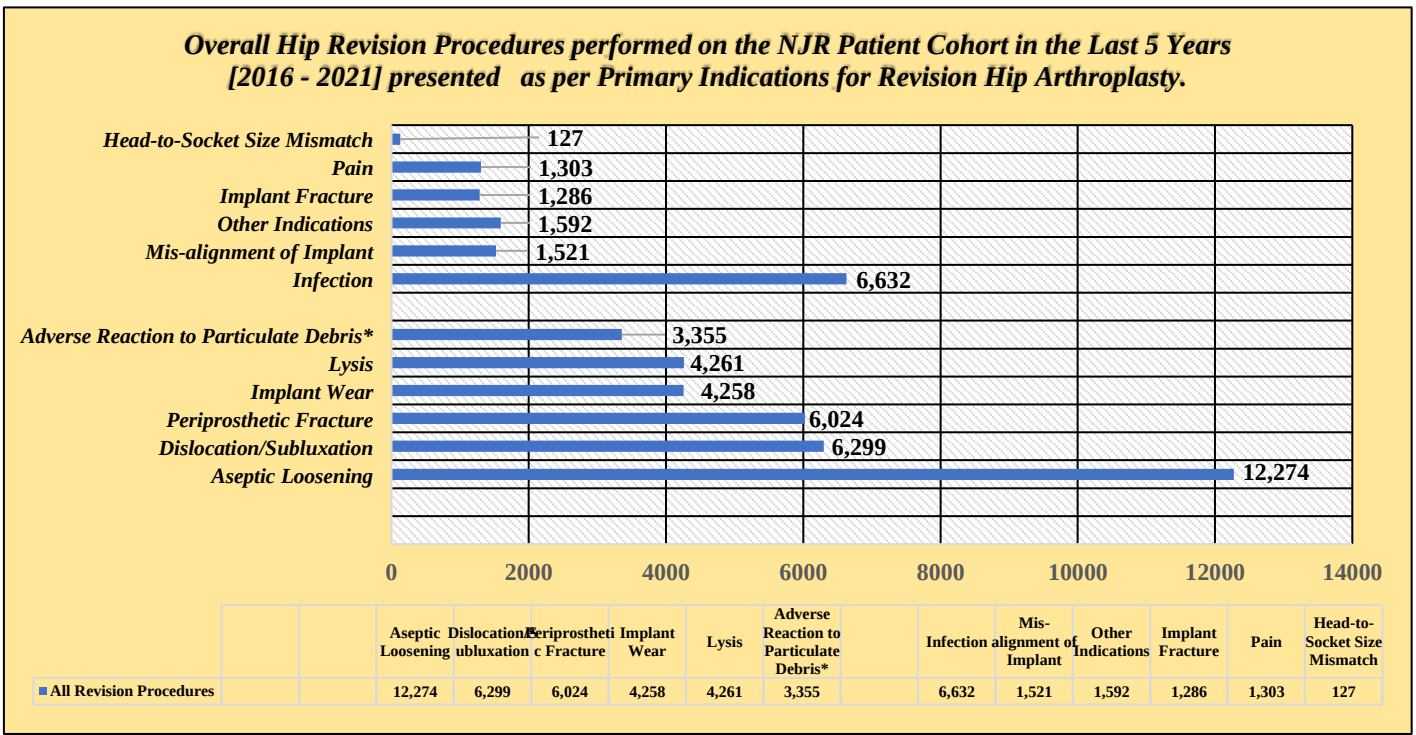


Figure 6.2.23 :- ***A Bar-Graph plot to illustrate the distribution share of the Various Majorly Reported Primary Indications, based on which the Greatest Number of Revision Hip Arthroplasties were performed on the British Patient Cohort, during the last five years of available data – 2016 - 2021.***

- It is evident that post-operative infection and post-operative aseptic loosening of the prosthesis are the revision causes with the greatest respective proportion of cases, among all the recognized causes/reasons.

Fractured Neck of Femur (NOF) based Primary Total Hip Arthroplasty Related Outcomes Scenarios in UK.

- Utilization of THAs for treating fractured NOF cases are becoming more prominent and standardized in UK's hip arthroplasty practices, similar to that of the global scenario.

- A cumulative total of 50,008 primary total hip arthroplasties, accounting for 3.80% of all primary total hip arthroplasties as recorded within the UK registry, were performed for the primary indication of a fractured neck of femur.

- The relative year-wise proportions of fractured NOF based primary hip arthroplasties rose to a maximum of 7.30% in relative proportions to all the causes stated for a primary THA in 2020.

- Consistent with the practices in some regions around the world, the utilization of dual mobility hip prostheses for primary hip arthroplasties of fractured NOFs is noted to become more common, and accounted for 8.40% of all such cases in 2020.

- Remarkably, there was a sharp decline in the annual number of fractured NOF based primary THAs in 2020, compared against the steady rise in the numbers of such procedures seen annually previously. This decline could be partially influenced by the COVID-19 pandemic in 2020, that reduced individual mobility, and therefore probabilities of undergoing a NOF fracture also decreases with that.

- There's a steady increase in the relative proportions of the primary THAs performed on British patients with a fractured neck of femur, that had a dual mobility hip prostheses implanted on them. Though, the in-general numbers are very low compared to the primary THAs due to fractured neck of femur that utilized an unipolar hip prostheses, but a steady growth in the DM hip utilization numbers is readily evident.

- Dual Mobility hip prostheses were utilized for 9.40% of all the primary THAs performed on the British patient cohort, for a primary indication/diagnosis of a fractured NOF in 2021, which was 8.60% and 8.00% in the former years of 2019 and 2020 respectively.

- A complete breakdown of the primary total hip arthroplasty procedures that were performed on the basis of a primary indication of a fractured NOF over the years on the British patient cohort, along with the prosthesis's mobility type deployed compared vis-à-vis for DM and conventional unipolar are presented through the following tabulation: -

Overall Number & Percentage of THAs performed to treat a Fracture of the Neck of Femur[NOF] as the Primary Indication over the Years for the NJR Patient Cohort, with the Distribution of the Prosthesis Mobility deployed.					
SL No.	Year of Primary THA Record	Total No. of Primary THAs for Other Indications.	No. of Fractured NOF Cases	NOF Treatment Choice	
				Dual Mobility N (%)	Unipolar N(%)
1	2003	14,977	143(1.0)	0(0.0)	143(100.0)
2	2004	29,263	298(1.0)	0(0.0)	298(100.0)
3	2005	41,698	395(0.9)	0(0.0)	395(100.0)
4	2006	48,561	529(1.1)	0(0.0)	529(100.0)
5	2007	61,729	787(1.3)	0(0.0)	787(100.0)
6	2008	67,715	868(1.3)	<4(0.1)	867(99.9)
7	2009	68,663	1,082(1.6)	11(1.0)	1,071(99.0)
8	2010	71,181	1,371(1.9)	8(0.6)	1,363(99.4)
9	2011	74,136	1,724(2.3)	19(1.1)	1,705(98.9)
10	2012	78,351	2,441(3.1)	21(0.9)	2,420(99.1)
11	2013	80,485	3,118(3.9)	76(2.4)	3,042(97.6)
12	2014	87,732	3,723(4.2)	149(4.0)	3,574(96.0)
13	2015	89,908	4,207(4.7)	186(4.4)	4,021(95.6)
14	2016	94,405	4,871(5.2)	295(6.1)	4,576(93.9)
15	2017	96,503	5,014(5.2)	311(6.2)	4,703(93.8)
16	2018	97,563	5,523(5.7)	343(6.2)	5,180(93.8)
17	2019	99,873	5,648(5.7)	451(8.0)	5,197(92.0)
18	2020	56,596	4,119(7.3)	353(8.6)	3,766(91.4)
19	2021	84,998	4,147(4.9)	390(9.4)	3,757(90.6)
Overall Total		**13,44,337**	**50,008(3.7)**	**2,614(5.2)**	**47,394(94.8)**
During the period of 2003 - 2008 the Data Collected/Reported by the Registry didn't have an Explicit Fractured Neck of Femur Category, only to be introduced via MDSv7 from 2007 onwards, which in a way can be Explainatory for the sudden surge from 2007 onwards, as it contained both Current & Back-Tracked Audited Numbers for the NJR Registry.					

Table 6.2.28 :-*Tabulation illustrating the Overall Number of Primary THAs performed on the British Patient Cohort for a Primary Diagnoses of a Fractured NOF, and the Comparative Distribution of Prostheses usage by Mobility*

Prostheses Specific Hip Arthroplasty Practices & Related Outcome Scenarios on the British Patient Cohort:-

- Metal on Polymer based bearing surfaces were utilized for the greatest proportion of recorded primary total hip arthroplasties on the general patient cohort of UK, accounting for 27.58% of all the available bearing surface and fixation method combinations, corresponding to 3,54,571 individuals primary THA procedures.

- While, reverse-hybrid fixation-based Ceramic-on-Polymer bearing surfaces was utilized for the least number of primary total hip arthroplasties accounting for only 0.85% of all the available bearing surface and fixation method combinations, corresponding to 10,957 individuals primary THA procedures.

- The overall distribution of the individual number of primary THAs performed on the British patient cohort, categorized as per the bearing surface of the hip prostheses utilized and the respective fixation method utilized are presented through the following tabulation and graph plot: -

Distribution of the Number of Total Hip Arthroplasties performed on the British Patient Cohort, as per the Prostheses Bearing Surface & Fixation Method Utilized.			
SL No.	**Bearing Surface - Fixation Type**	**No. of Arthroplasty**	**% of Overall**
1	MoP Cemented	3,54,571	27.58%
2	CoP Cemented	54,658	4.25%
3	MoP Uncemented	1,91,950	14.94%
4	MoM Uncemented	28,740	2.24%
5	CoP Uncemented	1,34,749	10.48%
6	CoC Uncemented	1,37,355	10.68%
7	MoP Hybrid	1,73,032	13.46%
8	CoP Hybrid	1,08,865	8.47%
9	CoC Hybrid	27,053	2.13%
10	MoP Reverse Hybrid	22,862	1.77%
11	CoP Reverse Hybrid	10,957	0.85%
12	MoM Resurfacing	40,497	3%
Grand Total		12,85,289	100.00%

Table 6.2.29 :- ***Tabulation illustrating the Overall Distribution of the Total Number of Primary THAs performed on the British Patient Cohort, based on the Bearing Surface of the Hip Prostheses and the respective Fixation Method utilized.***

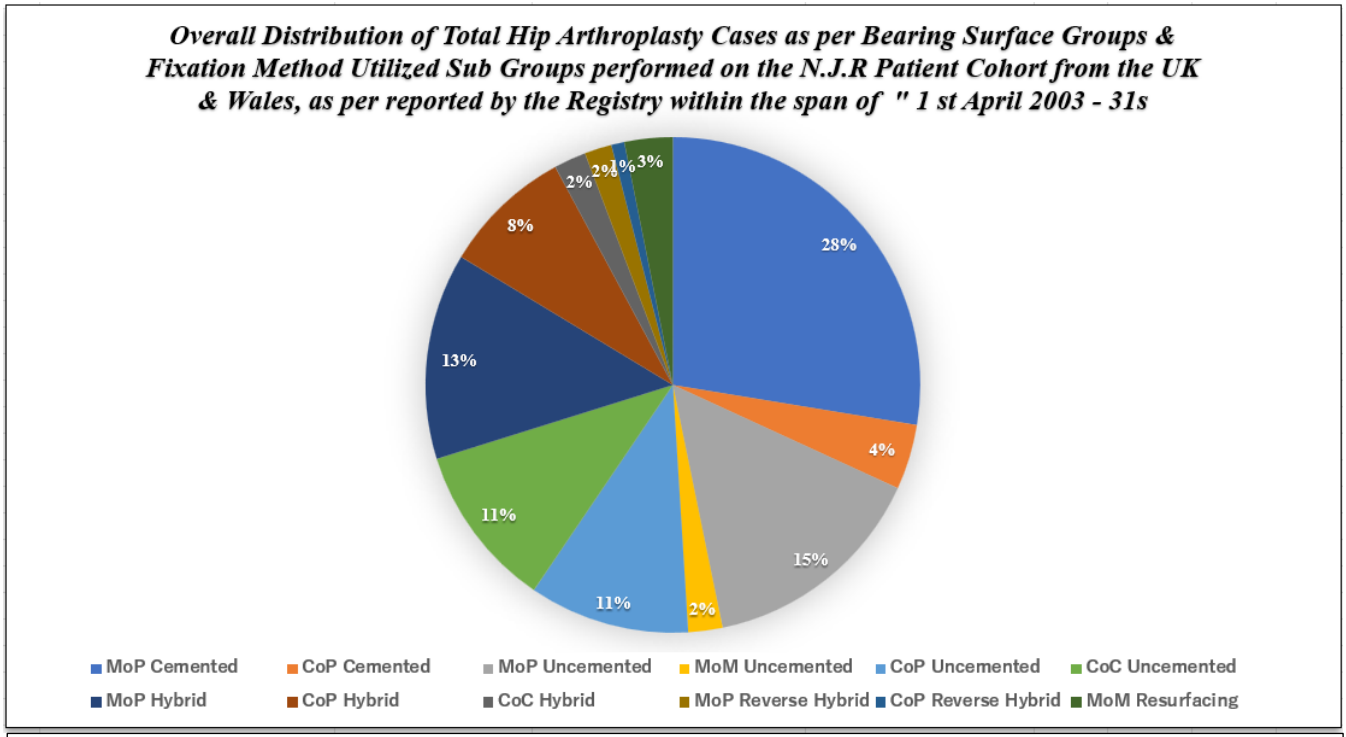


Figure 6.2.24 :- ***A Pie-Chart illustration Plot to illustrate the Overall Distribution Percentages of the Various Hip Prostheses Bearing Surface Combinations along-with the respective Fixation Method deployed, during the primary THA of the British Patient Cohort.***

- The prosthesis combination of Stryker's '*Exeter V40*' femoral stem and the '*Exeter Contemporary Flanged*' acetabular cup was the most commonly utilized prostheses combination for the cemented primary total hip arthroplasty of the British patient cohort.

- The patient age-group and gender linked distribution of the most commonly utilized prostheses combinations (femoral stem and acetabular cup/shell) for the cemented primary total hip arthroplasty of the British patient cohort, along with their respective cumulative revision rates percentages noted across various follow-up timepoints in the post-operative window are presented through the following tabulations: -

Distribution of the Overall Cumulative Revision Rate Percentages of the Majorly utilized Femoral Stem & Acetabular Shell / Cup Hip Prostheses Combinations for the Cemented fixation based Primary Total Hip Arthroplasty of the British Patient Cohort, with their respective ODEP Rating Statuses and other Informations.

SL No.	Femoral Stem : Acetabular Cup / Shell Prostheses	Manufacturer / Supplier of the Prosthesis	No. of Reported Cases	Median Age at Primary THA	Male %	Time Span since Primary THA						Current ODEP Rating	Year of First Use(YoFU) [Femoral : Acetabular]	Present Status
						1 Year	3 Years	5 Years	10 Years	15 Years	18 Years			
1	C-Stem AMT Cemented Stem : Charnley and Elite Plus LPW	Depuy Synthes : Depuy Synthes	3,461	75(70-79)	30	0.61(0.40-0.94)	1.31(0.97-1.76)	1.59(1.21-2.09)	2.64(2.07-3.37)	*4.05(3.06-5.35)*	NA	15A* : 15A*	2005 : 1972	ACTIVE
2	C-Stem AMT Cemented Stem : Elite Plus Ogee		5,068	77(72-81)	34	0.30(0.18-0.50)	0.94(0.69-1.27)	1.28(0.98-1.69)	2.00(1.54-2.59)	*2.82(1.91-4.16)*	NA		2005 : 1982	
3	C-Stem AMT Cemented Stem : Marathon		16,906	75(70-80)	32	0.56(0.46-0.70)	1.00(0.85-1.18)	1.32(1.13-1.55)	2.11(1.66-2.68)	NA	NA	15A* : 13A*	2005 : 2007	
4	C-Stem Cemented Stem : Elite Plus Ogee		6,223	72(66-77)	39	0.41(0.28-0.60)	0.89(0.68-1.16)	1.18(0.93-1.50)	2.56(2.10-3.12)	4.40(3.61-5.37)	*4.84(3.88-6.04)*	15A : 15A*	YoFU NA : 1982	
5	C-Stem Cemented Stem : Marathon		10,122	68(60-75)	41	0.45(0.34-0.61)	0.90(0.73-1.11)	1.31(1.08-1.57)	2.02(1.68-2.44)	NA	NA	15A : 13A*	YoFU NA : 2007	
6	CPT CoCr Stem : Elite Plus Ogee	Zimmer Biomet : Depuy Synthes	2,522	73(67-79)	36	0.60(0.36-0.99)	1.51(1.09-2.07)	2.22(1.70-2.89)	3.95(3.17-4.91)	*5.47(4.29-6.97)*	NA	15A* : 15A*	1990 : 1982	
7	CPT CoCr Stem : ZCA	Zimmer Biomet	18,403	77(71-81)	31	0.91(0.78-1.05)	1.51(1.34-1.71)	2.14(1.92-2.38)	4.00(3.60-4.45)	5.50(4.80-6.29)	*6.63(5.25-8.35)*	15A* : 15A*	1990 : 1992	
8	Charnley Cemented Stem : Charnley Cemented Cup	Depuy Synthes : Depuy Synthes	4,700	72(66-78)	38	0.32(0.19-0.54)	1.12(0.85-1.47)	1.82(1.46-2.26)	3.68(3.14-4.32)	6.09(5.26-7.05)	*7.25(6.14-8.55)*	Lapsed(Last Rated 13A) : Not Rated	1988 : YoFU NA	
9	Charnley Cemented Stem : Charnley Ogee		10,628	73(67-78)	38	0.37(0.27-0.51)	1.20(1.01-1.44)	1.85(1.61-2.14)	3.63(3.26-4.05)	5.94(5.35-6.60)	6.78(6.02-7.62)	15A*		
10	Charnley Cemented Stem : Charnley and Elite Plus LPW		7,117	74(68-79)	29	0.38(0.26-0.56)	0.76(0.58-1.00)	1.15(0.92-1.44)	2.46(2.08-2.91)	3.88(3.31-4.55)	*4.85(3.93-5.98)*	Lapsed : 15A*	1988 : 1972	
11	Exeter V40 : Cenator Cemented Cup	Stryker : Corin Group	2,528	75(69-80)	32	0.64(0.39-1.04)	1.38(0.99-1.93)	2.05(1.55-2.70)	2.72(2.11-3.49)	4.42(3.45-5.64)	*6.00(4.05-8.84)*	15A* : Withdrawn since 2022	1970 : 1992	Non-Active
12	Exeter V40 : Charnley and Elite Plus LPW	Stryker : Depuy Synthes	5,585	73(68-79)	31	0.67(0.49-0.92)	1.24(0.97-1.57)	1.51(1.21-1.88)	2.16(1.75-2.66)	3.16(2.39-4.16)	*3.83(2.54-5.75)*	15A* : 15A*	1970 : 1972	ACTIVE
13	Exeter V40 : Elite Plus Cemented Cup		5,261	73(67-79)	32	0.33(0.20-0.52)	0.64(0.46-0.90)	0.88(0.66-1.18)	1.46(1.14-1.87)	2.91(2.19-3.87)	*4.80(2.83-8.07)*	15A* : 10A as of 2011	1970	
14	Exeter V40 : Elite Plus Ogee		27,116	74(69-80)	35	0.38(0.31-0.46)	0.85(0.74-0.97)	1.20(1.07-1.34)	2.16(1.96-2.37)	3.19(2.86-3.56)	*3.77(3.25-4.36)*	15A* : 15A*	1970:1982	
15	Exeter V40 : Exeter Contemporary Flanged	Stryker	99,589	74(69-80)	34	0.58(0.53-0.63)	1.02(0.96-1.08)	1.37(1.30-1.45)	2.36(2.23-2.49)	4.17(3.87-4.50)	*5.13(4.45-5.90)*	15A* : 15A*	1970 : 1991	
16	Exeter V40 : Exeter Contemporary Hooded		29,260	75(70-80)	32	0.95(0.85-1.07)	1.61(1.47-1.76)	2.12(1.95-2.30)	3.94(3.67-4.23)	7.11(6.53-7.74)	*9.67(8.16-11.43)*	15A* : 15A*	1970 : 1991	
17	Exeter V40 : Exeter Duration Cup		17,042	73(67-79)	32	0.60(0.49-0.73)	1.19(1.04-1.37)	1.63(1.44-1.83)	3.74(3.43-4.08)	6.67(6.10-7.28)	*9.03(7.82-10.42)*	15A* : Withdrawn	1970 : 1995	
18	Exeter V40 : Exeter X3 Rimfit		44,539	71(64-78)	34	0.50(0.44-0.57)	0.86(0.77-0.96)	1.20(1.09-1.32)	1.86(1.61-2.15)	NA	NA	15A* : 10A*	1970 : YoFU Not Available	
19	Exeter V40 : Marathon	Stryker : Depuy Synthes	9,468	72(64-78)	35	0.50(0.38-0.67)	0.83(0.66-1.05)	1.09(0.88-1.35)	1.50(1.18-1.92)	NA	NA	15A* : 13A*	1970 : 2007	
20	Exeter V40 : Opera Cup	Stryker : Smith & Nephew	2,846	74(68-80)	32	0.39(0.22-0.71)	0.84(0.56-1.26)	1.27(0.91-1.78)	3.08(2.42-3.91)	6.71(5.16-8.71)	*8.00(6.01-10.61)*	15A* : ODEP Rating Not Found	1970 : YoFU Not Available [510(k) cleared on 1999]	
21	MS - 30 : Original ME Müller Low Profile Cup	Zimmer Biomet	4,200	75(69-81)	32	0.24(0.13-0.45)	0.50(0.32-0.78)	0.72(0.49-1.05)	1.51(1.10-2.07)	*3.28(2.16-4.97)*	*3.71(2.41-5.69)*	15A* : 15A*	1989 : 1980	
22	Müller Straight Stem : Original ME Müller Low Profile Cup	Mathys Ltd : Zimmer Biomet	3,009	75(70-80)	27	0.40(0.23-0.71)	0.80(0.53-1.20)	1.17(0.83-1.66)	2.70(2.06-3.53)	*5.14(3.71-7.12)*	*7.22(4.55-11.37)*	13A : 15A*	1996 : 1980	
23	Stanmore Modular Stem : Stanmore - Arcom Cup	Zimmer Biomet	5,469	75(70-80)	29	0.44(0.30-0.66)	1.08(0.83-1.39)	1.51(1.21-1.89)	2.41(1.99-2.92)	4.35(3.54-5.35)	*5.64(4.25-7.48)*	WITHDRAWN in July 2021, Last Rating 13A*	1973 : 1973	
TOTAL CEMENTED FIXATION CASES			3,41,062	*Blue Italics signify that fewer than 250 cases remained at risk at these time points / Data were available ; The above data is only for Hip Implant Combinations / Stem-Cup combinations, having atleast 2,500 Registered Procedures with the Registry Database for Cemented, Non-Cemented & Hybrid Fixation based Implant ; Combinations, while Resurfacing Combinations with atleast 1,000 Registered Cases ; "NA" is mentioned for those segments wherein either the data was not available/accessible/way too low(<10) for the Registry to report ; [St] = Femoral Stem ; [C] = Acetabular Cup ; [SL] = Acetabular Shell / Shell Liner.*								

Table 6.2.30 :- ***Tabulation illustrating the Cumulative Revision Rate Percentages of the Majorly Utilized Hip Prostheses Combinations (Femoral Stem + Acetabular Cup/Shell) across various time-points in the Post-Operative window, deployed for the Cemented Primary THA of the British Patient Cohort, with their respective ODEP Rating Statuses and Year of First Usage and Manufacturer/Supplier firm details.***

- Similarly, the hip prostheses combinations that saw the greatest number of utilizations for the non-cemented fixation based primary THAs on the British patient cohort, with their respective ODEP Rating statuses and year of first usage details, and the respective revision rates obtained across various time-points in the post-operative window are presented as follows: -

Distribution of the Overall Cumulative Revision Rate Percentages of the Majorly utilized Femoral Stem & Acetabular Shell / Cup Hip Prostheses Combinations for the Non-Cemented fixation based Primary Total Hip Arthroplasty of the British Patient Cohort, with their respective ODEP Rating Statuses and other Informations.

SL No.	Femoral Stem : Acetabular Cup / Shell Prostheses	Manufacturer / Supplier of the Prosthesis	No. of Reported Cases	Median Age at Primary THA	Male %	Time Span since Primary THA						Current ODEP Rating	Year of First Use(YoFU) [Femoral : Acetabular]	Present Status
						1 Year	3 Years	5 Years	10 Years	15 Years	18 Years			
1	Accolade : Trident [SL]	Stryker	27,279	66(59-73)	44	0.94(0.83-1.06)	1.89(1.73-2.06)	2.51(2.33-2.71)	3.97(3.72-4.24)	5.62(5.10-6.18)	*5.62(5.10-6.18)*	15A* : 15A	2000 : 1999	ACTIVE
2	Accolade II : Trident [SL]		17,477	65(57-72)	47	0.81(0.68-0.96)	1.32(1.14-1.53)	1.60(1.36-1.88)	NA	NA	NA	7A* : 15A*	YoFU Not Available : 1999	
3	Accolade II : Tritanium [SL]		2,725	61(53-70)	50	0.72(0.46-1.15)	1.57(1.09-2.26)	2.24(1.60-3.13)	NA	NA	NA	7A* : 10A*	YoFU Not Available : 2009	
4	Anthology : R3 Cementless [SL]	Smith & Nephew	5,174	62(53-69)	42	1.08(0.83-1.410	1.66(1.34-2.06)	2.05(1.68-2.50)	3.18(2.51-4.01)	NA	NA	13A* : 13A*	2005 : 2007	
5	Corail : ASR Resurfacing Cup	Depuy Synthes	2,776	61(54-67)	55	0.97(0.67-1.42)	7.35(6.43-8.39)	23.40(21.84-25.04)	43.66(41.77-45.59)	48.44(46.45-50.47)	NA	15A* : Withdrawn	Device Recalled / Banned	BANNED
6	Corail : Duraloc Cementless Cup [SL]		4,040	70(64-75)	39	0.75(0.52-1.06)	1.66(1.31-2.11)	2.44(2.00-2.98)	5.42(4.72-6.21)	10.55(9.38-11.85)	*12.84(11.15-14.78)*	15A* : 15A	1986 : 1990	ACTIVE
7	Corail : Pinnacle Gription [SL]		14,794	66(58-73)	42	0.86(0.72-1.03)	1.47(1.26-1.71)	2.03(1.75-2.35)	2.76(2.23-3.42)	NA	NA	15A* : 10A*	1986 : 2007	
8	Corail : Pinnacle [SL]		1,79,988	66(59-73)	45	0.76(0.72-0.80)	1.44(1.38-1.50)	2.07(2.00-2.14)	4.25(4.12-4.38)	6.93(6.63-7.24)	NA	15A* : 15A*	1986 : 2000	
9	Corail : Trilogy [SL]	Depuy Synthes : Zimmer Biomet	3,311	67(61-74)	40	0.58(0.37-0.91)	1.08(0.77-1.50)	1.63(1.24-2.14)	2.83(2.26-3.54)	3.53(2.73-4.56)	7.84(3.83-15.69)	15A* : 15A*	1986 : 1995	
10	Furlong Evolution Cementless : Furlong HAC CSF Plus [SL]	JRI Orthopedics	5,683	62(52-70)	39	1.27(1.00-1.60)	1.77(1.45-2.17)	2.01(1.66-2.44)	NA	NA	NA	7A* : 13A	YoFU Not Available : 2007	
11	Furlong HAC Stem : CSF [SL]		17,256	69(63-76)	40	1.10(0.96-1.27)	1.82(1.63-2.03)	2.21(1.99-2.44)	3.53(3.25-3.84)	5.06(4.67-5.49)	5.78(5.22-6.40)	15A* : 15A*	1985 : 1991	
12	Furlong HAC Stem : Furlong HAC CSF Plus[SL]		25,078	66(59-73)	45	1.09(0.97-1.23)	1.73(1.57-1.90)	2.00(1.83-2.19)	2.62(2.41-2.86)	NA	NA	15A* : 13A	1985 : 2007	
13	M/L Taper Cementless : Continuum [SL]	Zimmer Biomet	6,338	61(53-68)	49	1.22(0.98-1.53)	1.78(1.48-2.14)	2.13(1.79-2.53)	2.76(2.34-3.26)	NA	NA	15A : 10A*	2003 : YoFU NA	
14	M/L Taper Cementless : Trilogy IT [SL]		5,773	63(55-71)	51	1.24(0.99-1.57)	1.98(1.65-2.39)	2.25(1.88-2.69)	2.97(2.31-3.82)	NA	NA	15A : 15A*	2003 : 1995	
15	Metafix Stem : Trinity [SL]	Corin Group	8,047	64(56-70)	46	0.70(0.54-0.91)	1.03(0.82-1.29)	1.29(1.04-1.60)	2.07(1.58-2.71)	NA	NA	13A : 10A*	2007 : 2009	
16	Polarstem Cementless : R3 Cementless [SL]	Smith & Nephew	22,895	65(58-72)	47	0.71(0.61-0.83)	0.96(0.84-1.11)	1.18(1.02-1.350	1.99(1.51-2.62)	NA	NA	10A* : 13A*	2002 : 2007	
17	SL-Plus Cementless Stem : EP-Fit Plus [SL]		3,815	66(59-74)	43	1.45(1.11-1.88)	3.12(2.61-3.72)	4.47(3.85-5.18)	7.20(6.36-8.16)	9.35(8.20-10.65)	NA	13A : 15A*	1993 : 1995	
18	Synergy Cementless Stem : R3 Cementless [SL]		4,014	65(57-71)	52	0.90(0.65-1.25)	1.29(0.98-1.70)	1.67(1.30-2.14)	2.71(2.06-3.54)	NA	NA	15A* : 13A*	1996 : 2007	
19	TaperLoc Cementless Stem : Exceed ABT [SL]	Zimmer Biomet	27,294	65(58-72)	44	1.09(0.98-1.22)	1.49(1.35-1.64)	1.76(1.60-1.92)	2.27(2.08-2.48)	2.61(2.26-3.02)	NA	15A* : 15A	1983 : 2006	
20	TaperLoc Complete Cementless Stem : Exceed ABT [SL]		3,831	63(55-70)	49	0.84(0.59-1.19)	1.35(1.02-1.77)	1.59(1.23-2.06)	1.88(1.45-2.44)	NA	NA	Unrated : 15A	YoFU NA : 2006	
21	Taperloc Complete Cementless Stem : G7 Cementless Acetabular Component [SL]		2,699	66(57-73)	46	0.58(0.35-0.95)	0.77(0.49-1.22)	0.87(0.55-1.37)	NA	NA	NA	Unrated : 7A	YoFU NA : YoFU NA	
22	miniHip : Trinity [SL]	Corin Group	2,615	56(49-63)	45	1.39(1.01-1.93)	2.07(1.58-2.71)	2.34(1.81-3.03)	3.08(2.30-4.12)	NA	NA	10A* : 10A*	2008 : 2009	
Total Cementless Fixation Cases			3,92,902	*Blue Italics signify that fewer than 250 cases remained at risk at these time points / Data were available ; The above data is only for Hip Implant Combinations / Stem-Cup combinations, having atleast 2,500 Registered Procedures with the Registry Database for Cemented, Non-Cemented & Hybrid Fixation based Implant ; Combinations, while Resurfacing Combinations with atleast 1,000 Registered Cases ; "NA" is mentioned for those segments wherein either the data was not available/accessible/way too low(<10) for the Registry to report ; [St] = Femoral Stem ; [C] = Acetabular Cup ; [SL] = Acetabular Shell / Shell Liner.*								

Table 6.2.31 :- ***Tabulation illustrating the Cumulative Revision Rate Percentages of the Majorly Utilized Hip Prostheses Combinations (Femoral Stem + Acetabular Cup/Shell) across various time-points in the Post-Operative window, deployed for the Non-Cemented Primary THA of the British Patient Cohort, with their respective ODEP Rating Statuses and Year of First Usage and Manufacturer/Supplier firm details.***

- The hybrid and reverse-hybrid fixation based most commonly utilized prostheses combinations for the primary THA of the British patient cohort along with their respective ODEP Rating statuses, manufacturer/supplier firm details and their relative cumulative revision rate percentages across various time-points in the post-operative window are presented through the following tabulation: -

Distribution of the Overall Cumulative Revision Rate Percentages of the Majorly utilized Femoral Stem & Acetabular Shell / Cup Hip Prostheses Combinations for the Hybrid fixation based Primary Total Hip Arthroplasty of the British Patient Cohort, with their respective ODEP Rating Statuses and other Informations.

SL No.	Femoral Stem : Acetabular Cup / Shell Prostheses	Manufacturer / Supplier of the Prosthesis	No. of Reported Cases	Median Age at Primary THA	Male %	Time Span since Primary THA						Current ODEP Rating	Year of First Use(YoFU) [Femoral : Acetabular]	Present Status
						1 Year	3 Years	5 Years	10 Years	15 Years	18 Years			
1	C-Stem AMT Cemented Stem : Pinnacle Gription [SL]	Depuy Synthes	4,263	73(66-78)	36	0.87(0.62-1.23)	1.28(0.92-1.77)	1.71(1.16-2.52)	NA	NA	NA	15A* : 10A*	2005 : 2007	ACTIVE
2	C-Stem AMT Cemented Stem : Pinnacle [SL]		21,241	72(65-77)	38	0.67(0.57-0.79)	1.12(0.98-1.28)	1.45(1.27-1.65)	2.58(2.16-3.08)	*2.99(2.38-3.74)*	NA	15A*: 15A*	2005 : 2000	
3	CPCS : R3 Cementless [SL]	Smith & Nephew	5,788	74(68-79)	32	0.86(0.65-1.14)	1.45(1.14-1.83)	1.79(1.40-2.29)	NA	NA	NA	10A* : 13A*	2002 : 2007	
4	CPT CoCr Stem : Continuum [SL]	Zimmer Biomet	12,578	70(62-77)	37	1.48(1.28-1.71)	2.11(1.86-2.39)	2.52(2.23-2.85)	3.69(3.06-4.45)	NA	NA	15A* : 10A*	1990 : YoFU NA	
5	CPT CoCr Stem : Trabecular Metal Modular Cementless Cup		2,933	72(64-79)	31	1.12(0.79-1.58)	1.86(1.42-2.45)	2.35(1.83-3.02)	4.16(3.25-5.32)	*5.66(4.10-7.79)*	NA	15A* : 15A*	1990 : 1997	
6	CPT CoCr Stem : Trilogy IT [SL]		13,312	69(62-76)	38	1.17(1.00-1.37)	1.76(1.54-2.01)	2.12(1.86-2.42)	*2.81(2.28-3.47)*	NA	NA	15A* : 15A*	1990 : 1995	
7	CPT CoCr Stem : Trilogy [SL]		25,243	71(65-78)	36	0.90(0.79-1.02)	1.44(1.29-1.60)	2.12(1.93-2.32)	3.71(3.40-4.06)	5.04(4.51-5.62)	*5.04(4.57-6.37)*	15A* : 15A*	1990 : 1995	
8	Exeter V40 : ABG II Cementless Cup	Stryker	2,714	65(59-73)	34	0.26(0.12-0.54)	0.71(0.45-1.11)	1.15(0.80-1.64)	2.16(1.64-2.85)	3.83(3.03-4.85)	*4.54(3.39-6.08)*	15A* : Withdrawn since 2021 [Last Rated 10A*]	1970 : 1999	Completely Recalled; High Metallosis / Chemical Reactivity / Fretting Corrosion
9	Exeter V40 : Pinnacle [SL]	Stryker : Depuy Synthes	10,310	72(65-78)	39	0.78(0.62-0.97)	1.14(0.94-1.37)	1.40(1.18-1.67)	2.52(2.08-3.05)	*3.32(2.64-4.16)*	NA	15A* : 15A*	1970 : 2000	ACTIVE
10	Exeter V40 : R3 Cementless [SL]	Stryker : Smith & Nephew	3,384	73(65-78)	31	0.73(0.49-1.08)	1.20(0.87-1.65)	1.59(1.17-2.15)	*2.14(1.45-3.16)*	NA	NA	15A* : 13A*	1970 : 2007	
11	Exeter V40 : Trident [SL]	Stryker : Stryker	1,26,367	69(61-76)	39	0.63(0.59-0.68)	1.07(1.01-1.13)	1.40(1.33-1.48)	2.39(2.26-2.53)	3.60(3.33-3.88)	*5.06(3.56-7.16)*	15A* : 15A	1970 : 1999	
12	Exeter V40 : Trilogy [SL]	Stryker : Zimmer Biomet	15,005	70(63-76)	40	0.56(0.46-0.70)	0.88(0.74-1.04)	1.22(1.05-1.42)	2.13(1.88-2.41)	3.21(2.82-3.65)	*3.84(3.22-4.57)*	15A* : 15A*	1970 : 1995	
13	Exeter V40 : Tritanium [SL]	Stryker : Stryker	7,880	68(60-75)	45	1.09(0.88-1.35)	1.64(1.36-1.98)	2.04(1.71-2.45)	3.03(2.46-3.73)	NA	NA	15A* : 10A*	1970 : 2009	
14	Taperfit Cemented Stem : Trinity [SL]	Corin Group	7,739	72(65-77)	34	0.95(0.75-1.20)	1.42(1.16-1.72)	1.61(1.32-1.95)	*2.24(1.64-3.07)*	NA	NA	15A : 10A*	1993 : 2009	
Total Hybrid Fixation Cases			2,58,757	*Blue Italics signify that fewer than 250 cases remained at risk at these time points / Data were available ; The above data is only for Hip Implant Combinations / Stem-Cup combinations, having atleast 2,500 Registered Procedures with the Registry Database for Cemented, Non-Cemented & Hybrid Fixation based Implant ; Combinations, while Resurfacing Combinations with atleast 1,000 Registered Cases ; "NA" is mentioned for those segments wherein either the data was not available/accessible/way too low(<10) for the Registry to report ; [St] = Femoral Stem ; [C] = Acetabular Cup ; [SL] = Acetabular Shell / Shell Liner.*								

Table 6.2.32 :- ***Tabulation illustrating the Cumulative Revision Rate Percentages of the Majorly Utilized Hip Prostheses Combinations (Femoral Stem + Acetabular Cup/Shell) across various time-points in the Post-Operative window, deployed for the Hybrid fixation based Primary THA of the British Patient Cohort, with their respective ODEP Rating Statuses and Year of First Usage and Manufacturer/Supplier firm details.***

Distribution of the Overall Cumulative Revision Rate Percentages of the Majorly utilized Femoral Stem & Acetabular Shell / Cup Hip Prostheses Combinations for the Reverse-Hybrid fixation based Primary Total Hip Arthroplasty of the British Patient Cohort, with their respective ODEP Rating Statuses and other Informations.

SL No.	Femoral Stem : Acetabular Cup / Shell Prostheses	Manufacturer / Supplier of the Prosthesis	No. of Reported Cases	Median Age at Primary THA	Male %	Time Span since Primary THA						Current ODEP Rating	Year of First Use(YoFU) [Femoral : Acetabular]	Present Status
						1 Year	3 Years	5 Years	10 Years	15 Years	18 Years			
1	Corail : Elite Plus Ogee [C]	Depuy Synthes	3,175	72(65-77)	37	0.67(0.43-1.02)	1.46(1.10-1.96)	1.85(1.42-2.41)	2.88(2.26-3.67)	*4.54(3.49-5.89)*	NA	15A* : 15A*	1986 : 1982	ACTIVE
2	Corail : Marathon [C]		17,767	70(64-76)	39	0.62(0.51-0.75)	1.04(0.90-1.21)	1.29(1.12-1.48)	2.11(1.77-2.51)	NA	NA	15A* : 13A*	1986 : 2000	
Total Reverse Hybrid Fixation Cases			20,942	*Blue Italics signify that fewer than 250 cases remained at risk at these time points / Data were available ; The above data is only for Hip Implant Combinations / Stem-Cup combinations, having atleast 2,500 Registered Procedures with the Registry Database for Cemented, Non-Cemented & Hybrid Fixation based Implant ; Combinations, while Resurfacing Combinations with atleast 1,000 Registered Cases ; "NA" is mentioned for those segments wherein either the data was not available/accessible/way too low(<10) for the Registry to report ; [St] = Femoral Stem ; [C] = Acetabular Cup ; [SL] = Acetabular Shell / Shell Liner.*									

Table 6.2.33 :- ***Tabulation illustrating the Cumulative Revision Rate Percentages of the Majorly Utilized Hip Prostheses Combinations (Femoral Stem + Acetabular Cup/Shell) across various time-points in the Post-Operative window, deployed for the Reverse Hybrid fixation based Primary THA of the British Patient Cohort, with their respective ODEP Rating Statuses and Year of First Usage and Manufacturer/Supplier firm details.***

- The revision rate percentage scenarios across various timepoints in the post-operative window for the most commonly utilizing resurfacing hip prostheses for the primary resurfacing hip arthroplasty of the British patient cohort, along with their respective ODEP rating statuses and year of first usage are presented through the following tabulation: -

Distribution of the Overall Cumulative Revision Rate Percentages of the Majorly utilized Femoral Stem & Acetabular Shell / Cup Hip Prostheses Combinations for the Resurfacing Hip Arthroplasty of the British Patient Cohort, with their respective ODEP Rating Statuses and other Informations.

SL No.	Femoral Stem : Acetabular Cup / Shell Prostheses	Manufacturer / Supplier of the Prosthesis	No. of Reported Cases	Median Age at Primary THA	Male %	Time Span since Primary THA						Current ODEP Rating	Year of First Use(YoFU) [Femoral : Acetabular]	Present Status	Company Size
						1 Year	3 Years	5 Years	10 Years	15 Years	18 Years				
1	ASR Resurfacing Cup	Depuy Synthes	2,958	55(49-60)	68	1.62(1.23-2.15)	5.83(5.04-6.74)	13.16(11.99-14.44)	26.10(24.54-27.74)	30.13(28.47-31.86)	NA	Withdrawn / Not Rated	YoFU NA : Device Recalled / Banned	Banned / Withdrawn	MNC
2	Adept Resurfacing Cup	MatOrtho Limited	3,956	54(47-59)	76	1.08(0.80-1.45)	2.37(1.93-2.91)	4.33(3.71-5.04)	7.73(6.89-8.68)	10.56(9.41-11.84)	NA	13A [Controversial Hip ; Multiple LawSuites ; Co-Mfger for Corin Products]	2004	Selective Operation : for 48-58mm heads in Males only	Local ; From : Leatherhead, UK
3	BHR Resurfacing Cup	Smith & Nephew	23,684	55(48-60)	76	0.99(0.88-1.13)	2.26(2.08-2.46)	3.48(3.25-3.73)	7.26(6.91-7.62)	10.26(9.81-10.72)	11.30(10.76-11.86)	15A*	1997	Selective Operation ; for 48-62mm heads in Males Only	
4	Conserve Plus Resurfacing Cup	Wright Medical [now C/o Stryker]	1,325	56(50-61)	63	2.04(1.40-2.96)	5.15(4.08-6.49)	8.28(6.91-9.90)	14.01(12.23-16.02)	16.45(14.45-18.68)	*17.28(15.03-19.82)*	Withdrawn / Not Rated	Around 2007s : Device Recalled / Banned	Banned/Recalled	MNC
5	Cormet 2000 Resurfacing Cup	Zimmer Biomet	3,679	55(48-60)	65	1.50(1.15-1.94)	3.71(3.14-4.37)	7.64(6.83-8.55)	16.72(15.54-17.98)	22.35(20.95-23.83)	*24.51(22.74-26.40)*				
6	Durom Resurfacing Cup		1,709	55(49-60)	70	1.35(0.90-2.02)	3.58(2.80-4.58)	5.47(4.49-6.66)	8.48(7.24-9.91)	10.36(8.96-11.96)	NA				
7	Recap Magnum		1,699	54(49-59)	73	1.94(1.39-2.72)	3.36(2.60-4.34)	5.56(4.57-6.77)	10.15(8.79-11.70)	*13.40(11.57-15.50)*	NA		YoFU NA - Device Recalled / Banned	Banned / Withdrawn	
Total Resurfacing Hip Cases			39,010	*Blue Italics signify that fewer than 250 cases remained at risk at these time points / Data were available ; The above data is only for Hip Implant Combinations / Stem-Cup combinations, having atleast 2,500 Registered Procedures with the Registry Database for Cemented, Non-Cemented & Hybrid Fixation based Implant ; Combinations, while Resurfacing Combinations with atleast 1,000 Registered Cases ; "NA" is mentioned for those segments wherein either the data was not available/accessible/way too low(<10) for the Registry to report ; [St] = Femoral Stem ; [C] = Acetabular Cup ; [SL] = Acetabular Shell / Shell Liner.*										

Table 6.2.34 :- ***Tabulation illustrating the Cumulative Revision Rate Percentages of the Majorly Utilized Hip Prostheses Combinations (Femoral Stem + Acetabular Cup/Shell) across various time-points in the Post-Operative window, deployed for the Resurfacing Hip Arthroplasty of the British Patient Cohort, with their respective ODEP Rating Statuses and Year of First Usage and Manufacturer/Supplier firm details.***

Resurfacing Hip Arthroplasty and MoM based Prostheses usage Scenarios in UK: -

- Stemmed Metal-on-Metal (MoM) and hip resurfacing implants continues to fail at a remarkably higher proportions and numbers than their respective expective rates, thereby leading to a drastic reduction in their utilization numbers across the United Kingdom.

- The best performing resurfacing hip implant is found to have a revision rate percentage of 11.30% at 18 years which still is remarkably higher than most other alternative hip prostheses combinations available for utilization.

- The thorough and care analysis of the revision and re-revision data revealed during the course of this probe, that the general annual revision rate percentage for primary hip arthroplasty recipients in United Kingdom, rose strikingly high during the years of 2008 to 2010 period, just when MoM heads and most importantly the resurfacing implants boomed all across the globe by major implant makers, with the promise of answering all the prevalent constraints all at once. This snowballed sooner than expected into a rat-race of MoM and Hip Resurfacing prostheses launches by all the competitive global and regional players in the international prostheses manufacturer/supplier arena.

- However, these launches were fuelled through a severe compromise in the pre-market clinical trials and designing level failure simulation studies, which led to the implants falling for time-driven prostheses failure issues, faster than any other prevalent and legacy products, through an accelerated wearing out of the femoral head, release of particulate debris into the musculature and adjoining body tissues, causing a chain of immunological rejection reactions, snowballing into an elevated blood metallosis conditions, that not just impaired the surgically replaced hip joint useless, but also severely impacted the general metabolism and functioning of vital organs, leading to hepatic and renal failure.

- The latest report of the NJR and related data across its databases highlights that, “the use of MoM bearings has led to a large excess of revisions which would (possibly) be avoided”, if alternate bearing options were utilized in the first place. This statement stands true to the actual data not just for the United Kingdom, but also for many other nations, using large scale MoM prostheses and resurfacing heads.

- This rationale is further exemplified and modelled for a subsequent publication in the ‘Journal of Bone and Joint Surgery’, wherein it is reported that “approximately” for every 100 MoM hip resurfacings procedures conducted or performed, there were an estimated 7.8 excess revisions by ten years and similarly for every 100 MoM stemmed THAs, there would be an even higher proportions of 15.9 excess revision procedures, equating for as much as 8,021 excess first revision arthroplasties of the British patient cohort[Hunt et.al., 2018], adding up to the already existent clinical burden, which may further snowball into a chain of delays for the present concurrent line-up of the patient groups awaiting for an arthroplasty driven therapeutic rescue from their respective ailments on respective hip and knees.

Knee Arthroplasty Practices & Prosthesis Utilization Scenarios on the Patient Cohort of the United Kingdom.

Overview of Knee Arthroplasty Practices in United Kingdom: -

Total No. of Total Knee Arthroplasties [T.K.A]	= 12,06,605
Total No. of Unicondylar Knee Arthroplasty [U.K.A]	= 1,03,385
Total No. of Patellofemoral Knee Arthroplasty [P.F.K.A]	= 16,476
Total No. of Multi Compart. Knee Arthro.	= 622
Total No. of Unconfirmed Knee Arthroplasties	= 22,558
Overall Cumulative Total No. of Knee Arthroplasties	= **13,49,646**

Preface of the British Knee Arthroplasty Practices: -

- The mean age of the knee arthroplasty recipient patient cohort in UK is 68.7 years for males and 69.2 years for females, with an overall mean of 68.9 and median of 70 years.

- The median age-group of the patient cohort receiving cemented primary total knee arthroplasty is 70 years, which is quite high compared with the global numbers, though the age lies very much within the core age-group of the patients.

- While for unicondylar knee arthroplasties, which was performed on a greater proportion of comparatively younger group of patients, with a median age-group of 64 years, i.e., six years younger than the median age group for conventional cemented primary total knee arthroplasty.

- The mean and median age-linked distribution of the knee arthroplasty procedures is presented through the following tabulation: -

NJR 2022 :- Mean Age-Group of the Male & Female UK Patient Cohort, receiving Primary Knee Arthroplasty.							
SL No.	Criteria	Male Patients		Female Patients		Overall Patients	
		Mean Age [S.D]	Median	Mean Age [S.D]	Median	Mean Age [S.D]	Median
1	Mean Age of the Primary Knee Arthroplasty recipient Patients in UK	68.7 [9.3]	69	69.2 [9.8]	70	68.9 [9.6]	70

Table 6.2.35 :- ***Tabulation illustrating the Mean and Median Gender-Linked Age of the Primary Knee Arthroplasty recipient patient cohort in UK.***

- While on the gender-linked aspect of knee arthroplasties, an interestingly unique practice in the UK's knee arthroplasty practices domain was noted, wherein patella-femoral knee arthroplasties, a form of partial knee arthroplasty has been categorically performed on female patients, accounting for over 77.30% of all such recorded procedures, and the mean age group is also younger than that of the usual TKA/UKA patient cohort in UK, with the median age at the time of the primary surgery of 58 years.

- While unicondylar knee arthroplasties using a non-cemented or a hybrid mode of prosthesis fixation, was applied in greater or rather majority proportions for the male patient cohort, accounting for 53.50% and 54.90% of all the procedures using the mentioned fixation methods respectively.

- The overall proportions of various knee arthroplasty types remained fairly constant over the years in British practices, but the annual proportion of Unicondylar Knees are seen to rise quite sharply since 2013, to reach an overall share of 10% for the first-time in recorded British arthroplasty practices, as far as data could be ascertained in 2017. The growth is sustained to 13.40% in 2021.

- Amongst the UKAs, the relative popularity of the non-cemented UKAs has risen quite rapidly, as is evident from the fact that it had a less than 1% footprint of all the knee arthroplasties in 2010, which at present accounts for nearly 1/3rd of all the UKAs performed on the British patient cohort as on date.

- The logically reasonable contributive factors towards the rise of UKAs are found to be multifactorial by this research, but what primarily stands out as the most significant reason behind the such a sharp rise in the recent years, was the British healthcare agency – "NICE" or the 'National Institute of Health and Care Excellence' 's laid down guidelines of 2020, wherein they suggested that clinicians upon diagnosing the patient condition should there be a scope for the patient to choose from a TKA or a UKA based surgical intervention for their condition, the practicing institutes and clinicians must allow for the patients to chose for themselves, while, the clinicians shall promote/encourage UKAs by presenting them with the involved pros & cons, of both the approaches.

- The guideline is 'reported' and to some extent also observed by this research to have been accepted well by the clinician and the patient cohort. However, a minute analyses of the said guideline by this research, precipitates a possible theory that the health agency in the pandemic or the post-pandemic era, aims to have a certain percentage of hospital beds always available, and to get the occupied beds to get freed up sooner than the earlier timelines of stays, to accommodate for any unforeseen critical healthcare emergencies or hazards, that risks the general life of a greater and common population of the nation.

- This theory is further consolidated by the fact that UKAs are usually promoted on the basis of their involving shorter hospital stays and faster recovery windows, compared to TKAs, and the guideline by the NICE being released in the pandemic year of 2020, thereby synchronizes the whole scenario.

- However, with the rise in the UKA procedures, the revision risk at both short and long terms rises abruptly, since the estimated revision risk, based on the present revision rates for UKAs vis-à-vis TKAs are quite higher.

- The revision rates for cemented UKA (both medial & lateral) are as much as 3.2x the observed rate of revision for cemented TKAs at 10 years and 3.5x at 18 years. Similar are the scenes for non-cemented UKAs, having a revision rate that is 2.3x than non-cemented TKA at 10years and 2.7x at 18years. UKAs seems to fare worse in terms of outcome and sustainability in the long term, particularly when the respective rate of revision at any of its time-point post-surgery is always higher or more than 1.5x the TKA rate using the same fixation method.

- When analyzed for age and gender-based influence of the revision risk distribution, it was found that younger patients, and most of them being males are more likely to undergo a revision of their primary UKA, and this may explain to some extent the demographics & the scenarios behind the higher revision rates observed for UKAs.

- The revision risk of a cemented UKA is at least 2x higher in males, and 2.4 higher in females at 10 years than a cemented TKA.

- Similar scenes are observable for patellofemoral and multicompartmental knee arthroplasties as well, which are having significantly higher revision rates than TKAs.

- The ASA-Grade linked distribution of the knee arthroplasty procedures performed on the patient cohort in UK, highlighting the general co-morbidity statuses of the recipient patients for the entire span of the available arthroplasty data, spread across the years of 2003 – 2021, are tabulated as follows: -

Distribution of the Primary Total Knee Arthroplasty Procedures that were performed on the British Patient Cohort, as per their Respective Gender and ASA Grade Categorization, for the Entire Period of Available Data [2003-2021].					
SL No.	**Parameter**	**Description**	**Male N (%)**	**Female N(%)**	**All N (%)**
1	ASA 1	A Normal Healthy Patient ; Non-Smoker / No or Minimal Alcohol Use	82,050 (13.1)	80,715(9.9)	1,62,765(11.3)
2	ASA 2	A Patient with Mild Systemic Disease; Smoker/Social Alcohol Consumption/Obesity(30<BMI<40); Mild Lung Disease	4,42,436(70.4)	5,95,820(73.2)	10,38,256(72.0)
3	ASA 3	A patient with Sever Systemic Disease; Substantive Func.Limit;One or More Moderate to Severe Disease. Morbid Obesity(BMI>=40);Active Hepatitis/Alcoholic/Pacemaker/ESRD;History of MI,CVA,TIA or CAD/Stents.	1,01,418(16.1)	1,34,881(16.6)	2,36,299(16.4)
4	ASA 4	A patient with Severe Systemic Disease that is a Constant Threat to Life. Recent(<3mnths) MI, CVA, TIA or CAD/Stents ; Ongoing Cardiac Ischemia/Severe Valve Dysfunction/Severe Reduction of Ejection Fraction/Sepsis/DIC-ARD-ESRD not undergoing regular Dialysis.	2,180(0.3)	2,409(0.3)	4,589(0.3)
5	ASA 5	A moribund patient who is not expected to survive without the Surgery; Ruptered Abdominal/Thoracic aneurysm, massive trauma, intracranial bleed with Mass Effect, Ischemic Bowel in the face of significant Cardiac pathology or MultiOrgan/System Failure.	61(<0.1)	81(<0.1)	142(<0.1)
Cumulative Total of All the ASA-Grade linked Knee Arthroplasties in UK			**6,28,145**	**8,13,906**	**14,42,051**

Table 6.2.36 :- ***Tabulation illustrating the General Distribution of the Primary Total Knee Arthroplasty Recipient British Patient Cohort, categorized as per their Respective Gender and ASA-Grade, highlighting their overall Co-Morbidity Statuses.***

- The complete breakdown of the primary reasons stated for the overall distribution of the major reasons cited by the patients and recognized by the clinicians/hospitals as reported to the registry and other healthcare databases, were not obtainable for the British patient cohort. Despite the well-established fact that worsening osteoarthritis is presently the leading cause for knee arthroplasties, which holds true for UK's arthroplasty scenario as well, but the due representation and recognition of other vital reasons / primary indications such as the number of knee fractures, instability issues, varus/valgus deformities are integrally critical for the general well-being of the common patient community and therefore this research infers such disclose should be made accessible and open, as is expected of a major first-world nation with a healthcare system and medical education of global repute.

- Considering osteoarthritis to be the giant leading cause for a primary knee arthroplasty in an undisputable magnitude, the relative incidences for being the sole reason and one of many reasons for the primary knee arthroplasty of the British patient cohort, segregated as per the respective patient gender groups is tabulated. The said tabulation is presented as follows: -

NJR 2022 :- Impact of Osteoarthritis as a Primary or One of the Major Indication for Primary Knee Arthroplasty of the UK Patient Cohort.							
SL No.	**Indication Trends**	**Male Patients**		**Female Patients**		**Overall**	
		No. of Cases	**% of Overall**	**No. of Cases**	**% of Overall**	**No. of Cases**	**% of Overall**
1	Osteoarthritis as the Sole Reason for Primary Knee Arthroplasty	6,16,628	43.89%	7,88,208	56.11%	14,04,836	100.00%
2	Osteoarthritis as One of Many Reasons for Primary Knee Arthroplasty	6,11,465	43.88%	7,81,798	56.11%	13,93,263	100.00%
Category Total		**12,28,093**	**43.89%**	**15,70,006**	**56.11%**	**27,98,099**	**100.00%**

Table 6.2.37 :- ***Tabulation illustrating the Distribution of the Primary Knee Arthroplasties performed on the British patient cohort, based on whether a worsening Osteoarthritis is cited as the Sole Reason or one of many Reasons to undergo a knee arthroplasty, segregated as per their respective gender.***

Revision Knee Arthroplasty Practices and Related Outcomes for the British Patient Cohort: -

- Unlike the scenario for hip arthroplasty practices on the same patient cohort, it is noted that some of the active lowest revision rates are obtained for cemented fixation based non-constrained or cruciate retaining fixed bearing total knee prostheses, and cemented fixation based total knee arthroplasties performed using monobloc polyethylene tibias.

- Comparatively the revision rates of the primary TKAs performed using posterior stabilized knee prostheses with cemented fixations and those using dual mobility bearings continues to be on the higher ends for the general patient cohort in the United Kingdom.

- While the cumulative revision rate scenarios across various time-points in the post-operative window of unicondylar knee arthroplasties are substantially higher than that of the TKAs, and the margin further widens when other forms of partial knee arthroplasty such as the patella-femoral and multi-compartmental knee arthroplasties are brought into the same round of comparison.

- The general revision rate percentage for cemented unicondylar knee arthroplasties are 3.2 and 3.5 times higher than the noted revision rate percentage for cemented total knee arthroplasty at post-operative 10 and 18 years respectively. Therefore, in consistency with the global scenario, unicondylar knee replacements were more susceptible to be converted into primary total hips, during their revision in their immediate to moderate short-term post-operative windows.

- While for patella-femoral arthroplasties the noted overall revision rate percentages in the long-term post-operative window are 5.6 – 5.8 times higher than that of the rate obtained for the conventional cemented total knee arthroplasty of the same patient cohort in the United Kingdom, at 10 and 18 years post-operatively.

- The scenario is not very different for multi-compartmental knee arthroplasty procedures, even though the number of the primary multi-compartmental knee arthroplasties are comparatively much less, their outcomes in terms of the respective revision rates across multiple time-points in the post-operative window is more than doubly high than the prevailing corresponding revision rate of conventional cemented / non-cemented TKAs.

- Females are slightly less vulnerable to first revision of an implant than in males for cemented total knee arthroplasty, however a patient from the youngest (<50 Years) or the younger group (>50 & <55 Years) age-group have received greater proportions of revisions, irrespective of the patient's gender with the youngest group having the worst possible outcome in terms of the entailing risk of subsequent revision.

- The considerable drop in the revision knee procedures performed in the years of 2020 and 2021, compared vis-à-vis to that of the prevalent numbers and related trends in 2019 and previous years respectively, highlights the significant impact of the COVID-19 pandemic in the non-critical healthcare aspects in UK. However, most other nations which were evaluated during the course of this research, posted an approximate 70-80% recovery to the pre-pandemic numbers across all segments in the year of 2021, which is not reflected in the official numbers published by the UK's NJR database, though not co-related against NHS's numbers.

- The year-wise breakdown of the number of revision knee arthroplasty procedures performed on the British patient cohort is presented through the following tabulation and line-graph plot: -

NJR 2022 :- Number of Revision Procedures Recorded/Reported to be Performed on the NJR Patient Cohort over the Years from 2003 - 2021, categorized as per the Type/Stage of Revision Arthroplasty Performed.

SL No.	Year of Revision Surgery	Type of Revision Procedure			All Revision Arthroplasty Procedures
		Single-Stage N(%)	Stage One of Dual Stage N (%)	Stage Two of Dual Stage N (%)	
1	2003*	7(1.1)	<4(0.2)	632(98.8)	640
2	2004	712(57.1)	78(6.3)	457(36.6)	1,247
3	2005	1,487(73.7)	211(10.5)	321(15.9)	2,019
4	2006	1,948(75.3)	282(10.9)	357(13.8)	2,587
5	2007	2,663(75.2)	387(10.9)	493(13.9)	3,543
6	2008	3,331(75.7)	473(10.8)	596(13.5)	4,400
7	2009	3,716(76.3)	527(10.8)	629(12.9)	4,872
8	2010	4,180(77.1)	573(10.6)	670(12.4)	5,423
9	2011	4,341(77.4)	620(11.0)	650(11.6)	5,611
10	2012	5,013(78.5)	631(9.9)	741(11.6)	6,385
11	2013	4,706(78.5)	631(10.5)	661(11.0)	5,998
12	2014	5,082(78.0)	736(11.3)	700(10.7)	6,518
13	2015	5,349(79.0)	746(11.0)	676(10.0)	6,771
14	2016	5,565(80.6)	699(10.1)	643(9.3)	6,907
15	2017	5,667(80.6)	701(10.0)	667(9.5)	7,035
16	2018	5,686(82.2)	627(9.1)	604(8.7)	6,917
17	2019	5,943(83.3)	639(9.0)	549(7.7)	7,131
18	2020	3,220(79.7)	456(11.3)	365(9.0)	4,041
19	2021	4,075(83.6)	403(8.3)	396(8.1)	4,874
TOTAL		72,691	9,421	10,807	92,919

Table 6.2.38 :- ***Tabulation illustrating the Year-wise Breakdown of the Annual Number of Revision Knee Arthroplasty procedures, performed on the British Patient cohort, segregated by the Type of Revision Surgery approach adopted.***

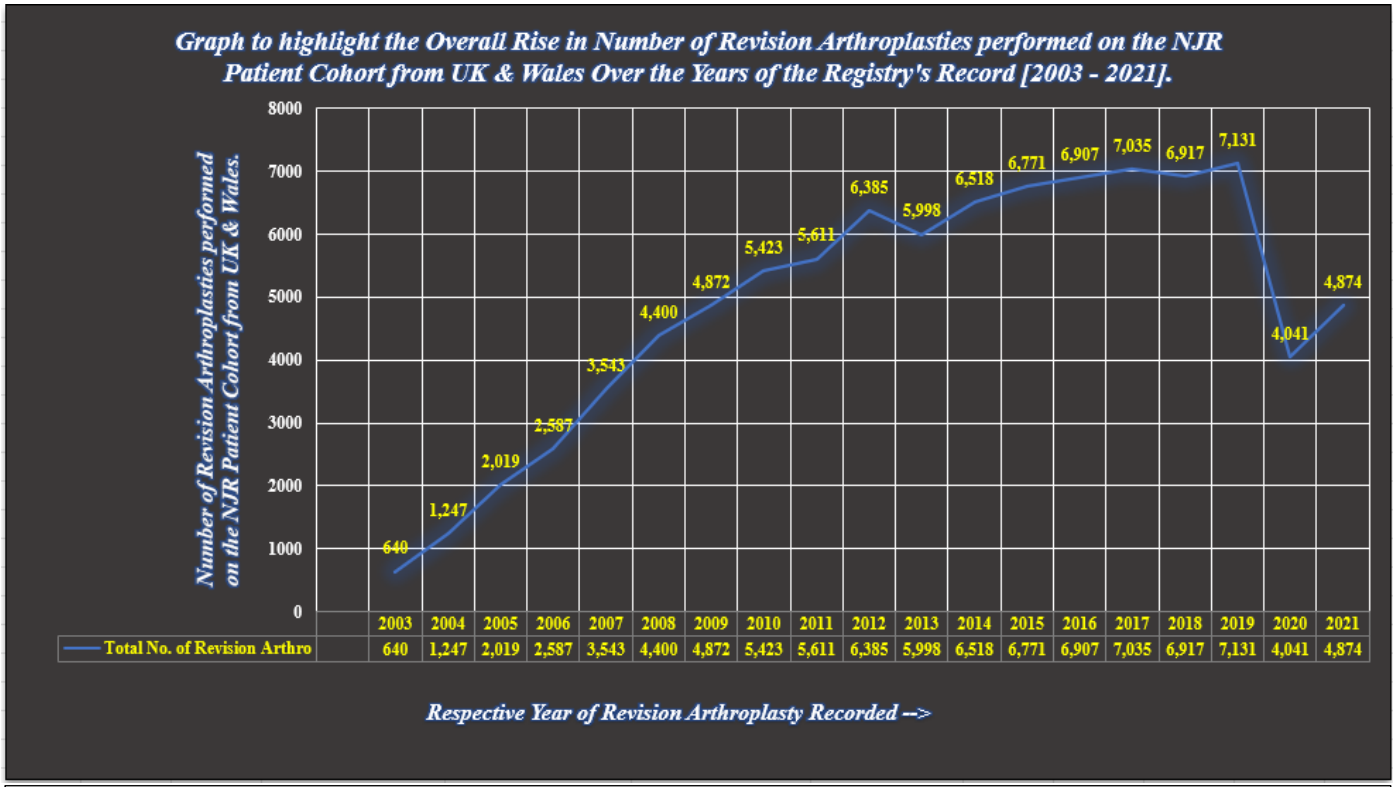


Figure 6.2.25 :- ***A Line Graph plot illustration highlighting the Year-Wise projectile of the Annual Number of the Revision Knee Arthroplasties performed on the British Patient Cohort.***

Leading Causes for the Revision Knee Arthroplasties in UK: -

- The most commonly reported indications for a revision of a failing or problematic primary total knee arthroplasty performed on a general patient in the UK, as per the relative number of procedures caused by them are categorized in the decreasing order of their respective number of procedures caused are as follows: -
    - Aseptic Loosening / Lysis.
    - Post-Operative Infection.
    - Progression of Arthritis.
    - Post-Operative Pain.
    - Instability Issues.

- While for all the types of partial knee arthroplasties – Unicondylar, Patello-Femoral and Multi-Compartmental, progressively worsening arthritis and post-operative pain were the major issues that caused the greatest number of revisions of their respective primaries.

- For conventional cemented TKAs, the decreasing order of impact in terms of actual revisions caused due to the respective indications are presented as follows: -

    - Aseptic Loosening.
    - Lysis.
    - Post-Operative Infection.
    - Instability.
    - Post-Operative Pain.
    - Other issues.

- The relative breakdown of the distribution of knee revisions based on the primary reasons cited for the procedure, categorized on whether a single stage or a dual stage revision protocol is followed, is presented through the following tabulation: -

NJR 2022 :- Overall Number & Percentage of Knee Revisions of the NJR Patient Cohort, by Indications & Stages of Revision Procedure.

SL No.	Indications for Revision Arthroplasty	Number of Revision Procedures as per Stages of Revision.			All Procedures
		No. of Single Stage Procedures (%)	Stage One of Dual Stage(%)	Stage Two of Dual Stage(%)	
1	Aseptic Loosening/Lysis	27,573(37.9)	1,638(17.4)	1,803(16.7)	31,014
2	Instability	12,548(17.3)	374(4.0)	517(4.8)	13,439
3	Pain	10,394(14.3)	371(3.9)	536(5.0)	11,301
4	Implant Wear	10,177(14.0)	297(3.2)	319(3.0)	10,793
5	Other Indication	8,017(11.0)	342(3.6)	636(5.9)	8,995
6	Infection	5,774(7.9)	8,042(85.4)	8,078(74.7)	21,894
7	Malalignment	5,244(7.2)	114(1.2)	179(1.7)	5,537
8	Periprosthetic Fracture	3,441(4.7)	138(1.5)	167(1.5)	3,746
9	Dislocation/Subluxation	2,940(4.0)	147(1.6)	143(1.3)	3,230
10	Stiffness*	4,103(5.6)	204(2.2)	170(1.7)	4,477
11	Progressive Arthritis*	10,090(15.4)	66 (0.8)	97(1.1)	10,253
TOTAL		1,00,301	11,733	12,645	1,24,679

**The parameters(Stiffness & Progressive Arthritis) were not recorded in the initial phase of the registry ; only since MDSv2 Rev. due to Stiffness and from MDSv3 onwards Rev. due to Progressive Arthritis data has been captured and presented / Real nos. could be higher.*

Table 6.2.39 :-***Tabulation illustrating the Primary Indication/Reasons wise Distribution of the Revision Knee Arthroplasties performed on the British Patient Cohort, alongside the Type of Revision Stage protocol followed, for the entire span of accessible data [2003-2021].***

- The revision incidences for non-cemented TKAs are noted to be lesser than that of the cemented TKAs, in case of post-operative infection and peri-prosthetic fractures, but is otherwise higher for all other indications.

- The practices of mixing antibiotics with the prosthesis fixating cement paste, is noted in most of the other nations which were evaluated for their respective arthroplasty practices, however, no such detailing was plausible to be accessed by this research from UK healthcare sources and relevant databases. Now though the utilization or the aspect of antibiotics might appear off-topic, compared to the track of this research/thesis work, but those antibiotics are placed in-situ along with the cement mixture pasture, so as to minimize the scopes for a negative foreign-body reaction or a post-operative bacterial infection, and these infection incidences formulate a significant proportion of the revisions performed within the short-term period of the primary arthroplasty.

- Similar to that of the revision scenarios for hip arthroplasties performed on the patient cohort in UK, majority of the revisions performed on primary TKAs/UKAs were due to the incidences of bacterial infection within the first two years of the primary surgery. Bacterial infections are the most commonly occurring infections, that troubles the greatest proportion of the primaries within a very short span since their primaries, with '*Staphylococcus aureus*', causing the greatest number of infections.

- Knee revisions due to infections are generally not seen post 5 years into the post-operative window, and therefore the general cumulative revision rate due to incidences of infections fall rapidly beyond 5 years of the timepoint since the primary.

- Conversely, the initial high revision numbers during the immediate short-term post-op window due to aseptic loosening, lysis and pain, post a primary TKA settles and drops after a couple of years, only to rise after 7 years have passed since the primary, thereby becoming the prime trouble-maker or cause for prostheses and patients in general, for the long-term aspect.

- Therefore, an incidence of aseptic loosening post 7-8 years since the primary procedure could be termed as a result of implant fatiguing, or some other intrinsic problems arising out of lifestyle-based causes, and not exactly as a clinical failure, which would have otherwise troubled the patient in the initial post-op recovery window itself.

Prostheses Specific Knee Arthroplasty Practices and Related Outcomes on British Patients: -

- Unlike hip arthroplasties, the general variety of prostheses options available in terms of the fixation methodologies, degree of constraint in the prostheses and the articulating surface bearing types for either a total or an unicondylar/partial knee prosthesis, are quite broad, and calls for separate discussion for an appropriate representation of the actual on-ground patient centric approaches, general practices and the related outcome scenarios.

- The mean age group and other general demography-based metrics of the British patients undergoing a non-cemented fixation based unconstrained fixed total knee prostheses and that of the cemented monobloc polyethylene tibia are not exactly the same, and hence, their respective outcomes analysed for their cumulative revision rate percentages and other parameters varies widely.

- Therefore, the overall number of the primary knee arthroplasties performed (total and unicondylar) for the British patient cohort, based on the prosthesis's fixation method applied, constraint level of the prostheses and the articulating bearing surface type, along-with other detailing are presented through the following tabulation: -

NJR 2022:- Overall Number & Percentage of Primary Knee Arthroplasties of the NJR Patient Cohort from the UK & Wales, based on Patient Age Groups, Fixation Method Utilized & Level of Knee Prosthesis Constraint, with their Gender based Distribution.

SL No.	Fixation, Constraint and Bearing Type	No. of Primary Knee Operations	% of Each Constraint Type Used for Each Fixation Method	% of All Primary Knee Operations	Age of Patients (Years)		Male (%)
					Median [Lower - Upper]	Mean [S.D]	
1	All Types	14,42,051	N.A	100	70 (63 - 76)	68.9(9.6)	43.6
	TOTAL KNEE ARTHROPLASTY						
2	All Cemented	12,06,605	N.A	83.7	70(64-76)	69.7(9.3)	42.5
3	Unconstrained, Fixed	8,32,844	69	57.8	70(64-76)	69.6(9.1)	43
4	Unconstrained, Mobile	41,741	3.5	2.9	69(62-76)	68.8(9.6)	42.1
5	Posterior-Stabilized, Fixed	2,84,858	23.6	19.8	70(64-77)	69.8(9.4)	41.2
6	Posterior-Stabilized, Mobile	13,486	1.1	0.9	67(60-74)	66.5(10.1)	44.6
7	Constrained Condylar	12,225	1	0.8	71(63-78)	69.9(10.3)	36.4
8	Monobloc Polyethylene Tibia	19,151	1.6	1.3	74(69-79)	73.4(8.3)	40.8
9	Pre-assembled/Hinged/Linked	2,300	0.2	0.2	75(66-82)	73.1(12.5)	27.2
	All Non-Cemented Fixation						
10	All Non-Cemented	48,781	N.A	3.4	69(62-75)	68.2(9.6)	48.7
11	Unconstrained, Fixed	19,115	39.2	1.3	68(61-75)	68.0(9.8)	50.2
12	Unconstrained, Mobile	25,860	53	1.8	69(62-75)	68.5(9.2)	46.8
13	Posterior-Stabilized, Fixed	3,510	7.2	0.2	67(59-74)	66.7(10.6)	53
14	Other Constraints	296	0.6	<0.1	67(60.5-73)	66.4(9.0)	73.6
	All Hybrid Fixation						
15	All Hybrid	10,116	NA	0.7	69(62-76)	68.7(9.8)	44.5
16	Unconstrained, Fixed	6,593	65.2	0.5	70(63-76)	69.0(9.5)	45.4
17	Unconstrained, Mobile	2,184	21.6	0.2	69(62-76)	68.7(9.8)	38.2
18	Posterior-Stabilized, Fixed	923	9.1	0.1	69(60-75)	67.4(10.5)	46.7
19	Other Constraints	416	4.1	<0.1	66(58.5-74.5)	65.8(10.7)	58.9
	UNICOMPARTMENTAL KNEE ARTHROPLASTY						
20	All Unicondylar, Cemented	1,03,385		7.2	64(57-71)	63.9(9.8)	53.5
21	Fixed	46,346	44.8	3.2	63(56-71)	63.5(9.9)	55.5
22	Mobile	50,506	48.9	3.5	64(57-71)	64.2(9.5)	51.6
23	Monobloc Polyethylene Tibia	6,533	6.3	0.5	64(57-71)	64.0(10.0)	53.5
24	All Unicondylar - Uncemented and Hybrid Fixation Arthroplasties	33,508	N.A	2.3	65(58-72)	64.8(9.6)	54.9
25	Fixed	1,421	4.2	0.1	66(57-74)	65.3(11.2)	43.8
26	Mobile	31,611	94.3	2.2	65(58-72)	64.8(9.5)	55.6
27	Monobloc Polyethylene Tibia	476	1.4	<0.1	65(58-71)	64.6(9.4)	42
28	Patellofemoral	16,476		1.1	58(50-67)	58.5(11.7)	22.7
29	Multi-compartmental	622		<0.1	60(53-68)	60.7(10.1)	46.9
30	Unconfirmed	22,558	N.A	1.6	69(61-76)	68.1(10.2)	43.8

Table 6.2.40 :- ***Tabulation illustrating the Distribution of the Overall Primary Knee Arthroplasty procedures, performed on the British Patient Cohort, and their respective Mean and Median Age Group, categorized as per the Knee Prostheses Type and Fixation Methodology applied.***

- The outcome scenarios with respect to the most commonly discussed and relatable parameter of the involving cumulative revision rate percentage, of the primary knee arthroplasty recipient British patient cohort, as per the respective prostheses type utilized and the fixation method adopted is presented through the following tabulation: -

NJR 2022:- Cumulative Revision Rate Percentage of the Primary Knee Arthroplasty Cases performed on the British Patient Cohort, as per the Fixation Method of Knee Arthroplasty & Constraint Level of the Knee Prosthesis used with Respective Prosthesis Bearing Type.

SL No.	Fixation, Constraint Level and Bearing Type	No. of Cases	Time Since Primary					
			1 Year	3 Years	5 Years	10 Years	15 Years	18 Years
2	All Cemented	12,06,605	0.42(0.41-0.43)	1.44(1.42-1.46)	2.07(2.04-2.09)	3.15(3.11-3.19)	4.26(4.19-4.33)	5.08(4.91-5.26)
3	Cemented and Non-Constrained, Fixed	8,32,844	0.38(0.37-0.40)	1.33(1.30-1.36)	1.88(1.85-1.91)	2.83(2.78-2.87)	3.93(3.84-4.01)	4.83(4.61-5.05)
4	Cemented and Non-Constrained, Mobile	41,741	0.51(0.45-0.59)	1.78(1.65-1.92)	2.64(2.48-2.81)	4.04(3.83-4.26)	5.17(4.88-5.48)	*5.53(5.05-6.06)*
5	Cemented and Posterior-Stabilized, Fixed	2,84,858	0.48(0.45-0.50)	1.65(1.60-1.70)	2.44(2.38-2.50)	3.83(3.74-3.92)	4.98(4.84-5.13)	5.77(5.40-6.16)
6	Cemented and Posterior-Stabilized, Mobile	13,486	0.63(0.51-0.78)	2.08(1.84-2.34)	2.82(2.55-3.13)	4.14(3.78-4.54)	5.29(4.77-5.86)	*5.42(4.85-6.05)*
7	Cemented Constrained Condylar	12,225	0.97(0.80-1.16)	2.10(1.84-2.40)	2.76(2.44-3.13)	3.93(3.36-4.60)	*5.24(4.02-6.83)*	
8	Cemented Monobloc Polyethylene Tibia	19,151	0.35(0.28-0.45)	1.24(1.08-1.41)	1.68(1.49-1.89)	2.18(1.94-2.45)	2.53(2.18-2.94)	*2.53(2.18-2.94)*
9	Cemented Pre-Assembled/Hinged/Linked	2,300	2.07(1.54-2.77)	4.28(3.47-5.29)	5.95(4.92-7.18)	8.72(7.09-10.70)	*10.05(7.95-12.66)*	
10	All Non-Cemented	48,781	0.56(0.49-0.63)	2.05(1.93-2.19)	2.78(2.63-2.94)	3.95(3.76-4.15)	5.23(4.96-5.52)	6.19(5.63-6.79)
11	Non-Cemented and Non-Constrained, Fixed	19,115	0.63(0.52-0.75)	2.25(2.04-2.48)	2.91(2.67-3.18)	4.10(3.79-4.44)	5.28(4.86-5.73)	*5.80(5.13-6.56)*
12	Non-Cemented and Non-Constrained, Mobile	25,860	0.49(0.41-0.58)	1.88(1.72-2.06)	2.63(2.43-2.84)	3.67(3.42-3.93)	4.90(4.54-5.30)	*5.64(4.97-6.39)*
13	Non-Cemented and Posterior-Stabilized, Fixed.	3,510	0.64(0.42-0.96)	2.27(1.82-2.83)	3.25(2.69-3.93)	5.44(4.61-6.40)	7.62(6.42-9.04)	*12.18(8.55-17.20)*
14	Non-Cemented and Other Constraints	296	0.68(0.17-2.69)	*2.14(0.97-4.71*	*2.54(1.22-5.26)*	*2.98(1.50-5.88)*		
15	All Hybrid	10,116	0.52(0.40-0.69)	1.69(1.45-1.97)	2.33(2.04-2.66)	3.51(3.13-3.93)	4.36(3.89-4.89)	*4.87(4.23-5.62)*
16	Hybrid Non-Constained, Fixed	6,593	0.46(0.32-0.66)	1.59(1.31-1.93)	2.19(1.86-2.59)	3.20(2.77-3.69)(	3.99(3.47-4.59)	*4.20(3.61-4.88)*
17	Hybrid Non-Constained, Mobile	2,184	0.92(0.60-1.43)	1.83(1.34-2.49)(	2.37(1.79-3.13)	3.85(2.94-5.02)	*5.71(4.13-7.86)*	*6.83(4.49-10.32)*
18	Hybrid Posterior-Stabilized, Fixed	923	0	1.94(1.15-3.27)	3.39(2.20-5.20)	5.42(3.74-7.82)	*5.80(4.01-8.34)*	
19	Hybrid with Other Constraints.	416	0.48(0.12-1.92)	2.20(1.15-4.19)	2.95(1.69-5.13)	*4.85(3.07-7.64)*	*5.39(3.42-8.46)*	
20	All Cemented Unicondylar	1,03,385	0.95(0.89-1.01)	3.58(3.46-3.70)	5.41(5.26-5.56)	10.03(9.80-10.27)	15.17(14.78-15.58)	17.90(17.11-18.73)
21	Cemented Unicondylar, Fixed	46,346	0.62(0.55-0.69)	2.48(2.32-2.64)	3.77(3.56-3.98)	7.17(6.77-7.58)	10.92(10.09-11.81)	*12.98(11.15-15.07)*
23	Cemented Unicondylar, Mobile	50,506	1.26(1.17-1.36)	4.34(4.16-4.52)	6.42(6.21-6.65)	11.47(11.17-11.79)	16.90(16.42-17.40)	19.80(18.88-20.77)
24	Cemented Monobloc Polyethylene Tibia	6,533	0.72(0.54-0.96)	4.31(3.83-4.84)	6.44(5.84-7.09)	10.69(9.86-11.58)	14.97(13.78-16.25)	*16.47(14.91-18.17)*
25	All Unicondylar NonCemented/Hybrid	33,508	1.18(1.07-1.31)	2.59(2.41-2.78)	3.71(3.48-3.96)	7.37(6.81-7.97)	*11.51(9.96-13.27)*	
26	Unicondylar Non-Cemented/Hybrid, Fixed	1,421	0.22(0.07-0.68)	2.44(1.69-3.52)	5.31(4.02-7.00)	9.52(7.44-12.15)	*12.96(9.95-16.78)*	
27	Unicondylar Non-Cemented/Hybrid, Mobile	31,611	1.24(1.12-1.37)	2.60(2.41-2.79)	3.61(3.37-3.86)	7.20(6.60-7.86)	*11.70(9.67-14.13)*	
28	Unicondylar Non-Cemented/Hybrid Monobloc Polyethylene Tibia	476	0.42(0.11-1.67)	2.56(1.46-4.47)	4.33(2.82-6.64)	8.58(6.24-11.73)	*12.13(8.49-17.18)*	
29	Patellofemoral Arthroplasty	16,476	1.04(0.89-1.21)	5.56(5.20-5.93)	9.21(8.74-9.70)	17.52(16.80-18.28)	24.40(23.22-25.63)	*27.66(25.55-29.91)*
30	MultiCompartmental Knee Arthroplasty	622	1.00(0.45-2.22)	7.09(5.27-9.51)	9.77(7.58-12.54)	*13.39(10.66-16.75)*		
Total Unconfirmed Cases & Related Revision Percent Over The Years		22,558	0.71 (0.61-0.83)	2.19(2.00-2.40)	3.10(2.88-3.35)	5.22(4.90-5.56)	7.20(6.72-7.71)	*8.35(7.60-9.18)*
Overall Grand Total of All Knee Cases & Respective Mean Revision Percent Over the Years		14,42,051	0.49 (0.48-0.51)	1.71(1.68-1.73)	2.48(2.45-2.50)	4.01(3.97-4.05)	5.66(5.58-5.73)	6.74(6.57-6.91)

Figures in Italics are for scenarios/cases where procedure numbers or the follow-up data at those particular time points were below 250 and may involve a minor degree of (+/-) compilation error ; Segments those are blank correspond to situations wherein either there were no respective data retrievable/recorded or reported by Registry/ contained for procedure follow-ups from less than 10 cases & therefore eliminated to reduce low-data biases.

Table 6.2.41 :- ***Tabulation illustrating the Distribution of the Total Number Overall Primary Knee Arthroplasty of All Modalities, performed on the British Patient Cohort, categorized on the basis of their respective Prostheses Specific Attributes/Characteristics and Fixation Method applied, with the respective post-operative Revision Rate percentages across multiple follow-up timepoints.***

- The utilization and deployment protocol of knee prostheses involve another critical parameter that is uniquely positioned to influence the revision rate and stability-based outcomes in the immediate to long-term aspects of the respective patients, which is the relative use of a patellar component with the artificially replaced knee, or without a patella.

- While there's a widespread debate amongst the clinical and allied scientific research communities regarding the patellar policy during a total knee replacement, with the presence of a sizeable scientific publication crediting either of the two practices of preserving/retaining a patella, or totally sacrificing it, wherein either of the two are either praised for their beneficial role, or blamed for any negative performance roles and other attributes, this research finds it necessary to analyze and represent the prostheses performances in terms of entailing revision rate percentages, segregated on with/ without patella basis.

- The fixation wise separation, identification and thereby tabulation is developed for the most commonly deployed prostheses combinations for primary TKA, their respective ODEP Rating statuses, manufacturer/supplier firm details, with the cumulative revision rate percentage across multiple timepoints in the post-operative window which are presented as follows: -

Table 6.2.42 :- ***Tabulation illustrating the prevailing Cumulative Revision Rate percentages of the Cemented Primary Total Knee Arthroplasties performed on the British patient cohort, segregated on the basis of the Patellar retention/sacrifice policy adopted, categorized as per the Most Commonly Deployed Knee Prostheses Combinations[Femoral + Tibial].***

Distribution of the Overall Revision Rate Percentages of Total Knee Prostheses Combinations used for Cemented Primary TKA of the British Patient Cohort, with atleast 1,000 Individual Registered & Reported Unique Knee Arthroplasty Cases against the Prostheses, highlighted Separately for Patellar Retention & Patella Sacrifice Cases with Prostheses ODEP Rating Statuses & Mfg/Supplier firm Details.

SL No.	Femoral Component ; Tibial Component	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Patella Status	No. of Cases	Median Age at Primary TKA	Male %	Time Span since Primary TKA					
								1 Year	3 Years	5 Years	10 Years	15 Years	18 Years
All Total Knee Arthroplasty(All Fixation Methods)+Unconfirmed+Left Out for Insufficient/Incomplete Data		N.A	N.A	With Patella	4,95,816	70(63-76)	38	0.41(0.39-0.43)	1.24(1.21-1.28)	1.80(1.76-1.84)	2.82(2.76-2.88)	3.87(3.76-3.97)	4.49(4.26-4.74)
				W/o Patella	7,69,686	70(63-76)	46	0.44(0.42-0.45)	1.61(1.58-1.64)	2.28(2.24-2.32)	3.41(3.36-3.46)	4.56(4.48-4.65)	5.50(5.28-5.72)
1	ACS PC [Fem] : ACS [Tib]	ImplantCast GmbH	10A[ACS] ; Unrated [ACS PC]	With Patella	94	68(61-74)	29	2.13(0.54-8.24)	3.28(1.07-9.83)	3.28(1.07-9.83)			
				W/o Patella	1,077	68(61-73)	52	0.65(0.31-1.37)	2.57(1.77-3.73)	3.18(2.27-4.44)	4.40(3.23-5.99)		
2	Advance MP Stature[Fem] : Advance[Tib]	MicroPort Orthopedics	Unrated[Advance Medial Pivot (MP) Stature] / ODEP Lapsed	With Patella	508	69(62-75)	12	0	0.60(0.19-1.84)	1.57(0.75-3.28)	1.86(0.93-3.71)		
				W/o Patella	999	69(62-75)	14	0.10(0.01-0.71)	2.26(1.49-3.41)	3.23(2.28-4.57)	4.00(2.84-5.61)		
3	Advance MP [Fem] : Advance [Tib]		15A / ODEP Lapsed	With Patella	3,059	70(63-76)	43	0.53(0.32-0.86)	1.50(1.12-2.00)	2.04(1.58-2.63)	3.18(2.54-3.98)	*3.61(2.83-4.59)*	
				W/o Patella	5,946	70(64-76)	50	0.60(0.43-0.83)	2.31(1.95-2.73)	3.27(2.84-3.78)	4.55(3.99-5.19)	5.36(4.62-6.21)	9.00(5.07-15.72)
4	Advance PS [Fem] : Advance [Tib]		15A /ODEP Lapsed/Unrated	With Patella	253	71(66-76)	36	1.20(0.39-3.69)	4.19(2.28-7.66)	5.15(2.95-8.90)	8.60(5.32-13.75)	10.94(6.25-18.78)	
				W/o Patella	1,191	72(66-78)	48	0.51(0.23-1.13)	2.26(1.54-3.30)	2.97(2.12-4.15)	5.08(3.73-6.89)	6.35(4.65-8.66)	
5	AGC V2[Fem : Tib]	Zimmer Biomet	Unrated	With Patella	12,200	71(65-77)	35	0.25(0.17-0.35)	1.24(1.06-1.46)	1.84(1.61-2.10)	2.99(2.68-3.34)	4.56(4.05-5.14)	*7.16(5.51-9.30)*
				W/o Patella	26,951	71(65-77)	46	0.34(0.28-0.42)	1.65(1.50-1.81)	2.36(2.18-2.55)	3.68(3.45-3.93)	5.77(5.39-6.17)	7.86(6.91-8.94)
6	AGC [Fem] : AGC V2 [Tib]			With Patella	9,807	71(64-77)	37	0.25(0.17-0.37)	1.18(0.98-1.41)	1.68(1.44-1.96)	2.92(2.57-3.33)	5.43(4.68-6.29)	5.91(4.93-7.09)
				W/o Patella	19,143	71(64-77)	45	0.33(0.25-0.42)	1.78(1.60-1.98)	2.50(2.28-2.73)	3.82(3.53-4.13)	*5.11(4.66-5.60)*	7.38(6.01-9.05)
7	AS Columbus Cemented[Fem]:Columbus CR/PS[Tib]	Aesculap/Bbraun	7A[Fem] : 7A/13A/10[Tib]	With Patella	984	66(60-72)	53	0.33(0.11-1.02)	1.76(1.02-3.04)	2.58(1.54-4.31)			
				W/o Patella	669	66(59-73)	54	0.66(0.25-1.76)	1.70(0.83-3.43)	3.09(1.62-5.85)			
8	Attune[Fem]: Attune FB[Tib]	Depuy Synthes	3A* / 3A [Attune / Attune FB]	With Patella	16,510	70(63-76)	40	0.33(0.25-0.43)	1.15(0.98-1.35)	1.77(1.52-2.06)			
				W/o Patella	17,259		47	0.44(0.35-0.56)	1.70(1.50-1.93)	2.33(2.07-2.61)			
9	Attune[Fem]: Attune RP[Tib]		3A*/3A / 5A/ 7A [Attune / Attune RP]	With Patella	3,759	69(62-76)	41	0.28(0.15-0.52)	0.84(0.57-1.25)	1.13(0.76-1.67)			
				W/o Patella	2,011	69(62-76)	50	0.23(0.09-0.61)	1.05(0.64-1.71)	1.80(1.18-2.74)			
10	Columbus Cemented [Fem] : Columbus CR/PS[Tib]	Aesculap/Bbraun	10A / 13A / 7A	With Patella	4,991	70(64-76)	36	0.64(0.45-0.91)	1.31(1.02-1.69)	1.74(1.39-2.18)	3.13(2.39-4.10)	5.64(3.64-8.70)	
				W/o Patella	11,693	71(65-77)	45	0.36(0.27-0.49)	1.48(1.27-1.72)	2.09(1.82-2.39)	2.99(2.60-3.42)	3.33(2.86-3.88)	
11	E-Motion Bicondylar Knee[Fem] : E-Motion FP[Tib]		13A	With Patella	299	66(60-73)	33	1.03(0.33-3.17)	5.60(3.47-8.98)	7.81(5.21-11.62)	8.43(5.65-12.49)		
				W/o Patella	3,079	68(61-74)	46	0.62(0.40-0.97)	2.00(1.55-2.57)	2.85(2.30-3.52)	3.99(3.29-4.82)	6.19(4.59-8.32)	
12	Endo-Model Standard Rotating Hinge [Fem:Tib]	Waldemar Link Orthopedics GmbH	5B	With Patella	290	75.5(68-82)	28	1.80(0.75-4.28)	3.19(1.60-6.33)	4.75(2.64-8.49)	6.58(3.31-12.87)		
				W/o Patella	1,095	76(69-83)	27	1.28(0.75-2.20)	3.38(2.40-4.75)	4.93(3.67-6.62)	7.14(5.27-9.65)	8.31(6.01-11.42)	
13	Evolution MP [Fem:Tib]	MicroPort Orthopedics	ODEP Lapsed	With Patella	856	72(65-78)	46	0.63(0.26-1.51)	1.33(0.69-2.56)	1.33(0.69-2.56)			
				W/o Patella	1,232	68(62-75)	45	0.34(0.13-0.90)	1.50(0.92-2.43)	1.96(1.24-3.09)			
14	Genesis II Oxinium [Fem] : Genesis II [Tib]	Smith & Nephew	Multiple Ratings Status across all Variants[15A* to Lapsed]	With Patella	6,464	59(54-65)	37	0.49(0.35-0.70)	1.69(1.39-2.05)	2.35(1.98-2.79)	4.26(3.65-4.96)	*5.64(4.65-6.83)*	
				W/o Patella	5,365	59(54-65)	43	0.66(0.48-0.92)	3.05(2.61-3.56)	4.65(4.09-5.29)	7.83(6.99-8.76)	9.31(8.23-10.52)	
15	Genesis II [Fem:Tib]			With Patella	43,008	71(65-77)	38	0.46(0.40-0.53)	1.21(1.11-1.32)	1.60(1.47-1.73)	2.40(2.21-2.60)	2.73(2.46-3.03)	*2.94(2.48-3.49)*
				W/o Patella	47,531	71(65-77)	46	0.47(0.42-0.54)	1.67(1.56-1.80)	2.35(2.20-2.50)	3.42(3.22-3.64)	3.93(3.63-4.26)	*4.03(3.68-4.41)*
16	Insall-Burstein II Microport [Fem] : Insall Burstein Microport [Tib]	MicroPort Orthopedics	Unrated / Withdrawn	With Patella	1,114	71(65-77)	43	0.09(0.01-0.64)	0.75(0.37-1.49)	2.22(1.48-3.33)	4.48(3.34-6.01)	6.44(4.96-8.35)	*7.05(5.40-9.17)*
				W/o Patella	917	71(65-77)	48	0.66(0.30-1.47)	2.93(2.01-4.28)	3.75(2.68-5.24)	5.89(4.48-7.73)	7.73(6.00-9.92)	*8.47(6.53-10.95)*
17	Journey II BCS Oxinium[Fem] : Journey [Tib]	Smith & Nephew	5A* / Pre-Entry A*[JourneyII BCS]	With Patella	4,126	66(59-73)	41	0.40(0.24-0.66)	1.24(0.90-1.70)	1.43(1.04-1.95)			
				W/o Patella	723	66(59-73)	43	1.12(0.56-2.22)	5.12(3.70-7.07)	*6.14(4.52-8.31)*			
18	Kinemax[Fem:Tib]	Stryker	Unrated	With Patella	4,418	71(64-77)	37	0.25(0.14-0.45)	1.23(0.94-1.61)	1.75(1.39-2.19)	3.64(3.09-4.29)	5.51(4.77-6.36)	*5.82(5.03-6.73)*
				W/o Patella	6,633	71(64-77)	47	0.24(0.15-0.40)	2.04(1.72-2.42)	3.27(2.86-3.74)	5.37(4.82-5.98)	7.60(6.89-8.37)	8.59(7.61-9.69)
19	LCS Complete[Fem] : MBT [Tib]	Depuy Synthes	15A/15A*/ 13A/7A ; Unrated[MBT]	With Patella	1,509	69(62-75)	33	0.54(0.27-1.07)	1.93(1.33-2.81)	3.17(2.34-4.29)	4.83(3.67-6.33)	6.13(4.55-8.23)	
				W/o Patella	28,417	70(63-76)	45	0.42(0.35-0.50)	1.66(1.51-1.82)	2.44(2.26-2.63)	3.55(3.31-3.80)	4.30(4.55-8.23)	
20	LCS [Fem:Tib]		15A/15A*/ 13A/7A	With Patella	225	70(63-76)	37	*1.33(0.43-4.08)*	*4.53(2.46-8.26)*	*5.01(2.80-8.86)*	5.54(3.18-9.55)	6.98(4.15-11.62)	6.98(4.15-11.62)
				W/o Patella	1,862	69(62-76)	42	0.54(0.29-1.00)	1.37(0.93-2.02)	1.89(1.35-2.63)	2.55(1.90-3.42)	3.23(2.46-4.24)	*3.47(2.65-4.55)*
21	Legion CR CoCr[Fem] : Genesis II [Tib]	Smith & Nephew	5A*[Legion CR CoCr] : Multiple Ratings for Genesis II	With Patella	173	71(66-78)	34	*1.18(0.30-4.62)*	*2.37(0.90-6.18)*	*3.01(1.26-7.07)*			
				W/o Patella	896	71(63-76)	47	0.34(0.11-1.06)	1.40(0.80-2.46)	1.96(1.20-3.19)			
22	Maxim [Fem:Tib]	Zimmer Biomet	Unrated	With Patella	515	71(63-76)	33	0.59(0.19-1.82)	1.61(0.81-3.20)	2.25(1.25-4.03)	5.10(3.33-7.77)	*7.18(4.84-10.59)*	
				W/o Patella	1,236	70(63-77)	47	0.33(0.12-0.87)	1.83(1.21-2.77)	2.97(2.14-4.11)	5.67(4.43-7.24)	9.90(7.97-12.28)	*16.77(11.49-24.12)*
23	MRK [Fem:Tib]	MatOrtho	15A	With Patella	5,599	71(64-77)	38	0.26(0.15-0.43)	1.06(0.81-1.39)	1.58(1.26-1.98)	2.47(2.00-3.06)	2.84(2.23-3.60)	
				W/o Patella	10,256	71(64-77)	48	0.35(0.25-0.49)	1.24(1.03-1.48)	1.64(1.39-1.92)	2.65(2.26-3.10)	*2.95(2.47-3.52)*	
Cemented Knee Arthroplasty Cases Total [3,16,942]				With Patella	1,20,761								
				W/o Patella	1,96,181								

Figures in Italics are for scenarios/cases where procedure numbers or the follow-up data at those particular time points were below 250 and may involve a minor degree of (+/-) compilation error ; Segments those are blank correspond to situations wherein either there were no respective data retrievable/recorded or reported by Registry/ contained for procedure follow-ups from less than 10 cases & therefore eliminated to reduce low-data biases. "[Fem]" indicates Femoral Prostheses ; "[Tib]" indicates Tibial Prostheses ; "[Fem:Tib]" indicates Both Femoral & Tibial Prostheses from the Same Brand.

Table 6.2.43 :- *Tabulation illustrating the prevailing Cumulative Revision Rate percentages of the Non-Cemented fixation based Primary Total Knee Arthroplasties performed on the British patient cohort, segregated on the basis of the Patellar retention/sacrifice policy adopted, categorized as per the Most Commonly Deployed Knee Prostheses Combinations[Femoral + Tibial].*

Distribution of the Overall Revision Rate Percentages of Total Knee Prostheses Combinations used for Non-Cemented Primary TKA of the British Patient Cohort, with atleast 1,000 Individual Reported Unique Knee Arthroplasty Cases against the Prostheses, highlighted Separately for Patellar Retention & Patella Sacrifice Cases with Prostheses ODEP Rating Statuses & Mfg/Supplier firm Details.

SL No.	Femoral Component ; Tibial Component	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Patella Status	No. of Cases	Median Age at Primary TKA	Male %	Time Span since Primary TKA					
								1 Year	3 Years	5 Years	10 Years	15 Years	18 Years
All Total Knee Arthroplasty(All Fixation Methods)+Unconfirmed+Left Out for Insufficient/Incomplete Data		N.A	N.A	With Patella	4,95,816	70(63-76)	38	0.41(0.39-0.43)	1.24(1.21-1.28)	1.80(1.76-1.84)	2.82(2.76-2.88)	3.87(3.76-3.97)	4.49(4.26-4.74)
				W/o Patella	7,69,686	70(63-76)	46	0.44(0.42-0.45)	1.61(1.58-1.64)	2.28(2.24-2.32)	3.41(3.36-3.46)	4.56(4.48-4.65)	5.50(5.28-5.72)
1	Natural Knee II [Fem] : NK2 [Tib]	Zimmer Biomet	Multiple ODEP Ratings across all variants of the particular Prosthesis Component identity. [15A to Unrated]	With Patella	1,540	70(64-76)	42	0.16(0.04-0.63)	0.96(0.55-1.68)	1.70(1.11-2.60)	3.56(2.63-4.81)	*5.81(4.38-7.69)*	*6.26(4.65-8.40)*
				W/o Patella	1,284	70(63-76)	26	1.17(0.49-2.79)	2.44(1.26-4.68)	3.75(2.10-6.66)	*3.75(2.10-6.66)*		
2	Nexgen Hinge Type[Fem:Tib]			With Patella	450	73(65-79)	27	1.20(0.58-2.51)	2.84(1.72-4.69)	3.99(2.53-6.26)	*9.39(6.08-14.35)*		
				W/o Patella	606	73(64-80)	36	0.53(0.17-1.65)	1.71(0.85-3.41)	1.71(0.85-3.41)	*4.95(2.38-10.13)*		
3	Nexgen LCCK [Fem] : Nexgen [Tib]			With Patella	570	71(63-78)	36	1.85(1.03-3.31)	3.56(2.31-5.47)	4.63(3.10-6.90)	*5.02(3.37-7.45)*	*9.81(4.58-20.36)*	
				W/o Patella	611	72(64-80)	37	0.41(0.36-0.47)	1.29(1.20-1.40)	2.07(1.94-2.21)	3.65(3.44-3.87)	4.77(4.42-5.14)	*4.99(4.56-5.45)*
4	Nexgen [Fem:Tib]			With Patella	54,617	70(63-76)	45	0.36(0.33-0.40)	1.24(1.18-1.31)	1.93(1.85-2.01)	3.28(3.15-3.41)	4.42(4.19-4.65)	5.48(4.76-6.30)
				W/o Patella	1,28,488	70(64-76)	37	0.45(0.19-1.07)	2.22(1.49-3.29)	3.05(2.17-4.29)	5.78(4.41-7.56)	*7.82(5.91-10.31)*	*7.82(5.91-10.31)*
5	Nexgen[Fem] : LPS(Legacy PS ZimmerBiomet)[Tib]			With Patella	1,149	67(59-74)	51	0.46(0.25-0.86)	1.65(1.19-2.29)	2.32(1.75-3.07)	3.43(2.67-4.39)	*4.87(3.72-6.36)*	*7.09(4.74-10.55)*
				W/o Patella	2,170	67(59-75)	56	0.73(0.23-2.23)	2.46(1.33-4.53)	3.25(1.90-5.53)	*5.37(3.49-8.23)*	*6.54(4.23-10.04)*	
6	Nexgen [Fem] : TM Monoblock [Tib]			With Patella	416	62(56-69)	57	0.60(0.40-0.90)	2.62(2.16-3.18)	3.28(2.76-3.91)	4.24(3.63-4.97)	5.10(4.35-5.98)	*5.52(4.60-6.60)*
				W/o Patella	3,870	64(58-71)	43	0.94(0.42-2.07)	2.39(1.45-3.93)	3.75(2.51-5.59)	7.74(5.75-10.39)	11.52(8.26-15.94)	
7	Optetrak CR [Fem] : Optetrak [Tib]	Exactech	ODEP Rating Withdrawn	With Patella	648	70(64-76)	43	0.81(0.41-1.62)	4.12(3.04-5.58)	5.64(4.35-7.30)	8.46(6.79-10.53)	10.18(7.90-13.06)	
				W/o Patella	993	69(63-76)	40	0.38(0.20-0.71)	0.63(0.34-1.16)	*0.83(0.43-1.62)*			
8	Persona CR [Fem] : Persona [Tib]	Zimmer Biomet	7A	With Patella	3,305	69(62-75)	49	0.29(0.16-0.53)	0.92(0.60-1.41)	1.72(1.03-2.87)			
				W/o Patella	4,401	70(63-76)	36	0.33(0.08-1.33)	1.41(0.67-2.98)	*2.75(1.50-5.04)*			
9	Persona PS [Fem] : Persona [Tib]		7A / 5A	With Patella	691	70(62-76)	47	0.61(0.28-1.36)	2.24(1.43-3.50)	3.47(2.31-5.20)			
				W/o Patella	1,021	70(64-76)	43	0.44(0.33-0.61)	1.69(1.44-1.99)	2.38(2.08-2.73)	3.48(3.09-3.91)	4.48(3.91-5.14)	4.64(4.00-5.37)
10	PFC Sigma Bicondylar Knee [Fem] : MBT [Tib]	Depuy Synthes	Multiple ODEP Ratings across all variants of the particular Prosthesis Component identity. [15A to Unrated] for PFC Sigma Series ; MBT [Unrated]	With Patella	8,848	65(58-72)	50	0.82(0.65-1.03)	2.31(2.01-2.65)	3.17(2.82-3.57)	4.41(3.97-4.90)	5.52(4.91-6.19)	5.52(4.91-6.19)
				W/o Patella	8,635	65(58-73)	38	0.36(0.32-0.41)	1.07(0.99-1.15)	1.51(1.42-1.61)	2.13(2.01-2.26)	2.77(2.60-2.94)	3.39(3.00-3.82)
11	PFC Sigma Bicondylar Knee [Fem] : PFC Bicondylar [Tib]			With Patella	69,639	71(64-77)	46	0.41(0.37-0.45)	1.39(1.32-1.47)				
				W/o Patella	1,08,132	70(64-76)	38	0.37(0.33-0.41)	1.15(1.08-1.23)				
12	PFC Sigma Bicondylar Knee [Fem] : PFC Sigma Bicondylar [Tib]			With Patella	87,727	71(64-77)	45	0.38(0.34-0.41)	1.55(1.48-1.62)	2.14(2.05-2.23)	2.84(2.72-2.96)		
				W/o Patella	1,14,110	70(64-77)	26				0	0	
13	Profix Oxinium [Fem] : Profix[Tib]	Smith & Nephew	Unrated / Commercially Withdrawn/Recalled	With Patella	42	61(58-68)	44	0.84(0.42-1.67)	3.06(2.14-4.37)	3.38(2.40-4.75)	4.73(3.54-6.31)	5.80(4.44-7.55)	*5.80(4.44-7.55)*
				W/o Patella	958	61(56-66)	30	*0*	*0*	*1.35(0.19-9.21)*	*4.07(1.33-12.10)*	*6.41(2.36-16.77)*	
14	Profix [Fem:Tib]			With Patella	83	73(65-78)	44	0.42(0.26-0.68)	1.40(1.07-1.82)	1.87(1.48-2.36)	2.67(2.19-3.26)	3.51(2.86-4.32)	*3.73(2.98-4.66)*
				W/o Patella	3,894	73(67-78)	42	0.85(0.46-1.58)	2.69(1.90-3.80)	3.50(2.58-4.75)	6.18(4.87-7.83)	8.48(6.81-10.54)	*8.48(6.81-10.54)*
15	Rotaglide+ [Fem:Tib]	Corin Group	ODEP Rating Withdrawn	With Patella	1,182	69(63-76)	45	0.36(0.12-1.12)	3.48(2.41-4.99)	4.40(3.18-6.07)	7.09(5.45-9.19)	9.01(7.04-11.49)	*9.01(7.04-11.49)*
				W/o Patella	830	71(64-77)	39	0.49(0.24-1.03)	2.37(1.69-3.31)	4.00(3.08-5.19)	4.65(3.62-5.97)	*6.43(4.89-8.43)*	
16	Rotaglide [Fem:Tib]		Unrated	With Patella	1,430	71(63-77)	37	*5.26(0.76-31.88)*	*5.26(0.76-31.88)*	*5.26(0.76-31.88)*			
				W/o Patella	19	67(60-75)	36	0.73(0.38-1.41)	0.99(0.54-1.82)	1.16(0.65-2.09)			
17	Saiph [Fem:Tib]	MatOrtho	7A	With Patella	1,373	69(63-75)	51	0.46(0.17-1.23)	1.68(0.97-2.90)	*1.68(0.97-2.90)*			
				W/o Patella	1,043	69(62-75)	39	0.45(0.32-0.64)	1.29(1.06-1.59)	1.98(1.67-2.33)	3.13(2.71-3.62)	*3.69(3.12-4.36)*	
18	Scorpio NRG [Fem:Tib]	Stryker	10A* / 10A [Scorpio NRG] ; Unrated[Scorpio]	With Patella	7,128	71(64-77)	46	0.37(0.25-0.55)	1.88(1.58-2.23)	2.85(2.48-3.28)	4.14(3.66-4.68)		
				W/o Patella	6,983	70(64-76)	40	0.21(0.05-0.84)	1.70(1.04-2.76)	2.35(1.56-3.55)	3.82(2.74-5.32)	4.94(3.52-6.91)	7.66(3.70-15.47)
19	Scorpio [Fem:Tib]			With Patella	965	68(60-75)	47	0.44(0.23-0.81)	2.36(1.80-3.07)	3.42(2.74-4.27)	5.00(4.15-6.02)	6.31(5.25-7.57)	8.11(5.14-12.69)
				W/o Patella	2,307	68(62-75)	38	0.32(0.22-0.47)	1.34(1.11-1.62)	2.04(1.75-2.38)	3.25(2.87-3.69)	4.25(3.78-4.77)	4.31(3.83-4.85)
20	Scorpio [Fem]: Scorpio NRG [Tib]			With Patella	8,149	71(65-77)	44	0.51(0.40-0.64)	2.11(1.88-2.37)	2.96(2.68-3.36)	4.45(4.10-4.82)	5.68(5.24-6.15)	6.38(5.65-7.19)
				W/o Patella	13,659	71(64-77)	37	1.23(0.55-2.72)	*2.01(1.04-3.85)*	*2.56(1.32-4.93)*			
21	Sphere [Fem] : GMK[Tib]	MedActa International	5A / 7A / ODEP Lapsed / Pre-Entry	With Patella	577	68(61-75)	45	1.00(0.61-1.66)	2.15(1.49-3.09)	2.76(1.96-3.88)			
				W/o Patella	1,615	69(62-76)	37	0.34(0.11-1.04)	1.37(0.78-2.39)	2.32(1.50-3.58)	3.71(2.58-5.32)		
22	TC Plus [Fem:Tib]	Smith & Nephew	10A / 10A* / 7A*	With Patella	893	71(64-76)	45	0.69(0.57-0.84)	1.78(1.58-2.01)	2.34(2.11-2.60)	3.44(3.15-3.75)		
				W/o Patella	15,371	70(64-76)	39	0.48(0.43-0.53)	1.22(1.14-1.31)	1.71(1.60-1.82)	2.55(2.37-2.73)		
23	Triathlon [Fem:Tib]	Stryker	15A* / 13A* / Unrated	With Patella	73,292	70(63-76)	47	0.49(0.44-0.54)	1.58(1.49-1.67)	2.20(2.09-2.31)	3.17(3.00-3.35)		
				W/o Patella	89,132	70(63-76)	43	0.26(0.08-0.80)	0.84(0.44-1.61)	1.23(0.69-2.17)			
24	Unity Knee [Fem] : Unity [Tib]	Corin Group	5A	With Patella	1,202	70(63-76)	49	0.55(0.14-2.16)	*0.88(0.28-2.72)*	*1.62(0.55-4.74)*			
				W/o Patella	397	69(61-75)	38	0.38(0.32-0.45)	1.07(0.97-1.19)	1.58(1.45-1.73)	2.59(2.29-2.93)		
Cementless Knee Arthroplasty Cases Total [8,36,445]				With Patella	3,25,916								
				W/o Patella	5,10,529								

Figures in Italics are for scenarios/cases where procedure numbers or the follow-up data at those particular time points were below 250 and may involve a minor degree of (+/-) compilation error ; Segments those are blank correspond to situations wherein either there were no respective data retrievable/recorded or reported by Registry/ contained for procedure follow-ups from less than 10 cases & therefore eliminated to reduce low-data biases. "[Fem]" indicates Femoral Prostheses ; "[Tib]" indicates Tibial Prostheses ; "[Fem:Tib]" indicates Both Femoral & Tibial Prostheses from the Same Brand.

Distribution of the Overall Revision Rate Percentages of Total Knee Prostheses Combinations used for Hybrid fixation based Primary TKA of the British Patient Cohort, with atleast 1,000 Individual Reported Unique Knee Arthroplasty Cases against the Prostheses, highlighted Separately for Patellar Retention & Patella Sacrifice Cases with Prostheses ODEP Rating Statuses & Mfg/Supplier firm Details.

SL No.	Femoral Component ; Tibial Component	Manufacturer / Supplier of the Prosthesis	ODEP Rating	Patella Status	No. of Cases	Median Age at Primary TKA	Male %	Time Span since Primary TKA					
								1 Year	3 Years	5 Years	10 Years	15 Years	18 Years
All Total Knee Arthroplasty(All Fixation Methods)+Unconfirmed+Left Out for Insufficient/Incomplete Data		N.A	N.A	With Patella	4,95,816	70(63-76)	38	0.41(0.39-0.43)	1.24(1.21-1.28)	1.80(1.76-1.84)	2.82(2.76-2.88)	3.87(3.76-3.97)	4.49(4.26-4.74)
				W/o Patella	7,69,886		46	0.44(0.42-0.45)	1.61(1.58-1.64)	2.28(2.24-2.32)	3.41(3.36-3.46)	4.56(4.48-4.65)	5.50(5.28-5.72)
1	Vanguard [Fem:Tib]	Zimmer Biomet	Multiple ODEP Ratings for Vanguard ; Maxim [Unrated]	With Patella	38,366	70(63-76)	38	0.38(0.32-0.45)	1.07(0.97-1.19)	1.58(1.45-1.73)	2.59(2.29-2.93)		
				W/o Patella	50,170	70(63-76)	45	0.41(0.36-0.47)	1.63(1.51-1.75)	2.27(2.13-2.42)	3.18(2.96-3.41)		
2	Vanguard [Fem] : Maxim[Tib]			With Patella	761	68(60-75)	35	0.26(0.07-1.06)	0.72(0.26-1.97)	1.21(0.53-2.74)	2.72(1.48-4.95)	*3.18(1.76-5.69)*	
				W/o Patella	1,607	70(62-76)	44	0.51(0.25-1.01)	2.32(1.66-3.24)	3.78(2.89-4.94)	5.30(4.20-6.68)	*5.93(4.69-7.48)*	
Hybrid Fixation Knee Arthroplasty Cases Total			90,904	With Patella	39,127								
				W/o Patella	51,777								

Figures in Italics are for scenarios/cases where procedure numbers or the follow-up data at those particular time points were below 250 and may involve a minor degree of (+/-) compilation error ; Segments those are blank correspond to situations wherein either there were no respective data retrievable/recorded or reported by Registry/ contained for procedure follow-ups from less than 10 cases & therefore eliminated to reduce low-data biases.
"[Fem]" indicates Femoral Prostheses ; "[Tib]" indicates Tibial Prostheses ; "[Fem:Tib]" indicates Both Femoral & Tibial Prostheses from the Same Brand.

Table 6.2.44 :- ***Tabulation illustrating the prevailing Cumulative Revision Rate percentages of the Hybrid fixation based Primary Total Knee Arthroplasties performed on the British patient cohort, segregated on the basis of the Patellar retention/sacrifice policy adopted, categorized as per the Most Commonly Deployed Knee Prostheses Combinations [Femoral + Tibial].***

- The available forms of partial knee arthroplasty are also more expanse than hip arthroplasties, and hence involves a whole new dimension of prostheses, patient demographics and ultimately revision scenario outcomes, for the recipient patients.

- For the British patient cohort, patello-femoral, unicondylar and multi-compartmental knee arthroplasties were the recognized forms of partial knee arthroplasties that were performed. However, despite having a remarkably high revision rate percentage for the multi-compartmental partial knee arthroplasties, the relative procedure count was very low, and hence it is excluded from the detailed purview of this research.

- In general, partial knee arthroplasties performed have a comparative much higher revision rate than the conventional TKAs irrespective of the fixation method and other prostheses attributes, and are often converted into primary TKAs, during their first revision incidences.

- Remarkably most of the prostheses/ prostheses variants which were in major use for the patellofemoral knee arthroplasty of the British patient cohort, were not assessed or ODEP rated. While, there may be a multitude of reasons that could be cited by the British healthcare agencies and by the respective manufacturer/suppliers of the said prostheses, however, considering the repute and general acceptance of the ODEP Rating mechanism and its related credibility, which itself being based in UK/England, it should have been more rational, had the prostheses which are deployed for such usually vulnerable arthroplasty procedures, to have been ODEP rated, besides the UKCA and other regulatory assessments.

- The distribution of the overall patellofemoral arthroplasties performed on the British patient cohort, using the most commonly deployed knee prosthesis / prostheses combinations, along with their entailing revision rate percentages across various time-points in the post-operative window, highlighted with their ODEP Rating Statuses and brief patient demographic details are presented through the following tabulation: -

Distribution of the Overall Number of Patellofemoral Knee Arthroplasties performed on the British Patient Cohort, along with their respective cumulative Revision Rate percentages, categorized as per Knee Prostheses with atleast 1,000 Individual Reported Unique Knee Arthroplasty Cases against the Prostheses, with its ODEP Rating Status & Mfg/Supplier Firm details.

SL No.	Femoral Component ; Tibial Component	Manufacturer / Supplier of the Prosthesis	No. of Cases	ODEP Rating	Median Age at Primary TKA	Male %	Time Span since Primary PFKA					
							1 Year	3 Years	5 Years	10 Years	15 Years	18 Years
All Unicondylar Knee Arthroplasty(All Fixation Methods)+Unconfirmed+Left Out for Insufficient/Incomplete Data		N.A	1,53,369	N.A	63(56-71)	50	1.01(0.96-1.06)	3.61(3.52-3.71)	5.55(5.42-5.68)	10.57(10.36-10.78)	15.93(15.56-16.30)	18.79(18.05-19.55)
1	Avon[Fem]	Stryker	6,685	Unrated	58(50-67)	22	0.66(0.49-0.89)	4.09(3.63-4.61)	7.24(6.60-7.94)	14.55(13.55-15.63)	21.35(19.82-22.99)	*24.67(22.05-27.54)*
2	FPV[Fem]	Wright Medical	1,651	Unrated	59(52-68)	23	0.85(0.50-1.43)	6.94(5.81-8.29)	10.17(8.79-11.75)	18.42(16.49-20.56)		
3	Journey PFJ Oxinium [Fem]	Smith & Nephew	2,290	Unrated	58(50-67)	23	1.85(1.36-2.50)	7.25(6.22-8.44)	12.29(10.90-13.85)	20.98(18.98-23.150	*25.54(22.64-28.73)*	
4	Sigma HP (PF) [Fem]	Depuy Synthes	1,304	13A /Unrated	58(50-66)	23	2.69(1.94-3.73)	9.42(7.95-11.14)	13.67(11.90-15.68)	24.31(21.56-27.34)		
5	Zimmer PFJ [Fem]	Zimmer Biomet	3,571	Unrated	56(49-65)	22	0.60(0.39-0.93)	4.04(3.39-4.81)	6.87(5.95-7.93)	13.18(11.41-15.20)		
TOTAL PATELLOFEMORAL KNEE ARTHROPLASTY [PFKA] Cases			15,501									

Figures in Italics are for scenarios/cases where procedure numbers or the follow-up data at those particular time points were below 250 and may involve a minor degree of (+/-) compilation error ; Segments those are blank correspond to situations wherein either there were no respective data retrievable/recorded or reported by Registry/ contained for procedure follow-ups from less than 10 cases & therefore eliminated to reduce low-data biases.
"[Fem]" indicates Femoral Prostheses ; "[Tib]" indicates Tibial Prostheses ; "[Fem:Tib]" indicates Both Femoral & Tibial Prostheses from the Same Brand.

Table6.2.45:- ***Tabulation illustrating the Overall Number of the Patellofemoral Knee Arthoplasties performed on the British Patient Cohort, utilizing the Most Commonly deployed Prostheses Combinations for the said form of Arthroplasty in UK, along-with their entailing revision rate percentages across Various Follow-Up timepoints in the Post-Operative Window.***

- Similarly, for the unicondylar knee arthroplasty of the British patient cohort, is presented through the following tabulation: -

Distribution of the Overall Number of Unicondylar Knee Arthroplasties performed on the British Patient Cohort, along with their respective cumulative Revision Rate percentages, categorized as per Knee Prostheses with atleast 1,000 Individual Reported Unique Knee Arthroplasty Cases against the Prostheses, with its ODEP Rating Status & Mfg/Supplier Firm details.

SL No.	Femoral Component ; Tibial Component	Manufacturer / Supplier of the Prosthesis	No. of Cases	ODEP Rating	Median Age at Primary TKA	Male %	Time Span since Primary UKA					
							1 Year	3 Years	5 Years	10 Years	15 Years	18 Years
All Unicondylar Knee Arthroplasty(All Fixation Methods)+Unconfirmed+Left Out for Insufficient/Incomplete Data		N.A	1,53,369	N.A	63(56-71)	50	1.01(0.96-1.06)	3.61(3.52-3.71)	5.55(5.42-5.68)	10.57(10.36-10.78)	15.93(15.56-16.30)	18.79(18.05-19.55)
1	AMC/Uniglide [Fem:Tib]	Corin Group	3,026	Withdrawn /Dispute	64(57-71)	51	2.35(1.87-2.96)	6.03(5.23-6.94)	7.68(6.78-8.70)	12.72(11.50-14.06)	*17.45(15.62-19.48)*	
2	Journey Uni Oxinium[Fem] : Journey Uni[Tib]	Smith & Nephew	1,665	5A*	63(56-70)	55	1.35(0.88-2.06)	3.25(2.43-4.34)	4.93(3.78-6.43)	*5.89(4.48-7.73)*		
3	MG Uni[Fem:Tib]	Zimmer Biomet	2,283	Unrated	63(57-70)	55	0.88(0.57-1.36)	4.02(3.29-4.91)	6.06(5.15-7.13)	10.24(9.04-11.60)	13.23(11.79-14.82)	*14.28(12.62-16.15)*
4	Oxford Cementless Partial Knee [Fem:Tib]		28,873	13A/15A/3A	65(58-72)	56	1.16(1.04-1.29)	2.28(2.10-2.48)	3.24(2.99-3.49)	5.95(5.32-6.65)		
5	Oxford Cementless Partial Knee[Fem] : Oxford Partial Knee [Tib]		2,098		66(58-74)	46	1.10(0.73-1.67)	3.48(2.73-4.44)	5.25(4.25-6.46)	8.90(7.31-10.82)	*12.33(9.65-15.68)*	
6	Oxford Single Peg Cemented Partial Knee[Fem] : Oxford Partial Knee [Tib]		43,408	Withdrawn / Previously Rated 15A(2020)	64(58-71)	52	1.22(1.12-1.32)	4.35(4.16-4.55)	6.46(6.23-6.70)	11.52(11.20-11.86)	16.89(16.39-17.40)	19.91(18.93 - 20.94)
8	Oxford Twin Peg Cemented Peg Cemented Partial Knee[Fem]: Oxford Partial Knee[Tib]		5,946	15A	65(57-72)	48	0.81(0.60-1.08)	2.46(2.08-2.92)	3.74(3.23-4.33)	7.29(6.30-8.44)	*11.50(9.03-14.59)*	
10	Persona Partial Knee [Fem:Tib]		3,826	5A	65(58-72)	58	0.19(0.09-0.43)	1.41(0.92-2.15)				
11	Physica ZUK [Fem:Tib]	Lima Corporate	21,737	10A*	63(56-71)	55	0.35(0.28-0.44)	1.77(1.59-1.98)	2.76(2.51-3.03)	5.79(5.25-6.40)	*7.99(6.61-9.63)*	
12	Preservation [Fem:Tib]	Depuy Synthes	1,512	Poor Results/Withdrawn /Unrated / Discontinued since 2009	62(56-69)	55	2.52(1.84-3.45)	8.16(6.88-9.67)	11.66(10.12-13.40	17.72(15.85-19.79)	*23.42(21.22-25.80)*	*25.41(22.71-28.36)*
13	Restoris [Fem:Tib]	Stryker	1,410	Lapsed [Last Rate 5A as of 2018] / Dispute [Restoris MCk 3A]	65(58-73)	59	0.37(0.14-0.99)	1.70(0.97-2.95)	*1.70(0.97-2.95)*			
14	Sigma HighPerformance{HP} (Uni)[Fem] : Sigma HP[Tib]	Depuy Synthes	14,147	13A	63(56-70)	58	0.70(0.57-0.85)	2.76(2.48-3.06)	3.86(3.52-4.24)	*6.58(5.95-7.27)*		
15	Triathlon Uni[Fem] : Triathlon [Tib]	Stryker	1,651	10A	62(56-70)	55	1.15(0.73-1.82)	3.87(3.00-4.99)	6.22(5.00-7.73)	*7.89(6.35-9.78)*		
TOTAL UNICONDYLAR KNEE ARTHROPLASTY [UKA] Cases			1,31,582									

Figures in Italics are for scenarios/cases where procedure numbers or the follow-up data at those particular time points were below 250 and may involve a minor degree of (+/-) compilation error ; Segments those are blank correspond to situations wherein either there were no respective data retrievable/recorded or reported by Registry/ contained for procedure follow-ups from less than 10 cases & therefore eliminated to reduce low-data biases.
"[Fem]" indicates Femoral Prostheses ; "[Tib]" indicates Tibial Prostheses ; "[Fem:Tib]" indicates Both Femoral & Tibial Prostheses from the Same Brand.

Activate Windows

Table 6.2.46 :- ***Tabulation illustrating the Overall Number of the Unicondylar Knee Arthoplasties performed on the British Patient Cohort, utilizing the Most Commonly deployed Prostheses Combinations for the said form of Arthroplasty in UK, along-with their entailing revision rate percentages across Various Follow-Up timepoints in the Post-Operative Window and Brief Patient Demographics.***

Multiple Revision Arthroplasty Scenarios and related Outcomes for the Patient Cohort in UK: -

- Re-revision or multiple revision arthroplasty surgeries either for hip or knee, is an unfortunate and very traumatic condition faced by several patients all across the globe.

- These cases despite being significantly challenging for the patient and their respective families both economically, physically and mentally, they receive very less attention or mainstream coverage, largely due to safeguard interests of various stakeholders involved, often leading the complete devastation of a severely unfortunate patient's life, with a loss of livelihood, functional abilities and general happiness.

- The total number of re-revision or multiple revision knee arthroplasty procedures against whom relevant data and information was accessed and thereby thoroughly evaluated, was 4,940.

- For most of the noted instances of re-revision knee arthroplasties, the first revision procedure was a single stage revision procedure, while the second one is noted to be a dual stage procedure, thereby signifying the ordeal the recipient patient cohort and their respective families have to undergo.

- Revised patella-femoral arthroplasties are noted to have the lowest prevailing revision rate and risk of falling vulnerable to the requirement of another revision or a 're-revision' incidence, until 10 years into the post-operative window, post which relevant data was not obtainable for this research to arrive at a definite conclusion regarding the re-revision risk scenarios for the said form of partial knee arthroplasties that were performed on the patient cohort of the United Kingdom.

- Similar trends are observed for revised cemented unicondylar knee arthroplasties as well, though in majority scenarios, a failing unicondylar knee is converted to a total knee during the first revision itself. Revised cemented unicondylar knees are noted to have the second lowest re-revision rate until post-operative 14 years, beyond which no data could be accessed.

- Comparatively revised non-cemented and hybrid unicondylar knee performed on the patient cohort of the United Kingdom, comprises of a higher re-revision rate, based on the prevailing rate percent than

their respective cemented counterparts and are equivalent to the revision rate percentages for revised cemented fixation based total knees, until 5 years post-op, beyond which the data could not be obtained.

- The prevailing scenario of re-revision or multiple revisions of the knee, for a primary cemented and non-cemented TKAs, as well as for the unicondylar and patellofemoral knee arthroplasties is that the respective patients who had to undergo a revision within a year of their initial primary, experienced the 'worst' re-revision rate percentages. However, for those with a hybrid fixated total knee, the 'worst' re-revision rates were observed on those who had their first revision within 3-5 years since their initial primary, though the general numbers of hybrid fixated primaries undergoing multiple revisions are very low.

- There's a noted rise in the patient level caution and awareness generated out of some of the mainstream media coverage about the incidences of such re-revision scenarios across the globe, especially in the Western nations, and too some extent in India (through the ASR debacle fiasco), which are discussed separately attended in this thesis.

Patient Reported Outcome Measures Scenario for Hip & Knee Arthroplasty Practices in UK: -

- In somewhat the most surprising revelation, despite being a clinical and academical powerhouse for arthroplasty and implant regulatory compliances, the active process of patient reported outcome measures capturing or the active and regular process of the arthroplasty recipient patients, participating in a free opinion capturing platform, to report about their self-assessed improvement or detoriation in their respective daily functioning capabilities and overall QoL, are not streamlined for the general public.

- Upon further detailed investigation into this particular finding, it is found and thereby inferred by this research that the flagship arthroplasty monitoring registry programme in the UK, i.e., the National Joint Registry (NJR), rolled out a pilot programme to capture patient's voices regarding the implant performance, and overall living and health standards, through the standardized PROMs capturing methodologies, however, the response they obtained, as per the official archive document wording was rather a "very depressingly poor" participation response from the participating institutes and from the British patient cohort in general.

- Now, the NJR's PROMs programme/mission was in the motion for a couple of years, throughout which there were no significant improvement in the overall participation process from the general public, regarding their prevailing conditions, following which, despite the much pompous rollout of the PROMs programme, the NJR reportedly closed its PROMs capturing mechanism programme, citing "poor response", and adding to the surprise, there were no public or scientific disclosure of the despite data, irrespective of its sample size and other related metrics.

- The mere existence of such a major incidence of total deletion of any PROMs related coverage and information within the registry reports or within its archive database, fuels the basic suspicion of the involvement of any '***systematic co-ordinated agreement'***, at any level, between any of the stakeholder organizations or members, to suppress and push the globally acclaimed process of patient reported outcome measuring into the general oblivion, of the general patient cohort in the United Kingdom, and of those in the scientific and biomedical community, through a carefully orchestrated 'information-bombing', thereby making it difficult to identify and find the loopholes.

- However, this research with a clear conviction continued to believe that the above-cited phenomenon simply doesn't fit the bill, given the healthcare standards and clinico-academic repute of the British healthcare organizations across the globe. It was therefore on the basis of this conviction, this research

after a thorough examination of multiple literature, archived documents and reports of various British, European and Global health agencies, got a positive affirmation to the primary conviction, through the UK's NHS database, which contained a certain amount of the British patient cohort's PROMS data.

- The NHS database and its archives comprises multitude of arthroplasty related intel which were of very useful utilization to this research, during various time-points, but the existence of a separate limited edition of active PROMs programme rolling on-ground across select public and private hospitals/clinics, reporting data on real-time or accumulated basis, was basically under-explored and unknown to this research, until the revelation of the NJR's flagship cover-up programme of its PROMs programme.

- The NHS data on the British patient reported outcome measures, were of EQ-VAS/EQ-5D-5L and Oxford Hip/Knee Score based standardizations. The involving sample size of the available or accessible data from the NHS sources, as of 2020, was significantly lower than the overall procedural volume of hip and knee arthroplasties in the UK, but certainly too less to be deemed negligible or statistically in-sufficient.

- However, the exact pre-operative and post-operative mean PROM scores for either of the parameters utilized to capture them, were not explicitly available to access from the NHS database and related portals in some cases, and only the mean pre-op vis-à-vis post-op change in the respective scores for those specific cases were available, for each year.

- Therefore, after careful consideration of the fractured PROMs reporting and data availability of the British patient cohort, who have receive an arthroplasty as an intervention for their ailing conditions in their respective hips or knees, this research would not include a separate coverage segment regarding the intrinsic findings of the PROMs based outcomes, and other patient-demography linked outcome scenarios based on the primary PROMs for the United Kingdom's Arthroplasty practices chapter of thesis. Rather, the relevant data accessed/obtained from NHS sources are quoted and appropriately included / tabulated in the 'Comparative Analyses' segment/chapter of this thesis.

- The mean pre-operative vis-à-vis post-operative change in the Oxford Hip Score for the primary hip arthroplasty recipient British patient cohort was 21.941 score-points. While for the case of primary knee arthroplasties, the mean pre-operative vis-à-vis post-operative Oxford Knee Scores of the recipient patient cohort in UK, was 17.608 score-points.

- Other relevant detailing on the primary and revision arthroplasty-based PROMs data across Oxford and EuroQoL parameters for the recipient British patient cohort is presented in the 'Comparative Analyses' chapter.

MODULE – VI

"Results & Discussion"

CHAPTER – 4

Swedish
Hip and Knee Arthroplasty Practices
and
Patient Related Outcome Scenarios.

Swedish Hip & Knee Arthroplasty Practices & Related Outcome Scenarios.

- ***Overall Swedish Arthroplasty Numbers at a Glance:***

General Number of Swedish Arthroplasty Numbers: -

Total No. of Arthroplasties Recorded [Hip + Knee] = **8,32,329**
Total No. of Hip Arthroplasties Recorded [Total + Hemi] = **5,10,977** [**1979 – 2021**]
Total No. of Knee Arthroplasties Recorded [TKA + UKA] = **3,27,352** [**1975 – 2021**]
Total No. of Revision Knee Arthroplasties [Hip + Knee] = **1,23,237**
Total No. of Revision Hip Arthroplasties = **92,966**
Total No. of Revision Knee Arthroplasties = **30,271**

Number of Swedish Hip Arthroplasties in 2021: -

Total No. of Total Hip Arthroplasties [THA] = **17,390**
Total No. of Hemi-Arthroplasties [H.A] = **4,456**
Total No. of Revision Hip Arthroplasties [Primary-THA] = **1,863**
Total No. of Revision Hemi-Arthroplasties [Primary-HA] = **266**

Number of Swedish Knee Arthroplasties in 2021: -

Total No. of Total Knee Arthroplasties [T.K.A] = **12,624**
Total No. of Revision Knee Arthroplasties [Primary TKA] = **1,050**

Primary Findings on Swedish Arthroplasty Practices: -

- With regards to the effects of the COVID-19 pandemic on the Swedish Arthroplasty scenario, it is found that there was around approx. 16,095 fewer primary hip and knee arthroplasty surgeries in 2020 & and 2021, compared to the pre-pandemic year of 2019, as per various Swedish healthcare reports & and the Registry database.

- The Revision Numbers in 2021 also decreased by 14% for Hips & and 17% for Knees, compared to 2019.

- Surprisingly, the number of hemi-arthroplasties, performed due to acute hip fractures remained the same throughout 2020 & 2021, as compared to 2019 in Sweden.

- The operations of the Swedish Arthroplasty Registry (S.A.R) are co-operated by similar functionary bodies in Sweden such as the National Patient Register or NPR, facilitated and sponsored by the National Board of Health & Welfare.

- The general number of patient admissions across all the recognized diagnoses and other rare diagnoses are tallied comparatively across both databases annually for data quality improvement.

- The Swedish Arthroplasty Registry data is co-linked and validated against only the Swedish Personal Identity Number, (like Aadhar in India), while, the NPR comprises data that are linked and are double cross-linked through both the Swedish Personal Identity Number and temporary Identity Numbers (such as Hospital MR No./Clinic ID), such that incidences of mis/over-representation of procedures or patients doesn't influence/bias the final outcome or data quality.

- All the prosthesis components commercially sold or utilized for clinical purposes are uniquely QR Coded or IDed, such that either of the registries can always get to know about the actual origin and transactions involving the particular prosthesis details, along with the actual procedure details, for both primary & revision arthroplasty cases.

- Furthermore, a uniquely commendable practice regarding the Swedish Arthroplasty scenario is that, for every revision procedure, irrespective of the primary modality or the concerning joint, the entire medical records with all procedural details are sent for the expert review of the Registry, mandatorily.

General Demography of the Swedish Arthroplasty Practises: -

Age-Linked & Gender-Based Demography of the Swedish Arthroplasty Recipient Patient Cohort: -

- The mean age of the Swedish patient cohort, undergoing elective total hip arthroplasty is 68.5 Years. While, the mean age of the Swedish patient cohort, undergoing THA due to a fracture, was much higher than the global average at 81.4 years of age.

- The mean age for total knee arthroplasty of the Swedish patient cohort was 68.7 Years.

- In broad terms, the mean age groups of both the hip and knee arthroplasty procedures are in line with the global average age group of arthroplasties.

- On the aspect of gender-based distribution of arthroplasty procedures in Sweden, it was observed that Swedish women had undergone more often a primary hip or knee arthroplasty, than men, which aligns with the global scenario, as well.

- The proportion of the Swedish women, having an elective primary THA, has been fairly stable since 2004 in Sweden, at around 56 – 58%. While for fractures, the proportion of Swedish women was 74% in 2004, which further decreased to 64% in 2021.

- For TKAs, the overall proportion of Swedish women patient cohort decreased from 62% in 2004 to 55% in 2021. The exact reasons for such a drastic shift or reduction of female arthroplasties are not known, and it would be hypothetical to state that Swedish women became less active or particularly shielded against the progressive wear of cartilaginous joints of the knee due to osteoarthritis, or from a fracture risk. Such gender-based drastic reduction is unique to the Swedish patient cohort, if compared with the other nations, that were evaluated during the course of this research.

- In the case of hip revision arthroplasties, the proportion of the male Swedish patients was equivalent to that of the Swedish female patients. However, for knee revisions, continuing the trend for knee primaries, Swedish female patients had a greater number of revisions than Swedish male patients.

- For THAs due to fracture, the mean age of the male patients was 73 years in 2004, while it was 75 years for female patients during the same period. This mean age increased to 79 years for men and 81 years for women in 2005 and remained fairly stable, till the latest reporting period of 2021.

- Whereas, for elective total hip arthroplasties, the mean age was around 68.5 years for both men & female Swedish arthroplasty recipients.
- The rise in the mean age in 2005, was primarily attributed to the linkage and recording of hemiarthroplasty procedures, which were until 2005, not registered with the arthroplasty registry databases in Sweden.

- For the overall scenario, the mean age of Swedish patient cohorts, undergoing hip revisions was 5 years greater than that of the mean age for elective primary hip arthroplasty. Similarly for knee revisions, the mean age was ½ years greater than the mean age for primary TKA, as of 2021.

- The overall picture of the patient cohort's gender-based distribution of the hip and knee arthroplasty procedures that were performed in 2021, along with the respective mean age of the patients for respective arthroplasty types is summarized in the following table: -

Gender based Distribution of the Swedish Patient Cohort, who received Hip & Knee Arthroplasty/Replacements in 2021.

SL No.	Parameter	No. of Cases	Male		Female Patients		Mean Age of Patients [S.D]
			No. of Cases	% of Overall	No. of Cases	% of Overall	
1	Primary Elective Hip Arthroplasty	15,302	6,468	42.26%	8,834	57.70%	68.5 [10.8]
2	Primary Hip Fracture Induced Arthroplasty	6,474	2,297	35.40%	4,177	64.50%	81.4 [9.3]
3	Revision Hip Arthroplasty	1,850	922	49.83%	928	50.20%	73.1 [11.4]
4	Primary Knee Arthroplasty	12,743	5,685	44.61%	7,058	55.40%	68.7 [9.2]
5	Revision Knee Arthroplasty	760	338	44.47%	422	55.50%	69.3 [10.3]
Cumulative Total		37,129	15,710	42.31%	21,419	57.68%	72.2 [10.2]

Table 6.4.1 :- ***Tabulation illustrating the Gender-based Distribution of the Swedish Patient Cohort, who have received various forms of Hip and Knee Arthroplasty in 2021, along with the respective mean-ages of the patients for each arthroplasty type.***

- The overall picture of the patient cohort's age-based distribution of the hip and knee arthroplasty procedures that were performed in 2021 is summarized in the following table: -

Age Group wise Distribution of the Swedish Patient Cohort, who received Hip & Knee Arthroplasty/Replacements in 2021.

SL No.	Parameter	Age-Group Wise Distribution of Hip & Knee Arthroplasty Procedures.					
		<45 Years	45 - 54 Years	55 - 64 Years	65 - 74 Years	75 - 84 Years	>/= 85 Years
1	Primary Elective Hip Arthroplasty	280 (1.80%)	1,393 (9.1%)	3,398 (22.2%)	5,253 (34.3%)	4,328 (28.3%)	650 (4.20%)
2	Primary Hip Fracture Induced Arthroplasty	14 (0.20%)	51 (0.80%)	235 (3.60%)	1,024 (15.80%)	2,444 (37.80%)	2,706 (41.80%)
3	Revision Hip Arthroplasty	22 (1.20%)	103 (5.6%)	292 (15.8%)	485 (26.2%)	652 (35.2%)	296(16.0%)
4	Primary Knee Arthroplasty	61 (0.5%)	804 (6.30%)	3,309 (26.0%)	4,810 (37.7%)	3,414 (26.8%)	345 (2.7%)
5	Revision Knee Arthroplasty	6 (0.8%)	54 (7.1%)	173 (22.8%)	266 (35.0%)	223 (29.3%)	38 (5.00%)
Cumulative Total		383 (1.03%)	2,405 (6.47%)	7,407 (19.9%)	11,838 (31.88%)	11,061 (29.79%)	4035 (10.86%)

Table 6.4.2 :- ***Tabulation illustrating the Age-Group wise distribution of the Swedish Patient Cohort, who had received various forms of Hip and Knee Arthroplasty in 2021, along with their overall cumulative category-wise total and mean percentages.***

<u>Body Mass Index (BMI) Based Demography of the Swedish Arthroplasty Recipient Patient Cohort: -</u>

- The mean BMI of the Swedish patient cohort, undergoing a THA was 27.3.

- The mean BMI of the Swedish patient cohort, undergoing a TKA was 28.7.

- Therefore, the proportion of the Swedish patient cohort, undergoing a TKA, was relatively more obese or had a greater BMI, than a similar fraction of the THA recipients.

- The proportion defined as obese was in line with the globally defined BMI Indices conventions and was adjudged at >= 30.

- Such proportion of obese patients with a BMI of >=30 was considerably higher for TKA, with an overall distribution share of 36.3% of all arthroplasties performed, compared to the distribution share of THAs, which stood at 25.7% and for hip arthroplasty due to fracture incidences was 9%.

- Besides, the usual ASA, and BMI metrics, the Swedish Heath records, also utilized the "Charnley Co-Morbidity Classification", for classifying the patient demographics with respect to the diseased hip joints. Charnley Co-Morbidity Classification has three categories, wherein; "A" refers to patients with

1 Hip involved; "2" to patients with Both Hips involved; and "C" to patients with multi-modal co-morbidities. Further specifics regarding the same parameter shall be discussed later on.

- The overall universally accepted BMI indices category-wise distribution of the Swedish Patient Cohort, receiving Hip and Knee Arthroplasties in 2021 is presented as follows: -

BMI Indices Category Wise Distribution of the Swedish Patient Cohort, receiving Hip & Knee Arthroplasty/Replacements in 2021.

SL No.	BMI Indices Categories	Primary Elective Hip Arthroplasty	Primary Hip Fracture Induced Arthroplasty	Revision Hip Arthroplasty	Primary Knee Arthroplasty	Revision Knee Arthroplasty
1	<18.5	117	408	40	24	3
2	18.5 - 24.9	4,798	2,897	556	2,422	144
3	25.00 - 29.99	6,344	1,524	673	5,611	287
4	30.00-34.90	3,079	380	325	3,581	219
5	35.00-39.90	729	75	110	924	67
6	>= 40	97	19	29	94	22
Cumulative Total		15164	5303	1733	12656	742

Table6.4.3 :- ***Tabulation illustrating the BMI Indices Category-wise distribution of the Swedish Patient Cohort, who had received various forms of Hip and Knee Arthroplasty in 2021.***

- The presence of different cumulative totals for similar categories across many such tabulations was due to the reason that not all sets of data involved the equivalent sample size of the concerning patient cohort, and there were in-accessible or broken data at some points.

SAR 2022 :- Patient Demography based Classification of the Swedish Patient Cohort, receiving Knee Arthroplasties of both Total & Unicondylar type, as per Charnley Patient Class.

SL No.	Charnley Class	Total Knee Arthroplasty		Unicondylar Knee Arthroplasties	
		No. of Cases	% of Overall	No. of Cases	% of Overall
1	Class A	775	22.00%	129	32.00%
2	Class B	1,317	37.00%	154	38.00%
3	Class C	1,483	41.00%	124	30.00%
TOTAL		3,575	100.00%	407	100.00%

Table6.4.4 :- ***Tabulation illustrating the Charnley Patient Class-based classification of Total Knee and Unicondylar Knee Arthroplasty recipients in Sweden.***

ASA (American Society of Anaesthesiologists' Physical Classification) Based Demography of the Swedish Patient Cohort: -

- The ASA Grade is a very useful and well-utilized, globally accepted form to categorize or demonstrate a patient's particular demography and condition for a generalized convention, to understand, who the particular groups of patients are. ASA Grades range from 1-5, with ASA 1 referring to the otherwise fit patient, without any health co-morbidities or ailments, while ASA 5 refers to an otherwise moribund patient, who requires a critical surgical intervention, for sustaining life, in total critical essence.

- For primary elective hip arthroplasty in Sweden, the patients from ASA III & IV categories relatively dominated. ASA III & IV patients received 17.7% of all the primary hemiarthroplasty in Sweden, which is higher than their relative proportion for primary knee arthroplasty in Sweden (16.2%).

- ASA III & IV patients in Sweden also undergone the majority number of primary hip arthroplasties in Sweden, due to a fracture incidence or fracture as the primary diagnosis, accounting for 62.4% of overall primary hip arthroplasties due to fractures.

- The overall universally accepted ASA category-wise distribution of the Swedish Patient Cohort, receiving Hip and Knee Arthroplasties in 2021 is presented as follows: -

ASA Category based Classification of the Swedish Patient Cohort, undergoing Various Forms of Hip and Knee Arthroplasty in Sweden.						
SL No.	**ASA Categories**	**Primary Elective Hip Arthroplasty**	**Primary Hip Fracture Induced**	**Revision Hip Arthroplasty**	**Primary Knee Arthroplasty**	**Revision Knee Arthroplasty**
1	ASA 1	3,045	200	106	2,082	72
2	ASA 2	9,488	2,168	835	8,572	425
3	ASA 3	2,655	3,469	831	2,049	236
4	ASA 4	48	462	45	15	16
Cumulative Total		15,236	6299	1817	12,718	749

Table6.4.5 :- ***Tabulation illustrating the ASA Category-wise distribution of the Swedish Patient Cohort, who had received various forms of Hip and Knee Arthroplasty in 2021.***

Primary Diagnosis-based Demography of the Swedish Patient Cohort: -

- As per diagnosis, osteoarthritis is the absolute most common primary diagnosis for primary elective hip and knee arthroplasties in Sweden, accounting for 92% and 97% of the overall arthroplasty distribution share, respectively.

- This is followed by osteonecrosis, which accounted for 3.9% of overall hip arthroplasty procedures, as the second most common primary diagnosis.

- For knee arthroplasties, it was the inflammatory joint disease, which stood out as the second most common primary diagnosis in Sweden, accounting for 1.3% of the overall. Inflammatory Joint Disease also includes rheumatoid arthritis, though which is reported to be under a continually declining trend, for requiring an arthroplasty-driven intervention, and other conservative forms of treatments, seem to have been answering well to the challenges put up by the said form of the disease. This is further proven by the fact that the number of arthroplasties (both hip & knee), due to rheumatoid arthritis, has largely decreased since the 2003 numbers, to that of the present 2021 scenario, in Sweden.

- The proportion of Swedish women patient cohort, receiving primary hip arthroplasty due to primary diagnosis of progressively damaging osteoarthritis, increased since 2006-2007, while decreasing somewhat in men for the same period, though in general progressively damaging osteoarthritis, as an indication for primary knee arthroplasty increased continually since 2003-2004 to 2020-2021, involving both men and women.

- The proportion of acute hip fracture as the primary diagnosis for primary hip arthroplasty has increased over the last five years from 24.9% to 27.9%, while the proportion of osteoarthritis decreased from 66.6% in 2017 to 64.4% in 2021, in Sweden.

- However, for primary knee arthroplasties, osteoarthritis remained unchanged as the leading indication.

- Interestingly, unlike the global scenario, wherein the risk of requiring an arthroplasty of the hip, continues to increase, with increasing age, in Sweden, it was different, as the Swedish Registry states, that progressively damaging osteoarthritis, as the primary diagnosis or reason for primary hip arthroplasty decreases with increase age from the age group of 55-64 years. Surprisingly, unlike the global scenario, wherein 65-75 years old, had the majority share of overall hip arthroplasty procedures, in Sweden, it was the 55 – 64 years group, that had the highest proportion for overall primary hip

arthroplasty, at 86.4%, and lowest for the >=85 years old group of the patient cohort, contributing to just 17% of the overall primary hip arthroplasties in Sweden.

- Contrastingly, in the case of knee arthroplasty, the proportion of osteoarthritic cases, increases with increasing age in Sweden, differing from the osteoarthritis-linked age-trends for hip arthroplasty for the same Swedish patient cohort.

- The overall scenario regarding the leading causes for hip arthroplasty and knee arthroplasty of the Swedish patient cohort between 2017 – 2021 is presented through the following tables: -

SAR 2022 : - Leading Primary Diagnoses for Overall Hip Arthroplasty of the Swedish Patient Cohort. [Data for the Period of 2017 - 2021]

SL No.	Primary Diagnosis for Hip Arthroplasty	No. of Hip Arthroplasties	% of Overall
1	Osteoarthritis	72,150	65.03%
2	Acute Hip Failure	29,754	26.80%
3	Sequelae Fracture/Trauma	2,171	1.95%
4	Osteonecrosis	2,493	2.24%
5	Congenital / Child-Hood Hip Disease Sequelae	1,484	1.33%
6	Inflammatory Joint Disease	497	0.44%
7	Tumor	619	0.55%
8	Acute Trauma	252	0.23%
9	Other Joint Diseases	1,514	1.36%
Cumulative Total		1,10,934	100.00%

Table6.4.6 :- ***Tabulation illustrating the Leading Primary Diagnoses or Common Causes for Overall Hip Arthroplasty(including Total and Hemi-arthroplasty), of the Swedish Patient Cohort during 2017 – 2021.***

SAR 2022 : - Leading Primary Diagnoses for Overall Knee Arthroplasty of the Swedish Patient Cohort. [Data for the Period of 2017 - 2021]

SL No.	Primary Diagnosis for Hip Arthroplasty	No. of Hip Arthroplasties	% of Overall
1	Osteoarthritis	69,825	96.99%
2	Inflammatory Joint Disease	983	1.36%
3	Osteonecrosis	624	0.86%
4	Sequelae Fracture/Trauma	442	0.61%
5	Tumor	29	0.04%
6	Acute Trauma	69	0.09%
7	Other Joint Diseases	16	0.02%
Cumulative Total		71,988	100.00%

Table 6.4.8 :- ***Tabulation illustrating the Leading Primary Diagnoses or Common Causes for Overall Knee Arthroplasty(including Total, Unicondylar, Patellofemoral, and Multi-Compartmental), of the Swedish Patient Cohort during 2017 – 2021.***

Hip Arthroplasty Practices and Scenario of Sweden

- In 2021, a total of 17,413 primary THAs were reported to have been conducted on the Swedish patient cohort, as per the SAR.

- Among these, 2,051 were due to a hip fracture or a hip fracture-related sequela, while, 15,291 were due to progressively damaging osteoarthritis. This marked a 16% YoY, increase in reported hip arthroplasty numbers in 2021, compared to 2020.

- Similar to the noted scenario for Australian arthroplasty practices, in Sweden as well, a continued increase in the proportion of arthroplasty procedures performed in non-public, private institutions and hospitals, is noted.

- The increase or shift towards non-public institutions/private clinics & hospitals was more accelerated and evident during the pandemic years of 2020 and post-2020, though such a shift is globally observed at more or less proportions, from 2017 onwards, though the scenarios for large populations such as India or China, remains to be examined.

- In 2021, about 41% of all hip arthroplasties in Sweden, were performed at private hospitals & clinical institutions. The corresponding proportion in Sweden from 2000-2017 was a mere 14%.

Fixation Method-Based Hip Arthroplasty Practices on the Swedish Patient Cohort: -

- During the thorough evaluation of the Swedish arthroplasty practises, it was inferred that in general or in overall terms, Swedish Health practices harbour an orthodox approach, towards improving technologies, and evolving practices. The reasons are well explained and have so far borne fruitful results for the Swedish patient cohort and clinicians as a whole, at the cost of delayed exposure to modern practices and techniques. These would be discussed throughout this segment when necessary and required.

- Cemented fixation for hip arthroplasty is reported to have been more commonly performed for females and Cementless for males, though Cemented fixation as a whole is the most common form of fixation method, for hip arthroplasties in Sweden.

- It was reported, that Sweden found “poor” results with uncemented fixation, in the 1990s resulting in an increase of all cemented fixation, attaining a peak in 2000, at 93%. However, it decreased gradually since then, though maintaining a steady majority over other non-cemented and hybrid prostheses over the years.

- In 2021, the proportion of all cemented prostheses was 52% used for hip arthroplasty of the Swedish patient cohort.

- For the case of non-cemented fixations, it has grown several—fold in utilization proportions, since the end of the 2000s.

- In 2000, non-cemented fixations accounted for 2.4% of the total number of reported arthroplasty procedures. This share of the overall arthroplasty procedures increased to 32% in 2021.

- This increase was largely centered around the arthroplasty of the patient cohorts, below 75 years and especially below 65, while the share of the hips operated with all non-cemented prostheses in Swedish patients 75 years of age and higher has remained relatively constant.

- Since 2012, the utilization of reverse hybrid fixation of the prosthesis for hip arthroplasty in Sweden has rapidly decreased. While, comparatively hybrid fixation methods, which remained steady at a meagre 1.5% between 2007-2010, rose to 8% in 2021, maybe completely replacing reverse hybrid approaches, that either remained out as a sophisticated custom use-only method, to be used for Swedish arthroplasty practices.

- No utilization of resurfacing hip arthroplasty in 2021, was reported by the Swedish registry.

- In somewhat an unconventional fashion, the Swedish registry – SAR, goes on to state or declare that they would "continue to encourage the use of cemented fixation in patients older than 70 years". This could be possibly attributed to the time-tested positive results and long-term prosthesis & and functionality status-specific outcomes that were attained due to cemented fixations.

- Similar to the resurfacing scenario, reverse hybrid-based primaries and revisions are very hard to find in the present Swedish arthroplasty practices, though some off-label or un-reported usage cannot be completely ruled out, but going as per the orthodoxical approach of the Swedish clinicians, is expected, even if there's a suppressed usage of such methods, it will be miniscule.

- With respect to the fixation methods adopted for revision hip procedures, there's an existent tendency to keep at least a single non-cemented component with a cemented one, resulting in hybrid fixation scenarios, in many such re-revision and revision hip arthroplasty cases in Sweden. These practices very well explain the reason behind hybrid fixation being the choice of first preference for internal prosthesis fixation in revisions in Sweden.

- The age-group-wise distribution of various fixation methods utilized for fixating hip prostheses during Hip replacement of the Swedish patient cohort in 2021 is as follows: -

Age-Group wise Distribution of the Fixation Methods that were Used for Hip Replacement of the Swedish Patient Cohort in 2021.

SL No.	Type of Fixation	Age-Group of the Patients					
		< 45	45 - 54	55 - 64	65 - 74	75 - 84	>= 85
1	Cemented	8	57	584	3,119	3,562	567
2	Hybrid	14	60	243	451	383	69
3	Non-Cemented	235	1,072	2,112	1,288	220	4
4	Reverse Hybrid	21	202	452	384	154	3
5	Resurfacing	0	0	0	0	0	0
Cumulative Total		278	1,391	3,391	5,242	4,319	643

Table6.4.8 :- ***Tabulation illustrating the Age-Group based Distribution of the Fixation Methods utilized for fixating Hip Prostheses during Hip Replacement of the Swedish Patient Cohort in 2021.***

Prosthesis-Specific Hip Arthroplasty Practices on the Swedish Patient Cohort; -

- The facts & figures about the prosthesis-specific arthroplasty practices and trends for hip arthroplasty of the Swedish patient cohort are in line, with the Swedish ideal of going orthodox, in every plausible way.
- The five most commonly utilized acetabular cups in 2021, accounted for 93% of the total number of the acetabular cups, used for hip arthroplasty in Sweden.

- On the aspect of femoral stems, it was Lubinus SPII (Waldemar LINK), Exeter (Stryker) and MS-30(Zimmer Biomet) were the most dominating ones. These three implants combined account for nearly 99% of all the cemented femoral stems, in active and current operations in Sweden, summing up the lack of variety or options, and highlighting the above-discussed streamlined orthodox approach of the Swedish clinicians and healthcare bodies.

- For the case of acetabular cups, the variation of non-cemented cups seems to be wider, compared to cemented ones. The five most utilized non-cemented acetabular cups accounted for 77% of all the non-cemented cups, reported to the registry.

- However, the reported risks of dislocation associated with these designs of the prosthesis of non-cemented fixation, keep the free and mass-scale open utilization of non-cemented designs at restraint and are only used for specifically necessitated conditions, with a greater deal of post-operative monitoring.

- Trabecular metal acetabular cups are reported to be on a continued declining trend, primarily due to the concern of undesirous long-term performance, with increased incidences of dislocations for some of the designs.

- Since, 2009 in Sweden, DePuy Synthes's Corail has been the most used non-cemented stem, and it presently accounted for 30% of all non-cemented THAs in 2021.

- Interestingly, with the adoption of HXLPE steaming up pace in Sweden, it is observed that the orthodox Swedish practitioners have channelized the utilization of HXLPE-based polyethylene liners, in greater proportions towards non-cemented hip arthroplasties of the Swedish patient cohort, such as so, as of 2021, 99% of all non-cemented hip arthroplasties are conducted using them.

- The HXLPE-based polyethylene liner adoption scenario for cemented procedures, was at 89%, with 11% still preferring traditional "older" HDPE & UHMWPE-based polyethylene liners, to be their choice for cemented hip arthroplasty of the Swedish patient cohort.

- Ceramic-on-Polyethylene (CoP) based bearings utilizations continue to grow in Swedish hip arthroplasty practices, with 27% of all arthroplasties in 2021, being conducted using such bearings, against a corresponding proportion in 2020, of 26%, registering 1% YoY growth, using such bearing surfaces for the Swedish patient cohort. This continued rise in the utilization of CoP bearings is consistent with the global scenario in this particular regard.

- Femoral head sizes with 32mm and 36mm diameters remain to be the optimal choice for hip arthroplasty, with the 32mm rising in greater proportions of utilizations, while, the 36mm utilization remained stable with a steady 10% usage of all femoral head sizes utilized in Sweden, over the last few years, including 2021.

- The most commonly deployed artificial hip prostheses combinations for hip arthroplasty of the Swedish patient cohort during the years of 2000 – 2021 are presented through the following tabulation:

Most Common Prostheses Combinations utilized for Hip Arthroplasty of the Swedish Patient Cohort.											
SL No.	Prosthesis Combination [Acetabular Cup/Shell (Femoral Stem)]	2000 - 2021		2000 - 2009		2010 - 2019		2020		2021	
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall
1	Lubinus (SPII Standard)	63,606	21.30%	43,866	35.50%	15,691	11.40%	504	3.80%	587	3.80%
2	Lubinus X-Link (SPII Standard)	33,500	11.20%	22	0.00%	26,819	19.60%	2,987	22.70%	3,672	24.10%
3	Exeter Rim-Fit (Exeter Standard)	13,620	4.60%	99	0.10%	11,355	8.30%	956	7.30%	1,210	7.90%
4	Exeter (Exeter Standard)	10,049	3.40%	8,628	7.00%	65	0.00%	0	0.00%	0	0.00%
5	Marathon (Exeter Standard)	9,851	3.30%	1,466	1.20%	7,649	5.60%	388	3.00%	348	2.30%
6	ZCA XLPE (MS-30 Polished)	9,112	3.10%	3,362	2.70%	5,360	3.90%	188	1.40%	202	1.30%
7	Elite Ogee (Exeter Standard)	6,651	2.20%	6,298	5.10%	20	0.00%	0	0.00%	0	0.00%
8	Pinnacle W / Gription 100 (Corail Standard)	6,351	2.10%	0	0.00%	4,493	3.40%	966	7.30%	892	5.80%
9	Contemporary Hooded Duration (Exeter Standard)	6,219	2.10%	4,208	3.40%	2,010	1.50%	0	0.00%	0	0.00%
10	Trilogy (CLS)	5,938	2.00%	2,546	2.10%	2,531	1.80%	402	3.10%	452	3.00%
11	FAL (SPII Standard)	5,501	1.80%	4,812	3.90%	528	0.40%	0	0.00%	0	0.00%
12	Exeter Rim-Fit (MS-30 Polished)	4,660	1.60%	20	0.00%	3,081	2.20%	687	5.20%	872	5.70%
13	Reflection All Poly (Spectron EF Primary)	4,803	1.60%	4,355	3.50%	5	0.00%	0	0.00%	0	0.00%
14	Contemporary (Exeter Standard)	3,482	1.20%	3,334	2.70%	129	0.10%	0	0.00%	0	0.00%
15	Trident Hemi (Exeter Standard)	3,432	1.10%	66	0.10%	2,648	1.90%	362	2.80%	356	2.30%
16	Other	1,11,840	37.50%	40,379	32.70%	54,695	39.90%	5,704	43.40%	6,700	43.80%
Cumulative Total		2,98,615	100.10%	1,23,461	100.00%	1,37,079	100.00%	13144	100.00%	15291	100.00%

Table 6.4.9 :- ***Tabulation illustrating the Most Common Prostheses Combinations, utilized for Overall Hip Arthroplasty(including Total, Hemi and Revision) of the Swedish Patient Cohort, during the years of 2000-2021.***

- The most commonly utilized artificial hip prosthesis combinations i.e., acetabular cup/shell and femoral stem combinations, for Cemented Hip Arthroplasty of the Swedish Patient Cohort is presented as follows: -

Most Commonly Utilized Cemented Fixation based Acetabular Cup/Shell & Femoral Stem Combinations for Hip Arthroplasty of the Swedish Patient Cohort.				
SL No.	Prostheses Name Acetabular Cup [Femoral Stem]	Cemented Hip Arthroplasty [2000-2021]		Mfg. Company / Supplier
		No. of Cases	% of Overall	
1	Lubinus (SPII Standard)	63,599	31.60%	Waldemar Link
2	Lubinus X-Link (SPII Standard)	33,447	16.60%	
3	Exeter Rim-Fit (Exeter Standard)	13,605	6.80%	Stryker
4	Exeter (Exeter Standard)	10,048	5.00%	
5	Marathon (Exeter Standard)	9,802	4.90%	DePuy Synthes ; Stryker
6	ZCA XLPE (MS-30 Polished)	9,111	4.50%	Zimmer Biomet
7	Elite Ogee (Exeter Standard)	6,650	3.30%	DePuy Synthes ; Stryker
8	Contemporary Hooded Duration (Exeter Standard)	6,218	3.10%	Stryker
9	FAL (SPII Standard)	5,499	2.70%	Waldemar Link
10	Reflection All Poly (Spectron-EF Primary)	4,803	2.40%	Smith&Nephew
11	Exeter Rim-Fit (MS-30 Polished)	4,659	2.30%	Stryker ; Zimmer Biomet
12	Contemporary (Exeter Standard)	3,482	1.70%	Stryker
13	Charnley LPW (Charnley)	2,009	1.00%	DePuy Synthes
14	ZCA XLPE (SPII Standard)	1,991	1.00%	Zimmer Biomet ; Waldemar Link
15	Charnley Ogee (Charnley)	1,972	1.00%	DePuy Synthes
16	Other	24,537	12.10%	
Cumulative Total		2,01,432	100.00%	

Table 6.4.10 :- ***Tabulation illustrating the Most Common Cemented Fixation based Prostheses Combinations(Femoral Stems and Acetabular Cups/Shells), utilized for Overall Hip Arthroplasty(including Total, Hemi and Revision) of the Swedish Patient Cohort, during the years of 2000-2021.***

- The most commonly utilized artificial hip prosthesis combinations i.e., acetabular cup/shell and femoral stem combinations, for Non-Cemented Hip Arthroplasty of the Swedish Patient Cohort, is presented as follows: -

Most Commonly Utilized Non-Cemented Acetabular Cup/Shell & Femoral Stem Prosthesis Combinations for Hip Arthroplasty of the Swedish Patient Cohort.				
SL No.	Prostheses Combinations Acetabular Cup [Femoral Stem]	No. of Cases [2000 - 2021]		Mfg. Company / Supplier
		No. of Cases	% of Overall	
1	Pinnacle W/Gription 100 (Corail Standard)	6,350	11.40%	DePuy Synthes
2	Trilogy (CLS)	5,936	10.70%	Zimmer Biomet
3	Pinnacle 100 (Corail Standard)	2,600	4.70%	DePuy Synthes
4	Pinnacle W/Gription 100 (Corail High Offset)	2,474	4.50%	DePuy Synthes
5	Allofit	2,086	3.80%	Zimmer Biomet
6	Trident Hemi (Accolade II)	1,920	3.50%	Stryker
7	Continuum (CLS)	1,749	3.20%	Zimmer Biomet
8	Pinnacle W/Gription 100 (Corail Coxa Vara)	1,559	2.80%	DePuy Synthes
9	Exceed ABT Ringlock [Bi-Metric X Por HA Non-Cemented(NC)]	1,494	2.70%	Zimmer Biomet
10	Pinnacle 100 (Corail Coxa Vara)	1,028	1.90%	Zimmer Biomet
11	Continuum (M/L Taper)	977	1.80%	Zimmer Biomet
12	CLS (CLS)	954	1.70%	Zimmer Biomet
13	Trilogy IT [Bi-Metric X Por HA Non-Cemented(NC)]	928	1.70%	Zimmer Biomet
14	G7 PPS [Echo Bi-Metric (FPP)]	906	1.60%	Zimmer Biomet
15	Trident AD WHA (Accolade Straight)	859	1.50%	Stryker
16	Other	23,647	42.60%	
Cumulative Total		55,467	100.10%	

Table 6.4.11 :- ***Tabulation illustrating the Most Common Non-Cemented Fixation based Prostheses Combinations(Femoral Stems and Acetabular Cups/Shells), utilized for Overall Hip Arthroplasty(including Total, Hemi and Revision) of the Swedish Patient Cohort, during the years of 2000-2021.***

- The most commonly utilized artificial hip prosthesis combinations i.e., acetabular cup/shell and femoral stem combinations, for Reverse - Hybrid Fixation Hip Arthroplasty of the Swedish Patient Cohort, are presented as follows: -

Most Commonly Utilized Reverse Hybrid Fixation based Acetabular Cup/Shell & Femoral Stem Prosthesis Combinations for Hip Arthroplasty of the Swedish Patient Cohort.				
SL No.	**Prostheses Name Acetabular Cup [Femoral Stem]**	**Reverse Hybrid Fixation Hip Arthroplasties [2000 - 2021]**		**Mfg. Company / Supplier**
		No. of Cases	**% of Overall**	
1	Exeter Rim Fit (Corail Standard)	2,327	8.50%	Stryker ; DePuy Synthes
2	Marathon (Corail Standard)	2,172	7.90%	DePuy Synthes
3	Lubinus (Corail Standard)	1,974	7.20%	Waldemar Link ; DePuy Synthes
4	Lubinus X-Link (Corail Standard)	1,937	7.00%	Waldemar Link ; DePuy Synthes
5	Marathon (Corail High Offset)	1,134	4.00%	DePuy Synthes
6	Marathon (ABG II HA)	1,019	3.70%	DePuy Synthes ; Stryker
7	Marathon (Bi-Metric X Por HA NC)	903	3.30%	DePuy Synthes ; Zimmer Biomet
8	Exeter Rim-Fit (M/L Taper)	841	3.10%	Stryker ; Zimmer Biomet
9	Exeter Rim Fit (Corail High Offset))	724	2.60%	Stryker ; DePuy Synthes
10	Lubinus X-Link (Corail Coxa Vara)	681	2.50%	Waldemar Link ; DePuy Synthes
11	Lubinus (Corail Coxa Vara)	649	2.40%	Waldemar Link ; DePuy Synthes
12	Lubinus (CLS)	598	2.20%	Waldemar Link ; Zimmer Biomet
13	Lubinus X-Link (Bi-Metric X Por HA NC)	553	2.00%	
14	Lubinus (Bi-Metric X Por HA NC)	552	2.00%	
15	ZCA XLPE (Corail Standard)	516	1.90%	Zimmer Biomet ; DePuy Synthes
16	Other	10,946	39.80%	
Cumulative Total		**27,526**	**100.00%**	

Table 6.4.12 :- ***Tabulation illustrating the Most Common Reverse Hybrid Fixation based Prostheses Combinations(Femoral Stems and Acetabular Cups/Shells), utilized for Overall Hip Arthroplasty(including Total, Hemi and Revision) of the Swedish Patient Cohort, during the years of 2000-2021.***

- The most commonly utilized artificial hip prosthesis combinations i.e., acetabular cup/shell and femoral stem combinations, for Hybrid Fixation Hip Arthroplasty of the Swedish Patient Cohort, are presented as follows: -

Most Commonly Utilized Hybrid Fixation Acetabular Cup/Shell & Femoral Stem Prosthesis Combinations for Hip Arthroplasty of the Swedish Patient Cohort.				
SL No.	**Prostheses Name Acetabular Cup [Femoral Stem]**	**No. of Cases [2000 - 2021]**		**Mfg. Company / Supplier**
		No. of Cases	**% of Overall**	
1	Trident Hemi (Exeter Standard)	3,432	29.60%	Stryker
2	Trilogy (SP II Standard)	1,251	10.80%	Zimmer Biomet ; Waldemar Link
3	Trilogy (Spectron EF Primary)	957	8.30%	Zimmer Biomet ; Smith&Nephew
4	Pinnacle W/Gription 100 (MS-30 Polished)	631	5.50%	DePuy Synthes ; Zimmer Biomet
5	Tritanium (Exeter Standard)	310	2.70%	Stryker
6	Pinnacle Sector (SP II Standard)	306	2.50%	DePuy Synthes ; Waldermar Link
7	Trident AD LW (Exeter Standard)	252	2.20%	Stryker
8	Pinnacle W/Gription Sector (MS-30 Polished)	227	2.00%	DePuy Synthes ; Zimmer Biomet
9	Pinnacle W/Gription Sector (Exeter Standard)	206	1.80%	DePuy Synthes ; Stryker
10	Trilogy IT (SP II Standard)	202	1.70%	Zimmer Biomet ; Waldemar Link
11	Trilogy (MS-30 Polerad)	195	1.70%	Zimmer Biomet
12	TOP Pressfit (SP II Standard)	159	1.40%	
13	Pinnacle W/Gription 100 (SPII Standard)	158	1.40%	DePuy Synthes ; Waldermar Link
14	Continuum (MS-30 Polished)	144	1.20%	Zimmer Biomet
15	Continuum (SPII Standard)	136	1.20%	Zimmer Biomet ; Waldemar Link
16	Other	3,010	26.00%	
Cumulative Total		**11,576**	**100.00%**	

Table6.4.13 :- ***Tabulation illustrating the Most Common Hybrid Fixation based Prostheses Combinations (Femoral Stems and Acetabular Cups/Shells), utilized for Overall Hip Arthroplasty(including Total, Hemi and Revision) of the Swedish Patient Cohort, during the years of 2000-2021.***

- The most commonly utilized acetabular cups and shells for overall hip arthroplasty of the Swedish patient cohort, including primary, hemi and revision hip arthroplasty irrespective of the fixation method deployed are presented in the tabulation as follows: -

Most Commonly Utilized Acetabular Cup/Shells for Hip Arthroplasty of the Swedish Patient Cohort, during the years of 2000 - 2021.					
SL No.	Name of Acetabular Cup	Overall Hip Arthro during [2000 - 2021]		Mfg. Company / Supplier	ODEP Rating
		No. of Cases	% of Overall		
1	Lubinus	68,494	22.90%	Waldemar Link	15A*
2	Lubinus X-Link	38,593	12.90%		10A*
3	Exeter Rim-Fit	22,827	7.60%	Stryker	10A*
4	Marathon	17,380	5.80%	DePuy Synthes	13A*
5	ZCA XLPE	14,182	4.80%	Zimmer Biomet	15A* / 10A
6	Trilogy	12,072	4.00%		15A*
7	Pinnacle W/Gription 100	11,938	4.00%	DePuy Synthes	10A*
8	Exeter	10,870	3.60%	Stryker	Unrated
9	Elite Ogee	10,406	3.50%	DePuy Synthes	15A*
10	Contemporary Hooded Duration	7,668	2.60%	Stryker	Rating Withdrawn
11	Trident Hemi	7,472	2.50%	Stryker	Multiple Rating
12	FAL	5,759	1.90%	Waldemar Link	Unrated
13	Continuum	5,554	1.90%	Zimmer Biomet	13A
14	Reflection All Poly	4,993	1.70%	Smith&Nephew	ODEP Lapsed / 15A[XLPE Version]
15	Pinnacle 100	4,635	1.60%	DePuy Synthes	15A*
16	Other	55,687	18.70%		
Cumulative Total		2,98,530	100.00%		

Table 6.4.14 :- ***Tabulation illustrating the Most Common Acetabular Cup and Shells utilized for Overall Hip Arthroplasty(including Total, Hemi and Revision) of the Swedish Patient Cohort, irrespective of the Fixation Method utilized during the years of 2000-2021.***

- The most commonly utilized femoral stems for overall hip arthroplasty of the Swedish patient cohort, including primary, hemi and revision hip arthroplasty irrespective of the fixation method deployed are presented in the tabulation as follows: -

Most Commonly Utilized Femoral Stems for Hip Arthroplasty of the Swedish Patient Cohort during 2000 - 2021.					
SL No.	Prostheses Name of Femoral Stem	Overall Hip Arthroplasty during [2000 - 2021]		Mfg. Company / Supplier	ODEP Rating
		No. of Cases	% of Overall		
1	SPII Standard	1,14,889	38.50%	Waldemar Link	15A*
2	Exeter Standard	59,478	19.90%	Stryker	15A*
3	Corail Standard	23,343	7.80%	DePuy Synthes	15A* / 10A / 3A
4	MS-30 Polished	18,429	6.20%	Zimmer Biomet	15A*
5	CLS	14,720	4.90%		
6	Bi-Metric X Por HA NC	8,964	3.00%		7A*
7	Spectron EF Primary	7,947	2.70%	Smith&Nephew	15A
8	Corail High Offset	7,245	2.40%	DePuy Synthes	15A* / 10A / 3A
9	Corail Coxa Vara	6,186	2.10%		
10	Accolade II	4,176	1.40%	Stryker	10A
11	Charnley	3,998	1.30%	DePuy Synthes	15A*
12	ABG II HA	3,409	1.10%	Stryker	Unrated
13	M/L Taper	3,265	1.10%	Zimmer Biomet	15A*
14	CPT	2,430	0.80%		15A* / Rating Withdrawn
15	Wagner Cone	2,185	0.70%		10B / Rating Withdrawn
16	Other	17,818	6.10%		
Cumulative Total		2,98,482	100.00%		

Table6.4.15 : - ***Tabulation illustrating the Most Femoral Stems utilized for Overall Hip Arthroplasty (including Total, Hemi and Revision) of the Swedish Patient Cohort, irrespective of the Fixation Method utilized during the years of 2000-2021.***

Revision Hip Arthroplasty Practices in Sweden on its Patient Cohort; -

- The Swedish registry has referred to revision arthroplasties as "re-operation" hip arthroplasties, and has defined them as a procedure that comprises all types of surgically intervened activity that can be performed, directly related or caused by an earlier inserted hip prosthesis, regardless of the prosthesis or any of its comprising parts being exchanged, extracted or left untouched".

- The above definition is in line with the globally accepted definition of revision arthroplasty, and a detailed literature review in this regard has further confirmed the synonymousness of the two terminologies.

- From 2001, until 2009, there was a steady rise in the re-operation procedures numbers annually rising from 1,945 to 2,450.

- Post 2009, the number of re-operation or revisions varied from around 2,380 to 2,474, till 2016, post which the annual numbers gradually fell to 1,833 in 2020 and 1,866 as of 2021.

- Between 1995-1997 vis-à-vis 2019-2021, the proportions of the revision hip cases contributing to the total number of overall hip arthroplasties decreased from 13.5% during the former to 10% during the latter periods.

- A major statistically influencing factor, that increased during this while, that could have contributed to the reduction in the overall revision numbers is the disproportionate rise of the primary arthroplasties, compared to the revision ones. In between the periods of 1995-1997 and 2019-2021, revision cases grew by 26.2% while, the primary hip procedures outpaced them disproportionately through growing by 68.9%, during the said periods comparatively. So, from a statistical point of view, the percent of revisions vis-à-vis primary arthroplasty procedures, ought to shrink, if the latter grows at a much faster rate than the former.

- The primary reason for the decrease in the proportions of revisions is due to the general reduction in the incidences of loosening, that was plaguing the arthroplasty domain, more or less in the 1990s. In Sweden, incidences of loosening of hip prosthesis implants reduced from 8.5% to 3.5% of all THAs conducted or performed between 1995-1997 vis-à-vis 2019-2021 periods, which happens to be first and last three-year periods of the Swedish hip arthroplasty data collection operations.

- The proportions of revision hip arthroplasties in the Swedish patient cohort, due to dislocation of the hip prosthesis, also decreased, but in a very modest manner from 1.5% to 1.1%.

- The incidences of the relative decrease of revision hip arthroplasty as per the Swedish registry is "probably" real, but they don't completely rule out the remote possibilities of under-reporting or 'specifically co-ordinated agreement' based data suppression, in some clinics and institutes, involving some or any particular prostheses.

- The proportion of Swedish males getting a revision is higher than that of the proportion of males, receiving primary hip arthroplasties. Swedish males have received more revisions than females in the Swedish patient cohort, which is a non-consistent picture, against the global scenario in this regard, where female patients, have continually undergone greater proportions of revisions.

- The gender-linked differences widened out in recent years, which is evident by the fact that between 2009-2011, 46% of all revision hip arthroplasties were performed on Swedish males, which increased to 51.6% during 2019 – 2021.

- On the aspect of the Body Mass Index or BMI-based distributions of revision hip arthroplasties in Sweden, this research finds that the Swedish patients receiving a revision arthroplasty of the hip possessed a higher BMI and also belonged to a higher ASA category, compared with the average BMI & ASA levels of primary hip arthroplasty.

- Swedish patients with the highest BMI were the most susceptible or vulnerable to revision arthroplasty.

- The BMI wise distribution of revision hip arthroplasty procedures in Sweden are presented through the following tabulation: -

BMI-Wise Distribution of the Re-Operation of the Hip Arthroplasty Cases in Sweden.

SL No.	BMI Indices Category	2009 - 2011		2013 - 2015		2019 - 2021	
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall
1	<18.5	112	2.00%	116	1.80%	83	1.50%
2	18.5 - 24.9	1,870	33.80%	2,126	33.00%	1,691	30.80%
3	25.00 - 29.99	2,242	40.60%	2,643	41.00%	2,214	40.30%
4	30.00 - 34.99	966	17.50%	1,085	16.80%	1,059	19.30%
5	35.00 - 39.99	253	4.60%	366	5.70%	336	6.10%
6	> = 40.00	85	1.50%	104	1.60%	108	2.00%
Cumulative Total		5,528	100.00%	6,440	99.90%	5,491	100.00%

Table6.4.16 : - ***Tabulation illustrating the Body Mass Index(BMI) wise Distribution of Revision Hip Arthroplasty procedures of the Swedish Patient Cohort, during the years of 2009 - 2021.***

- The ASA Grade wise distribution of the revision hip arthroplasty procedures in Sweden are presented through the following tabulation: -

ASA-Wise Distribution of the Re-Operation of the Hip Arthroplasty Cases in Sweden.

SL No.	ASA Category	2009 - 2011		2013 - 2015		2019 - 2021	
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall
1	ASA 1	799	12.50%	690	10.00%	388	6.80%
2	ASA 2	3,298	51.80%	3,474	50.40%	2,875	50.20%
3	ASA 3	2,135	33.50%	2,577	37.40%	2,312	40.40%
4	ASA 4	136	2.20%	155	2.20%	150	2.60%
Cumulative Total		6,368	100.00%	6,896	100.00%	5,725	100.00%

Table 6.4.17 : - ***Tabulation illustrating the ASA-Category wise Distribution of Revision Hip Arthroplasty procedures of the Swedish Patient Cohort, during the years of 2009 - 2021.***

- The patient age-group wise distribution of the revision hip arthroplasty procedures in Sweden are presented through the following tabulation: -

Age-Wise Distribution of the Re-Operation of the Hip Arthroplasty Cases in Sweden.							
SL No.	Age Group	2009 - 2011		2013 - 2015		2019 - 2021	
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall
Mean Age Group [S.D]		71.97		71.81		72.35	
1	<45 Years	550	7.50%	554	7.60%	418	7.10%
2	45 - 54 Years	1,114	15.30%	1,065	14.50%	927	15.80%
3	55 - 64 Years	2,280	31.20%	2,540	34.70%	1,765	30.10%
4	65 - 74 Years	2,451	33.60%	2,317	31.60%	1,998	34.10%
5	75 - 84 Years	896	12.20%	845	11.50%	748	12.80%
6	>= 85 Years	154	0.50%	151	0.50%	148	0.50%
Cumulative Total		7,445	100.30%	7,472	100.40%	6,004	100.40%

Table 6.4.18 : - ***Tabulation illustrating the Age-Group wise Distribution of Revision Hip Arthroplasty procedures of the Swedish Patient Cohort, during the years of 2009 – 2021, along with the Mean Age & Standard Deviation of the Overall Patient cohort during Specific Periods of the Accessible Data.***

- The Swedish registry also acknowledges that resurfacing and large metal head hip prostheses led to the formulation of an increased number of revisions, which were primarily due to the elevated blood metal ionic concentration, resulting from active metallosis and corrosion of the implanted metal prosthesis into the patient anatomy. These conditions were also attributed to the rapid decline to almost negligible or no-use stage of resurfacing hip arthroplasties in Sweden, which syncs with the global scenario regarding resurfacing hips, though many other nations evaluated during the course of this research probe, have not completely ruled out or banned resurfacing hip arthroplasty from active clinical and patient usage.

- The Swedish registry reported that during 2001 – 2021, all originally implanted components were exchanged in single or dual-stage revision procedures for 39.3% of all first-time revision hip arthroplasties and in 45.5% of all re-revision or multiple-revision hip arthroplasty cases in Sweden.

- In somewhat a first of its kind approach, it was found that amidst all other laxation provided by the registry to clinics and institutes with regards to reporting the arthroplasty procedures, the Swedish registry along with other regulatory bodies, mandates for all revision procedures of hip or knee joints, with or without the replacement / alteration / modification of the prosthesis or any of its comprising components, has to be mandatorily reported, and all the clinical documents and data pertaining to such a procedure, with primary case files and possible causes for the requirement of the revision procedure, are to be sent for the expert review of the registry and other healthcare regulatory bodies in Sweden, for due verification, validation and archiving purposes. Such a regulation is definitely a commendable step in the right direction, for tracking and monitoring the performances of the prosthesis being used in Sweden, thereby maintaining a thorough vigilance against sub-standard prosthesis designs or surgical approaches that could jeopardize the recovery process of any Swedish patient.

- The reporting and subsequent revision procedure numbering policy for hips in Sweden, was found to be different from the global scenario, wherein it was found that the Swedish registry, and other healthcare databases/registers based in Sweden, registers two stage revisions, or in some cases dual stage DAIRs (Debridement and Implant Retention) surgeries, as a singular one, and not by the number of times, a particular Swedish patient is operated post-operatively to his/her primary arthroplasty. While, the Swedish agencies might have their own reasons, but the general assumption is each time a patient, who is expected to be past 50-55 years of age as per the generalized mean age groups observed, is operated, no-matter the intent and duration, a certain degree of trauma both physical and economical is exerted upon him/her, and the overall outcome or his/her living standards, QoL and abilities in performing daily activities such as toiletries might get hampered or influenced. In such situations, individual procedure-based numbering, though might have propelled the overall revision numbers, a

bit higher, but would possibly have allowed for a greater deal of transparency and tracking, for regulatory bodies and researchers, if not definitely.

- Factoring these parameters & influences, it shall be pertinent to state that the overall revision numbers for hip and knee, by the Swedish registry, are much lesser than the actual real-life revisions, performed on the Swedish patient, which could be adjusted and determined, if the detailed hip revision procedures are assessed as per global standards, of case numbering/registering, as stated above.

- Since 1979, revision hip arthroplasty data has been collected by the registry, and other Swedish healthcare databases on an individual level, but surprisingly revision & primary linked data with standalone primary hip arthroplasty procedures are collected only since 1992, based on Swedish personal identity numbers, for unique identification of the respective patients that were reported to be the beneficiaries or recipients of the said arthroplasty treatments.

- With regards to the major reasons for revision hip arthroplasties of the Swedish patient cohort, it was found that during the examined and evaluated period of 2004 – 2021, aseptic loosening of the implanted prosthesis, contributed towards the most number of revision hip arthroplasties, with an overall distribution share of 49.20%, which is closely followed by post-operative infection with 21.50% and dislocation/subluxation of the prosthesis contributing towards 13.4% of overall numbers of revisions. Other major failure reasons include periprosthetic fracture, post-operatively that resulted in 9.2% of all the recorded revision hip arthroplasties during the mentioned timeframe period.

- During the recent years of 2020 – 2021, post-operative loosening of the hip prosthesis still dominates in causing the greatest number of revision hip arthroplasties, but their overall distribution percent has reduced from 49% to 44%, followed by post-operative infections (13.2%), peri-prosthetic fractures (13.2%) and dislocation (12.4%).

- Post-operative deep infection was attributed to be the major reason for a re-revision or multiple revision hip arthroplasties (hips which have been revised more than once) during the same period of 2020 & 2021, with an overall share of 56.2%, for all the indications for re-revision or multiple revision hip arthroplasties in Sweden. This is followed by loosening of the prosthesis (21.8%), dislocation/subluxation of the prosthesis at (13.2%) and peri-prosthetic fracture (5%).

Implant Fracture Scenarios in Swedish Arthroplasty Practices: -

- The Swedish registry and other healthcare databases have defined “Implant Fractures”, to be a bestowment of all the following three plausible conditions: -
    - Fracture of the Prosthesis Femoral Stem.
    - Fracture of the Fixation Material.
    - Rare Incidences of the Acetabular Cup or Shell Fracture.
- These all are clubbed into a singular cause i.e., Implant Fractures (hip implant fracture, in this case).
- It was found that in general, the overall number of revisions caused due to such implant fractures is low, but the risk involved is higher for implants, utilized for revision hip arthroplasties, at 0.23%, somewhat more than a primary procedure at 0.05%.

- Cemented fixation-based prostheses were the most vulnerable designs of the prosthesis, from implant fractures, compared to non-cemented ones, with an incidence rate of 0.06% vis-à-vis 0.02% respectively.

- The risk of implant fracture is reported to be on the increased plateau for certain cemented stems and mini-stems, by the SAR. The utilization of small stems of certain prosthesis models was discouraged for active clinical purposes in Swedish patients, with a narrow medullary cavity of the femur bone. However, it is inferred by this research that the stem fracture risk is not entirely avoidable, and it may still happen based on multiple intrinsic and extrinsic factors.

- For hip fracture cases of the Swedish patient cohort, a significant proportion of the most utilized prostheses, especially the acetabular cups are of local manufacturing and from other turnkey supplier chains.

- The overall scenario of most popular acetabular cup/shells for hip fracture based primary hip arthroplasty is presented through the following tabulation: -

Most Common Acetabular Cup Utilizations for Hip Fracture based Primary Hip Arthroplasty of the Swedish Patient Cohort.					
SL No.	**Acetabular Cup**	**No. of Cases**	**% of Overall**	**Mfg. Company / Supplier Brand**	**ODEP Rating**
1	Unipolar Femoral Head	5,337	28.00%	Local Mfg/Turnkey Supplier	
2	UHR Universal Head	2,322	12.20%	Stryker	Unrated
3	Unitrax Modular Endo-head	1,360	7.10%	Stryker	Unrated
4	Lubinus X-Link	1,356	7.10%	Waldemar Link	10A*
5	Modular Trauma Heads	1,239	6.50%	Local Mfg/Turnkey Supplier	
6	Lubinus (UHMWPE)	922	4.80%	Waldemar Link	15A*
7	Avantage	818	4.30%	Zimmer Biomet	10A / 7A / ODEP Withdrawn [DM Ver.]
8	Marathon	736	3.90%	DePuy Synthes	13A*
9	Co-Vision Unipolar	674	3.50%	Local Mfg/Turnkey Supplier	
10	Vario Cup	566	3.00%	Waldemar Link	Unrated
11	Exeter Rim-Fit	560	2.90%	Stryker	10A*
12	MultiPolar BiPolar Cup	466	2.40%	Zimmer Biomet	Unrated
13	V40 Unipolar	430	2.30%	Stryker	
14	Unipolar	301	1.60%	Local Mfg/Turnkey Supplier	
15	PolarCup Cemented	287	1.50%	Smith&Nephew	5A
16	Other	1,688	8.90%		
Cumulative Total		**19,062**	**100.00%**		

Table 6.4.19 : - ***Tabulation illustrating the Most Common Acetabular Cups utilized for Primary Hip Arthroplasty of the Swedish Patient Cohort, caused due to Hip Fractures, with their respective ODEP Rating Statuses, as 2021.***

Femoral Heads in Primary and Revision Hip Arthroplasty

- Femoral heads are the most commonly exchanged component of a hip prosthesis during a revision hip arthroplasty in Sweden and get almost routinely replaced or exchanged in all revisions, accounting for nearly 92.9% of all recorded revision hip procedures in the Swedish registry since 2001.

- The Swedish registry further affirms the global inference that has been so far obtained, based on the prevalent practices and conditions with respect to femoral head sizes and articular surface material, i.e., the use of 32mm and 36mm femoral heads with HXLPE-based articular bearing surfaces. Amidst the pre-valent practices of using sub 30mm or in general 26 / 28mm femoral heads, the transition into larger diameter sized 32 mm and 36 mm femoral heads was plausible due to availability and real-time

living up to the promised standards performance by the HXLPE bearings, that has sealed the transition process without much of fatal outcomes or collaterals.

- This has largely reduced the major risks plaguing the Swedish patient cohort – polymer liner wear and the dislocation of the femoral head, which now seems to be under control in Sweden.

- Since 2013, the relative proportion of the 36mm femoral heads remained largely stable and stagnant in their overall utilization distribution numbers of the overall pool of femoral heads, at a steady 16–20% without any reported tendencies to increase, with majority share occupied by 32 mm for both primary and revision hip arthroplasty.

- Similar trends for primary and revision are noted regarding the usage of DM Hips / femoral heads, which generally have a larger outer diameter to provide for the articulation arc of the mobile polyethene (HXLPE) liner surface, ranging from 40mm and higher.

- The greater sizes are aim at providing for the adequate dishing surface, such that the bearing surface or the liner doesn't fall out of place, though it hasn't been very fruitful in most of the global applications, as found during the course of this research.

- From a biomaterials point of view, for revision hip arthroplasties, most procedures in Sweden are performed using a conventional femoral head of metallic origin, which is as much as in 90% of all cases of hip revisions in Sweden, regardless of the first-time or multiple revision. Ceramic femoral heads were used only in 9% of revision hips in Sweden, and in 1% of the cases, the material details could not be accessed.

- Now, this is quite a contrasting scenario, given that the metallic femoral heads are almost globally condemned and involve metallosis concerns, and ceramic heads are turning up on the tide in modern-day global arthroplasty practices.

- The most commonly utilized femoral stems for hip arthroplasty of the Swedish patient cohort, between the period of 2000 – 2021 are presented in the following tabulation: -

Most Commonly Utilized Femoral Stems for Hip Arthroplasty of the Swedish Patient Cohort during 2000 - 2021.

SL No.	Prostheses Name of Femoral Stem	Hip Arthroplasty during [2000 - 2021]		Mfg. Company / Supplier	ODEP Rating
		No. of Cases	% of Overall		
1	SPII Standard	1,14,889	38.50%	Waldemar Link	15A*
2	Exeter Standard	59,478	19.90%	Stryker	15A*
3	Corail Standard	23,343	7.80%	DePuy Synthes	15A* / 10A / 3A
4	MS-30 Polished	18,429	6.20%	Zimmer Biomet	15A*
5	CLS	14,720	4.90%		
6	Bi-Metric X Por HA NC	8,964	3.00%		7A*
7	Spectron EF Primary	7,947	2.70%	Smith&Nephew	15A
8	Corail High Offset	7,245	2.40%	DePuy Synthes	15A* / 10A / 3A
9	Corail Coxa Vara	6,186	2.10%		
10	Accolade II	4,176	1.40%	Stryker	10A
11	Charnley	3,998	1.30%	DePuy Synthes	15A*
12	ABG II HA	3,409	1.10%	Stryker	Unrated
13	M/L Taper	3,265	1.10%	Zimmer Biomet	15A*
14	CPT	2,430	0.80%		15A* / Rating Withdrawn
15	Wagner Cone	2,185	0.70%		10B / Rating Withdrawn
16	Other	17,818	6.10%		
Cumulative Total		2,98,482	100.00%		

Table 6.4.20 :- ***Tabulation illustrating the Most Commonly Utilized Femoral Stems for Hip Arthroplasty of the Swedish Patient Cohort, during the years 2000 – 2021, with their respective ODEP Rating Statuses and Manufacturing Company/Supplier details..***

Femoral Stems in Revision Hip Arthroplasty

- Roughly 50-60% of the cemented stem revisions performed on the Swedish patient cohort comprised either a cement-in-cement revision or a revision combined with some type of bone transplantation, to make up for the lost part of the long bone-femur, rather than a long-stemmed femoral prosthesis.

- Utilization of long stems fixated through cement, reduced in their relative proportions of usage from 32% in 2001-2003 to 13.1% in 2016-2018, rising a little to 17.4% in 2019-2021.

- Two femoral stems, namely the – SPII Stem by Waldemar Link and the Exeter standard-sized design by Stryker, are the clear most used femoral stems in Swedish arthroplasty practices.

Dual Mobility Hip Prostheses for Primary & Revision Hip Arthroplasty in Sweden: -

- Interesting insights and inferences emerged from the evaluation of the Swedish arthroplasty practices concerning the much-talked-about Dual Mobility or DM Hips. The Swedish registry presents an intriguing scenario, wherein it is found; -

    - Dual Mobility or DM Hips were first implanted in 2002 for a revision procedure and have been on a continually increasing trend since 2018, only to decrease thereafter. In 2018, as per the evaluated data from Swedish sources, 500 revisions, were performed on the respective patient cohort, using the said form of hip prostheses.

    - In 2020-2021, around 370 revisions using DM hip prostheses are reported to have been utilized in the Swedish patient cohort.

    - Unlike the global scenario, the Swedish registry SAR reported that DM hip prostheses have seen the greatest number of utilizations for primary hip arthroplasty, using an unconventional method, of cementing the said form of mobile prosthesis, and not in the globally propagated or conventional non-cemented approach, which formed the bulk of the global practise scenario so far.

    - However, it has become increasingly common to cement a DM hip prosthesis in an existent acetabular shell, during revision hip arthroplasties, or that the acetabular cup is converted to a dual mobile function, by using a metallic insert between the DM acetabular component and the pre-existent non-dysfunctional-acetabular-shell.

    - Such improvisation in using the latest design in the world of joint-replacement prosthesis, may not be manufacturing company or brand's specified operation manual compliant, but it has yielded some of the best results, and post-operative patient-centric outcomes in Sweden. This could possibly be an apt reason for no mentions of the plaguing issue of DM hip failure in the form of IPD (intra-prosthetic dislocation), anywhere in the registry, its report, or in many such documents and archives of the Swedish arthroplasty databases.

- In the context of DM hip prosthesis utilization, as per the Swedish registry and other healthcare databases in Sweden, it was evidently obtained that, unlike the global scenario, DM hips in Sweden

found more accepted usage and were majorly implanted during revision procedures. In 2021, DM hips accounted for 54.1% of the total number of cemented revision acetabular cups.

- Particularly when the global practice has largely been to use a DM hip through cementless fixation method, the Swedish arthroplasty practices have been different by cementing the DM hips in most of the times, it is implanted. Contrary to the same, only 28 such procedures were found to be reported wherein dual mobility hip prosthesis, is fixated through the standalone cementless manner.

- Interestingly, 183 procedures were cited by the SAR to have been reported in 2021, where a dual mobility acetabular cup has been cemented within a non-cemented acetabular shell, with 69% of such shells, being the remnants from the earlier respective primary arthroplasty procedures.

- For both cemented and non-cemented fixation techniques applied, the Avantage dual mobility hip prosthesis by Zimmer Biomet, has been the most popular choice of implantation in Swedish arthroplasty practices.

Utilization Practices regarding Cemented vis-à-vis Non-Cemented Acetabular Cups in Revision Hip Arthroplasty: -.

- The most used non-cemented acetabular cups in the Swedish patient cohort, for revision hip arthroplasty have been the Tritanium Revision and TM Revision.

- Trabecular metal surfaces are reported to be underwhelming in terms of performance advantages over the generic porous surface metallic prostheses, especially when the former came with much superior prices than the latter ones for the standard design type.

- For cemented fixations-based revision hip arthroplasties of the Swedish patient cohort, different variants of the Exeter and Lubinus SPII stems dominate, across the entire obtainable database period in Sweden.

- While for non-cemented revisions, the Corail KAR / Corail revision stems have an increased usage proportion in the Swedish patient cohort.

Prosthesis Performances in Repeated Revisions Scenarios of the Swedish Patient Cohort: -

- The general risks of a prosthesis failure increase proportionately with the greater number of times a hip joint prosthesis is revised.

- Contributing factors include, but are not limited to, the general physio-mental trauma of the patient, the extent of bone loss due to repeated revisions, the extent of adjoining musculature and ligamentous loss or alteration and finally the quality of the remnant portions of the surgically altered bone-prosthesis complex shaft to withstand the general biomechanical stresses and strains for performing multitude of daily activities.

- The cumulative revision rate at 15 years for hip arthroplasty of the Swedish patient cohort, for the evaluation timeframe of 2000-2021 is 8.8% (+/- 0.2 – 1%) for nearly 36,761 observations.

- The post-operative revision rates based on the above parameters and other clinical attributes, the Swedish registry reported a 23.2% (+/- 0.8%) for first-time revisions, 27.2% (+/- 1.6%) for second-time revisions and 36.5% (+/- 2.8%) for third-time revisions.

Implant Combinations in Total Hip Arthroplasty, based Specific Evaluation Analyses: -

- The incidences of early revisions in primary THAs regardless of the reasons for such revisions, have increased, but in the longer-term perspective, the results have improved.

- The increase of early revision incidences after a primary THA is partially due to the infections, but there were other factors contributing to the development of such a scenario, which are more linked either directly or indirectly with the prosthesis performance and the arthroplasty approaches adopted, rather than post-operative infection incidences which are ideally not under human or scientific control at all times.

- An increased use of non-cemented femoral stems with an increased risk of early peri-prosthetic fractures could possibly have played a role.

- The transition of the primary polyethylene articulating surface liner choice material from the conventional HDPE(high-density polyethylene) and UHMWPE(ultra-high molecular weight polyethylene), to the promising HXLPE(highly cross-linked polyethylene), even in an orthodox setting, has reduced the post-operative incidences and issues of accelerated prosthesis wear, osteolysis, loosening, preponed generation of polyethylene liner debris, due to immense frictional wear against metallic femoral heads, due to the excellent wear resistant capabilities of the HXLPE based liners.

- Non-cemented fixation usage in the longer term is reported to have benefitted due to the HXLPE-based articular liners and the decreased risks of loosening involved.

Legal Framework and Implant Introduction, Regulation Policy in Sweden: -

- In Sweden, the implants and prosthesis component's introduction and their subsequent commercial circulation for clinical usage have largely been under restricted approach by the Swedish health authorities.

- The general protocol is that no newer version of any pre-existing prostheses or any freshly developed innovative product shall be introduced for free and open clinical usage, until there's a well-attributed cause and established necessity validating the purpose, which justifies the actual need for a newer prosthesis or a newer version of the older in use prosthesis design.

- Changes to implant designs, material compositions, and packaging details, can only be allowed where there's a well-evident or documented clinical need or benefit in existence, and where such replacement or alteration/modification changes have a documented advantage from the pre-existing ones.

- The durability and the expected life of a prosthesis with its related costs is also a factor towards proclaiming any particular prosthesis whether new or re-designed to be advantageous over the pre-existent ones.

- However, considering the orthodox mindset towards joint-replacement of the Swedish stakeholders in the holistic picture of the arthroplasty practises, the Swedish registry made a consistent claim that such a restrictive approach towards prosthesis regulation in Sweden has proved out to be largely successful since, "the clinical trials of the newest implants at best are on par with already existing ones", and several of them "worse" than the existing ones.

- Such a cautious approach on their part has surely made it possible for the delayed introduction of modern-day implants and prosthesis models with maybe characteristic features and properties than the

current existing ones, or in other words allowed for the sustenance of the traditional hegemony of the legacy products for reasons best known to them.

Resurfacing Prosthesis Trends of Usage in the Hip Replacement of the Swedish Patient Cohort: -

- Though resurfacing hip arthroplasty in Sweden is reduced to almost bare minimum proportions, with regards to the prosthesis choice it was the Birmingham Hip Resurfacing or BHR that was the most utilized prosthesis.

- The BHR resurfacing head also faced similar concerns of failure in terms of a disproportionately high number of revisions and failures due to fractures, osteolysis and metal debris wear, but it was somewhat controlled and limited in magnitude, compared to the ASR fiasco.

- The major revision reason for BHR resurfacings in Sweden was the loosening of the component, which contributed to 38.5% of overall revisions of resurfacing heads, closely followed by fracture of the femoral neck/sub-trochanteric region due to irregular stress distribution plateaus at 23.1%.

- Other indications included pseudo-tumour and unclear pain in mobility contributing to 15.4% of overall revisions in this particular category, each.

- The incidences of sub-trochanteric fracture due to misplaced stress distribution of resurfacing heads is somewhat the first public acknowledgement amongst all other nations (not individual articles or scientific journals), that were evaluated during the course of this research.

Utilization of THA vis-à-vis Hemi-arthroplasty of the Swedish Patient Cohort for Hip Fracture: -

- Like many other nations, arthroplasty or joint replacement was certainly not the first line of treatment for acute osteoarthritis and other diagnoses, in the 1950s-1960s.

- While for hip fracture, femoral dislocation and related diagnoses, the standard operating protocol or SOP was to primarily address the cases via internal and closed fixation techniques, while hip arthroplasty remained more or less as a niche idea, mostly reserved as the secondary form of treatment, when all other primary approaches have failed to generate favourable outcomes, limited by economic viability issues as well.

- These scenarios have now changed for the better, with the emergence of an ample number of time-tested and well-documented benefits of hip arthroplasty or hip joint replacement towards resolving the plaguing trouble of progressively worsening osteoarthritis and hip fracture, with their relative safety and advantages being clearly demonstrated clear enough across the globe and in Sweden as well.

- This has enabled us to address hip fractures and severely painful osteoarthritis in the oldest and frailest patient groups as well, besides the usual patient groups, as the first line of treatment, replacing the closed fixation methods.

- In 2006, 755 Swedish patients aged more than 90 years received hip arthroplasty for their hip fractures. This has now progressed to 1,187 Swedish patients of the same age group to get their failing and fractured hips replaced by an artificial hip joint prosthesis, in 2021. Amongst the 1,187 groups of 90+ aged Swedish patients in 2021, 29 such individuals were 100-104 years old, which clearly demonstrates the relative safety and general public acceptance of hip arthroplasty as a beneficial form of treatment for them in Sweden.

- The proportions of ASA III & IV patients, i.e., the patient groups with serious co-morbidities have also increased from 51 to 63%, in the overall number of proportions receiving a hip replacement treatment for their failing or fractured hip, also underlines the same willingness to accept a prosthesis combination to replicate the acetabular and femoral head jointly articulating mobility action, to improve their living standards.

- Unlike the other national arthroplasty practices evaluated, the general trends of pushing or opting for a partial hip-joint replacement/arthroplasty or hemi-arthroplasty, for the sake of a shorter hospital stay and a faster recovery window, in most of the hip fracture indications, in Sweden, such forms of treatment were performed on only a mere 2% of all hip fracture incidences.

- For hip fracture cases as well, the Lubinus & SPII acetabular cup and femoral stem combinations were the most popular ones, registering utilization in 64% of hip-fracture-diagnosed arthroplasties in 2021.

- True to the orthodox arthroplasty practices in Sweden, 98% of the hip fracture cases of the Swedish patient cohort, were treated using cemented fixation, with SPII, Exeter, MS-30 and Co-Vision being the top four choices of cemented stems. The reported revision rates of these four cemented stems were 4 – 6% after 12 years of primary arthroplasty.

- In 2021, non-cemented stems contributed to less than 1% of the procedures in hip fractures.

- Similar to osteoarthritis diagnoses, Corail was the popular choice in Sweden for resolving hip fractures of the Swedish patient groups, in a non-cemented fixation modality. However, the long-term performance of such non-cemented femoral stems besides the popular choice, were all comparatively poorer than their cemented alternatives, with a revision rate of 9.6% post 12 years of primary arthroplasty.

Knee Arthroplasty Practices and Scenario of Sweden

- In 2021, 12,742 primary knee arthroplasty procedures were registered within the SAR databases, which was 8% more than the annual number of knee arthroplasties from 2020, but about 16% less than that of the annual numbers in 2019.

- The reduced numbers of knee arthroplasties in 2020 and 2021, vis-à-vis the 2019 standards, might highlight a COVID-19 pandemic-induced unforeseen change, as was observed in the annual procedure numbers from all the nations evaluated during the course of this research.

- Much like the hip arthroplasty scenario of the Swedish patient cohort, it was Total Knee Arthroplasty or TKA that dominated in major proportions than other modalities of knee arthroplasty in Sweden.

- In 2021, TKA alone accounted for 86.3% of all knee arthroplasties, while Unicondylar Knee Arthroplasty or UKA had a share of 12.8% of all knee arthroplasties.

- Other modalities of knee arthroplasty such as the Patellofemoral Knee Arthroplasty or PFKA accounted for less than 1% number of all knee arthroplasties performed on the Swedish patient cohort in 2021.

Age-Linked & Gender-Based Demography of the Swedish Knee Arthroplasty Recipient Patient Cohort:
-

- The mean age for primary knee arthroplasties in 2021 was 68.7 years. On a historical basis, the mean age of knee arthroplasty recipients in Sweden increased from over 65 years in 1975 to 71 in 1994. However, post 1994 onwards, greater proportions of patients below 65 years continued to receive knee arthroplasty, which led to a steady decline in the overall mean age for knee arthroplasties.

- The patient age group of 65-74 years, make up the largest proportion of primary knee arthroplasty receivers in Sweden. The 65-74 age group alone constitute 37.7% of all primary knee arthroplasties, followed by the 75-84 years age group with a distribution share of 26.8%. While, 32.3% of the primary knee arthroplasties of 2021, were performed on Swedish patients of less than 65 years of age.

- The mean patient age group of the UKA recipients is 65.9 years in Sweden, which turns out to be 3.2 years less than that of the TKA mean age group, amongst the Swedish patient cohort.

- In line with the global scenario in Sweden, as well it was the female patient cohort, who received more knee arthroplasties than males.

- The age-group wise distribution of the Swedish patient cohort, who received either of Total or Unicondylar knee arthroplasty, is presented in the following tabulation: -

Age Group Wise Distribution of the Swedish Patient Cohort, undergoing Total Knee Arthroplasty & Unicondylar Knee Arthroplasty.

SL No.	Age-Group	TKA		UKA	
		No. of Cases	% of Overall	No. of Cases	% of Overall
1	<45 Years	40	0.40%	10	0.60%
2	45 - 54 Years	622	5.70%	165	10.10%
3	55 - 64 Years	2,744	24.90%	544	33.30%
4	65 - 74 Years	4,182	38.00%	602	36.80%
5	75 - 84 Years	3,090	28.10%	293	17.90%
6	85+ Years	321	2.90%	22	1.30%
Cumulative Total		10,999	100.00%	1,636	100.00%

Table6.4.21 :- ***Tabulation illustrating the Age-Group wise Break-up of the Swedish Patient Cohort, who received either of Total or Unicondylar Knee Arthroplasty in 2021, with the relative percent of overall.***

- The gender-based distribution of knee arthroplasty was heavily inclined towards females in the 1970s, wherein 70% of all knee arthroplasties in Sweden were done on female patients.

- Since then, the gender distribution has equalized by quite some margin, wherein as of 2021, Swedish males received 44.6% of all primary knee arthroplasties, while females 55.4% of all, still continuing the lead in terms of knee arthroplasty recipients, as is noted in many other nations.

- The gender-based distribution when segregated for total knee arthroplasty and unicondylar knee arthroplasty gives out the following distribution scenarios: -

    - Swedish Females (Total Knee Arthroplasty) = 56.40%
    - Swedish Males (Total Knee Arthroplasty) = 43.60%
    - Swedish Females (Unicondylar Knee Arthroplasty) = 48.00%
    - Swedish Males (Unicondylar Knee Arthroplasty) = 52.00%

- However, for UKAs the proportions of male recipients were greater than female patients in Sweden.

ASA & BMI Categories-based Distribution of the Patient Cohort receiving Knee Arthroplasty in Sweden: -

- The American Society of Anaesthesiologists Grade of Patient Classification, also known as the ASA Grade, is a globally accepted and universal form of classifying patient cohorts or individuals based on the general level of co-morbidity levels of the respective patient.

- The detailed explanation of the individual ASA Grade Classification is discussed separately in the introductory segments of this work.

- Unlike most other nations, Sweden saw most of the patients, belonging to ASA 2 grade, receiving the greatest number of knee arthroplasties, irrespective of the arthroplasty type or modality.

- The following tabulation illustrates the ASA Grade wise distribution of the Swedish patient cohort receiving either of a TKA or UKA in 2021: -

ASA-Wise Distribution of the Swedish Patient Cohort, undergoing Total Knee Arthroplasty & Unicondylar Knee Arthroplasty.

SL No.	ASA Category	TKA		UKA	
		No. of Cases	% of Overall	No. of Cases	% of Overall
1	ASA 1	1,671	15.20%	393	24.10%
2	ASA 2	7,443	67.80%	1,065	65.30%
3	ASA 3 & 4	1,864	17.00%	174	10.70%
Cumulative Total		10,978	100.00%	1,632	100.10%

Table6.4.22 :- ***Tabulation illustrating the ASA Grade or Category based Distribution of the Swedish Patient Cohort, undergoing either a Total or Unicondylar Knee Arthroplasty, as of 2021, with their relative percent of the Overall Number of Arthroplasty Procedures.***

- With regards to the BMI category of the Swedish patients receiving either a Total or a Unicondylar Knee Arthroplasty procedure in 2021, it was the patients who were of pre-obese nature with a BMI of 25.00 to 29.99 as per the universal standard, who had undergone the greatest number of said procedures, unlike other nations, wherein various grades of obese patients received the greatest number of knee arthroplasties.

- The Body Mass Indices or BMI-based distribution of the Swedish patient cohort, who had undergone either of a Total or Unicondylar Knee Arthroplasty is enclosed in the following tabulation: -

BMI Indices Wise Distribution of the Swedish Patient Cohort, undergoing Total Knee Arthroplasty & Unicondylar Knee Arthroplasty.

SL No.	BMI Indices Category	TKA		UKA	
		No. of Cases	% of Overall	No. of Cases	% of Overall
1	<18.5	19	0.20%	2	0.10%
2	18.5 - 24.9	2,083	19.10%	302	18.60%
3	25.00 - 29.99	4,773	43.70%	796	49.00%
4	30.00 - 34.99	3,121	28.60%	442	27.20%
5	35.00 - 39.99	840	7.70%	79	4.90%
6	> = 40.00	87	0.80%	5	0.30%
Cumulative Total		10,923	100.10%	1,626	100.10%

Table :- ***Tabulation illustrating the BMI Indices Category-based Distribution of the Swedish Patient Cohort, undergoing either a Total or Unicondylar Knee Arthroplasty, as of 2021, with their relative percent of the Overall Number of Arthroplasty Procedures.***

Leading Cause for a Primary TKA or UKA in Sweden: -

- Progressively worsening Osteoarthritis remains the single most common reason a knee arthroplasty is performed on the Swedish patient cohort, as of 2021.

- Osteoarthritis alone was the primary indication or the patient-stated reason for arthroplasty in 97.10% of all Total Knee Arthroplasties and 97.90% of all Unicondylar Knee Arthroplasties, as of 2021.

- Whether the possibilities of any 'systematically co-ordinated agreement' at any level is not completely avoidable in this particular aspect of primary indications, since specific exclusion and other related hindrances led to the inaccessibility of the entire primary indication spectrum of the reported or trackable arthroplasty procedures.

- However, it could be safely assumable, as per the global scenario with respect to the primary indication for a knee replacement arthroplasty, it is surely osteoarthritis of a progressively worsening nature, that could be the leading cause for a primary TKA or UKA, and only the sanctity of the reported relative percent of overall, that remains to be a point of a query of this research probe.

- The following tabulation comprises the distribution of the leading causes for Total and Unicondylar Knee Arthroplasties in Sweden: -

Distribution of Total Knee & Unicondylar Knee Arthroplasty of the Swedish Patient Cohort, as per Primary Indications.

SL No.	Primary Indication	TKA		UKA	
		No. of Cases	% of Overall	No. of Cases	% of Overall
1	Osteoarthritis	10,672	97.10%	1,601	97.90%
2	Inflammatory Joint Disease	159	1.40%	0	0.00%
3	Fracture related Sequelae	73	0.70%	0	0%
4	Osteonecrosis	62	0.60%	30	1.80%
5	Acute Trauma	21	0.20%	3	0.20%
6	Other Joint Diseases	2	0.00%	2	0.10%
Cumulative Total		10,989	100.00%	1,636	100.00%

Table 6.4.24 :- ***Tabulation illustrating the Distribution of Primary Total Knee and Unicondylar Knee Arthroplasty of the Swedish Patient Cohort, as per their stated Primary Indication or Primary Reason.***

Fixation Method-Based Knee Arthroplasty Practices on the Swedish Patient Cohort: -

- Similar to hip arthroplasty practices, the use of cement for the internal fixation of the knee prosthesis within the joint capsule is the most popular choice of internal fixation for knee arthroplasties as well, in Sweden.

- Though cement continues to remain the most common form of fixating knee prosthesis components to the remnant bones of the femur and tibia, the utilization of non-cemented-based fixation is also on the steady rise.

- In 2010, only 2.4% of all TKAs in Sweden were fixated through a non-cementless approach, which increased to 9.1% of all TKAs in 2021, though cemented fixation continued to be the first choice of preference.

- Compared to global scenarios, hybrid fixation is utilized on very limited proportions with only 0.4% of all TKAs of 2021, utilizing such fixation methods on the Swedish patient cohort.

- In the case of Unicondylar Knee Arthroplasties or UKAs, as of 2021 in Sweden, 62.5% of all UKAs were performed without cement, and only 2.2% were of hybrid fixation.

- The data obtained from Swedish health databases and the registry also attributes a higher rate of revision involved with UKAs, just as similar to the trends noted in other nations evaluated during the course of this research.

- It is safe to assume, given the orthodox approach standards in Sweden, the involvement of a greater revision rate, and ultimately a greater risk for every patient receiving one, to come up again with an accelerated decay of the other non-replaced condyles of the femur/knee joint, due to progressive wearing osteoarthritis, led to the decline in the overall number of UKA procedures in Sweden.

Prosthesis-Specific Knee Arthroplasty Practices on the Swedish Patient Cohort; -

- The usage of hinged prostheses for uncomplicated osteoarthritis-based arthroplasty procedures on the Swedish patient cohort has depleted severely to be limited on to specific critical and complicated primary procedures and severely traumatic revision fractures.

- Cruciate retaining and posterior stabilized knee implants are the choice of implantation on the Swedish patient cohort for general uncomplicated procedures.

- For uncomplicated procedures, the Swedish preference is for a total knee arthroplasty, over a partial unicondylar one, mostly due to the widely available instances of greater possibilities of the recurring requirement to revise an unicondylar knee replacement, into a total knee, which would add further trauma to the physical, mental and economic aspects of the patients.

- In terms of most commonly deployed total knee prosthesis combinations, the NexGen (Zimmer Biomet) – MBT (DePuy Synthes) combination was the most popular one in Sweden as of 2021, including both primary and revision knee arthroplasties as of 2021. As per accessible data, the combination was utilized for 5,830 total knee replacements, proportioning to 53.00% of all TKAs on the Swedish patient cohort, as of 2021.

- While for Unicondylar knee replacements of the Swedish patient cohort in 2021, the Oxford Knee by Zimmer Biomet were the most utilized ones, with a recorded usage of 1,057 UKAs, which was 65.7% of all UKAs in Sweden as of 2021.

- The most commonly utilized prostheses combinations for Total Knee Arthroplasty of the Swedish Patient Cohort, as of 2021, as far as data on Swedish arthroplasty practices could be accessed by this research, is presented in the following tabulation, alongside the respective ODEP rating statuses of the prostheses in concern.

- The most commonly utilized knee implant combinations involving femoral and tibial components, for TKA and UKA, are tabulated in the following tabulations: -

Most Commonly Utilized Prosthesis Combinations for Total Knee Arthroplasty of the Swedish Patient Cohort as of 2021.					
SL No.	Prostheses Name Femoral Component [Tibial Component]	Total Knee Arthroplasties Performed		Mfg. Company / Supplier	ODEP Rating
		No. of Cases	% of Overall		
1	Nexgen [MBT]	5,830	53.00%	Zimmer Biomet ; DePuy Synthes	15A* [NexGen] ; Unrated [MBT]
2	PFC Sigma [MBT]	1,766	16.00%	DePuy Synthes	15A / 15A*[PFC Sigma] ; Unrated[MBT]
3	Triathlon [MBT]	1,670	15.20%	Stryker ; DePuy Synthes	15A*/13A*/13A [Triathlon] ; Unrated [MBT]
4	Persona TKA	536	5.00%	Zimmer Biomet	Multiple Ratings[7A to Pre-Entry A* - Persona]
5	Genesis II [MBT]	226	2.00%	Smith &Nephew ; DePuy Synthes	Multiple Ratings[15A*to Lapsed] ; Unrated [MBT]
6	Legion/Genesis II Primary [MBT]	184	2.00%	Smith & Nephew	Multiple Ratings[15A*to Lapsed] ;
7	PFC Sigma TKA [APT/Apta]	165	1.50%	DePuy Synthes ; Adler Ortho	7A / 10A / 15A[PFC Sigma] ; 15A/3A*[APT/Apta]
8	Persona TKA [Trabecular Metal]	138	1.20%	Zimmer Biomet	Multiple Ratings[7A to Pre-Entry A* - Persona] ; 15A* [Trabecular Metal]
	NexGen [Trabecular Metal]	137	1.20%		15A*[NexGen] ; 15A*[Trabecular Metal]
9	Triathlon [Total Stabilizer]	114	1.00%	Stryker	15A*/13A*
10	Nexgen [Revision]	66	0.60%	Zimmer Biomet	15A*
11	Attune MB TKA	56	0.50%	DePuy Synthes	Multiple Ratings[7A* to 3A]
12	PFC Sigma TC-3 [Revision]	48	0.40%		Multiple Ratings
13	Journey TKA	18	0.20%	Smith & Nephew	Multiple Ratings [Pre-Entry A* to 3A]
14	Legion/Genesis II Primary [Revision]	12	0.10%		Multiple Ratings[15A*to Lapsed] ;
	PFC Constrained[Revision]	11	0.10%	DePuy Synthes	Unrated
15	PFC Sigma TKA Rotating Platform	5	0.00%		7A / 10A / 15A[PFC Sigma]
16	Attune RP TKA	3	0.00%		Multiple Ratings[7A* to 3A]
17	Persona Revision	3	0.00%	Zimmer Biomet	Unrated
18	NexGen Unspecified	2	0.00%		15A*
Cumulative Total		10,990	100.00%		

Table 6.4.25 :- ***Tabulation illustrating the Most Commonly Utilized Artificial Knee Prostheses Combinations [Femoral and Tibial Component], for performing Total Knee Arthroplasty of the Swedish Patient Cohort, as of 2021, with respective Orthopedic Data Evaluation Panel (ODEP) Rating Statuses and Manufacturer Company/Supplier Details.***

Most Commonly Utilized Prosthesis Combinations for Unicondylar Knee Arthroplasty of the Swedish Patient Cohort in 2021.					
SL No.	Prostheses Name Femoral Component [Tibial Component]	Unicondylar Knee Arthroplasties Performed		Mfg. Company / Supplier	ODEP Rating
		No. of Cases	% of Overall		
1	Oxford	1,075	65.70%	Zimmer Biomet	Multiple Rating [15A/13A/10B/3A/Withdrawn Rating]
2	Triathlon Uni	193	11.90%	Stryker	Uni Version Unrated
3	Link	131	8.00%	Waldemar Link	10B
4	ZUK	116	7.10%	Lima Corporate	13A*/10A*
5	Persona-PK [Partial Knee]	61	3.70%	Zimmer Biomet	5A*
6	Sigma-PKR	59	3.60%	DePuy Synthes	
7	Ibalance	1	0.00%	Arthrex	ODEP Rating Withdrawn
Cumulative Total		1,636	100.00%		

Table6.4.26 :- ***Tabulation illustrating the Most Commonly Utilized Artificial Knee Prostheses Combinations [Femoral and Tibial Component], for performing Total Knee Arthroplasty of the Swedish Patient Cohort, as of 2021, with respective Orthopedic Data Evaluation Panel (ODEP) Rating Statuses and Manufacturer Company/Supplier Details.***

Types of Polyethylene Utilization Trends & Scenarios of Usage in Knee Prostheses for the Swedish Patient Cohort: -

- With regards to the types of polyethylene utilized as a part of the artificial knee prosthesis on the Swedish patient cohort, it was noted that the general trend of replacing UHMWPE-based articulating liners, with HXLPE-based ones, started off, in somewhat delayed timelines in Sweden, possibly due to their orthodox practices and rigorous pre-market clinical trials, only from late 2006 onwards, by when the Australian practices already been using HXLPE based articulating liner inserts for their knee prosthesis, in almost one-fourth proportions, of their overall implanted numbers.

- However, in somewhat striking contrast to the global narrative & the widely accredited positively beneficial performance of highly cross-linked polyethene-based articulation liner inserts, the Swedish registry had claimed that: -

    - The most commonly utilized knee implant combinations using a HXLPE-based liner insert, until 2021, in Sweden were the –

        a. Triathlon X3 Polyethylene [Stryker].
        b. PFC XLK Polyethylene [DePuy Synthes].
        c. Persona Vivacit-E Polyethylene [Zimmer Biomet].

    - Now, interestingly, the Swedish registry states that, of the above three most-utilized HXLPE based knee implants, there were "no observable remarking benefits", in terms of a "reduced revision rate", on their respective patient cohort, though it is said to have been beneficial for the general knee arthroplasty recipient patient groups of Australia and other nations evaluated during the course of this research.

- Now it was noted and inferred during multiple instances during the course of this research that, the extra benefit of lasting durable performance of the knee prosthesis's polyethylene liner, which is "vitamin-e" infused or 'treated/coated' in any way, was more of a marketing gimmick, than an actual improvement or upgrade to the pre-existent performance capabilities of the particular liner, whose capabilities are in-turn actually governed and contributed by the highly cross-linked polyethylene's characteristics and behavioural nature to resist wear and provide a smooth articulation of the femoral end.

- Anything further beyond would definitely add to the marketing gimmick, and provide for an excuse to justify the 'extra' price for the same, as part of a broader and usual corporate agenda.

- But, the claim of the HXLPE-based liners for knee prosthesis itself to be of no particular benefits or an upgrade in terms of its performance in the immediate short-term to long term than the conventional polyethylene models, by the Swedish registry, itself sounds self-contradictory, for the sole reason that the Swedish registry and healthcare databases have boasted-ly cited about its rigorous regulations for a new or an altered product to be allowed for open commercial and clinical utilization, only when they have proven to their own set standards of clinical trials and other inspections to have actually a benefitting upgrade than the pre-existent ones.

- Now, if these are allowed for such wide-scale operations on the general Swedish patient cohort, then it is assumable that these were of some actual or proven benefits than the other conventional ones, for them to have been allowed to be implanted on the general patient cohort, notwithstanding the fact these were some of the most used ones of all the available variants of knee prostheses, hence such claims are surely be of contradictory magnitude.

Patellar Resurfacing vs. No Patella Scenario in Swedish Knee Arthroplasty Practices: -

- The utilization of a patellar component in Swedish knee arthroplasties has decreased largely since the 1980s, wherein it was used in almost half of all TKA procedures, to the present day mere 4.6% proportions of overall TKA procedures.

- It was more likely for Swedish female patients receiving TKA, to have their patella resurfaced, compared to Swedish male patients. As of 2021, about 3.7% of all the male patients in Sweden who have undergone a TKA procedure, had their patella resurfaced, compared to 5.1% of all female patients.

- On the age-centric analyses, it is found that the general practice of using or preserving the patella post a total knee arthroplasty is more common in the younger aged patient groups (<55 years).

Cruciate Retaining vs Posterior Stabilized vs Constrained Knee Prostheses Scenario in Swedish Knee Arthroplasty Practices: -

- Cruciate Retaining or CR knee prostheses are the most preferred choice of knee prostheses in Sweden, for the patient cohort in general. While, it is kind of a norm for them to utilize such a prosthetic arrangement for the artificial knee replacement procedure, retaining the cruciate ligaments, if the knee joint is not plagued by any gross mal-alignment or the inherent posterior cruciate ligament is intact and in pristine condition, and therefore can be operationally reliable.

- Though the exact reason for the comparative non-popularity of such types of knee prostheses is not exactly stated clearly by the Swedish registry or most other databases from the said region, an assumable rationale is the "theoretical increased risk of wear" and subsequent "loosening", due to added stability stresses on the polyethylene insert and the bone ends.

Revision Knee Arthroplasty Practices and Related Scenarios in Sweden: -

- The Swedish registry defined Revision Knee Arthroplasties to be only those 're-operation' procedures that can be linked to a previously performed primary knee arthroplasty, regardless of whether the comprising units of the inserted implant or prosthesis are replaced, modified or removed (including arthrodesis and amputation) or a fresh inclusion is made, or just left untouched, during the said procedure.

General Demography of the Swedish Patient Cohort, undergoing Revision Knee Arthroplasty: -

- The mean age of the Swedish patient cohort, that received a revision knee arthroplasty in 2021, was 68.8 years. This was almost the same as that of the mean age for primary knee arthroplasty in 2021, involving the same patient cohort, which was 68.7 years.

- Swedish female patients undergo a comparatively greater proportion of revision knee arthroplasties, than their male counterparts. The Swedish female patient cohort contributed to 55.1% of all knee revisions in 2021, while Swedish males accounted for 44.9% of all.

- Patient groups belonging to the Pre-Obese and Obese Class 1 categories of the universally accepted BMI indices classification, received the greatest number of revision arthroplasties, accounting for over 38.1% and 28.8% of overall revision arthroplasties in 2021 respectively.

- Younger groups of patients received a greater number of knee revisions than the usual age group, possibly due to their higher level of physical activity and greater functionality requirements.

- The registry also attributed the ability to withstand the involving amount of trauma of revisions due to younger age and comparatively fresher health status, as another reason for such groups of patients undergoing another revision arthroplasty.

Patient-Reported Outcome Measures or PROMs for the Swedish Patient Cohort: -

- During the course of this research probe, it was inferred that the general form of capturing patient-reported outcome measures or in simpler terms, the patient-centric assessment of themselves and their operated hip or knees, are through:

    - EuroQoL-5 Dimensions-5 Levels (EQ-5D-5L).
    - EuroQoL Visual Analogue Score (EQ-VAS).
    - Hip Disability and Osteoarthritis Outcome Score – 12 (HOOS-12).
    - Knee Injury and Osteoarthritis Outcome Score – 12 (KOOS-12).

- Besides, a descriptive form of the general Oxford Hip assessment parameters is circulated and captured in a wide manner, though the generation of any Oxford Hip Score for the patient-reported inputs was not obtainable or was not in practice.

- The levels of pre-operative vis-à-vis post-operative satisfaction from their arthroplasty and their life in general, as reported by the Swedish patient cohort, are also represented within the following tabulation.

- In 95% of the tracked procedures, the patients reported moderate or severe pain in their affected hips pre-operatively.

- The scenario for the same cohort of patients, within a year of postoperative follow-up, changed in the way that 76% of all the reporting patients reported no to very mild pain existent on their operated hips, for daily functioning purposes.

- The general satisfaction levels of the Swedish patient cohort from their hip arthroplasties and the detailed tabulation illustrating the outcomes obtained through the descriptive Oxford based PROMs capture, is enclosed in table number : -

Oxford Hip Score based Descriptive General Patient Reported Outcome Measures (PROM)s and the General Satisfaction Levels of the Swedish Patient Cohort, undergoing Hip Arthroplasty during 2018 - 2021.

SL No.	PROMs Criteria	Primary Arthroplasty								Revision Arthroplasty			
		Pre-Operative Assessement		Post-Operative Assessement						Pre-Operative Assessement		Post-Operative 1 Year	
				1 Year		6 Years		10 Years					
		No. of Responses	% of Overall	No. of Responses	% of Overall	No. of Responses	% of Overall	No. of Responses	% of Overall	No. of Responses	% of Overall	No. of Responses	% of Overall
1	No. of Responses	49,583	NA	57,397	NA	44,581	NA	32,485	NA	1,610	NA	5,338	NA
Hip Pain in the Operated Hip													
2	None	385	1.00%	29,875	52.00%	24,742	56.00%	17,419	54.00%	70	5.00%	1,744	33.00%
3	Very Mild	449	1.00%	13,567	24.00%	8,175	18.00%	5,865	18.00%	86	5.00%	1,200	22.00%
4	Mild	1,463	3.00%	6,715	12.00%	5,042	11.00%	3,993	12.00%	150	9.00%	878	17.00%
5	Moderate	16,648	33.00%	5,499	10.00%	4,855	11.00%	3,898	12.00%	600	37.00%	1,073	20.00%
6	Severe	30,477	62.00%	1,498	2.00%	1,548	4.00%	1,128	4.00%	702	44.00%	415	8.00%
Cumulative Total		49,422	100.00%	57,154	100.00%	44,362	100.00%	32,303	100.00%	1,608	100.00%	5,310	100.00%
Mobility of the Hip Joint													
7	No Problems in Walking About	1,291	3.00%	28,208	49.00%	21,030	47.00%	14,073	43.00%	124	8.00%	1,459	27.00%
8	Slight Problems in Walking About	5,036	10.00%	14,361	25.00%	9,822	22.00%	7,278	23.00%	223	14.00%	1,371	26.00%
9	Moderate Problems in Walking About	16,575	33.00%	9,724	17.00%	8,346	19.00%	6,431	20.00%	538	33.00%	1,380	26.00%
10	Severe Problems in Walking About	25,026	51.00%	4,513	8.00%	4,653	10.00%	3,920	12.00%	603	37.00%	878	16.00%
11	Unable to Walk About	1,655	3.00%	591	1.00%	730	2.00%	783	2.00%	122	8.00%	250	5.00%
Cumulative Total		49,583	100.00%	57,397	100.00%	44,581	100.00%	32,485	100.00%	1,610	100.00%	5,338	100.00%
Self-Care of the Patient													
12	No Problems in Washing or Dressing	13,750	28.00%	41,935	73.00%	32,760	73.00%	22,711	70.00%	660	41.00%	2,991	56.00%
13	Slight Problems in Washing or Dressing	15,794	32.00%	10,574	18.00%	7,097	16.00%	5,546	17.00%	448	28.00%	1,280	24.00%
14	Moderate Problems in Washing or Dressing	14,924	30.00%	3,782	7.00%	3,358	8.00%	2,870	9.00%	353	22.00%	733	14.00%
15	Severe Problems in Washing or Dressing	4,915	10.00%	875	2.00%	965	2.00%	938	3.00%	127	8.00%	226	4.00%
16	Unable to Wash or Dress	200	0.00%	231	0.00%	401	1.00%	420	1.00%	21	1.00%	102	2.00%
Cumulative Total		49,583	100.00%	57,397	100.00%	44,581	100.00%	32,485	100.00%	1,609	100.00%	5,332	100.00%
Usual Activities of the Patient													
17	No Problems in Doing Usual Activities	2,326	5.00%	27,815	48.00%	21,543	48.00%	14,700	45.00%	172	11.00%	1,502	28.00%
18	Slight Problems in Doing Usual Activities.	8,059	16.00%	16,537	29.00%	11,434	25.00%	8,278	26.00%	341	21.00%	1,564	29.00%
19	Moderate Problems in Doing Usual Activities	16,056	32.00%	8,447	15.00%	7,045	16.00%	5,613	17.00%	465	29.00%	1,265	24.00%
20	Severe Problems in Doing Usual Activities	18,354	37.00%	3,551	6.00%	3,411	8.00%	2,765	9.00%	430	27.00%	676	13.00%
21	Unable to Perform Usual Activities	4,788	10.00%	1047	2.00%	1148	3.00%	1,129	3.00%	201	12.00%	324	6.00%
Cumulative Total		49,583	100.00%	57,397	100.00%	44,581	100.00%	32,485	100.00%	1,609	100.00%	5,331	100.00%
General Pain & Discomfort													
22	No Pain/Discomfort	108	0.00%	20,889	36.00%	15,579	35.00%	10,757	33.00%	56	3.00%	1,100	21.00%
23	Slight Pain/Discomfort	1,446	3.00%	19,737	34.00%	13,399	30.00%	9,529	30.00%	181	11.00%	1,753	33.00%
24	Moderate Pain/Discomfort	17,878	36.00%	12,571	22.00%	11,361	26.00%	8,842	27.00%	662	41.00%	1,717	32.00%
25	Severe Pain/Discomfort	26,796	54.00%	3,896	7.00%	3,848	8.00%	3,036	9.00%	617	39.00%	671	12.00%
26	Extreme Pain/Discomfort	3,355	7.00%	304	1.00%	394	1.00%	321	1.00%	94	6.00%	89	2.00%
Cumulative Total		49,583	100.00%	57,397	100.00%	44,581	100.00%	32,485	100.00%	1,609	100.00%	5,330	100.00%
General Level of Anxiety / Depression related with the Hip Performance Pre vs Post Operatively													
27	Not Anxious or Depressed	17,808	36.00%	39,597	69.00%	29,603	66.00%	20,618	63.00%	634	39.50%	2,809	53.00%
28	Slightly Anxious or Depressed	19,602	39.00%	12,756	22.20%	10,518	25.00%	8,243	25.00%	616	38.30%	1,566	29.00%
29	Moderately Anxious or Depressed	8,729	18.00%	3,605	6.30%	3,175	7.00%	2,605	8.00%	231	14.40%	655	12.00%
30	Severely Anxious or Depressed	2,934	6.00%	1,208	2.10%	1,085	2.00%	864	3.00%	105	6.50%	255	5.00%
31	Extremely Anxious or Depressed	510	1.00%	231	0.40%	200	0.00%	155	1.00%	21	1.30%	48	1.00%
Cumulative Total		49,583	100.00%	57,397	100.00%	44,581	100.00%	32,485	100.00%	1,609	100.00%	5,333	100.00%
General Level of Satisfaction with Hip Arthroplasty													
32	Very Dis-Satisfied	NA	NA	1,113	2.00%	1,221	3.00%	800	3.00%	NA	NA	367	7.00%
33	Dis-Satisfied	NA	NA	2,152	3.00%	1,929	4.00%	1,271	4.00%	NA	NA	539	10.00%
34	Neither Satisfied nor Dis-Satisfied	NA	NA	4,428	8.00%	3,591	8.00%	2,667	8.00%	NA	NA	879	17.00%
35	Satisfied	NA	NA	12,972	23.00%	10,305	24.00%	8,019	25.00%	NA	NA	1,599	30.00%
36	Very Satisfied	NA	NA	36,063	64.00%	26,930	61.00%	19,281	60.00%	NA	NA	1,922	36.00%
Cumulative Total				56,728	100.00%	43,976	100.00%	32,038	100.00%			5,306	100.00%

Table6.4.27 :- ***Tabulation illustrating the Oxford Hip Score-based Descriptive Patient Reported Outcome Measures of Primary and Revision Hip Arthroplasty, involving the Pre-Operative vis-à-vis Post-Operative Hip Pain Levels, Mobility of the Hip Joint, Ability to Perform Self-Caring and usual Activities, the General Pain and Discomfort Levels, along with the General level of Anxiety or Depression pertaining to their Hip Performances and their Overall Satisfaction from the Arthroplasty Procedure.***

- With respect to the pain levels of the Swedish patient cohort, undergoing knee arthroplasty, about 94% of the tracked patients for TKA-pre-operative PROMs, and 91% of the tracked patients for UKA-pre-operative PROMs reported moderate to severe pain in their knees.

- Post 1 year into the post-operative period of follow-up, the same group of patients in Sweden who received either a TKA or a UKA, reported an overall reduction in their long-existing pain levels, and presently had negligible to mild pain in their operated artificial knees while performing activities of daily functioning.

- About 66% of all the Swedish cohort of patients receiving Total Knee Arthroplasty, and 58% of the patient cohort receiving Unicondylar Knee Arthroplasty reported the above change in their relative pre-operative to post-operative pain levels, for performing activities of daily functioning.

- The generalized patient reported outcome measures from those who received either a Primary or a Revision Knee Arthroplasty during 2020, with respect to their experienced pre-operative vis-à-vis post-operative pain levels and their overall satisfaction from their arthroplasty post a year, is presented in the following tabulation: -

Generalized Patient Reported Outcome Measures (PROM) of the Swedish Patient Cohort, undergoing Knee Arthroplasty during 2020.

SL No.	PROMs Criteria	Primary Arthroplasty				Revision Arthroplasty			
		Pre-Operative		Post-Operative		Pre-Operative		Post-Operative	
		Reported PROM Scores	% of Overall	Reported PROM Scores	% of Overall	Reported PROM Scores	% of Overall	Reported PROM Scores	% of Overall
1	No. of Responses	3,458	NA	3,458	NA	391	NA	391	NA
Knee Pain in the Operated Knee									
2	None	5	0.00%	961	36.00%	0	0.00%	99	31.00%
3	Very Mild	24	1.00%	813	30.00%	6	2.00%	87	27.00%
4	Mild	127	5.00%	484	18.00%	22	7.00%	62	19.00%
5	Moderate	1,183	44.00%	250	13.00%	135	42.00%	54	17.00%
6	Severe	1,349	50.00%	80	3.00%	159	49.00%	20	6.00%
Cumulative Total		2,688	100.00%	2,588	100.00%	322	100.00%	322	100.00%
General Level of Post-Operative Satisfaction of the Swedish Patients with Knee Arthroplasty									
7	Very Dis-Satisfied	NA	NA	110	3.00%	NA	NA	19	5.20%
8	Dis-Satisfied	NA	NA	204	6.00%	NA	NA	23	6.30%
9	Neither Satisfied nor Dis-Satisfied	NA	NA	292	9.00%	NA	NA	44	11.10%
10	Satisfied	NA	NA	874	27.00%	NA	NA	109	28.40%
11	Very Satisfied	NA	NA	1,756	55.00%	NA	NA	188	49.00%
Cumulative Total		NA		3,236	100.00%	0	0.00%	383	100.00%

Table6.4.28 :- ***Tabulation illustrating the Obtained Patient Reported Outcome Measures from the Swedish Patient Cohort, undergoing Knee Arthroplasty, highlighting the Pre-Operative vis-à-vis Post-Operative Changes in their respective Knee Pain Levels and their Comparative Satisfaction from the Arthroplasty Procedure.***

- The EQ-VAS and KOOS–12–based general health standards improvement of the operated patients for both knee arthroplasty of the Swedish patient cohort, during the period of 2020 - 2021 is enclosed in the following tabulation: -

EQ-VAS & KOOS - 12 Based PROM Responses of the Swedish Patient Cohort, undergoing Knee Arthroplasty 2020-21.											
SL No.	PROMs Criteria	Primary Arthroplasty					Revision Arthroplasty				
		Pre-Operative		Post-Operative		Net Change in Pre-Post Op Scores	Pre-Operative		Post-Operative		Net Change in Pre-Post Op Scores
		Reported PROM Scores	S.D	Reported PROM Scores	S.D		Reported PROM Scores	S.D	Reported PROM Scores	S.D	
Mean Post-Operative KOOS-12 of the Swedish Knee Arthroplasty Recipients											
1	Pain	38	15	80	20	42	39	15	77	21	38
2	Activities of Daily Life [ADL]	35	17	76	21	41	39	16	76	21	37
3	Quality of Life [QoL]	21	13	67	23	46	22	13	65	23	43
Mean KOOS-12 Score		31.33	15	74.33	21.33	43	33.33	14.66	72.66	21.66	39.33
EuroQoL Visual Analogue Scale Responses of the Swedish Knee Arthroplasty Recipients											
4	EuroQoL Visual Analogue Scale [EQ-VAS]	65	22	76	19	11	63	23	76	19	13

Table6.4.29 :- ***Tabulation illustrating the Obtained Patient Reported Outcome Measures from the Swedish Patient Cohort, undergoing Knee Arthroplasty, for both the Pre-Operative vis-à-vis Post-Operative Changes in their respective Knee Pain Levels, Ease of performing Activities of Daily Life, and their General Quality of Life, through the universally accredited KOOS-12 PROMs tool and their Comparative Health Standards for both Primary and Revision Knee Arthroplasty, through the EuroQoL-VAS from the Arthroplasty Procedure.***

- The EQ-VAS and HOOS – 12 based general health standards improvement of the operated patients for both knee arthroplasty of the Swedish patient cohort, during the period of 2020 - 2021 is enclosed in the following tabulation: -

EuroQoL based EQ-VAS & EQ-5D-5L PROMs Capture of the Swedish Patient Cohort, undergoing Hip Arthroplasty during 2018 - 2021.												
SL No.	PROMs Criteria	Primary Arthroplasty								Revision Arthroplasty			
		Pre-Operative Assessement		Post-Operative Assessement						Pre-Operative Assessement		Post-Operative 1 Year	
				1 Year		6 Years		10 Years					
		Reported PROM Scores	S.D	Reported PROM Scores	S.D	Reported PROM Scores	S.D	Reported PROM Scores	S.D	Reported PROM Scores	S.D	Reported PROM Scores	S.D
1	EuroQoL Visual Analogue Score [EQ-VAS]	56	22	75	19	72	21	70	22	57	23	66	22
2	EuroQoL 5 Dimensions-5 Levels Index [EQ-5D-5L]	0.64	0.14	0.86	0.13	0.85	0.14	0.84	0.15	0.68	0.15	0.79	0.16

Table 6.4.30 :- ***Tabulation illustrating the Obtained Patient Reported Outcome Measures from the Swedish Patient Cohort, undergoing both Primary and Revision Hip Arthroplasty, through the EQ-VAS and EQ-5D-5L based patient-reported outcome assessment tools, for both the Pre-Operative vis-à-vis Post-Operative Changes in their respective Hip functionality for daily purposes and Overall Health Standard pre and post a hip arthroplasty.***

MODULE – VI

"Results & Discussion"

CHAPTER – 5

Comparative Report of the Global Hip & Knee Arthroplasty Practices and Patient-Related Outcome Scenarios.

Comparative Study Report On The Global Hip & Knee Arthroplasty Practices –
UK, USA, AUS, IRE, SWE.



(No. of Cases, Patient Demographics, Prostheses Usage, Fixation Methods, PROMs Trends & Related Analyses.)

Preface to the Comparative Analyses of the Global Arthroplasty Practices & Patient-related Outcomes: -

- In the initial stages of this research, and after post few initial progress meetings it was felt unequivocally necessary to establish a comparative study analysis of the selected major centres of global arthroplasty scenario, in order to attain the primary objective, of developing a holistic & comprehensive understanding of the global general arthroplasty practices and the differential approaches towards various indications with the prevailing predominant pre-operative vis-à-vis post-operative Patient Reported Outcome Measures or PROMs, that comprise/entail the patient's side of the story from their respective arthroplasties.

- This was attained through the careful examination and thorough evaluation/scrutinization of the globally accepted and acknowledged regions(countries) whose healthcare system and arthroplasty infrastructure / overall arthroplasty practices in particular are of general positive repute. However, this ascertainment of the global positive repute and ultimately the selection of the nations, whose arthroplasty practices were to be studied in the course of this research was backed and formulated through a strong & and rigorous related literature review, that spanned not just the conventional scientific journals, but also reliable and logically conclusive pieces of articles, case studies, various reports & recommendations that were sourced from validated sources with cross-verification analyses with concrete citations and related references study.

- Based on the same, countries like – the United Kingdom, the United States of America, Australia, Ireland and Sweden were selected for the said purpose and activity. A few other nations such as Germany, Switzerland, Canada, Japan, New Zealand, Brazil, Italy and the Netherlands were initially selected as well, however, they were later excluded from the overall purview of this research and this report, on either the grounds of data incompleteness, linguistic issues, repeated or questionable facts & figures, or in some cases all of the above, which were ascertained after primary investigation and analysis of the obtainable facts & figures of arthroplasty practices from these nations. The detailing about the selection and exclusion criterion are discussed elaborately in the "Methodology Adopted" chapter/module of this thesis.

- Also, it would've been otherwise an extraordinarily lengthy & and time-consuming process, to have evaluated all of the nations for the said purpose.

- India, was and continues, to remain in the purview of this research, and the related Indian data on hip and knee arthroplasty practices remains to be sourced via multiple formats, since singular and conventional methods of accessing arthroplasty data through national registries, were not possible till the time of composing this report. Further actions, with regard to the Indian arthroplasty scenario, is presented in the "Future Scope" chapter/module of this thesis work.

- It is therefore pertinent to state, that the comparative report is developed, after carefully examining and evaluating the arthroplasty practices of the above-mentioned selected nations.

Multi-Parameter based Comparison of the Global Arthroplasty Practices:

1. ***Comparative Analysis on the Basis of Respective Regional Arthroplasty Procedure Reporting Criteria & and the Monitoring/Registry body's Working Policy.***

a. The overall comparative data on the respective methodology of respective regional hip and knee arthroplasty data collection, by the primary source of the arthroplasty data, which has been fundamentally utilized during the course of this research, is tabulated as follows: -

Comparative Data on the Methodology of Respective Regional Arthroplasty Data Collection or Reporting Norm of the Global Regions, which have been Considered for the Evaluation Process of this Research Work.				
SL No.	**Region of Arthroplasty Data**	**Primary Source of Arthroplasty Data**	**Respective Regional Procedure Reporting Policy/Criteria**	**Arthroplasty Domains Considered**
1	United Kingdom & Wales	National Joint Registry [NJR]	Mandatory Reporting Policy & Backed/Supported by Agencies / Bodies/Societies of all Types[Clinical/Academical/Regulatory] ; Recognized by the UK Government as well.	Hip / Knee Arthroplasty
2	Australia	Australian Orthropedic Association National Joint Replacement Registry [AOANJRR]	Non-Mandatory ; But Registry Operation is Legally Enforced & Supported by the Government of Australia.	
3	United States of America	American Joint Replacement Registry [AJRR]	Run / Operated / Maintained by the American Academy of Orthopaedic Surgeons[AAOS] ; Not Government Sponsored / Private Society - Corporate Supported.	
4	Ireland	Irish National Orthopedic Register [INOR]	Run / Operated / Maintained by the National Office of Clinical Audit (NOCA) ; Registry still in Infancy / Pilot Roll-Out Stage with Partial Coverage from Government Hospitals only.	
5	Sweden	Swedish Arthroplasty Register [SAR]	Government backed/sponsored Association Body ; Mandatory Reporting Policy to either of 3 Major Health Regulatory, Monitoring & Tracking Agencies.	
6	India	Indian Joint Registry [IJR], Clinical Regulatory Bodies & Other Third Party Sources		

Table 6.5.1 : - ***Comparative Tabulation Data on the Methodology of Respective Regional Data Collection by the Primary Validated Source of Arthroplasty Data (Arthroplasty Registries).***

b. The Hip and Knee Arthroplasty Data for the Patient Cohort belonging to the United Kingdom and Wales, was primarily sourced from the National Joint Registry or the NJR. The NJR is a globally accredited and accepted organization, which is academically and technically backed or supported by the Premier academic institutes of the UK, such the Oxford University, and is enforced through the various Orthopaedic Associations, Healthcare Agencies such as MHRA and the NHS, thereby getting well recognized and supported by the UK Government as well.

c. The NJR through the active enforcement and support from various other healthcare regulatory bodies, agencies, and clinical societies envisages a mandatory reporting policy for all arthroplasty procedures – Hip, Knee, Ankle, Shoulder, and Elbow, to be positively reported to the registry via the Registry specified and issued specialized reporting forms, known as the Minimum Data Set or MDS, available through both physical and digital portal-based reporting facilities. These MDS forms comprise a set of well-evidenced questionnaire, that captures vital pieces of information, with regard to the arthroplasty being performed. Over the course of time, these primary data-capturing MDSs also evolved, to incorporate, missed parameters and information requirement

tabs/questions, that were required to be added in the newer versions of the MDS, denoted, as MDSv3, MDSv7, etc. to capture some of the crucial indications and parameters, those were later found to be intricately crucial in the analysis of the arthroplasty practices.

d. The evolution of the MDS into newer and more sophisticated versions, led to the capturing of the ASA & BMI linked Patient Demographics, which turned out to be integrally crucial to demarcate the basic population trends of the patients, who were lining up for arthroplasty procedures, or the trends of the patient cohorts, undergoing post-operative implant failures. Further details in this regard will be discussed separately in the relevant segment of this report.

e. The Hip and Knee Arthroplasty Data for the Patient Cohort from Australia, was primarily sourced from the Australian Orthopaedic Association National Joint Replacement Registry or the AOANJRR.

f. The AOANJRR's operation is legally enforced and supported by the Australian Federal Government, through appropriate Parliamentary legislation, in close co-ordination/support of the Therapeutics Goods Administration or the TGA (Australian equivalent of the USFDA). This legally enforced backing has worked in favour of the Registry and the Overall Arthroplasty Reporting numbers in a great way, such that even without a mandatory reporting policy/criterion in place, it has regularly posted and has an overall reporting coverage rate of 97%.

g. Similar to the NJR, the AOANJRR also has an evolving MDS which is utilized at the hospital/clinic ground level to capture all the relevant information of patients undergoing an arthroplasty, to formulate the raw information, into meaningful and constructive data, ready for research and further analysis by the biomedical, statistical, clinical and scientific community in general. This fact remains consistent for all other registries as well.

h. The AOANJRR's activity is largely governed and run by the South Australian Health and Medical Research Institute (SAHMRI) for the data collection, management, and statistical analysis of the arthroplasty practices/trends in Australia, in academic co-operation with the University of South Australia.

i. The Hip and Knee Arthroplasty Data for the patient cohort from the United States of America, is sourced from the American Joint Replacement Registry or the AJRR. The AJRR is actively monitored, regulated, and run by the non-governmental/private association – 'The American Academy of Orthopaedic Surgeons' or AAOS.

j. The AJRR doesn't involve a mandatory reporting policy/criterion for all the empanelled hospitals or for all other public, and private clinics, institutes, and hospitals spread across the USA. The general coverage or reporting with regards to the scale of its operation, and the period of existential operations, is relatively lower than other nations, which are analyzed and reported in detail in this report. Also, many of the presented and obtainable resources and facts were questionable, which are discussed separately in the '*Arthroplasty Practices & Patient Related Outcomes in USA*' chapter of this thesis work.

k. The Hip and Knee Arthroplasty Data for the patient cohort from Ireland, is sourced from the Irish National Orthopaedic Register or the INOR. The INOR is run, operated, and maintained by the 'National Office of Clinical Audit (NOCA)' body in Ireland.

l. The Irish Registry is still in its very infancy and has only a single publicly available registry report which also is its first full-scale report, as per records and other sources converging confirmed in

this regard. The arthroplasty data reporting has only partial coverage from a selected few public hospital, and many of the vital parameters are at their pilot roll-out stages.

m. The only logical rationale that was considered for the selection of this particular nation and its infant registry, is to analyze exactly how a modern and infant registry report should be, or how an infant / young registry/registry should be performing/operating, particularly when a major portion of its population remains in close contact, with a geographically and societally impactful and major nation as its neighbour – UK, with a registry as globally revered and matured as the NJR. It was also one of the concerns, whether, there be any shadow influence or kind of similar trends on two geographically and to some extent epidemiologically close populations.

n. The Hip and Knee Arthroplasty Data for the Swedish patient cohort, is primarily sourced from the now merged and formulated Swedish Arthroplasty Register or SAR. The Swedish Arthroplasty Register is possibly the oldest existing arthroplasty registry in functional operations since the 1970s, and therefore is globally accredited and revered to almost the highest levels, as is evident by the plethora of journals publications based on the registry's data, accessible and available across nearly all of the major to medium scale journal houses.

o. However, the Swedish registry primarily existed separately for Hip and Knee Arthroplasties, in almost total differences. These separate registries, as may be due to the laws of time & and nature, were to be evolved and hence merged into a singular registry body, that collects arthroplasty data, manages them, and publishes a singular annual registry report, on the Swedish arthroplasty trends and practices.

p. The functioning is backed/sponsored by the Government and has a mandatory arthroplasty procedure reporting policy/criterion to either of the three major health regulatory, monitoring, and tracking agencies in Sweden, of which the SAR is one them. The complete reporting of any revision procedure irrespective of its related level of complication, is non-negotiable mandatory, with the entire case records being analyzed for any possible health hazards, or plausible malpractice at any level.

2. ***Comparative Analysis for the Overall Number of Hip Arthroplasties Performed Globally.***

a. The overall comparatively tabulated data on the overall number of hip arthroplasties performed on the patient cohorts, from the US, UK, AUS, IRE and SWE, is presented through the following the tabulation: -

Comparative Tabulation for the Overall Hip Arthroplasty Numbers and the Respective Breakdown of Different Types of Hip Arthroplasty Categories, performed on the Patient Cohorts of Australia, United States of America, United Kingdom, Ireland and Sweden.

SL No.	Region of Arthroplasty Data	Primary Source of Arthroplasty Data	Overall Arthroplasty Procedure Numbers						
			Hip Arthroplasty						
			Overall Hip Arthroplasty	Overall Revision Hip Arthroplasty	Total Hip Arthroplasty	Hemi-Arthroplasty	THA for Fracture	Hip Resurfacing Arthroplasty	Other Hip Arthroplasty / Unconfirmed
1	United Kingdom & Wales	National Joint Registry [NJR]	13,44,357	1,35,690				41,428	38,760
2	Australia	Australian Orthropedic Association National Joint Replacement Registry [AOANJRR]	7,99,686	83,206	5,99,656	1,13,824		Not Separatedly Available ; Included with Total	3,000
3	United States of America	American Joint Replacement Registry [AJRR]	10,64,750	1,03,514	8,21,640	95,099	28,079	5,935	10,483
4	Ireland	Irish National Orthopedic Register [INOR]	3,723	379	3,344				
5	Sweden	Swedish Arthroplasty Register [SAR]	5,10,977	92,966					
6	India	Indian Joint Registry [IJR], Clinical Regulatory Bodies & Other Third Party Sources							
Cumulative Category Total			37,23,493	4,15,755	14,24,640	2,08,923	28,079	47,363	52,243

Stated Figures & Data is presented for the Latest Available year of Arthroplasty Record and are either the only Reasonable Data Accessed or the Highest Pre-Post Change Value obtained across any time point in the Postoperative period for Any Reporting Criterion which has been considered during the Research Evaluation Process. ; Blank Cells indicate either no corresponding data was Available/Accessible, or no such suitable data has been published.

Table 6.5.2 :- ***Comparative Tabulation for the Overall Number of Hip Arthroplasties and the Respective Category-wise Breakdown of Different Types of Hip Arthroplasty for the Accessible Data, performed on the Patient Cohorts of US, UK, Australia, Ireland and Sweden.***

b. The combined cumulative number of overall hip arthroplasty procedures, that formed the base for all the hip arthroplasty practices and prostheses analyses of this research was 37,23,493 procedures.

c. Out of the 37.23 Lac procedures, the United Kingdom had the biggest share of hip arthroplasty procedure numbers which stood at 13,44,357, followed by a close second of the United States of America at 10,64,750, forming the Top-2 Hip Arthroplasty Regions of the globally recognizable and validated data.

d. Australia and Sweden attained 3rd and 4th positions respectively, in terms of overall hip arthroplasty procedures numbers at 7,99,686 and 5,10,977 respectively.

e. Ireland with the smallest population of the 5 nations, evaluated, and also due to its infant registry, reports a 3,723 overall hip arthroplasty number, which is expected to rise several-fold in the successive reports of the INOR, if it manages to improve its data collection, and coverage rates.

f. The overall Revision Arthroplasty Numbers corresponding to the Overall primary Hip Arthroplasty numbers, involving all types of Hip Arthroplasties (THAs, Hemi-arthroplasties), stood at; -

United Kingdom	= 1,35,690 Revision Hip Arthroplasty Procedures (out of 13,44,357).
United States of America	= 1,03,514 Revision Hip Arthroplasty Procedures (out of 10,64,750).
Australia	= 83,206 Revision Hip Arthroplasty Procedures (out of 7,99,686).
Sweden	= 92,966 Revision Hip Arthroplasty Procedures (out of 5,10,977).
Ireland	= 379 Revision Hip Arthroplasty Procedures (out of 3,723).

3. ***Comparative Analysis for the Overall Number of Knee Arthroplasties Performed Globally.***

a. The overall comparatively tabulated data on the overall number of hip arthroplasties performed on the patient cohorts, from the US, UK, AUS, IRE and SWE, is presented through the following the tabulation: -

Comparative Tabulation for the Overall Knee Arthroplasty Numbers & the Respective Breakdown of Different Types of Hip Arthroplasty Categories, performed on the Patient Cohorts of Australia, United States of America, United Kingdom, Ireland and Sweden.

SL No.	Region of Arthroplasty Data	Primary Source of Arthroplasty Data	Overall Arthroplasty Procedure Numbers						
			Knee Arthroplasty						
			Overall Knee Arthroplasty	Overall Revision Knee Arthroplasty	Total Knee Arthroplasty	Unicompartmental Knee Arthroplasty	Partial Knee Arthroplasty	Patellofemoral Knee Arthroplasty	Unconfirmed Procedures
1	United Kingdom & Wales	National Joint Registry [NJR]	14,42,051	92,919	12,65,502	1,36,893	622	16,476	22,558
2	Australia	Australian Orthropedic Association National Joint Replacement Registry [AOANJRR]	9,80,419	78,373	8,29,272	67,497	72,774	5,032 [Bi-Compartmental(165);Patella (4827);Unispacer(40)]	245[Partial Resurfacing Knee]
3	United States of America	American Joint Replacement Registry [AJRR]	14,95,965	1,22,852	13,06,719	NA	66,394	NA	
4	Ireland	Irish National Orthopedic Register [INOR]	2,871	194	2,677				
5	Sweden	Swedish Arthroplasty Register [SAR]	3,27,352	30,271					
6	India	Indian Joint Registry [IJR], Clinical Regulatory Bodies & Other Third Party Sources							
Cumulative Category Total			42,48,658	3,24,609	34,04,170	2,04,390	1,39,790	21,508	22,803

Stated Figures & Data is presented for the Latest Available year of Arthroplasty Record and are either the only Reasonable Data Accessed or the Highest Pre-Post Change Value obtained across any time point in the Postoperative period for Any Reporting Criterion which has been considered during the Research Evaluation Process. ; Blank Cells indicate either no corresponding data was Available/Accessible, or no such suitable data has been published.

Table 6.5.3 :- ***Comparative Tabulation for the Overall Number of Knee Arthroplasties and the Respective Category-wise Breakdown of Different Types of Knee Arthroplasty, performed on the Patient Cohorts of US, UK, Australia, Ireland and Sweden, as far as relevant data could be accessed/analyzed.***

b. The combined cumulative number of overall knee arthroplasty procedures, that formed the base for all the hip arthroplasty practices and prostheses analyses of this research was 42,48,658 individual arthroplasty procedures.

c. Out of the 42.48 Lac procedures, the USA had the biggest share of hip arthroplasty procedure numbers which stood at 14,95,965, followed by a close second of the United Kingdom at 14,42,051, forming the Top-2 Knee Arthroplasty Regions of the globally recognizable and validated data.

d. Australia and Sweden attained 3rd and 4th positions respectively, in terms of overall knee arthroplasty procedures numbers at 9,80,419 and 3,27,352 respectively.

e. Ireland with the smallest population of the 5 nations, evaluated, and also due to its infant registry database, reports a 2,871 overall knee arthroplasty number, which is expected to rise several-fold in the successive reports of the INOR, if it manages to improve its data collection, and coverage rates and include historical data into its mainframe analyses reporting.

f. The overall Revision Arthroplasty Numbers corresponding to the Overall primary Knee Arthroplasty numbers, involving all types of Knee Arthroplasties (TKAs, UKAs/PFKA/MCKAs), stood at; -

United Kingdom	= 92,919 Revision Knee Arthroplasty Procedures (out of 14,42,051).
United States of America	= 1,22,852 Revision Knee Arthroplasty Procedures (out of 14,95,965).
Australia	= 78,373 Revision Knee Arthroplasty Procedures (out of 9,80,419).
Sweden	= 30,271 Revision Knee Arthroplasty Procedures (out of 3,27,352).
Ireland	= 194 Revision Knee Arthroplasty Procedures (out of 2,871).

4. ***Comparative Analysis of the Global Patient Demography as per ASA Grade & BMI Categorization.***

a. The globally accepted and conventional practice of identification and classification of the patient demography in-line or recipients of an arthroplasty-based intervention for their worsening hip and knee performances, is performed on the basis of their respective body mass indices or the BMI index categorization as per the globally accepted reference ranges, and the American Society of Anaesthesiologists (ASA) Grade classification procedure, which is based on the general co-morbidity statuses of the patients.

b. There may be unique methodologies for patient identification and demarcation across the geographies of the world, based on different rationales, but the common parameter to classify the overall patient cohort as a group, and not on an individual basis is done via an ASA Grade and BMI indices-based categorization.

c. The overall classification reference ranges for each of the ASA grades and BMI categories are presented as follows, for ready reference: -

ASA Classification	Definition	Examples
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

Table 6.5.4 :- ***Globally Accepted ASA – Grade-wise Classification Definition and Standardization to distinguish and classify general patient cohorts on the basis of their respective co-morbidity statuses.***

Body-Mass Index (BMI) Category	Definition
Below 18.5	**Underweight**
18.5 – 24.99	**Normal Weighed**
25.00 – 29.99	**Pre-Obese**
30.00 – 34.99	**Obese Class 1**
35.00 – 39.99	**Obese Class 2**
Above 40.00	**Obese Class 3**

Table6.5.5 :- ***Globally Accepted Body Mass Indices (BMI) – Categories with its Classification Definition to distinguish and classify general patient cohorts on the basis of their respective body-mass indices.***

d. The total number of ASA- Grade linked overall hip arthroplasty data from the respective nations that were assessed by this research during its evaluation processes is 17,80,220, across all ASA categories and irrespective of any primary / revision or total/partial segregation.

e. Similarly, for overall knee arthroplasties, a total number of 19,90,717 unique ASA – Grade categorization linked knee procedures could be accessed by this research for its intended aim and objectives.

f. While for BMI indices-based categorization, a total of 9,34,202 unique BMI data linked hip arthroplasty procedures performed on the patient cohort across the nations evaluated for their respective arthroplasty practices.

g. The overall distribution of the hip and knee arthroplasty procedures performed on the patient cohort, across the nations whose arthroplasty practices and patient-related outcomes were evaluated by this research, categorised as per their respective ASA-Grade wise categorisation, highlighting the general level of comorbidity statuses of the recipient patients, are presented through the following tabulations: -

Comparative Tabulation of the ASA Linked Distribution of the Patient Demography undergoing Hip Arthroplasties in the Respective Nations.

SL No.	Region of Arthroplasty Data	Total No. of Hip Arthroplasty Procedures	ASA Grade of the Respective Patient Cohort										Total No. of ASA Category Linked Arthroplasties
			ASA 1		ASA 2		ASA 3		ASA 4		ASA 5 / Unknown		
			No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	
1	United Kingdom & Wales	13,44,357	2,05,930	15.31%	9,08,907	67.60%	2,21,601	16.48%	7,760	0.58%	159	0.01%	13,44,357
2	United States of America	10,64,750	*ASA Linked Distribution of the Patient Cohort, undergoing Hip Arthroplasty is not available/accessible.*										
3	Australia	7,99,686	31,355	7.70%	1,87,231	45.80%	1,66,100	40.60%	23,837	5.80%	264	0.10%	4,08,787
4	Ireland	3,723	468	14%	2,274	68%	468	14%	0	0%	134	4%	3,344
			23	6%	250	66%	95	25%	3	0%	8	2%	379
5	Sweden	5,10,977	3,351	14.34%	12,491	53.49%	6,955	29.78%	555	2.37%			23,353
6	India												
Cumulative Category Total		37,23,493	2,41,127	13.54%	11,11,153	62.41%	3,95,219	22.20%	32,155	1.81%	565	0.03%	17,80,220

The ASA Linked Patient Cohort Distribution receiving Hip Arthroplasty, separately for Primary & Revision Arthroplasty was only available for the Irish Patient Cohort, and hence tabulated accordingly ; 379 Revisions & 3,344 Primaries.

Table 6.5.6 :- ***Comparative Tabulation for the Overall Number of ASA – Grade linked distribution of the Hip Arthroplasties performed on the Patient Cohort, across the nations evaluated for their respective arthroplasty practices and patient-related outcomes.***

Comparative Tabulation of the ASA Linked Distribution of the Patient Demography undergoing Knee Arthroplasties in the Respective Nations.

SL No.	Region of Arthroplasty Data	Total No. of Knee Arthroplasty Procedures	ASA Grade of the Respective Patient Cohort										Total No. of ASA Category Linked Arthroplasties
			ASA 1		ASA 2		ASA 3		ASA 4		ASA 5 / Unknown		
			No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	
1	United Kingdom & Wales	14,42,051	1,62,765	11.28%	10,38,256	71.99%	2,36,299	16.38%	4,589	0.31%	142	<0.01%	14,42,051
2	United States of America	14,95,965	*ASA Linked Distribution of the Patient Cohort, undergoing Hip Arthroplasty is not available/accessible.*										
3	Australia	9,80,419	31,483	5.90%	2,86,972	53.90%	2,07,011	38.90%	6,832	1.30%	30	<0.01%	5,32,328
4	Ireland	2,871	252	9.40%	1,857	69.40%	407	15.20%	0	0%	161	6%	2,677
			17	9%	132	68%	39	20%	2	1%	4	2%	194
5	Sweden	3,27,352	2,154	15.99%	8,997	66.80%	2,285	16.96%	31	0.23%	0	0%	13,467
6	India												
Cumulative Category Total		42,48,658	1,96,671	9.87%	13,36,214	67.12%	4,46,041	22.40%	11,454	0.57%	337	0.02%	19,90,717

The ASA Linked Patient Cohort Distribution receiving Knee Arthroplasty, separately for Primary & Revision Arthroplasty was only available for the Irish Patient Cohort, and hence tabulated accordingly ; 194 Revisions & 2,677 Primaries.

Table 6.5.7 :- ***Comparative Tabulation for the Overall Number of ASA – Grade linked distribution of the Knee Arthroplasties performed on the Patient Cohort, across the five nations evaluated for their respective arthroplasty practices and patient-related outcomes.***

h. The overall distribution of the hip and knee arthroplasty procedures performed on the patient cohort, across the nations whose arthroplasty practices and patient-related outcomes were evaluated by this research, categorised as per their respective BMI-indices wise categorisation, highlighting the general level of comorbidity statuses of the recipient patients, are presented through the following tabulations: -

Comparative Tabulation of the BMI Linked Distribution of the Patient Demography undergoing Hip Arthroplasties in the Respective Nations.

Sl. No.	Region of Arthroplasty Data	Total No. of Hip Arthroplasty Procedures	BMI Category of the Respective Patient Cohort												Total No. of BMI Indices Category Linked Arthroplasties
			Underweight [<18.5]		Normal Weighed [18.5-24.9]		Pre-Obese [25 - 29.9]		Obese Class 1 [30 - 34.9]		Obese Class 2 [35-39.9]		Obese Class 3 [>= 40]		
			No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	
1	United Kingdom & Wales	13,44,357	*BMI Linked Distribution of the Patient Cohort, undergoing Hip Arthroplasty is not available/accessible.*												
2	United States of America	10,64,750	4,370	0.97%	88,845	19.77%	1,48,346	33.00%	1,15,921	25.79%	61,510	13.68%	30,500	6.79%	4,49,492
3	Australia	7,99,686	5,306	1.80%	72,634	24.30%	1,07,283	35.90%	70,022	23.40%	29,246	9.80%	14,389	4.80%	2,98,880
4	Ireland	3,723	1	<0.01%	702	21%	1,271	38%	936	28%	334	10%	100	3%	3,344
			0	0%	72	19%	136	36%	110	29%	42	11%	19	5%	379
5	Sweden	5,10,977	2,216	1.21%	60,433	33.18%	75,409	41.40%	33,856	18.59%	8,582	4.71%	1,611	0.88%	1,82,107
6	India														
Cumulative Category Total		37,23,493	11,893	1.27%	2,22,686	23.83%	3,32,445	35.58%	2,20,845	23.63%	99,714	10.67%	46,619	4.99%	9,34,202

The BMI Linked Patient Cohort Distribution receiving Hip Arthroplasty, separately for Primary & Revision Arthroplasty was only available for the Irish Patient Cohort, and hence tabulated accordingly ; 379 Revisions & 3,344 Primaries. ; All Figures Correspond to the Latest Available Data on the Respective Regional Arthroplasty Practices and are Inclusive of Both Primary & Revision Numbers, explicited stated otherwise.

Table 6.5.8 :- ***Comparative Tabulation for the Overall Number of BMI – Grade linked distribution of the Overall Hip Arthroplasties performed on the Patient Cohort, across the five nations evaluated for their respective arthroplasty practices and patient-related outcomes.***

Comparative Tabulation of the BMI Linked Distribution of the Patient Cohort Demography undergoing Knee Arthroplasties in the Respective Nations.

SL No.	Region of Arthroplasty Data	Total No. of Knee Arthroplasty Procedures	BMI Category of the Respective Patient Cohort												Total No. of BMI Indices Category Linked Arthroplasties
			Underweight [<18.5]		Normal Weighed [18.5-24.9]		Pre-Obese [25 - 29.9]		Obese Class 1 [30 - 34.9]		Obese Class 2 [35-39.9]		Obese Class 3 [> = 40]		
			No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	
1	United Kingdom & Wales	14,42,051	*BMI Linked Distribution of the Patient Cohort, undergoing Knee Arthroplasty is not available/accessible.*												
2	United States of America	14,95,965	2,008	0.30%	69,136	10.29%	1,84,988	27.52%	1,96,009	29.16%	1,33,521	19.87%	86,476	12.87%	6,72,138
3	Australia	9,80,419	891	0.20%	45,528	10.80%	1,33,709	31.70%	1,30,023	30.80%	69,924	16.60%	42,177	10.00%	4,22,252
4	Ireland	2,871	0	0%	268	10%	830	31%	829	31%	509	19%	241	9%	2,677
			1	<0.01%	17	9%	70	36%	62	32%	27	14%	17	9%	194
5	Sweden	3,27,352	21	0.16%	2,385	19.00%	5,569	44.37%	3,563	28.39%	919	7.32%	92	0.73%	12549 [Only 2021 BMI Data could be Accessed.]
6	India														
Cumulative Category Total		**42,48,658**	**2,921**	**0.27%**	**1,17,334**	**10.58%**	**3,25,166**	**29.29%**	**3,30,486**	**29.77%**	**2,04,900**	**18.46%**	**1,29,003**	**11.63%**	**11,09,810**

The BMI Linked Patient Cohort Distribution receiving Hip Arthroplasty, separately for Primary & Revision Arthroplasty was only available for the Irish Patient Cohort, and hence tabulated accordingly ; 194 Revisions & 2,677 Primaries. ; All Figures Correspond to the Latest Available Data on the Respective Regional Arthroplasty Practices and are Inclusive of Both Primary & Revision Numbers, explicited stated otherwise.

Table 6.5.9 :- ***Comparative Tabulation for the Overall Number of BMI – Grade linked distribution of the Overall Knee Arthroplasties performed on the Patient Cohort, across the five nations evaluated for their respective arthroplasty practices and patient-related outcomes.***

i. Based on the above comparative tabulation, it can be evidently noted that patient groups belonging to the pre-obese category, as per the globally accepted conventions/norms of BMI grade categorization, received the greatest proportion of hip arthroplasties, combinedly across all the five nations, whose individual arthroplasty practices and patient-related outcomes have been evaluated in the course of this research.

j. Pre-obese category-based patient groups accounted for the greatest relative proportion of the overall number of hip arthroplasties performed across the five nations. The said group received 3,32,445 individual hip arthroplasty procedures, irrespective of any primary/revision or partial/total segregation, which was 35.58% of all the BMI-grade linked hip arthroplasty data that was plausible to access.

k. While for knee arthroplasties performed across the five nations that were evaluated, it was seen that the patients belonging to Obese Class 1, with respective body mass indices (BMI) ranging from 30.00 to 34.99, received the greatest number of knee arthroplasties, amounting to 3,30,486, which accounted for a proportion of 29.77% of overall BMI data linked knee arthroplasties.

l. Patient groups belonging to the pre-obese category, with a respective body mass index (BMI) ranging between 25.00 to 29.99, received the second highest number of knee arthroplasties globally, as far as BMI-linked data could be evaluated/accessed. They accounted for 3,25,166 individual knee arthroplasty procedures, which was 29.29% of all the BMI-grade linked knee arthroplasties.

m. This particular insight further emboldens the rationale proposed by this research in the earlier sections, that not always being ‘healthy’ or over-weighed, makes a patient particularly vulnerable to various knee ailments, or in any particular urgent need to undergo a knee arthroplasty in order to get rid of the diseased condition, which is however propagated by the modern day ‘health-influencers’ and some sections of the clinicians across the world. Had the prevalent narrative been true, then patients belonging to the highest class of obesity, as per the BMI grade classification norms, i.e., to the Obese Class 3, would have been the greatest recipients of hip and knee arthroplasties globally.

n. Upon examining the prevalent arthroplasty practices and related patient demographics in the above-specified nations, it is noted that in most of the places, the ASA – Grade or BMI – linked categorization of the arthroplasty-undergoing patients, primarily started off at different time-points leading to the unequal number of the procedure numbers as quoted in the tabulation above. It was further noted that in some places, even though ASA grade and BMI-linked categorizations

were performed at the grassroots level during pre-operative and post-operative stages, they couldn't be accessed for the relevant analyses due to various restrictions/obstacles.

5. ***<u>Comparative Analysis of the Global Patient Demographics: Mean / Median Patient Age, Gender Distribution and the Leading Primary Causes for Primary/Revision Hip/Knee Procedures.</u>***

a. Besides the ASA Grade and BMI data-based categorizations, it is necessary to separately distinguish the gender-based distribution of the overall hip and knee arthroplasty procedures performed across the nations, evaluated for their respective arthroplasty practices, along with the mean and median age group of the patient cohorts.

b. This is primarily due to the fact that various age groups for each of the genders have shown various characteristic differences and influences in the overall picture of the prevalent national arthroplasty scenario. While the age groups are more intricately linked with the post-operative outcome aspects, the gender of the patients is more linked to the primary causes and arthroplasty modalities adopted.

c. Therefore, a comparative tabulation of the global mean and median patient age, gender-based distribution of the hip/knee arthroplasty procedures, and the respective causes for the primary / revision hip and knee arthroplasty procedures, irrespective of the type of primary (total/partial) or revision (single-stage or dual stage revision) is developed, and is presented as follows: -

Comparative Analysis Tabulation for the Gender, Age Linked Number & Distribution of Hip Arthroplasties performed on the Patient Cohort from the UK, USA, AUS, IRE & SWE, with their Respective Major Causes / Indications for Primary & Revision Arthroplasty.

Sl. No.	Region of Arthroplasty Data	Male		Female		Mean Age of Overall Arthroplasty Patients	Median Age of Overall Arthroplasty Patients	Major Cause of Primary Hip Arthroplasty			Major Cause of Revision Hip Arthroplasty		
		No. of Cases	Percent Share	No. of Cases	Percent Share			Primary Indication	Percent of Overall Indications	No. of Hip Procedures caused by the Respective Leading Cause of Primary Arthroplasties.	Primary Indication for Revision Arthroplasty	Percent of Overall Indications	No. of Revision Arthroplasties due to the Leading Cause of Revisions.
1	United Kingdom & Wales	5,40,432	40.20%	8,03,925	59.80%	68.1	69	Osteoarthritis	88.00%	11,83,460	Aseptic Loosening	28.49%	56,895
2	Australia	2,61,420	45.10%	3,18,609	54.90%	67.8			87.60%	3,97,261	Post-Op Infection	22.70%	2,972
3	United States of America	4,37,612	41.1	6,27,138	58.50%	67.8		Not Explicitly Reported ; Indirect trails leads to OA.	77.17%	8,21,640	Infection & Inflammatory Reaction	21.20%	21,945
4	Ireland	1,862	50.00%	1,862	50.00%	65	67	Osteoarthritis	93.30%	3,119	Aseptic Loosening	41.40%	157
5	Sweden	9,687	41.00%	13,939	58.99%	74.33			92.10%		Loosening	36.05%	16,882
6	India												
Cumulative Total		12,51,013	43.48%	17,65,473	56.42%	68.6			87.63%	24,05,480		29.96%	98,851

The General Arthroplasty numbers for the Latest Year is reported/tabulated where the Overall data is not specifically reported/accessible like the Swedish Gender Segregated Arthroplasty Numbers; Mean Age of Overall Arthroplasty includes all types of Arthroplasties[Total, Partial, Revision, Resurfacings etc.). Actual Gender-wise Arthroplasty numbers may vary [+/- 10%].; Blank Cells indicate Data yet to be Accessed or Data Not Available.

Table6.5.10 :-***Tabulation illustrating the Comparative picture of the respective Mean and Median Age Groups, Gender segregated distribution of the Overall Hip Arthroplasties performed, along with their respective Major Causes of Primary and Revision Hip Arthroplasty on the patient cohorts of US, AUS, UK, IRE and SWE.***

Comparative Analysis Tabulation for the Gender, Age Linked Number & Distribution of Knee Arthroplasties performed on the Patient Cohort from the UK, USA, AUS, IRE & SWE, with their Respective Major Causes / Indications for Primary & Revision Arthroplasty.

Sl. No.	Region of Arthroplasty Data	Male		Female		Mean Age of Overall Patients	Median Age of Overall Patients	Major Cause of Primary Knee Arthroplasty			Major Cause of Revision Knee Arthroplasty		
		No. of Cases	Percent Share	No. of Cases	Percent Share			Primary Indication	Percent of Overall Indications	No. of Knee Procedures caused by the Respective Leading Cause of Primary Arthroplasties.	Primary Indication for Revision Arthroplasty	Respective Distribution Share of Overall Revision Indication in the Respective National Arthroplasty Scenario	No. of Revision Arthroplasties due to the Leading Cause of Revisions.
1	United Kingdom & Wales	6,31,618	43.80%	8,10,433	56.20%	68.9	70	Osteoarthritis	96.60%	13,93,263	Aseptic Loosening / Lysis	24.87%	31,014
2	Australia	3,64,431	43.90%	4,64,841	56.10%	66.95			97.80%	7,11,978	Post-Op Infection	26.60%	6,724
3	United States of America	6,14,842	41.10%	8,81,123	58.50%	67.2		Details on the Major Indications for Primary Knee Arthroplasty for Total, Partial and other forms of Knee Arthroplasty were Neither Reported, nor any Procedure Distribution/Indication was available.			Infection & Inflammatory Reaction	28.40%	30,547
4	Ireland	1,120	39.00%	1,751	61.00%	67	68	Osteoarthritis	97.50%	2,611	Instability	27.30%	53
5	Sweden	6,023	44.60%	7,480	55.39%	69			97.10%				
6	India												
Cumulative Total & Mean		16,18,034	42.48%	21,65,628	57.43%	67.81			97.25%	21,07,852		26.79%	68,338

The Gender Distribution of TKA is taken where the Overall data is not specifically reported; Mean Age of Overall Arthroplasty includes all types of Arthroplasties[Total, Partial, Revision, Resurfacings etc.) ; Actual Gender-wise Arthroplasty numbers may vary [+/- 10%]. Data yet to be Accessed or Data Not Available.; The Revision Distributional Data for American Revision Knee is back-tracked and might involve some discrepancies to actual Numbers, since Incomplete Data for Revision Knee was Intentionally/Un-Intentionally published.

Table6.5.11 :-***Tabulation illustrating the Comparative picture of the respective Mean and Median Age Groups, Gender segregated distribution of the Overall Knee Arthroplasties performed, along with their respective Major Causes of Primary and Revision Knee Arthroplasty on the patient cohorts of US, AUS, UK, IRE and SWE.***

A. <u>Globally Comparative Scenario for Hip Arthroplasty</u> –

a. Based on the above-presented tabulations, it can be evidently seen that barring Ireland, wherein there was an equivalent distribution of hip arthroplasty cases between both males and females, in the remaining other nations, the female patient cohort, dominated in their relative proportions than their male counterparts by some margins. The biggest margin on the gender-based distribution of the hip

arthroplasties is seen for the female patients in the USA, who received 58.50% of the total number of the reported arthroplasties, leaving out 41.10% for the male patients group.

b. The overall mean age of the hip arthroplasty recipient patient cohort across the five nations evaluated for their respective hip arthroplasty practices, is 68.6 years, with the highest individual mean age obtained for the Swedish hip arthroplasty recipient patient cohort at 74.33 years. While the youngest mean age obtained was for the Irish patient cohort at 65 years.

c. Osteoarthritis or to be more specific, a progressively worsening osteoarthritis of the hip joint, is the globally consistent leading cause for the primary hip arthroplasties performed across the global patient community, including the five nations whose detailed arthroplasty practices have been studied, evaluated and discussed in great detail in this thesis work.

d. A progressively worsening osteoarthritis is found to be the prime cause attributed for an overall of 87.63% of all the hip arthroplasties evaluated from the five nations, with being the single largest cause for Irish patient cohorts, with an overall indication rate of 93.30%.

e. In a comparative aspect, a progressively worsening osteoarthritis was attributed as the sole cause or one of many, for 24,05,480 unique primary hip arthroplasty procedures performed across the five nations, outside of the cases performed for other non-osteoarthritis diagnoses.

f. While for revision hip arthroplasties, aseptic loosening of the prosthesis unit in the post-operative window, was the primary major / leading cause for the revision of the primary hip arthroplasties performed on the British and Irish patient cohort. Comparatively, the Swedish patient cohort had to get their primaries revised for an incidence of ‘loosening’ of the prosthesis in the post-operative window, however the driving cause for the loosening being a septic or an aseptic one, could not be ascertained, and it would be grossly erroneous to club the same, into a same basket, given the whole paradigm difference a septic vis-à-vis aseptic scenario of prostheses loosening entails.

g. Post-operative aseptic loosening of the hip prosthesis unit was attributed as the primary cause or reason for performing a revision of the primary hip arthroplasty, for 28.49% and 41.40% of the overall revision hip arthroplasty cases for the British and Irish patient cohort respectively. The relative percentages accounted for 56,895 and 157 unique revision hip procedures recorded for the British and Irish patient cohorts respectively.

h. While for the Swedish patient cohort, for whom the exact nature or causative force behind the post-operative loosening of the hip prostheses unit could not be separately identified and ascertained, there were 16,882 unique revision hip procedures, attributed to the afore-mentioned cause, that accounted for 36.05% of overall revision hip arthroplasties in Sweden.

i. The scenario for the leading cause for revision hip arthroplasties was however different for the patient cohorts in Australia and in the USA, wherein an indication of ‘Post-Op Infection’ and ‘Infection & Inflammatory Reaction’ was attributed as the prime reasons behind revision hip arthroplasties.

j. For the American patient cohort for whom an incidence of ‘Infection and Inflammatory Reaction’ was attributed as the leading cause for a revision hip arthroplasty, there were 21,945 unique such procedures caused due to the aforementioned indication, as reported by the respective registry, accounting for 21.20% of overall revision hip arthroplasty numbers. However, the general level of transparency and the truth involved within the American data is something that this research is very doubtful about.

k. While the reported numbers for the Australian scenario involving 2,972 unique revision hip arthroplasties for their respective leading cause for it, represent the figure for the year 2021 only, the overall data couldn't be compiled for analyses due to its vast size, and time limitations of this research.

B. <u>Globally Comparative Scenario for Knee Arthroplasty –</u>

a. On the gender-specific distribution of the knee arthroplasty procedures performed on the general patient cohort, across the examined five nations, the dominance of the female patient groups in every respective country, and on the overall perspective on the relative proportions of knee arthroplasties performed vis-à-vis their male counterparts, is found to be more prominent than that was for hip arthroplasties.

b. On an overall point-of-view for all the knee arthroplasty data accessed by this research, female patient groups constituted 57.43% of the overall numbers, while their equivalent male patient groups accounted for the remaining 42.48%.

c. On an individual nation basis, the dominance of the female patient groups in the relative proportions for arthroplasty recipients compared vis-à-vis to that of the male patient groups was the highest for Irish and American patient cohorts, wherein they constituted an overall percentage share of 61.00% and 58.50% of the overall number of knee arthroplasties performed on the respective nations.

d. The above gender-linked comparative data, thus makes it sufficiently clear that whatever the scientific journal or literature has to comment on the gender-linked demography, the actual on-ground statuses, reflect a clear case of the female populace, in greater requirements for an arthroplasty intervention for their failing hip and knee joints, with the margin of dominance being more concrete for knee arthroplasties.

e. The overall mean age of the patient cohort, irrespective of their genders, in recipients of a knee arthroplasty from any of the five nations evaluated is 67.8 years. The overall mean age of the patient cohort from these countries for the knee arthroplasty scenario is noted to be slightly less or younger than that for the hip arthroplasty scenarios.

f. The senior most mean age of the knee arthroplasty recipient groups is noted for the Swedish and British populace, irrespective of their respective genders, which was 69 and 68.9 respectively.

g. Regarding the most common or the leading cause/reason cited for primary knee arthroplasties performed globally is the osteoarthritis of the knee acting in a progressively worsening nature. This was also consistent in the five nations examined for their respective arthroplasty practices, barring the USA, wherein the individual primary indication data for any form of knee arthroplasties could be accessed.

h. Worsening of the osteoarthritis scenario of the knee was the primary cause of undergoing a primary knee replacement surgery in more than 90% of all knee arthroplasty procedures recorded, with the greatest reason proportion of osteoarthritis-led cases being established for the Australian patient cohort, wherein it accounted for 97.80% of all the indications cited as the reasons to perform a primary knee procedure.

i. Globally (based on the five nations evaluated) progressively worsening osteoarthritis was cited as the primary reason for 21,07,852 individual unique knee procedures, with an overall percentage of 97.25% of all the knee arthroplasties.

j. The issue of problematic osteoarthritis is therefore found more significantly impactful on the general QoL and functional capabilities, on its occurrence in the knees, relative in a greater sense than the hips.

k. For revision knee arthroplasties performed on the patient cohorts, across the five nations evaluated for their respective arthroplasty-related practices and outcomes, the primary leading cause for a revision knee arthroplasty is found to be variating on the region-to-region basis or on the basis of the changing patient demographics with change in geographies.

l. The leading cause for revision knee arthroplasty varied on a wide spectrum of physical conditions, ranging from 'aseptic loosening' of the prosthesis, lysis or bone decay, post-operative instability, post-operative infection and post-operative infection coupled with inflammatory reaction.

m. Amongst all of the afore-mentioned indications the relative proportion in the respective country is the greatest for the indication of post-operative infection and inflammatory reaction of the patient cohort in the USA, which made the leading cause of revision knee arthroplasty lead the charts with an overall share of 28.40% based out of 30,547 individual revision knee procedures.

6. ***Comparative Analysis of the Utilization of Various Fixation Methods for Hip / Knee Arthroplasty: -***

a. The fixation method deployed to internally fix a prostheses unit to the bone shaft is integrally critical to the general levels of postoperative outcomes of the respective patients.

b. There are four prime recognized forms of fixation methodologies that are in wide and open practice across the globe, which are – Cemented, Non-Cemented, Hybrid and Reverse-Hybrid.

c. The basic difference between a hybrid and reverse hybrid fixation method is the relative positioning of the cement component on the prosthesis module. For a hybrid fixation of a total hip prosthesis, the femoral stem is cemented into the femoral shaft, while the acetabular cavity / acetabular shell/cup is left out as a non-cemented one. For a reverse hybrid scenario of prosthesis fixation, the reverse is followed, wherein the acetabular cavity & the acetabular shell/cup are cemented, while the femoral head and stem remain non-cemented.

d. The comparative analyses of the fixation method utilization trends are captured from the databases of the prevalent arthroplasty registry databases and other related healthcare sources from the five nations which are selected for the due scrutinization and evaluation for their respective practices, and their respective distribution towards the global and the regional level of hip/knee arthroplasty numbers are tabulated and therefore presented through the following tabulation: -

Comparative Tabulation on the Utilization of the Various Fixation Methods for Hip Arthroplasty on the Patient Cohorts, from UK, AUS, IRE, USA & SWE.

SL No.	Region of Arthroplasty Data	Hip Arthroplasty Fixation Method										Unconfirmed / In-complete / Missing	Unconfirmed %	Overall Gross Total No. of Hip Arthroplasty	Actual Tracked No. of Arthroplasty for Fixation Data
		Cemented		Cementless		Hybrid		Reverse-Hybrid		Resurfacing					
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall				
1	United Kingdom & Wales	4,12,582	30.70%	4,98,529	37.10%	3,18,261	23.70%	34,797	2.60%	41,428	3.10%	38,760	2.90%	13,44,357	13,05,597
2	Australia	9,048	1.13%	2,33,665	29.21%	1,53,246	19.16%	*No Data Obtained*		19,369	2.42%	3,84,358	48.06%*	7,99,686	4,15,328
3	United States of America	36,521	3.43%	9,68,923	91%	*Missing / Non - Accessible Data*				5,935	0.55%	53,371	5.01%	10,64,750	10,11,379
4	Ireland	198	6.00%	1,977	60%	1,092	33.00%	33	1.00%	*No Data Accessible*		0		3,302	3,302
5	Sweden	2,01,432	39.40%	55,467	10.85%	11,576	2.26%	27,526	5.38%	0	0%	2,14,976	42.07%	5,10,977	2,96,001
6	India														
Cumulative Category Total		**6,59,781**	**18.80%**	**17,58,561**	**50.12%**	**4,84,175**	**13.80%**	**62,356**	**1.77%**	**66,732**	**1.90%**	**6,91,465**	**13.58%**	**37,23,072**	**30,31,607**

**The Australian Hip Arthroplasty Data as per Fixation Type were Adjusted for Modern Prostheses (prostheses in 2021 Utilization or Circulation), leading to the exclusion of legacy data, amounting to a Comparatively Higher Percent of the Overall to be Missing / Non-Reported. ; Swedish Numbers are of only 2021, remaining numbers couldn't be verified. ; Respective Percentages are Calculated out of the Overall Gross Number of Arthroplasties, unless Explicitly Specified.*

Table 6.5.12 :- ***Comparative Tabulation illustrating the Distribution of the Hip Arthroplasty procedures performed on the Patient Cohorts from the five nations evaluated for their respective Arthroplasty related practices and patient related outcomes, categorized as per the Fixation Methodologies adopted.***

Comparative Tabulation on the Utilization of the Various Fixation Methods for Knee Arthroplasty on the UK, AUS, IRE, USA & SWE Patient Cohorts.													
SL No.	Region of Arthroplasty Data	Knee Arthroplasty Fixation Method								Unconfirmed / In-complete / Missing	Unconfirmed %	Overall Gross Total No. of Knee Arthroplasty	Actual Tracked No. of Arthroplasty for Fixation Data
		Cemented		Cementless		Hybrid		Others					
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall				
1	United Kingdom & Wales	13,09,990	90.90%	48,781	3.40%	10,116	0.70%	50,606	3.50%	22,558	1.60%	14,42,051	14,19,493
2	Australia	4,45,588	45.44%	1,26,539	12.90%	1,60,292	16.34%	0	0.00%	248000*	25.29%	9,80,419	7,32,419
3	United States of America	13,44,723	89.89%	1,04,119	6.96%	47,123	3.15%			NA	NA	14,95,965	9,39,141
4	Ireland	*Knee Arthroplasty Numbers by the Fixation Method utilized were not Accessible / Obtainable from a Validated Source.**											
5	Sweden												
6	India												
Cumulative Total		31,00,301	79.12%	2,79,439	7.13%	2,17,531	5.55%	50,606	1.29%	2,70,558	6.90%	39,18,435	30,91,053
Fixation Method Breakdown of Knee Arthroplasty Numbers was not Available through a Validated Source. However, it is reported Cemented Knee Arthroplasties to have the lead over Other Fixation Methods of Knee Arthroplasties.; The US Knee Arthroplasty Data is Adjusted & Back-Tracked to Obtain the Partially Reported/Un-Reported Fixation Method Breakdown of the Arthroplasty Numbers and May Vary by +/- 10% in Reality.													

Table 6.5.13 :- ***Comparative Tabulation illustrating the Distribution of the Knee Arthroplasty procedures performed on the Patient Cohorts from the five nations evaluated for their respective Arthroplasty related practices and patient related outcomes, categorized as per the Fixation Methodologies adopted.***

A. <u>Globally Comparative Scenario for Hip Arthroplasty</u> –

a. Based on the comparative tabulations illustrating the distribution of hip arthroplasties performed across the five nations, it can be evidently seen and thereby noted that the general go-to practice in the recent years of clinical practice in those countries has been to fixate the hip prostheses unit, without the utilization of cement.

b. Non-cemented based fixation was therefore the most commonly utilized form of fixation methodology in hip arthroplasties of the general patient cohort. It was also the leading form of prosthesis fixation at the individual level for each of these countries evaluated.

c. Non-cemented or Cementless fixation alone accounted for 50.12% of all the recorded unique hip arthroplasties across these nations, irrespective of primary/revision or total/partial statuses.

d. The utilization scenario of a cementless-based hip prosthesis fixation is at its respective highest proportion for the hip arthroplasties performed on the American patient cohort, with an overall share of 91.00%, based out of 9,68,923 recorded unique hip procedures, though in reality in could be more, since the complete scenario data for the American arthroplasty practices couldn't be accessed.

e. Comparatively, cemented fixation was the second-most commonly deployed fixation methodology for fixating hip prostheses around the world, with a comparative distribution share of 18.80%, accounting for 6,59,781 individual unique hip arthroplasty procedures.

f. It is generally noted while individually evaluating the respective arthroplasty practices across these nations, that cemented hip procedures have been on a general declining trend, for quite some years now, which is primarily attributed towards the rise of high-precision surgical systems like computer-navigated surgical systems and robotic surgical systems, and also due to the concerns of cement-based systemic interaction leading to cardiac diseases and other serious conditions in some sections of the populations. The role of improved prosthesis characteristics with the advent of CoP-based hip solutions with enhanced bone resorption capabilities, over the conventional MoM and MoP solutions which generally required a cement promoted adhesive capabilities with the degenerating bone shaft, has to be credited with the globally noted decline in the cemented fixation based hip arthroplasties.

g. However, the scenario in other key regions of the world, more specifically from across the nations from the Global South and APAC regions, regarding their respective fixation methodology policies remains to be examined, since modern-day technology and implants might not be adequately available in those low-resource centres catering to a relatively large populace of patient cohorts from Tier – 2 and 3 towns and cities, notwithstanding the remotest villages.

h. While, for the hybrid vis-à-vis reverse hybrid-based fixation methodologies for hip prosthesis fixation into a hip arthroplasty scenario, the utilization of hybrid fixations is implemented in greater proportions comparatively than reverse-hybrids.

i. Overall, across the five nations evaluated, hybrid fixation was deployed for 4,84,175 unique individual hip arthroplasty procedures, which accounted for 13.80% of the overall cumulative total number of procedures recorded and thereby processed from these nations. While, reverse hybrid fixations were utilized for only 62,356 unique individual hip arthroplasty procedures, that accounts for only 1.77% of the overall number of hip arthroplasty procedures conducted.

j. Interestingly, for Australian practices it was noted that hybrid fixation was more commonly utilized than cemented fixations, outside of their general favourite of going cementless. Hybrid fixations of hip prostheses in Australia accounted for 1,53,246 unique individual hip arthroplasty procedures, which was 19.16% of all the hip procedures recorded to have been performed on the Australian patient cohort, across the Australian registry database and few other sources, thereby making it the second most commonly deployed fixation method after non-cemented methods, while cemented ones stood third in terms of relative utilization numbers.

k. Apart from the four different recognized forms of hip prosthesis fixation methodologies, there's another method, which entails a completely different story of hip arthroplasty practices and the main surgical procedure itself. The scenario around the resurfacing hip arthroplasty is discussed in the later segments of this chapter.

l. However most surprisingly, a massive number of unique hip arthroplasty records were accessed for whom relevant fixation details and other comprising pieces of information were either missing or incomplete or reported to be "unconfirmed", by the respective registry and other health care regulatory organizations. The relative proportion of hip arthroplasty procedures that are termed as "unconfirmed" or "incomplete/missing", also includes those cases which have been excluded from present databases, owing to their legacy data and irrelevance to modern-day practices.

m. The cumulative total number of such "unconfirmed" hip arthroplasty procedures as noted across the five nations is 6,91,465, which accounts for 13.58% of the overall number of hip arthroplasties, from whom their relevant is analysed in this research.

B. <u>Globally Comparative Scenario for Knee Arthroplasty –</u>

a. Unlike the case for hip arthroplasties, wherein it was noted that cementless procedures were the general favourites for implementation on the general case scenario of the patient cohorts, unless there's a specific complication linked requirement, that requires be answered through a cemented aided fixation of the hip prosthesis, cemented fixation of the knee prosthesis module is noted to be the most commonly utilized fixation method for knee arthroplasties performed globally including the five nations discussed in great detail, in this thesis work.

b. Cemented knee prosthesis fixation was performed on 31,00,301 unique individual knee arthroplasty procedures, which accounts for 79.12% of the overall cumulative total number of knee arthroplasty data, for which have been under the purview of this research probe.

c. On an individual country basis, it was for the region of United Kingdom and Wales, where cemented-based knee prosthesis fixation was utilized for the greatest proportions, comprising 13,09,990 uniquely reported individual knee arthroplasty procedures, accounting for an overall 90.90% of all the respective knee arthroplasty procedures performed on the British patient cohort (maybe a portion of the Welsh populace as well).

d. Non–Cemented and Hybrid fixations were the respective second and third-ranked fixation methods when it came to the relative comparison with the cemented fixation numbers for all the five nations evaluated.

e. A significant portion of the knee arthroplasty data could not be accessed for them being 'excluded' to preserve the 'contemporariness' of the present database and related intel sources, for the Australian knee arthroplasty. Now, what percentage of this 'excluded' data really comprised of legacy prosthesis information and those that are not so pleasant to be publicly declassified, remains to be examined for the future scope of this work.

f. Cementless fixation-based knee arthroplasties were performed on 2,79,439 individual unique knee arthroplasty procedures, which was 7.13% of all the knee arthroplasty records accessed and subsequently evaluated and assessed from the five nations.

g. The greatest number of cementless fixation-based knee arthroplasties corresponded to the Australian knee arthroplasty practices, wherein there were 1,26,539 unique individual knee arthroplasty records available for relevant evaluation of this research.

h. Comparatively, the hybrid fixation-based knee replacements are performed a lot less than the former two discussed fixation methodologies. On an overall basis, hybrid fixation-based knee replacement data was obtained or found to have been performed in reality on the patient cohorts from the evaluated nations, was 2,17,531, which accounted for 5.55% of the overall procedural volume across all these nations combined for knee arthroplasties.

i. The fixation data for Irish knee arthroplasties could not be obtained or accessed to be included in the main frame analyses processes of this research probe, which may be excused at this present moment, considering the fact that the Irish populace is the smallest of all the nations evaluated, and also for the fact that the Irish arthroplasty registry database is the newest of all, and presently operating in it very infancy stages.

7. ***Comparative Analysis of Fixation Method-based Prostheses Combination utilization scenarios for Hip Arthroplasty: -***

a. The comparative analyses of prostheses, in their combination form, and on an individual basis is of more practical sense, since a prosthesis component with a particularly suitable other component might give the best results possible in terms of postoperative stability and in terms of the general cumulative revision rate percentage scenarios across multiple timepoints in the respective post-operative window, which might not be the case if the prostheses are utilized within different combination formulae involving different subsets of components.

b. While most of the implant manufacturing companies don't recommend or approve the mixed combination or heterogenous utilization of prostheses components for obvious reasons, surprisingly some of the healthcare agencies in particular are also noted to be of the same preferences, however, the perception and practice at large is of the mixed heterogeneous combination of variety of prosthesis components with one another, for yielding the best results on the patients.

c. Subsequently, it was seen despite the notion mentioned above being in practice, a plethora of arthroplasty procedures worldwide have been performed using a heterogeneous combination of the prostheses, and interestingly, those with a heterogenous combination provided for a comparatively better result in the long-term, vis-à-vis to the homogeneous company specified combinations.

d. Especially in Swedish arthroplasty practices it was seen that the general practice has been centred around the legacy prosthesis units, which are practically 'time-tested', and mostly of heterogenous combinations, except for the leading choice, involving none of the modern-day variants of the prosthesis offerings by the implant maker quadropoly and other firms. The Swedish point-of-view behind such a rationale has been discussed to great lengths in the Swedish arthroplasty chapter of this thesis.

e. The most commonly utilized cemented femoral stem and head component for cemented fixation-based hip arthroplasties, irrespective of them being a primary or a revision one is the '*Exeter V40*' of Stryker, which has been utilized with a variety of acetabular components (cup/shell) ranges from various manufacturers.

f. Across the five nations, whose arthroplasty practices and patient-related outcome scenarios have been widely discussed through the length and widths of this thesis work, the "*Exeter V40*" femoral component is noted to have been implanted on the biggest populace, with the greatest nation wise implantation being noted for the British patient cohort, with 99,589 unique utilizations of the said prosthesis for both primary and revision hip arthroplasties performed across the United Kingdom.

g. While for the Swedish patient cohort, wherein the orthodox text-book approaches to the arthroplasty scenario are the general picture, it was their 'time-tested' prostheses combination both made by the German firm of Waldemar LINK – "*Lubinus SPII Standard*" femoral component with the "*Lubinus Cup*", that has seen the greatest number of recorded implantations on the respective patient cohort.

h. Combinedly, the aforementioned prosthesis combination was utilized for 63,432 unique hip arthroplasty procedures inclusive of primary and revision procedures, which accounted for 31.62% of all the hip arthroplasties recorded across various healthcare registries in Sweden.

i. Both the femoral components discussed above are in possession of an active ODEP rating status of 15A*, while the Lubinus Cup is rated 7A*.

j. While for cementless hip fixations, which have been implemented in greater proportions across the five countries that were evaluated and discussed in detail in this thesis work, the leading femoral stem/head was the much talked about – the "*Corail*" stem by DePuy Synthes. The "*Corail*" stem is found to have been implemented in the greatest proportions with the "*Pinnacle*" acetabular component from the same manufacturer, across the United Kingdom, Australia and Sweden.

k. The "*Corail*" femoral component and the "*Pinnacle*" acetabular component, both are presently having an active ODEP rating status, which are 10A and 15A* respectively.

l. While in the USA and Ireland, it was the "*Accolade II*" and "*Trident*", both of Stryker origin, which have seen the greatest number of utilizations for the cementless hip arthroplasty of the respective patient cohort.

m. For hybrid fixations of the hip, "*Exeter V40*" and "*Trident (Shell)*" were the most utilized prostheses combinations. For reverse hybrid applications, the "Corail" femoral component with "*Marathon*" and "*Exeter Rim-Fit*" acetabular shells/liners have been noted to be the most commonly utilized ones. However, the entire dataset for reverse hybrid-based hip arthroplasties couldn't be accessed for relevant evaluation, since such data corresponding to the nations of Australia, the USA and Ireland couldn't be obtained, even though such practice may be prevalent in the reality in those respective regions.

n. The respective scenarios of the prosthesis combinations for hip arthroplasty utilizations, across various fixation methodologies are presented through the following tabulations: -

Comparative Tabulation of the Most Commonly Utilized Prostheses Combinations for Cemented Hip Arthroplasty of the Respective Patient Cohorts from the Nations Evaluated for their Respective Arthroplasty Practices, in the Course of this Research.

SL No.	Region of Arthroplasty Data	Most Utilized Hip Prostheses							
		Name of the Prosthesis		Mfg. Company / Supplier		No. of Cases using the Prosthesis [Primary+Revision]	% of Overall using the Most Commonly Utilized Prostheses	ODEP Rating	
		Femoral Component	Acetabular Component	Femoral Component	Acetabular Component			Femoral Component	Acetabular Component
1	United Kingdom & Wales	Exeter V40	Exeter Contemporary Flanged	Stryker	Stryker	99,589	29.19%	15A*	15A*
2	Australia	Exeter V40	Contemporary	Stryker	Stryker	6,078	23.75%	15A*	15A*
3	United States of America	Summit Total Hip System		DePuy Synthes	DePuy Synthes	2,057	16.01%	7A [Cemented Version]	
4	Ireland	Exeter V40 & Trident		Stryker	Stryker	958	58.20%	15A*	Multiple Rating Status[15A* - 7A]
		Exeter V40		Stryker		1,247	96.10%		
			Exeter X3 Rimfit		Stryker	98	41.70%		10A*[E.RimFitX3]
5	Sweden	Lubinus SP II Standard	Lubinus Cup	Waldemar LINK	Waldemar LINK	63,432	31.60%	15A*	15A* / 7A*
Cumulative Total & Mean Percentage of Utilization of Most Utilized Prosthesis						1,73,459	42.36%	*US Data doesn't highlight the entire prevalent picture of the real-time arthroplasty scenario.*	

Table 6.5.14 :- ***Comparative Tabulation illustrating the Most Commonly utilized Prostheses Combination for Cemented Hip Arthroplasty of the patient cohorts from UK, AUS, USA, IRE and SWE, along with their respective ODEP Rating statuses and manufacturer/supplier details.***

Comparative Tabulation of the Most Commonly Utilized Prostheses Combinations for Non-Cemented Hip Arthroplasty of the Respective Patient Cohorts from the Nations Evaluated for their Respective Arthroplasty Practices, in the Course of this Research.

SL No.	Region of Arthroplasty Data	Most Utilized Hip Prostheses Combination							
		Name of the Prosthesis		Mfg. Company / Supplier		No. of Cases using the Prosthesis [Primary+Revision]	% of Overall using the Most Commonly Utilized Prostheses	ODEP Rating	
		Femoral Component	Acetabular Component	Femoral Component	Acetabular Component			Femoral Component	Acetabular Component
1	United Kingdom & Wales	Corail	Pinnacle	Depuy Synthes	Depuy Synthes	1,79,988	45.80%	10A	15A*
2	Australia	Corail	Pinnacle	Depuy Synthes	Depuy Synthes	61,278	22.80%	10A	15A*
3	United States of America	Accolade II & Trident Combination		Stryker	Stryker	38,154	14.10%	15A*/7A	10A
			Pinnacle		Depuy Synthes	1,04,312	32.95%		15A*
		Accolade II		Stryker		55,928	19.30%		
4	Ireland	Exeter V40 & Trident		Stryker	Stryker	958	58.20%	15A*	15A*
		Accolade II		Stryker		882	44.10%	7A*	
			Trident		Stryker	1,648	53.70%		15A*
5	Sweden	Corail	Pinnacle W / Griptionn 100	Depuy Synthes	Depuy Synthes	6,350	11.40%	10A	15A*[Pinnacle] / 10A* [Pinnacle Griptionn]
Cumulative Total & Mean Percentage of Utilization of Most Utilized Prosthesis						4,49,498	33.59%	*US Data doesn't highlight the entire prevalent picture of the real-time arthroplasty scenario.*	

Table 6.5.15 :- ***Comparative Tabulation illustrating the Most Commonly utilized Prostheses Combination for Non Cemented Hip Arthroplasty of the patient cohorts from UK, AUS, USA, IRE and SWE, along with their respective ODEP Rating statuses and manufacturer/supplier details.***

Comparative Tabulation of the Most Commonly Utilized Prostheses Combinations for Hybrid fixation based Hip Arthroplasty of the Respective Patient Cohorts from the Nations Evaluated for their Respective Arthroplasty Practices, in the Course of this Research.									
SL No.	Region of Arthroplasty Data	Most Utilized Hip Prostheses Combination							
		Name of the Prosthesis		Mfg. Company / Supplier		No. of Cases using the Prosthesis [Primary+Revision]	% of Overall using the Most Commonly Utilized Prostheses	ODEP Rating	
		Femoral Component	Acetabular Component	Femoral Component	Acetabular Component			Femoral Component	Acetabular Component
1	United Kingdom & Wales	Exeter V40	Trident (Shell)	Stryker	Stryker	1,26,367	48.83%	15A*	Multiple Rating Status[15A* - 7A]
2	Australia	Exeter V40	Trident (Shell)	Stryker	Stryker	83,616	47.13%	15A*	
3	United States of America	*No Data for Hybrid Prostheses Obtained*							
4	Ireland	Exeter V40 & Trident		Stryker	Stryker	958	58.20%	15A*	Multiple Rating Status
5	Sweden	Exeter	Trident Hemi	Stryker	Stryker	3,432	29.60%	15A*	Unrated
Cumulative Total of the Most Utilized Prostheses Combinations						2,14,373			

Table 6.5.16 :- ***Comparative Tabulation illustrating the Most Commonly utilized Prostheses Combination for Hybrid fixation based Hip Arthroplasty of the patient cohorts from UK, AUS, USA, IRE and SWE, along with their respective ODEP Rating statuses and manufacturer/supplier details.***

Comparative Tabulation of the Most Commonly Utilized Prostheses Combinations for Reverse - Hybrid fixation based Hip Arthroplasty of the Respective Patient Cohorts from the Nations Evaluated for their Respective Arthroplasty Practices, in the Course of this Research.									
SL No.	Region of Arthroplasty Data	Most Utilized Hip Prostheses Combination							
		Name of the Prosthesis		Mfg. Company / Supplier		No. of Cases using the Prosthesis [Primary+Revision]	% of Overall using the Most Commonly Utilized Prostheses	ODEP Rating	
		Femoral Component	Acetabular Component	Femoral Component	Acetabular Component			Femoral Component	Acetabular Component
1	United Kingdom & Wales	Corail	Marathon	Depuy Synthes	Depuy Synthes	17,767	84.83%	10A	13A*
2	Australia	*No Data for Hybrid Prostheses Obtained*							
3	United States of America								
4	Ireland								
5	Sweden	Corail	Exeter Rim Fit	Depuy Synthes	Stryker	2,327	8.50%	10A	10A*
Cumulative Total of the Most Utilized Prostheses Combinations						20,094			

Table 6.5.17 :- ***Comparative Tabulation illustrating the Most Commonly utilized Prostheses Combination for Reverse Hybrid fixation based Hip Arthroplasty of the patient cohorts from UK, AUS, USA, IRE and SWE, along with their respective ODEP Rating statuses and manufacturer/supplier details.***

8. ***Comparative Analysis of Fixation Method-based Prostheses Combination utilization scenarios for Knee Arthroplasty: -***

a. Unlike hip arthroplasties, the general practice globally is to cement the knee prosthesis to the femoral and tibial ends, for their respective internal fixations, and only a handful number of procedures globally, were fixated through other fixation mediums such as non-cemented, hybrid and reverse hybrid.

b. Overall, it is noted that the general preference across the nations evaluated for their respective arthroplasty practices is to preserve the cruciate ligaments unless there's a condition-specific requirement or they are too lax to support the in-coming artificial knee prostheses unit, for which they are sacrificed for a posterior stabilized implant.

c. The utilization of constrained hinged knee implants remains primarily limited to revision knee procedures of the failed primary TKAs, and on those with a highly decayed femoral shaft with a progressively worsening osteoporotic bone characteristic. These are implanted with cement and in most of the scenarios with a longer stem, to compensate for the decayed/resected bone.

d. Some of the utilization of posterior stabilized knees with longer stems and the usual constrained hinged knee prosthesis, is noted to be utilized in specific patient groups for correcting those with a diseased lower limb alignment condition as in varus and valgus deformities of the knee.

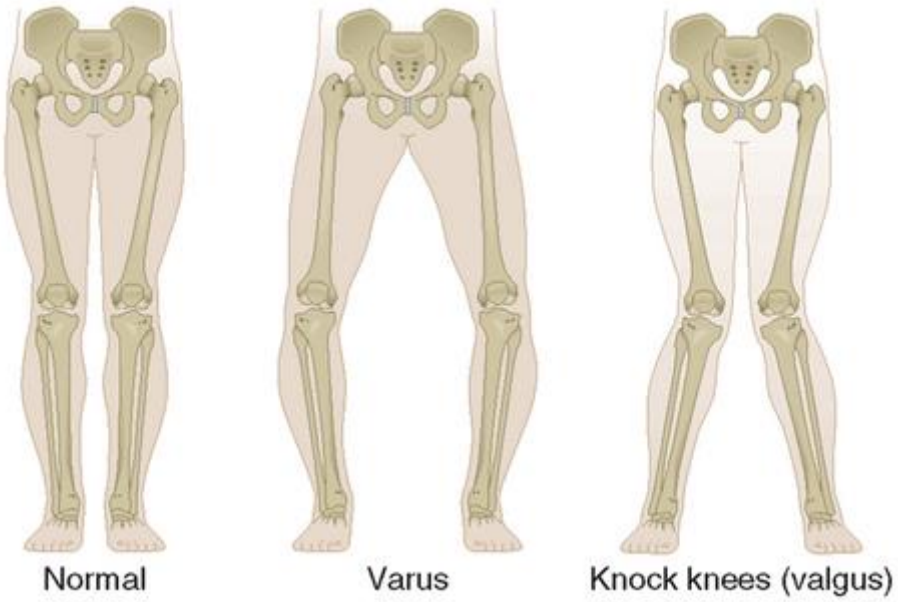


Figure 6.5.1 :- ***An illustrative image to demonstrate the crooked or diseased lower limb alignment conditions, through the Varus & Valgus deformities of the Knee.***

Image Source: - "SelectFlex: Guide to Valgus Knee Prevention - https://selectflex.com/blogs/how-to-tips/guide-to-valgus-knee-prevention".

e. The valgus knee condition is a lower limb deformity, "that exists when the bone at the knee joint is angled out and away from the main body's midline". This condition is severely impairing to the individuals having it, since it impairs the ability to bow down, to touch their ankles, while their knees are touching or 'knocking' each other. The misalignment causes further vulnerabilities to the knee from getting fractured or wearing out prematurely due to the inappropriate distribution of the additional stress placed on the knee joint, resulting in immense discomfort and instability issues, coupled with occasional to regular pain, as the person ages.

f. While, a varus deformity involves an excess inward angulation, towards the body's midline, of the knee joint.

g. For Cemented knee arthroplasties, the "*Triathlon CR*" by Stryker was the leading prosthesis unit, that had the greatest number of respective utilizations, on the patient cohorts from Australia and the USA.

h. The "Triathlon CR" had relatively fair patient-related outcomes both in terms of the observed revision rate percentages of the populace having them, and the overall post-operative QoL of the same cohort, which are discussed in great detail, in the respective chapters of the Australian and American arthroplasty practices. The said implant is reported to have been utilized for 65,194 and 58,906 unique individual knee arthroplasty procedures, irrespective of any primary or revision segregation across the two aforementioned countries.

i. While, it is the "Genesis II" total knee prostheses component, that has seen the greatest number of recorded knee arthroplasty procedures on the British patient cohort.

j. In Sweden however, the most commonly utilized knee prostheses combination in the year of 2021 comprises of the "NexGen" femoral component by Zimmer Biomet and "MBT" tibial component by DePuy Synthes, for the cemented knee arthroplasty of its respective patient cohort.

k. The following tabulation highlights the most commonly utilized knee prostheses combinations, that were deployed for the cemented knee arthroplasty of the patient cohort from the five nations, evaluated in detail, in this research: -

Comparative Tabulation of the Most Commonly Utilized Prostheses Combinations for Cemented Knee Arthroplasty of the Respective Patient Cohorts from the Nations Evaluated for their Respective Arthroplasty Practices, in the Course of this Research.									
SL No.	Region of Arthroplasty Data	Most Utilized Knee Prostheses							
		Name of the Prosthesis		Mfg. Company / Supplier		No. of Cases using the Prosthesis [Primary+Revision]	% of Overall	ODEP Rating	
		Femoral Component	Tibial Component	Femoral Component	Tibial Component			Femoral Component	Tibial Component
1	United Kingdom & Wales	Genesis II [Both Femoral & Tibial]		Smith & Nephew		90,539	28.56%	Multiple Ratings Status across all Variants[15A* to Lapsed]	
2	Australia	Triathlon CR	Triathlon	Stryker	Stryker	65,164	14.10%	15A*	13A*
3	United States of America	Triathlon CR	Triathlon	Stryker	Stryker	58,906	11.99%	15A*	13A*
4	Ireland	Triathlon TS/Attune		Stryker / Depuy Synthes		1,297	47.63%	Multiple Ratings for Triathlon ; Attune [7A*/7A/5A*/3A*/3A]	
5	Sweden	Nexgen	MBT	Zimmer Biomet	Depuy Synthes	5,830	53.00%	15A*	Unrated
Cumulative Total & Mean Percentage of Utilization of Most Utilized Prosthesis						2,21,736	31.06%		

Table 6.5.18 :- ***Comparative Tabulation illustrating the Most Commonly Utilized Knee Prostheses Combinations for the Cemented Knee Arthroplasties, performed on the patient cohorts from the five nations of UK, AUS, USA, IRE and SWE, along with their Relative Utilization Numbers, present ODEP Rating statuses and Manufacturer/Supplier firm details.***

l. For non-cemented knee arthroplasties, the "*Triathlon*" knee implant was the leading choice for the Australian and Irish patient cohorts. In contrast, for the British patient cohort, it was the "*PFC Sigma Bicondylar Knee*" implant from DePuy Synthes that was utilized in the greatest proportions than all other available implants. Both the aforementioned knee implants are presently noted to have Multiple ODEP Rating Statuses, based on a wide range of variants and sizes.

m. However, for the American and Swedish arthroplasty practices, no logically conclusive data for prosthesis utilization scenarios based on specific fixation methods could be obtained. There may be some other routes to avail them, but due to some binding limitations, those can't be pursued and therefore processed.

n. The most commonly utilized knee prostheses combinations that are utilized for the non-cemented knee arthroplasty of the involved patient cohorts from the nations, those were evaluated for their respective arthroplasty practices and are discussed within this thesis work, are presented through the following tabulation: -

Comparative Tabulation of the Most Commonly Utilized Prostheses Combinations for Non-Cemented Knee Arthroplasty of the Respective Patient Cohorts from the Nations Evaluated for their Respective Arthroplasty Practices, in the Course of this Research.									
SL No.	Region of Arthroplasty Data	Most Utilized Knee Prostheses							
		Name of the Prosthesis		Mfg. Company / Supplier		No. of Cases using the Prosthesis [Primary+Revision]	% of Overall	ODEP Rating	
		Femoral Component	Tibial Component	Femoral Component	Tibial Component			Femoral Component	Tibial Component
1	United Kingdom & Wales	PFC Sigma Bicondylar Knee	PFC Sigma Bicondylar	Depuy Synthes	Depuy Synthes	2,01,837	24.13%	Multiple ODEP Ratings across all variants of the particular Prosthesis Component identity. [15A to Unrated] for PFC Sigma Series	
2	Australia	Triathlon CR	Triathlon	Stryker	Stryker	31,364	24.40%	15A*	13A*
3	United States of America	*No Logically Conclusive Data Obtained for Prosthesis & Fixation Specific Utilization.*							
4	Ireland	Triathlon		Stryker		1,234	47.30%	Multiple Ratings for Triathlon [15A* to 3A]	
5	Sweden	*No Logically Conclusive Data Obtained for Prosthesis & Fixation Specific Utilization.*							
Cumulative Total & Mean Percentage of Utilization of Most Utilized Prosthesis						2,34,435	31.94%		

Table 6.5.19 :- ***Comparative Tabulation illustrating the Most Commonly Utilized Knee Prostheses Combinations for the Non-Cemented Knee Arthroplasties, performed on the patient cohorts from the five nations of UK, AUS, USA, IRE and SWE, along with their Relative Utilization Numbers, present ODEP Rating statuses and Manufacturer/Supplier firm details.***

o. While for hybrid knee arthroplasties, there were no unanimous leading prosthesis models across the nations, those are discussed in great detail, within this thesis.

p. For the British patient cohort, Zimmer Biomet's "Vanguard" knee prostheses, saw the greatest number of implantations, on a hybrid fixation approach, during either a primary or a revision arthroplasty procedure. The "Vanguard" knee presently has multiple ODEP rating statuses, across its wide range of configurations and sizes. The aforementioned prosthesis alone accounted for 97.39% of all the

hybrid fixation-based knee arthroplasties performed on the British patient cohort, across the United Kingdom, which amounts to 88,536 uniquely reported individual knee arthroplasty procedures.

q. While for the Australian and American patient cohorts, it was the "*Triathlon*" and the combination of "*Sigma CR*" femoral component with the "*PFC Sigma*" tibial component of DePuy Synthes origin, were the respective leading choices for hybrid fixation-based knee arthroplasties.

r. No logically conclusive data could be obtained from Swedish and Irish healthcare sources, to ascertain their hybrid fixation related practices for knee arthroplasties.

s. The overall scenario for hybrid fixation knee arthroplasties is therefore presented through the following tabulation: -

Comparative Tabulation of the Most Commonly Utilized Prostheses Combinations for Hybrid Fixation based Knee Arthroplasty of the Respective Patient Cohorts from the Nations Evaluated for their Respective Arthroplasty Practices, in the Course of this Research.

SL No.	Region of Arthroplasty Data	Most Utilized Knee Prostheses							
		Name of the Prosthesis		Mfg. Company / Supplier		No. of Cases using the Prosthesis [Primary+Revision]	% of Overall	ODEP Rating	
		Femoral Component	Tibial Component	Femoral Component	Tibial Component			Femoral Component	Tibial Component
1	United Kingdom & Wales	Vanguard	Vanguard	Zimmer Biomet	Zimmer Biomet	88,536	97.39%	Multiple ODEP Ratings for Vanguard	
2	Australia	Triathlon CR	Triathlon	Stryker	Stryker	33,753	20.60%	15A*	13A*
3	United States of America	Sigma CR	PFC Sigma	Depuy Synthes	Depuy Synthes	2,553	29.03%	15A*/10A/7A	15A / 15A*
4	Ireland	*No Logically Conclusive Data Obtained for Prosthesis & Fixation Specific Utilization.*							
5	Sweden								
Cumulative Total & Mean Percentage of Utilization of Most Utilized Prosthesis						1,24,842	49.00%		

Table 6.5.20 :- ***Comparative Tabulation illustrating the Most Commonly Utilized Knee Prostheses Combinations for the Hybrid fixation based Knee Arthroplasties, performed on the patient cohorts from the five nations of UK, AUS, USA, IRE and SWE, along with their Relative Utilization Numbers, present ODEP Rating statuses and Manufacturer/Supplier firm details.***

9. ***Comparative Scenarios of the Patient Satisfaction Levels from their Hip/Knee Arthroplasty: -***

A. Comparative Scenarios of Patient Satisfaction Levels from their Hip Arthroplasties –

a. Beyond the standardized parameters devised to capture patient's reported outcome measures, highlighting the general level of patient's own voice/opinion regarding multi-faceted parameters linked with the arthroplasty they have undergone, the basic form of their self-analysed and self-expressed satisfactory levels, is what this research feels to of relevance and practical from a common patient's point-of-view. It is practically easier to express either a satisfied or dis-satisfied status than to fill in multi-parametric data forms or answer multiple parameter questions, that sum up the general living standards and the QoL.

b. This is due to the fact that many patients without a clear idea of the purpose of PROMs, either don't participate in the overall procedure, thereby missing out on voicing their concerns/fulfilments in a standardized globally recognized and widely emphasized platform, or, they just not participate in the procedure just for the sake of it, or citing privacy-related concerns.

c. The afore-mentioned phenomenon is evidently notable, through the pre-operative vis-à-vis post-operative individual patient responses numbers across the various sets of patients reported outcome measuring parameters, that are globally in active practice, which implies a lot lesser number of linked post-operative responses, compared to the pre-operative response's numbers.

d. This gap however can be bridged by placing a simpler parameter for the patient to respond against, which might not be as scientifically relevant as the prevalent PROM tools are, but it is better to have at least some of the patient responses than nothing at all.

e. Therefore, this research hereby presents the patient reported satisfaction levels from their respective hip arthroplasties, through the following tabulation: -

Comparative Tabulation of Patient Satisfaction Levels with Total Hip Arthroplasty across the Global Patient Cohort/Nation's Evaluated for their Respective Arthroplasty Practices.														
SL No.	Region of Arthroplasty Data	Extent of Satisfaction with Total Hip Arthroplasty												Satisfaction Level for the Type of Arthroplasty undergone
		Very Satisfied		Satisfied		Neutral		Dis-satisfied		Very Dis-satisfied		Total		
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	
1	United Kingdom & Wales	*No Hip Arthroplasty Related Post-Operative Satisfaction Levels of the Respective Patient Cohort was Obtained/Available/Performed.*												
2	Australia	6,195	73.10%	1,365	16.10%	361	4.30%	175	2.10%	375	4.40%	8,471	100.00%	Primary Hip Arthroplasty
3	United States of America	*No Hip Arthroplasty Related Post-Operative Satisfaction Levels of the Respective Patient Cohort was Obtained/Available/Performed in the first place.*												
4	Ireland													
5	Sweden	19,281	60%	8,019	25%	2,667	8.01%	1,271	4.00%	800	3.00%	32,038	100.01%	Primary Hip Arthroplasty
		1,922	36.00%	1,599	30.00%	879	17%	539	10%	367	7.00%	5,306	100.00%	Revision Hip Arthroplasty
6	Germany		63.40%				28.70%		8.00%			1106 [as of 2009-10]	100.00%	Sourced from White Paper
Category Total		27,398	59.80%	10,983	23.97%	3,907	8.53%	1,985	4.33%	1,542	3.37%	45,815	100.00%	

Table6.5.21 :- ***Comparative Tabulation illustrating the General Post-Operative Patient Reported Satisfaction Levels from their undergone Total Hip Arthroplasty, performed across the five nations of UK, US, AUS, IRE and SWE.***

f. Besides the usual five nations, which have been evaluated and discussed to great lengths in this thesis work, the general level of patient-reported satisfaction level of the German patient cohort, is also represented in the above-mentioned tabulation. The overall arthroplasty practices in Germany are not included in the main-frame analysis procedure of this research primarily due to a lack of coherent and complete resources comprising of modern-day data, and partially due to linguistic issues of the sourced materials.

g. While, there were no signs of any patient-reported outcome measures, nor any signs of capturing or acknowledging patient-reported opinions of their undergone treatment in the form of hip or knee arthroplasty in quite a few nations, initially picked up which were later disqualified, due to multifarious reasons, however, the stark contrasting scenario that stands out is the absence of an active patient-reported outcome measuring or patient satisfaction level capturing mechanism/programme in the powerhouse of a country like the USA. The research doesn't completely rule out the possibility of the existence of a prevalent programme performing the aforementioned, in some regions or throughout the said country, but there were no signs of it, obtained, during various stages of investigations across various healthcare sources, during the initial stages of this research.

h. A cumulative total of 45,815 patient-reported satisfaction responses have been collected and tabulated in the above-mentioned tabulation, which might be far less than the actual number of procedures carried out in those particular nations involved, but it must be noted, that even after the existence of a full-scale patient reporting program, or a mandatory reporting criterion, such goals of capturing patient's self-reflected data for maximal number of the recipient patient cohorts on their respective prosthesis performance and QoL post-operatively, could not be attained in nations like the United Kingdom(which has a mandatory reporting criterion), and in Australia as well(with a legally supported programme/framework).

i. Based on the 45,815 responses across five plus one nations, 27,398 individual primary THA recipient patients, reported themselves to be "Very Satisfied", from their undergone arthroplasty procedure, which made up 59.80% of the total volume of the satisfaction level responses obtained. While, 10,983 patients which were 23.97% of all the responses tabulated responded to be just "Satisfied", from their undergone total hip arthroplasty procedure.

j. The overall level of patient-reported dis-satisfaction level from their total hip arthroplasty is comparatively much lower than the overall satisfaction level noted, on a comparative basis across all

the nations, and this is consistent with the individual scenarios noted in those particular nations, however since the overall responses are much lower than the actual number of procedures performed, the plausible scope of missing out, dis-satisfied populace of the arthroplasty recipients, continues to exist.

k. On the dis-satisfaction aspect, 1,985 and 1,542 patients individually reported themselves to be "Dis-satisfied" and "Very Dis-satisfied", respectively, which was 4.33% and 3.37% of the overall comparative number of satisfaction responses tabulated for total hip arthroplasties performed.

B. <u>Comparative Scenarios of Patient Satisfaction Levels from their Knee Arthroplasties</u> –

a. On the basis of the total knee arthroplasties performed on the patient cohort, across the five plus one nations, for whom, the respective patient cohort reported TKA procedure satisfaction levels are collected across various sources and tabulated as follows: -

Comparative Tabulation of Patient Satisfaction Levels with Total Knee Arthroplasty across the Global Patient Cohort/Nation's Evaluated for their Respective Arthroplasty Practices.

SL No.	Region of Arthroplasty Data	Extent of Satisfaction with Total Knee Arthroplasty												Form of Arthroplasty
		Very Satisfied		Satisfied		Neutral		Dis-satisfied		Very Dis-satisfied		Total		
		No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	No. of Cases	% of Overall	
1	United Kingdom & Wales	*No Knee Arthroplasty Related Post-Operative Satisfaction Levels of the Respective Patient Cohort was Obtained/Available/Performed.*												
2	Australia	7,795	58.50%	3,363	25.20%	1,158	8.70%	512	3.80%	504	3.80%	13,332	100.00%	Primary Knee Arthroplasty
3	United States of America	*No Knee Arthroplasty Related Post-Operative Satisfaction Levels of the Respective Patient Cohort was Obtained/Available/Performed in the first place.*												
4	Ireland													
5	Sweden	1,756	55%	874	27%	292	9.00%	204	6.00%	110	3.00%	3,236	100.01%	Primary Knee
		188	49%	109	28%	44	11%	23	6%	19	5.00%	383	100.00%	Revision Knee Arthroplasty
6	Germany		43.20%	NA	NA		38.50%		18.30%	NA	NA	1106 [as of 2009-10]	100.00%	Sourced from White Paper
Category Total		9,739	57.45%	4,346	25.63%	1,494	8.81%	739	4.36%	633	3.73%	16,951	100.00%	

Table 6.5.22 :- ***Comparative Tabulation illustrating the General Post-Operative Patient Reported Satisfaction Levels from their undergone Total Knee Arthroplasty, performed across the five nations of UK, US, AUS, IRE and SWE.***

b. On a comparative sense, a lot smaller number of responses have been gathered on a global scale for the patient-reported satisfaction levels, who have received a form of total knee arthroplasty either as a primary surgical intervention to their diseased knee joint or as a revision to their unicondylar/partially replaced knees. Compared to the 45,815 satisfaction level responses obtained for the hip arthroplasty recipients, only 16,951 similar responses could be obtained and tabulated by this research for the total knee arthroplasty recipients.

c. Out of the 16,951 responses, 9,739 individual knee arthroplasty recipients reported themselves to be "Very Satisfied", with their TKA procedure, while, 4,346 individuals were just "Satisfied" from their procedure, and their life following it. The populace reporting either a "Very Satisfied" or a "Satisfied" status, made up 57.45% and 25.63% of the overall response volume, respectively.

d. Only 739 and 633 respective individual patient groups, reported about them being "Dis-Satisfied" and "Very Dis-satisfied", from their primary TKA, and the post-operative life/health standard followed. This corresponded to 4.36% and 3.73% of the overall response volume.

e. While, 1,494 individual TKA recipients reported a "Neutral" response, that essentially implies that their respective QoL and overall functional capabilities were neither improved nor degraded, or anyway influenced, by the surgical intervention they went through for their prevailing condition.

10. ***Comparative Scenarios of the Patient Reported Outcome Measures (PROMs) scenarios for their respective Hip/Knee Arthroplasty: -***

A. ***Comparative Patient Reported Outcome Measures(PROMs) scenarios for Knee Arthroplasties*** –

a. Patient Reported Outcome Measures or PROMs formulate a very critical parameter to adjudge the overall success/failure of a singular knee arthroplasty or a collective group of knee arthroplasties performed on a particular cohort of patients, and to quantify, the net improvement margins, assessed through various pre-operative vis-à-vis post-operative parameters, that implies the general functional capabilities and the QoL of the recipient patients.

b. The essence of such a practice is endorsed by the global and regional healthcare regulatory authorities, alongside the global research community across the lines of clinical and biomedical engineering arenas, with an enhanced encouragement or push towards it, with each passing day.

c. This research opines that the patient community being the worst hit with the troubles of a worsening osteoarthritic hip or knee or a fracture condition, has to undergo a serious and ideally once-in-a-lifetime clinical intervention for their condition, involving tremendous trauma both physical and financial, so, it is rationally practical to let the end-recipients be the ultimate judge of the overall procedure. While, it is understandable, that most of the patient groups are not very well versed with the clinical jargon, therefore simplest of tools to assess their self-reflected opinions such as the satisfaction level survey, alongside the globally recognized standardized proforma-based Oxford Hip/Knee Scores and the EuroQoL based parameters must be deployed to accumulate a resourceful data regarding the overall patient reported relative success/failures of the prosthesis and overall procedure performances post-operatively vis-à-vis their promises pre-operatively.

d. This research during its detailed investigation into the prevalent arthroplasty practices across the major nations with a healthcare infra of general repute, noted that three main forms of standardized tools or questionnaire datasets are utilized to capture patient-reported outcome measures of the arthroplasty recipient patient cohorts. These three were the Oxford Hip/Knee Scores (OHS/OKS), the EuroQoL Visual Analogue Scale (EQ-VAS) and the EuroQoL-5Dimensions-5Levels (EQ-5D-5L).

e. Besides the above-mentioned trio, which are the most commonly utilized PROMs tools, there are other tools or standardized datasets that are in present practice to capture the same, which are namely the Hip Disability & Osteoarthritis Outcome Score (HOOS), Knee Injury & Osteoarthritis Outcome Score (KOOS), Patient Reported Outcome Measurement Information System 10 (PROMIS-10), The Veterans RAND 12 Item Health Survey (VR-12).

f. Different nations have different prevalent and prescribed practices to follow standardized PROMs tools, such as in the American practices, the HOOS/KOOS, PROMIS-10, and VR-12 were the ones that are in relative prominent usage, than the otherwise globally popular forms of the OHS/OKS or the EuroQoL based tools, that finds greater adoption in the European Union and APAC.

g. Some regions have modified the above-standardized protocols to their customized patient-specific requirements or utilized them in a different manner than usually they are used, as per their respective convenience and demands. This is evident from the fact that in Swedish practices, the descriptive form of the Oxford Hip/Knee score PROMs tool is utilized and circulated for capturing patient-reported outcome measures, but no question or parameter-specific score is formulated, as per the original norms of the OHS/OKS.

h. Similarly, in Indian practices, despite no specific data obtained due to multi-faceted obstacles and roadblocks, which possibly could've been bypassed had there been a larger time-frame window for this research to perform and compile, it is noted from few of governmental archives, and internal circular/notices, that the premier regulatory and advisory body in India – the 'Indian Council of Medical Research (ICMR)', was in the process of developing an Indian version of the Oxford Hip and Knee Score, and the same was in a trial and semi-pilot rollout stages across selected premium centrally funded and MoHFW run hospitals across the countries during the pre-pandemic and the initial stages of the pandemic in the years of 2020-2021, however, the end results of the programme and whether the said programme was completed or not, couldn't be ascertained due to the lack of appropriate resources.

i. On the Oxford Knee Score scale, the biggest margin of score improvement on the pre-op vis-à-vis post-op basis, was noted for the Irish patient cohort, receiving a primary knee arthroplasty, for their respective failing knees, wherein the patients posted a net mean improvement in their scores by 22.30 scores points, post-operatively than what it was for the same group, pre-operatively.

j. While for the UK-based arthroplasty practices, since no intricate and individual score data could be obtained, the only PROMs data that could be obtained by this research, was the mean pre-op vis-à-vis post-op score change, which was 17.608 score points, of the Oxford Knee Score parameter.

k. The best improvement on the EQ-5D-5L scale of PROMs is noted for the Irish patient recipients of a revision knee arthroplasty, with a net improvement margin of 0.39 score points, reported post-operatively, than the pre-operative reported scores.

l. The biggest margin of improvement in the mean pre-operative vis-à-vis post-operative EQ-VAS score, reported by the respective patient cohort, highlighting their general health standards, was by 9.77 score points, as is noted for the Australian patient cohort receiving TKA for their failing knees. For the Australian cohort, the mean pre-operative EQ-VAS score was 69.82 points [+/-18.46(S.D)], which improved to 79.59 points [+/-15.80(S.D)].

m. The KOOS/HOOS parameters have been in the process of constant evolution and therefore involve multiple versions of the same scoring protocol, in relevant practices across the globe. While in Swedish practices, the KOOS-12 methodology is utilized, the American practice involves the use of the KOOS-JR version. This stands true for the Hip modality variants (HOOS) as well, wherein HOOS-12 and HOOS-JR are utilized for PROMs capture, and is reported accordingly for Swedish and American arthroplasty outcome measurement scenarios.

n. The overall PROM captures scenarios of the respective knee arthroplasty recipient groups of patients across the five nations, which are being discussed in detail within this report, which is compiled and formulated by this research, is presented as follows: -
The following tables comprises of the respective cumulative total and mean data obtained for the following parameters
    - Oxford Knee Score.
    - EuroQoL Visual Analogue Scale [EQ-VAS].
    - EuroQoL 5Dimensions-5Levels [EQ-5D-5L].
    - Knee Injury and Osteoarthritis Outcome Score [KOOS – 12] ; KOOS – JR is presented through separate successive tabulation, due to paucity of space in the former table.

Tabulation representing the Comparative Distribution of PROMs captured through Knee Injury & Osteoarthritis Outcome Score for Joint Replacement (KOOS JR.), Patient Reported Outcome Measurement Information System-10(PROMIS-10) & The Veterans RAND - 12 Item Health Survey Score (VR-12) of the Patient Cohort undergoing Knee Arthroplasty.

SL. No.	Region of Arthroplasty Data	Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR.)				Patient Reported Outcome Measurement Information System 10 (PROMIS-10)								The Veterans RAND 12 Item Health Survey (VR-12)									
		Mean Pre-Operative Score		Mean Post-Operative Score		Mean - Pre Operative Score			Mean - Post Operative Score			Net. Change in Pre-Op vis-à-vis Post-Op Scores		Mean Pre-Operative Score				Mean Post-Operative Score				Net. Change in Pre-Op vis-à-vis Post-Op Scores	
		No. of Cases	Mean Score	No. of Cases	Mean Score	No. of Cases	Pre-Op Mental T Score	Pre-Op Physical T Score	No. of Cases	Post-Op Mental T Score	Post-Op Physical T Score	Mental T Score	Physical T Score	No. of Cases	Mental Health Component Score (MCS)	Physical Health Component Score (PCS)	No. of Cases	Mental Health Component Score (MCS)	Physical Health Component Score (PCS)	Mental Health Component Score (MCS)	Physical Health Component Score (PCS)
1	United Kingdom & Wales	*No Recognizable or Reported utilization of KOOS JR., PROMIS-10 and VR-12 as PROMs Capturing Tool for the Respective Patient Cohort, in either of Post Operative & Pre-Operative Follow-up Time Points.*																			
2	Australia																				
3	United States of America	73,847	47.9	29,347	76.3	1,09,027	49.1	40.2	46,134	51.9	48.2	2.8	8.00	49,532	52.3	32.00	20,055	56.2	43.4	3.9	11.40
4	Ireland	*No Recognizable or Reported utilization of HOOS JR., PROMIS-10 and VR-12 as PROMs Capturing Tool for the Respective Patient Cohort, in either of Post Operative & Pre-Operative Follow-up Time Points.*																			
5	Sweden	*New Version of KOOS - KOOS-12 is Utilized & Reported Separately*				*No Recognizable or Reported utilization of PROMIS-10 and VR-12 PROMs Capturing Tools for the Respective Patient Cohorts, undergoing Primary or Revision Hip Arthroplasty, across Multiple Follow-Up Timepoints in the Pre/Post-Op Period.*															
TOTAL		73,847	47.9	29,347	76.3	1,09,027	49.1	40.2	46,134	51.9	48.2	2.8	8	49,532	52.3	32	20,055	56.2	43.4	3.9	11.4

Table 6.5.23 :- ***Comparative tabulation illustrating the Patient Reported Outcome Measures (PROMs) scenarios for the Global Knee Arthroplasty recipients, categorized as per the Mean Pre-Operative Scores and Post-Post-Operative Scores, with their Relative Net Change in the Score on Pre-Op vis-à-vis Post-Op basis, across the VR-12, KOOS-JR and PROMIS-10 methodologies of PROMs capturing and reporting.***

Tabulation representing the Comparative Distribution of Oxford Knee Score (O.K.S), EuroQoL Visual Analogue Scale (EQ-VAS), EuroQoL 5-Dimensions-5-Levels (EQ-5D-5L) & Knee Disability and Osteoarthritis Outcome Score - 12 (KOOS-12) based Patient Reported Outcome Measures(PROMs) of the Global Patient Cohort undergoing Knee Arthroplasty.

Sl. No.	Region of Arthroplasty Data	Regional Standard of PROMs Scale/Parameter for Knee Arthroplasty	Oxford Knee Score (O.K.S)					EuroQoL Visual Analogue Scale (EQ-VAS) / EuroQoL-5 Dimensions-5 Levels (EQ-5D-5L)							Knee Injury and Osteoarthritis Outcome Score (KOOS - 12)											
			No. of Cases [Pre-Op]	Mean - Pre Operative Score +/- S.D	No. of Cases [Post-Op]	Mean - Post Operative Score	Mean Pre-Op vis-à-vis Post-Op Change	No. of Cases [Pre-Op]	Mean - Pre Operative Score [EQ-VAS]	Mean Pre-Operative Score [EQ-5D-5L]	No. of Cases [Post Op]	Mean - Post Operative Score [EQ-VAS]	No. of Cases	Mean Post-Operative Score [EQ-5D-5L]	Mean Pre-Operative vis-à-vis Post-Operative Change [EQ-VAS]	Mean Pre-Op vis-à-vis Post-Op Change [EQ-5D-5L]	No. of PROMs Responses Captured Pre-Operatively	No. of PROMs Responses Captured Post-Operatively	Assessment of Pain		Assessment of Activities of Daily Living (ADL)		Assessment of Quality of Life (QoL)	
																			Pre-Operative Pain Score (+/- S.D)	Post-Operative Pain Score (+/- S.D)	Pre-Operative ADL Score (+/- S.D)	Post-Operative ADL Score (+/- S.D)	Pre-Operative QoL Score (+/- S.D)	Post-Operative QoL Score (+/- S.D)
1	United Kingdom & Wales	OKS / EQ-VAS / EQ-5D-5L [For Primary]	32,089		2,612		17.608	32,089			2,307		2,497		8.033	0.354								
		For Revision OKS / EQ-VAS / EQ-5D-5L			101		14.248				95		101		7.926	0.275								
2	Australia	OKS / EQ-VAS / EQ-5D-5L	21,087	22.42 (+/- 8.34)	13,354	37.59 (+/- 7.97)	15.17	21,087	69.82 (+/- 18.46)		13,321	79.59 (+/- 15.80)			9.77									
3	United States of America	HOOS JR., PROMIS-10, VR-12	*PROMs Data captured via HOOS JR., PROMIS-10 and VR-12 is enclosed separately due to paucity of space.*																					
4	Ireland	OHS / EQ-VAS / EQ-5D-5L	2,548	17.8	334	40.1	22.3	1,982		0.36			1,982	0.74		0.38								
		For Revision OHS / EQ-VAS / EQ-5D-5L	154	13.8	96	32.2	58	116		0.28			61	0.67		0.39								
5	Sweden	EQ-VAS/EQ-5D-5L/KOOS-12 [For TKA]	*Descriptive Oxford Hip Parameters are Collected as Patient Reported Outcome Measures, and are Reported accordingly; without the Formulation of any relevant Oxford Hip Scores.*					3,458	65 (+/- 22.01)		3,458	76 (+/- 19.00)					2,878	2,878	38 (+/-15.00)	80 (+/- 20.10)	35 (+/- 17.00)	76 (+/- 21.02)	21 (+/- 13.01)	67 (+/- 23.00)
		EQ-VAS/EQ-5D-5L/KOOS-12 [For UKA]						391	63 (23.02)		391	76 (+/- 19.00)					352	352	39 (+/- 15.00)	77 (+/- 21)	39 (+/- 16.02)	76 (+/- 21.11)	22 (+/- 13.00)	65 (+/- 23.11)
	TOTAL		55,878	18.006	16,497	36.63	25.4652	59,123	65.94	0.32	19,572	77.19	4,641	0.705	8.576	0.34975	3,230	3,230	38.5	78.5	76	76	21.5	66

PROMs Data is presented for the latest available year of PROMs record ; The values of Pre-Op & Post-Op PROMs values of Different Types, with their Mean Differences, are either the only reasonable data accessed or the Highest Pre-Post Change Value obtained across any time point in the Postoperative period is considered during the Research Evaluation Process. ; Blank Cells indicate either no corresponding data was Available/Accessible, or no such suitable data has been published. ; No relevant data pertaining to EQ-5D index PROMs from Australian Patient Cohort receiving TKA & No PROMs metric of any form was obtainable for the same cohort receiving UKA. ; Only the Mean Change in PreOp vis-a-vis PostOp PROMs scores was available for the UK Patient cohort, through NHS Digital / NJR cited poor response rates for their non publication of PROMs data, / NJR PROMs weren't accessible either.

Table 6.5.24 :- ***Comparative tabulation illustrating the Patient Reported Outcome Measures (PROMs) scenarios, for the Global Knee Arthroplasty recipients categorized as per the Mean Pre-Operative Scores and Post-Post-Operative Scores, with their Relative Net Change in the Score on Pre-Op vis-à-vis Post-Op basis, across the Oxford Knee Score (OKS), Knee Injury and Osteoarthritis Outcome Score (KOOS-12), EuroQoL Visual Analogue Score (EQ-VAS), EuroQoL 5Dimensions-5Levels (EQ-5D-5L) methodologies of PROMs capturing and reporting.***

B. <u>Comparative Patient Reported Outcome Measures (PROMs) scenarios for Hip Arthroplasties</u> –

a. On similar notes, the comparative tabulation for the patient-reported outcome measure or PROMs scenarios, as reported by the hip arthroplasty recipient patient cohort, across the nations which are being discussed in detail within this thesis work is compiled and formulated.

b. The various forms of PROMs metric in wide and active utilizations to capture patient reported responses on their functional statuses and general health standard pre and post an arthroplasty procedure, requires prior licensing from the parent authorities, as far as an official usage policy is concerned.
For Example – the PROMIS-10 is licensed and distributed by the PROMIS-10 Health Corporation ; EQ-VAS/EQ-5D-5L are licensed and distributed for open usage by the EuroQoL Group; OHS/OKS by the concerned authority at Oxford University.

c. For hip arthroplasties, the relevance of the Oxford Hip Score as a crucial parameter to adjudge the stage of hip functionality deterioration, and the general ability of the person to perform daily activities, is noted to be comparatively more, than that of the Oxford Knee Score. This is due to the fact, that nearly most of the nations that were initially evaluated but not discussed in detail, and even for those which are being evaluated and discussed in great detail, within this thesis, Oxford Hip Score is noted to be a very common parameter, utilized by the performing surgeons and clinicians to adjudge the patient's capabilities and condition pre-operatively and post-operatively in greater proportions, if not utilizing it as its intended purpose of capturing meaningful patient reported opinions on their hip arthroplasty and implant performance on their overall living and functionality standards.

d. In Swedish practices, the Oxford Hip parameters are utilized and the patient-reported responses to those set of parameters are regularly collected and reported accordingly, across its registry database and other sets of regulatory literature, however without the formulation of any practical relevant Oxford Hip Scores, which would be otherwise generated, if it was used in the prescribed formats. The descriptive form of the Oxford hip PROMs parameter still stands out as a very critical parameter to assess a patient's life after a hip arthroplasty.

e. Besides the OHS, the other set of PROMs tools that are actively utilized are EQ-VAS, EQ-5D-5L and the HOOS-JR/HOOS-12.

f. The greatest margin of pre-operative vis-à-vis post-operative change in the patient-reported Oxford Hip Scores, was noted for the Irish patient cohort, undergoing a primary hip arthroplasty, for whom the net mean pre-op vis-à-vis post-op change was 25.1 score points.

g. For the Irish cohort, the mean pre-operative OHS was 16.7 which improved drastically to 41.8 as the mean post-operative OHS.

h. The second-best improvement is noted for the British hip arthroplasty recipients, wherein a net mean pre- to post-change of 21.941 points is noted.

i. The lowest margin of OHS linked pre-op vis-à-vis post-op change was noted for the revision hip arthroplasty recipients in the United Kingdom, posting a change of 17.293.

j. While, for EQ-VAS-based patient-reported outcome measures, Swedish primary total hip arthroplasty recipients posted the greatest margin of improvement in their EQ-VAS scores by 27.11 points, highlighting a remarkable improvement in the relative health standards and the QoL of the respective patient cohort, post-operatively to a primary THA based intervention.

k. The overall scenario of the wide variety of the PROM-based hip arthroplasty recipient responses are sourced, compiled and tabulated in the following tabulations: -

Tabulation representing the Comparative Distribution of Oxford Hip Score, EuroQoL Visual Analogue Scale, EuroQoL 5-Dimensions-5-Levels Index and Hip Disability and Osteoarthritis Outcome-12 Score (HOOS-12) for Hip Arthroplasty performed on the Global Patient Cohort.

Sl. No.	Region of Arthroplasty Data	Regional Standard of PROMs Scale/Parameter for Hip Arthroplasty	Oxford Hip Score (O.H.S)					EuroQol. Visual Analogue Scale (EQ-VAS) / EuroQoL-5-Dimensions-5-Levels (EQ-5D-5L)							Hip Disability and Osteoarthritis Outcome Score (HOOS - 12)							
			No. of Cases	Mean - Pre Operative Score +/- S.D	No. of Cases	Mean - Post Operative Score	Mean Pre-Op vis-à-vis Post-Op Change	No. of Cases	Mean - Pre Operative Score [EQ.VAS]	Mean Pre-Operative Score [EQ-5D-5L]	No. of Cases	Mean - Post Operative Score [EQ-VAS]	Mean Post-Operative Score [EQ-5D-5L]	Mean Pre-Operative vis-à-vis Post-Operative Change [EQ.VAS]	Mean Pre-Op vis-à-vis Post-Op Change [EQ-5D-5L]	No. of PROMs Responses Captured Pre-Operatively	No. of PROMs Responses Captured Post Operatively	Assessment of Pain		Assessment of Activities of Daily Living (ADL)		Assessment of Quality of Life (QoL)	
																		Pre-Operative Pain Score (+/- S.D)	Post Operative Pain Score (+/- S.D)	Pre-Operative ADL Score (+/- S.D)	Post Operative ADL Score (+/- S.D)	Pre-Operative QoL Score (+/- S.D)	Post-Operative QoL Score (+/- S.D)
1	United Kingdom & Wales	OHS / EQ-VAS / EQ-5D-5L [For Primary]	30,175		2,621		21.941	30,175			2,384					*No Provision / Standardization for Hip Disability and Osteoarthritis Outcome Score (HOOS - 12) Parameter to be used for the PROMs Capture of the Hip Arthroplasty Recipients.*							
		For Revision OHS / EQ-VAS / EQ-5D-5L			116		17.293																
2	Australia	OKS / EQ-VAS / EQ-5D-5L	13,409	20.69 (+/-8.92)	8,484	41.24 (+/-.7.44)	20.55	13,418	66.50 (+/-20.07)		8,461	80.48 (+/-16.24)		13.98									
3	United States of America	HOOS JR., PROMIS-10, VR-12																					
4	Ireland	OHS / EQ-VAS / EQ-5D-5L	2,980	16.7	268	41.8	25.1	2,443		0.3	1,264			0.42									
		For Revision OHS / EQ-VAS / EQ-5D-5L	267	17.3	22	37	19.7	207		0.28	120			0.35									
5	Sweden	EQ-VAS/EQ-5D-5L/Descriptive Oxford Score/HOOS-12	*Descriptive Oxford Hip Parameters are Collected as Patient Reported Outcome Measures, and are Reported accordingly, without the Formulation of any relevant Oxford Hip Scores. Detailing in this regard shall be discussed separately, subject to critical importance and relevance to this Research Probe.*					8,664	47.26 (+/- 13.07)	0.64 (+/- 0.13)	8,664	74.37 (+/- 15.15)	8,664	0.87 (+/- 0.12)	27.11	0.23	3,210	5,924	31 (15.00)	83(21.00)	37 (18.00)	82 (20.00)	21 (14.00)	75 (23.01)
		EQ-VAS / EQ-5D-5L / Descriptive Oxford Score for Revision Hip Arthroplasty						1,610	51.27 (+/- 15.87)	0.68 (+/- 0.15)	5,338	63.74 (+/- 18.37)	5,338	0.79 (+/- 0.16)	12.47	0.11							
6	India	*ICMR led Indian Equivalent of OHS is set to be in development. ; OHS otherwise maybe in Use,Subject to Availability]*	*ICMR Indian EQ-VAS / EQ-5D Index Developed & Rolled Out on Pilot basis on Selected Premium Govt. Hospitals & Institutes, as of 2020.*																				
TOTAL			46,831	18.23	11,511	40.013	20.9168	56,517	55.01	0.475	26,231	72.863	16,536	0.6956	16.77025	0.2775	3,210	5,924						

PROMs Data is presented for the latest available year of PROMs record ; The values of Pre-Op & Post-Op PROMs values of Different Types, with their Mean Differences, are either the only reasonable data accessed or the Highest Pre-Post Change Value obtained across any time point in the Postoperative period is considered during the Research Evaluation Process. ; Sweden utilized Oxford Hip Score parameters as a separate PROMs tool to identify Patient Outcomes, without exactly using OHS or generating/reporting/publishing OHS Scores ; Blank Cells indicate either no corresponding data was Available/Accessible, or no such suitable data has been published.

The following tables comprises of the respective cumulative total and mean data obtained for the following parameters

- Oxford Hip Score.
- EuroQoL Visual Analogue Scale [EQ-VAS].
- EuroQoL 5Dimensions-5Levels [EQ-5D-5L].
- Hip Disability and Osteoarthritis Outcome Score [HOOS – 12] ; HOOS – JR is presented through separate successive tabulation, due to paucity of space in the former table.

Table 6.5.25 :- ***Comparative tabulation illustrating the Patient Reported Outcome Measures (PROMs) scenarios, for the Global Knee Arthroplasty recipients categorized as per the Mean Pre-Operative Scores and Post-Post-Operative Scores, with their Relative Net Change in the Score on Pre-Op vis-à-vis Post-Op basis, across the Oxford Hip Score (OHS), Hip Disability and Osteoarthritis Outcome Score (HOOS-12), EuroQoL Visual Analogue Score (EQ-VAS), EuroQoL 5Dimensions-5Levels (EQ-5D-5L) methodologies of PROMs capturing and reporting.***

Tabulation representing the Comparative Distribution of PROMs captured through Hip Disability & Osteoarthritis Outcome Score for Joint Replacement (HOOS JR.), Reported Outcome Measurement Information System-10 (PROMIS-10) & The Veterans RAND-12 Item Health Survey Score (VR-12) for Hip Arthroplasty. — *Patient*

Sl. No.	Region of Arthroplasty Data	Hip Disability & Osteoarthritis Outcome Score for Joint Replacement (HOOS JR.)				Patient Reported Outcome Measurement Information System 10 (PROMIS-10)						The Veterans RAND 12 Item Health Survey (VR-12)							
		Mean - Pre Operative Score		Mean - Post Operative Score		Net. Change in Pre-Op vis-à-vis Post-Op Scores	Mean - Pre Operative Score		Mean - Post Operative Score		Net. Change in Pre-Op vis-à-vis Post-Op Scores	Mean - Pre Operative Score				Mean - Pre Operative Score		Net. Change in Pre-Op vis-à-vis Post-Op Scores	
		No. of Cases	Score	No. of Cases	Score		No. of Cases	Mental T Score	Physical T Score	Mental T Score	Physical T Score	No. of Cases	Mental Health Component Score (MCS)	Physical Health Component Score (PCS)	No. of Cases	Mental Health Component Score (MCS)	Physical Health Component Score (PCS)	Mental Health Component Score (MCS)	Physical Health Component Score (PCS)
1	United Kingdom & Wales	*No Recognizable or Reported utilization of HOOS JR., PROMIS-10 and VR-12 as PROMs Capturing Tool for the Respective Patient Cohort, in either of Post Operative & Pre-Operative Follow-up Time Points.*										30,043	51.2	30.9	11,234	56.1	45.5	4.9	14.6
2	Australia																		
3	United States of America	45,059	47.9	17,422	85.6	37.7	63,624	48.4	39.3	26,275	52.4	49.7	4	10.4					
4	Ireland	*No Recognizable or Reported utilization of HOOS JR., PROMIS-10 and VR-12 as PROMs Capturing Tool for the Respective Patient Cohort, in either of Post Operative & Pre-Operative Follow-up Time Points.*																	
5	Sweden	HOOS-12 (The Newer Version of HOOS PROMs is Utilized and Reported)				*No Recognizable or Reported utilization of PROMIS-10 and VR-12 PROMs Capturing Tools for the Respective Patient Cohorts, undergoing Primary or Revision Hip Arthroplasty, across Multiple Follow-Up Timepoints in the Pre/Post-Op Period.*													

Table 6.5.26 :- ***Comparative tabulation illustrating the Patient Reported Outcome Measures (PROMs) scenarios for the Global Hip Arthroplasty recipients, categorized as per the Mean Pre-Operative Scores and Post-Post-Operative Scores, with their Relative Net Change in the Score on Pre-Op vis-à-vis Post-Op basis, across the VR-12, HOOS-JR and PROMIS-10 methodologies of PROMs capturing and reporting.***

l. The globally acknowledged interpretation reference scale for each of these PROMs parameters are affixed as follows, for the ready reference of the presented values, and to interpret their relative implications whether positive or negative.

m. The EuroQoL VAS couldn't be affixed since it is basically a form with a scoring line from 0 (indicating worse possible health) to 100 (best possible health), where the patient is required to mark their response for their prevalent overall health standard/quality, on the 0-100 scale. While, the EQ-5D-5L involves a similar marking scheme, for each of the responses presented by the patients, like that of the OHS/OKS, however, it is too expanse to be illustrated within this thesis.

Hip Disability & Osteoarthritis Outcome Score (HOOS) Interpretation Table		
HOOS JR. Scoring Instruction/Criterion		
SL No.	**Raw Summed Score (0-24)**	**Interval Score (0 - 100 Scale)**
1	0	100
2	1	92.34
3	2	85.257
4	3	80.55
5	4	76.776
6	5	73.472
7	6	70.426
8	7	67.516
9	8	64.664
10	9	61.815
11	10	58.93
12	11	55.985
13	12	52.965
14	13	49.858
15	14	46.652
16	15	43.335
17	16	39.902
18	17	36.363
19	18	32.735
20	19	29.009
21	20	25.103
22	21	20.805
23	22	15.633
24	23	8.104
25	24	0

Knee Injury & Osteoarthritis Outcome Score (KOOS) Interpretation Table		
KOOS JR. Scoring Instruction/Criterion		
SL No.	**Raw Summed Score (0-28)**	**Interval Score (0 - 100 Scale)**
1	0	100
2	1	91.975
3	2	84.6
4	3	79.914
5	4	76.332
6	5	73.342
7	6	70.704
8	7	68.284
9	8	65.994
10	9	63.776
11	10	61.583
12	11	59.381
13	12	57.14
14	13	54.84
15	14	52.465
16	15	50.012
17	16	47.487
18	17	44.905
19	18	42.281
20	19	39.625
21	20	36.931
22	21	34.174
23	22	31.307
24	23	28.251
25	24	24.875
26	25	20.941
27	26	15.939
28	27	8.291
29	28	0

Table 6.5.27 :- ***Tabulations illustrating the Globally Accredited Hip Disability and Osteoarthritis Score (HOOS) and Knee Injury and Osteoarthritis Score (KOOS) Scoring Criterion and their Interpretation Reference Ranges.***
Note: - The column for "Raw Summed Score" represents the possible scores a patient could possibly attain when responding for HOOS/KOOS PROMs, while the "Interval Score" represents the actual reference range of scoring.

Universal Grading Parameter for Oxford Hip Score		
SL No.	**Score**	**Grading Indication**
1	Score 0 to 19	May indicate Severe Hip Arthritis. It is highly likely that the Patient may very well require some form of surgical intervention of an Orthopedic Surgeon.
2	Score 20 to 29	May indicate Moderate to Severe Hip Arthritis. Consultation with an Orthopedic Surgeon for general assesement & X-Ray should be considered.
3	Score 30 to 39	May indicate Mild to Moderate Hip Arthritis. Consider a consultation with an Orthopedic Surgeon for general assesement & X-Ray should be considered, for Benefit from Non-Surgical Treatment involving Weight-Loss, Exercise & Anti-Inflammatory Medications.
4	Score 40 to 48	Indicates a Satisfactory Joint Function & therfore No Requirement of any Formal Treatment.

Universal Grading Parameter for Oxford Knee Score		
SL No.	**Score**	**Grading Indication**
1	Score 0 to 19	"May indicate Severe Knee Osteoarthritis. It is highly likely that the Patient may very well require some form of surgical intervention of an Orthopedic Surgeon."
2	Score 20 to 29	"May indicate Moderate to Severe Knee Arthritis. Consultation with an Orthopedic Surgeon for general assesement & X-Ray should be considered."
3	Score 30 to 39	"May indicate Mild to Moderate Knee Arthritis. Consider a consultation with an Orthopedic Surgeon for general assessment & X-Ray should be considered, for Benefit from Non-Surgical Treatment involving Weight-Loss, Exercise & Anti-Inflammatory Medications."
4	Score 40 to 48	Indicates a Satisfactory Joint Function & therfore No Requirement of any Formal Treatment.

Table 6.5.28 :- ***Tabulations illustrating the Globally Accredited and Utilized Oxford Hip Score (OHS) and Oxford Knee Score (OKS) Scoring Criterion and their Interpretation Reference Ranges.***

11. *Comparative Scenarios of the Resurfacing Hip Arthroplasty and Related Responses: -*

a. Resurfacing Hip Arthroplasty was launched as the next big thing in the domain of hip arthroplasties, by the major global implant manufacturers, through their respective resurfacing femoral heads. However, in all possibilities, the first one to launch a prosthesis and a whole new paradigm of hip arthroplasty approaches was done by DePuy Synthes (a Johnson & Johnson company), through their "*ASR*" resurfacing hip prosthesis.

b. The "*ASR*" resurfacing hip prosthesis was launched in 2008 primarily in Europe, taking advantage of the then-existent pre-MDR era regulations, which were of relatively loose magnitude than the present stringent policies in place through the enactment of the MDR in the EU. Subsequently, it was launched for clinical and commercial utilizations in Australia and a few other nations. The prosthesis launch

was fueled through an intense campaign and all-stakeholders, an outreach programme by DePuy, to promote their product and the new technique of arthroplasty/implant and to introduce the resurfacing technique to orthodox and fresher arthroplasty practicing surgeons worldwide.

c. The "*ASR*" was promoted on terms of easier post-operative life through much lesser bone resection than the existent conventional methods, which is evident from the fact that "*ASR*" only substituted a problematic femoral head with a partial shaft opening for the head axle to fit in, while conventional total hips involve the complete resection of the femoral head and a significant portion of the subtrochanteric region up to the greater trochanter, with deeper shafts into the femur bone, for the placement of the femoral stem.

d. The "*ASR*" resurfacing hip was a MoM-based prosthesis, and given the widescale campaign and faster-than-usual consumption for clinical utilization numbers of the ASR, than other prostheses, many manufacturers/ suppliers and turnkey brands were drawn into a snowballing rat race to launch a resurfacing prosthesis, outpacing the others, to capture a newly opening vertical / horizon in the global arthroplasty domain.

e. In response to DePuy's "*ASR*", various other major implant makers came up with their versions of resurfacing prostheses, and surgical techniques, such as the "*Birmingham Hip Resurfacing*" or "*BHR*" resurfacing prostheses, which though was in selected utilization in niche cases, was licensed/taken up by Smith & Nephew, for widescale roll-out, as their answer to the ASR. Similarly, many other implants which were either in very limited utilization in the general cohort, or were commercially available but not clinically implemented, started to get implanted in greater proportions for the non-complicated procedures during the period of 2008-2010s.

f. While the "*ASR*" in its design aspects, was quite revolutionary, compared to other available options, however, the end results were not at all favorable to the "*ASR*"'s credit, across the global cohort. This is evidently presented across the various prostheses utilization and related post-operative revision rate scenarios presented for the various country-specific arthroplasty-related practices, within this thesis.

g. However, all of the promises of answering all of the existent time-bound constraints of prostheses performance, such as prosthesis wearing, took a turn for worse, giving rise to the second most critical hip arthroplasty-based health hazard, in a very short span of the historical window, after the 3M's Capital hip's debacle. However, the Capital hip fiasco was largely limited to the United Kingdom, whereas "*ASR*" was in large usage all across the globe, except for the USA, wherein it still lacked USFDA clearance, which stood pending by the time, the failure stories started to come up.

h. The manufacturer/supplier organization, 'DePuy Synthes', initially attempted a textbook approach of shredding off their part of the shared responsibilities in terms of prosthesis outcome scenarios in the patients, wherein these were implanted, citing, 'improper implantation' or surgical inaccuracy of the performing surgeons, to be the reason for such elevated revision rates, sooner than expected failures, instability, post-operative periprosthetic fracture and most importantly the release of metallic particulate debris into the mainstream anatomy of the patient, that caused severe blood metallosis on the recipient patients, confirmed through their respective serum B[Co] or blood cobalt levels.

i. Various legacy prostheses design and utilization consultants of DePuy Synthes claimed that the implant release was by far too hurried, bypassing all the existent in-house quality control protocols and addressing the red flags raised by the testing, designing and clinical consultants.

j. The rise of the resurfacing and MoM-based total hip prostheses in general implementations, was, therefore, a very brief and short-lived one, though not all resurfacing hips in global circulation as of

the period of 2008 – 2010s or later faced the heat of similar magnitude, which "*ASR*" faced, nor all of MoM prostheses combinations were taken off the markets, and withdrawn/banned from clinical implementations. This is evident by the fact that "*BHR*" hips at the peak of its time was seen as a prime rival to the "*ASR*", though according to some sources, being older than the "*ASR*" in the open market, despite facing similar sort of unusual rates of revisions across some of the patient groups in all (or at least some) of the major nations, continued its operation though severely limited to as late as 2021.

k. In true sense, possibly "*BHR*" was/is the only resurfacing hip with the longest commercial operational period, amidst all the concerns in nearly most of the major nations, with other major resurfacing hips such as – "*ASR*" (DePuy Synthes), "*Durom*" (Zimmer Biomet), "*Cormet/Cormet 2000 HAP*" (Corin Group), "*Conserve Plus*" (Wright Medical – now 'Stryker') etc., either getting 'withdrawn' by their respective manufacturing companies citing 'commercial reasons', or have faced complete banning in nations like that of Australia and India.

l. In the Indian context, the matter of "*ASR*" implant failures took a faster and more concrete steam than most other health concerns, with various state-level regulatory authorities stepping in to probe the revision case scenarios, while the apex body of healthcare decision-making of the Government of India(GoI)'s Ministry of Health and Family Welfare(MoHFW), appointed a high-level investigative committee involving representative from all the stakeholders involved in the fiasco, which after a thorough and relatively prompt delegation, that submitted its primary investigation and further course correction recommendatory consolidated report to the MoHFW.

m. The primary corrective recommendation suggested by the central expert committee that the parent implant maker organization- DePuy Synthes (M/S. Johnson & Johnson Pvt Ltd), also referred hereon as 'J&J', were to compensate the recipient patients or the next in kin (for the deceased) a compensatory sum of INR 20 Lacs and separate hospitalization costs for them to undergo revision surgery to remove the faulty piece of implant for a safer alternative. However, this primary recommendation for compensation to the patients was further re-enhanced to a compensatory sum ranging from INR 30 Lacs to INR 1.20 Crore, apart from non-pecuniary damages, within 15 days of the issuance of the official governmental order circular.

n. The company officially declared a figure of an unused number of ASR units left with them/they withdrew from the market, but the number of units in secondary markets in remote towns and across various tertiary vendors is presently implausible to determine by this research, due to lack of relevant resources in this regard.

o. A reconciliation of the order from judicial benches was attempted by the manufacturing firm in India, with J&J approaching the Delhi High Court challenging the government's order to compensate patients, and also appealed against the CDSCO (Central Drugs Standard Control Organization - India's premier national regulatory body for pharmaceutical, medical devices and cosmetics)'s initial orders, citing their intention of only paying INR 25 Lac to each of the patients. However, the Supreme Court of India in a separate plea matter, gave its supreme seal of accreditation to the government's recommendation, including the compensation amount and disposed of the matter.

p. However, unlike many other nations, who identified and resolved the matter within comparatively shorter timelines, since the first incidences of the exceedingly higher rate of revisions, or maybe shortly post J&J's global withdrawal of the product, the overall investigative scenario in India continued longer than most other nations, with the entailing legal battle, further delaying the patient-centric compensation process, to as late as 2019.

q. Comparatively, Australia was the first to make bold steps to compel J&J to accept their faults withdraw the said products from further commercialization, and participate in the patient compensatory programmes as devised by the TGA authorities in collaboration with the Federal Government of Australia.

r. While, in the USA patients as much as 8,000 in strength sued the parent company for their faulty implants, which agreed to pay damages of $ 2.5 billion to the compromised and troubled US citizens.

s. As of the present day, across the nations those are evaluated during the process of this research probe, the utilization of resurfacing hip arthroplasties is found to have been severely marginalized and limited only to the very young subset of patient groups, possibly for the sake of reason, they are 'expected to live' long enough to undergo further revision surgeries or at least be able to 'withstand/bear' the general level of trauma.



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News / India / 'Johnson & Johnson buried key facts on faulty hip implant surgeries, kept regulator in dark'

Premium

'Johnson & Johnson buried key facts on faulty hip implant surgeries, kept regulator in dark'

The report by a government panel states that over 3,600 patients with the faulty implants remain untraceable and that at least four deaths have been reported from those who underwent surgeries using these devices.

Written by Kaunain Sheriff M | Follow
New Delhi | Updated: August 25, 2018 00:39 IST

NewsGuard

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Broken completely: Vijay Vajhala, who had revision surgery. (Express Photo/Kaunain Sheriff M)

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BEST OF EXPRESS

Figure 6.5.2 :- ***Excerpts from a Indian News daily reporting about the practice of Implant Manufacturer driven Suppression of 'Key Facts' and Information from the Regulatory bodies in India. – Exhibit 1.***

The committee, chaired by Dr Arun Agarwal, ex-Dean and Professor of ENT, Maulana Azad Medical College, New Delhi, has recommended that J&J be made liable to pay at least Rs 20 lakh to each affected patient, and that the reimbursement programme for revision surgeries should continue until August 2025.

The report's findings constitute the first official indictment in India against J&J, which imported and sold ASR XL Acetabular Hip System and ASR Hip Resurfacing System in the country — these devices were globally recalled in 2010.

The committee concluded: "…the ASR hip implants were found to be faulty, which resulted in higher revision surgeries"; the "…accelerated wear of metal on metal implant leads to higher levels of cobalt and chromium in the blood which lead to toxicity… these metal ions damage tissues and further damage body organs" and "may also cause localised and systematic health problems".

All of this, the panel found, "results in increased pain and decreases mobility affecting their family and social life" and has "a negative impact on their self esteem and mental health".

Figure 6.5.3 :- ***Excerpts from a Indian News daily reporting about the practice of Implant Manufacturer driven Suppression of 'Key Facts' and Information from the Regulatory bodies in India. – Exhibit 2.***

Highlighting the Need for a Patient Centric Implant Rating and Procedure Reporting Platform for enhanced All-round Transparency.

Suppressed facts on revision surgery

The committee found that the revision surgery rate was not 12 per cent, as reported by the company, but could be as high as 35 per cent.

"…as per 2014 data, the cases of revision surgery were very high almost 35%. However, as per the latest data, the rate comes out to be 25%. Even assuming it to be the correct figure, the data is very startling on the number of patients who had undergone revision surgery, let alone their pain and sufferings. The committee noted that this data is only for the patients who had contacted the registry of the

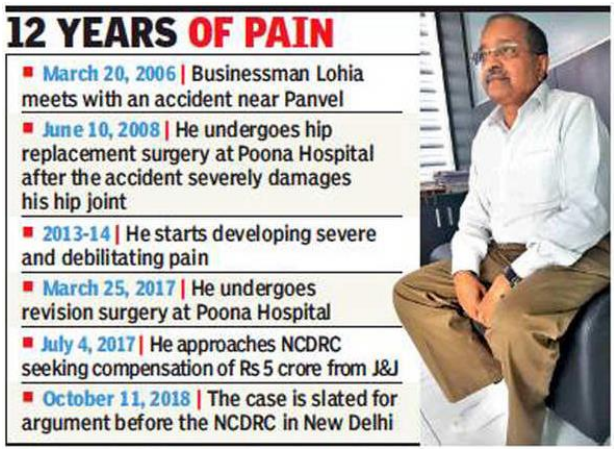


Figure 6.5.4 :- ***Patient Case Study illustrating the Impact of the ASR Hip Implant failure and resurfacing arthroplasty on the Indian patient cohort. – Exhibit 1.***

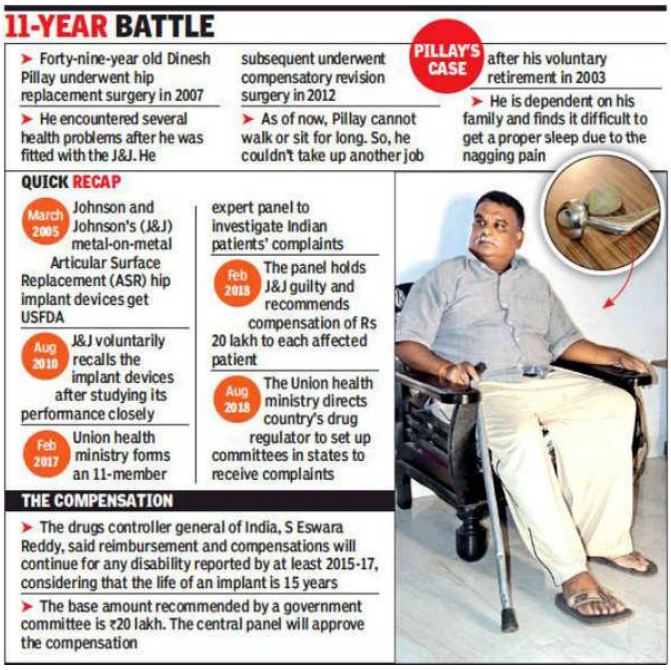


Figure 6.5.5 :- ***Patient Case Study illustrating the Impact of the ASR Hip Implant failure and resurfacing arthroplasty on the Indian patient cohort. – Exhibit 2.***

NEWS

India patients reject government's compensation scheme for recalled hip implants

BMJ India Correspondent

India's health ministry has asked Johnson and Johnson to pay between $42 000 (£33 600; €37 000) and $170 000 in compensation to patients in India who received DePuy's Articular Surface Replacement hip implants, which were recalled worldwide in August 2010.

But patients, angry at what they view as a seven year delay in the government's response to the scandal, have said they cannot accept a deal that was finalised without any patient involvement.

The health ministry approved a formula proposed by a government appointed medical panel on 29 November. It factors in the age of the implant recipient and the degree of disability.

About 4700 patients in India—among about 93 000 worldwide—received the implants until August 2010, when the company recalled the models amid concerns about high rates of revision surgery and shedding of metal debris into tissue and the bloodstream.

The Hip Implants Patients Support Group, a network of patients and their families in India, has written to the health ministry complaining that the proposed process for compensation has reduced patients to "mere spectators."

The formula ignores the specific medical circumstances of many patients, the group said. Vijay Vojhala, an implant recipient in Mumbai, said: "The government has ignored repeated requests by patients to be included in the consultations."

Patients are also comparing the compensation with a $2.5bn settlement for 8000 US patients in 2013 that involved a base award of $250 000 per patient, with adjustment for age, smoking history, and length of time of the implant, among other factors.

Manoj Sangabattula, a 31 year old implant hip recipient in Hyderabad, told *The BMJ*: "The most affected patient in India gets less than the least affected patient in America. This makes me wonder if our government think our lives have less value than those of Americans."

Patients say they are also concerned at the government's pace of response.

The Central Drugs Standard Control Organisation, the top regulatory agency for drugs and medical devices, issued an alert about the implants in December 2013, three years after their worldwide recall. The health ministry appointed a panel to probe the implants in February 2017, five years after a Maharashtra state drug commissioner complained that the company had not taken remedial measures for all patients.

Mahesh Zagade, former commissioner at Maharashtra's Food and Drug Administration, who had sought a government investigation in 2012, told *The BMJ*: "Our regulatory system has failed to protect patients' interests."

A Johnson and Johnson spokesperson in Mumbai declined to comment on the compensation formula. The company said in August this year that it had tracked nearly 1100 patients and reimbursed the costs of revision surgery and related medical expenses to 275 eligible patients.

It said that it has no access to patient data and has had to rely on doctors, hospitals, and helplines to find implant recipients. But some patients say that doctors did not alert them to the recall despite annual follow-up visits.

Jyoti Rani Kona said that she learnt about the recall from her doctor only after she had a miscarriage in 2016, nearly eight years after she had received the implant. Kona, who had revision surgery in 2017, told *The BMJ*: "The compensation formula takes into account age and disability—it does not take into account the delay, the mental trauma, and the long term medical care some patients will need."

Figure 6.5.6 :- ***A news journal coverage by the British Medical Journal (BMJ), highlighting the Patient reported responses towards the Resurfacing Hip Arthroplasty/ASR hip implant fiasco in India.***

12. <u>Multiple Revision Arthroplasty Practices and Implant Recalls Scenarios for the Global Patient Cohort: -</u>

a. Re-revision or multiple revision arthroplasty surgeries either for hip or knee, is an unfortunate and very traumatic condition faced by several patients all across the globe.

b. Multiple revisions are mostly caused due to significant implant failures and surgical inaccuracies from the first primary arthroplasty, that snowballs into a series of complications, that decapacitates the general and basic functioning capabilities of the joint alongside the involving bones and musculatures. Most of such cases also involve a certain degree of cytotoxic and physiologically hazard of the patient, through blood metallosis and particulate debris caused deep infection.

c. These cases despite being significantly challenging for the patient and their respective families both economically, physically and mentally, they receive very less attention or mainstream coverage, largely due to safeguard interests of various stakeholders involved, often leading the complete devastation of a severely unfortunate patient's life, with a loss of livelihood, functional abilities and general happiness.

d. During the course of this research, a multitude of incidences involving the multiple revision surgeries of a hip / knee are noted across major nations across the globe, including those which were evaluated for their respective arthroplasty practices, however, no official acknowledgement or a prevailing scenario report of the said condition, or a regulatory policy regarding such incidents were not prominently visible / was possible to access by this research, notwithstanding the fact it may be a classified information held by the respective registry and healthcare agencies of the nations.

e. It was only for United Kingdom and India, for whom an official locus standi could be obtained, besides the respective action taken for the past and presently prevailing incidents of multiple revisions, and their official recognition and due acknowledgement of such a condition plaguing some sections of the patient community.

f. For United Kingdom, relevant information regarding the prevailing scenarios, primary indications and other relevant documents were possible to be extracted from various sources, while it was not completely possible to access relevant information and literature regarding multiple revision arthroplasties performed for the reason of multiple failure incidences of implants, though certain case studies and government archive documents regarding the action taken to control and answer the problem was possible to get hold off.

g. In the other nations evaluated and discussed in great detail within this thesis as well, there are reports of multiple revisions of hip and knees, which are not adequately acknowledged and thereby discussed on the respective registry databases, and therefore the data pertaining to such scenarios, happening in these particular geographies, could only be accessed through various secondary sources such as – news reportings, whistle-blower accounts, declassified archives etc.

h. In some of cases particularly linked to prosthesis specific failure, there are multiple reports and the research inferred instances of cover-ups, only to be confirmed through further digging in the appropriate direction, wherein manufacturer firm internal communications, confirm the previous theory.

   For E.g. – Exactech's "Connexion GXL", which is a "moderately cross-linked polyethylene acetabular hip liner", was red flagged by a peer reviewed journal [WC T, HK P, RG V, CF G, Early polyethylene failure in a

modern total hip prosthesis: a note of caution, *The Journal of Arthroplasty* (2020), doi: https://doi.org/10.1016/j.arth.2019.12.043.] to have a pre-mature failure leading to higher-than-expected revision numbers.

i. Now, such incidences were not reported separately by covered in any of the pertaining primary resources availed during the course of this research, and whether, such incidences or in this case, this particular scenario are/is appropriately acknowledged by the country specific registries and the regulatory authorities in the future to the time of composing this thesis, remains to be seen.

j. Implant recalls though not always have been triggered due to a patient reported outrage for higher than expected revisions, or premature failure red-flags pointed out by scientific publications, but also from the manufacturer/supplier firm's own post-market surveillances and through the premier Drug/Medical Devices regulatory authority interventions, though these conditions generally snowball into a larger chain of events, usually involving legal suites filed by the compromised patients.

k. Some of the excerpts pertaining to the multiple revision scenarios faced by a section of the hip/knee arthroplasty recipient populace from across the globe, and implant recall situations are presented through the following figures/images: -



Stryker Hip Replacement Recalls

Stryker hip implant recalls occurred after reports revealed fretting, corrosion and other complications in patients implanted with the devices. The hip manufacturer's biggest recalls involved Rejuvenate and ABG II Modular stems and LFIT V40 femoral heads. As a result of Stryker's hip recalls, thousands have filed lawsuits against the manufacturer.

Another hip stem, the Accolade TMZF, has also been associated with adverse health events. The company recalled the product in 2009, 2011, 2012 and 2013 because of

The Accolade TMZF is made of the same proprietary titanium alloy that the Rejuvenate and ABG II are made from, so it may corrode and fret when used with cobalt chromium femoral heads. However, Stryker sells it with ceramic heads today.

Stryker also recalled hip implants in 2008 because of manufacturing issues. After receiving an FDA warning letter, the company stated that its Trident PSL and Hemispherical Acetabular Cups were safe and reliable, but it voluntarily recalled the products because they did not meet company standards in residual tests.

Figure 6.5.7 :- ***A Pictorial Illustration of an Implant Recall Scenario by a leading global implant manufacturer, citing manufacturing Material Compromises/Issues – Exhibit 1.***



*****URGENT DEAR HEALTHCARE PROFESSIONAL COMMUNICATION*****

11 August 2022

To: Surgeons, Hospitals, Health care professionals
Description: Exactech moderately crosslinked and conventional UHMWPE Acetabular Hip Liners (CONNEXION GXL, ACUMATCH, MCS and NOVATION)

Expanded Field Correction: US Specific

Product Family	US Clearance Date	Affected Devices Distributed in US
Acumatch GXL	September 2005	4422
MCS GXL	September 2005	238
Novation GXL	March 2007	33,654
Exactech All Polyethylene Cemented Cup	September 1996	37
Acumatch Conventional UHMWPE	November 1993	1,224
MCS Conventional UHMWPE	October 1993	28
NOVATION Conventional UHMWPE	July 2007	502

Product specific information is listed in Attachment 1

Dear Surgeon:

In July 2021, Exactech issued a worldwide Urgent Dear Healthcare Professional (DHCP) communication regarding Exactech Connexion GXL, moderately crosslinked polyethylene acetabular hip liners (link to Exactech website: https://www.exac.com/medical-professionals/recall-information/).The purpose of the July 2021 communication was to inform surgeons that Exactech had observed a higher-than-expected number of cases in which the Connexion GXL liner exhibited early linear and volumetric wear with associated periacetabular and proximal femoral osteolysis. Exactech also characterized some of the risk factors that were associated with early polyethylene wear, including the following:

1. Use of the thinnest available liner for a given acetabular shell (e.g. a 36mm inner diameter liner in a 52mm outer diameter acetabular shell)
2. A lateralized (+5mm) or face-changing liner.
3. Implantation of the femoral and acetabular components in such a way that edge loading between the femoral head and acetabular liner was occurring.

Exactech has identified an additional risk factor for premature wear that was not known at the time of the prior DHCP communication. GXL inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary oxygen barrier layer known as ethylene vinyl alcohol (EVOH), which further

Figure 6.5.8 :- ***A Pictorial Illustration of an Implant Recall Scenario by a leading global implant manufacturer, citing manufacturing Material Compromises/Issues – Exhibit 2.***



augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the polyethylene insert resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of the Connexion GXL polyethylene, which, in conjunction with other surgical factors, can lead to both accelerated wear and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

Since issuance of the July 2021 communication, Exactech has also learned that additional conventional (i.e. non-crosslinked) ultra-high molecular weight polyethylene acetabular liners were packaged in non-conforming vacuum bags. These conventional liners are identified in Attachment 1. These polyethylene liners differ from Connexion GXL in that they are composed of conventional, non-crosslinked ultra-high molecular weight polyethylene (hereafter referred to as UHMWPE). Like the Connexion GXL, these liners are susceptible to increased oxygen diffusion during shelf storage, with subsequent risks for component fatigue and damage after implantation.

The purpose of the current letter is to update surgeons regarding the implications of the packaging non-conformity on performance of the Connexion GXL and other conventional UHMWPE acetabular liners. In addition, this letter provides updates to patient management and follow-up recommendations since issuance of the July 2021 DHCP letter. (link to Exactech website for initial DHCP letter: https://www.exac.com/medical-professionals/recall-information/). Please make note of the following updates:

1. We are expanding the scope of the recall communication to include all surgeons who have implanted either GXL liners or nonconforming conventional UHMWPE liners since 2004. The previous letter included only surgeons that had implanted Connexion GXL liners between 2015 and 2021.
2. We are expanding the patient follow-up guidance to include all patients who have received either a:
    a. GXL liner regardless of packaging materials and have not been examined in the past 12 months.
    b. Conventional UHMWPE acetabular liners packaged in nonconforming packaging and have not been examined in the past 12 months.
3. Patient management instructions, including X-rays and other diagnostic workup instructions, remain the same as identified in the prior letter.
4. Exactech has already provided many US surgeons with personalized lists of their Connexion GXL patients; however, those lists did not include patients that had index surgery prior to 2015, nor did they include conventional UHMWPE patients. We are now providing surgeons with full lists of both patient groups.
5. This communication relates ONLY to Exactech Connexion GXL and conventional UHMWPE acetabular liners sold in the US. Exactech's highly crosslinked, vitamin E infused polyethylene liner, known as Alteon® XLE Liner, is not affected by this recall.

Figure 6.5.9 :- ***A Pictorial Illustration of an Implant Recall Scenario linked Official Clarification of the Reason behind, citing manufacturing Material Compromises/Issues – Exhibit 2.***

l. Therefore, in conclusion to the Results & Discussion Module of this thesis work, this research would like to particularly put forward the general need of the hour for a patient centric and reported platform of implant performance rating and arthroplasty procedure reporting. A thoroughly user-friendly web based or mobile application-based platform, wherein any patient can directly post their relative opinion or satisfaction/dis-satisfaction expressions, regarding the performance of the implant they have received for their failing hip and knees, and their general QoL post a THA/TKA/UKA.

More on such a platform is conceived and discussed in detail in the "Future Scope" chapter of this thesis work.

MODULE – VII

"Major Observations & Future Aspects/Scope of the Work."

CHAPTER – 1

Major Observations
across
Global Hip and Knee Arthroplasty Practices
and
Patient Related Outcome Scenarios.

Major Observations
across the Prevalent
Global Hip & Knee Arthroplasty Practices
&
Patient Related Outcomes.

The major observations irrespective of them being positive or negative, are discussed in this segment, with major stresses around the critically important and significant loop-holes that this research has noted across the evaluation and detailed scrutinization processes of the presently prevalent practices with regards to arthroplasty practices. These are discussed as follows: -

a. **Patient – Implant Maker & Regulator Gap –** This research noted very specifically that there's a prominent gap between the implant manufacturer and designing companies/agencies.
Unlike most other businesses, the manufacturing companies do not come in direct contact with the patient community, rather an intermediate section involving clinicians and hospital staff are primarily dealt with, who in turn addresses the patient community.
On the regulator aspect as well, major regulatory authorities are noted to reach out to hospitals, clinicians, concerned supplier firms on the occasion of any unforeseen adverse reaction scenario, but a direct tracking and intimation system involving the real-data arthroplasty data, might be the need of the hour in the modern day, to prevent any unforeseen situation.

b. **Uneven Transparency of Arthroplasty Outcome Data** – There were numerous incidences noted during the course of this research, wherein it was seen that for some of the crucial outcome scenario data, either those were not accessible or they were termed as "not reported/collected" / "poor responses". While, it is totally understandable that concerning such large pool of data, not every vertical might receive equal attention and is developed the same way, the other portions are done, but again, incidences of 'systematically co-ordinated agreement', can't be ruled out and therefore, any chances of those data being actually 'suppressed' for their best-known interests, continues to remain.

c. **Non-Coverage of Medical Tourism induced Arthroplasty Data: -** Medical tourism on the modern day has attained an 'industry' status, given the overall commerce and the involved populace availing medical tourism either domestic or internationally. While, domestic data might or be surely captured within the registry and tracking databases, if there's a mandatory reporting criterion in place, or a health regulatory / arthroplasty monitoring body that is highly vigilant on the on-going practices, cross-border or international medical tourism might not relevantly captured.

Albeit, the procedures performed and the patient count related to medical tourism, is smaller than the original home patient cohort, but on a global basis the total number of patients undergoing complicated hip and knee surgeries is quite big.

During the course of this research, it was observed and thereby noted from across numerous news articles, clinical blogs, YouTube videos of patients from the West Asian, African and Central Asian nations arriving in South Asian countries popular for medical tourism such as India, Singapore to get their complicated hip and knee conditions fixed. Since such procedures and incidents operate and happen beyond the horizons of a national arthroplasty registry or a healthcare database or any particular scientific article, these cases often go unreported and unexplored for their ultimate or final outcomes, i.e., whether these revision surgeries that take places in clinical centers, other the hospital or centre where their initial primary was conducted

Therefore, a non-geography based patient centric and patient reported real-time arthroplasty procedure reporting, ranking and reviewing platform, must be developed so as to formulate an even ground of post-operative attention to the patients, left out of the mainframe databases.

Based on the above-mentioned scenarios, this research, as a part of a tangible outcome from this work, conceived the idea of 'Prosthopedia', that aims to answer the above scenarios, in the best magnitude possible.

MODULE – VII

"Major Observations & Future Aspects/Scope of the Work."

CHAPTER – 2

Future Scope of this Work.

Future Aspects/Scope of this Work

[Potential Role of "Prosthopedia" in Resolving the Major Challenges]

Based on the above-discussed scenarios, this research would like to propose, a web or mobile application-based platform, "Prosthopedia", as a part of tangible outcome from this thesis, that would attain the following attributes, as its salient features, to resolve the prevailing major patient centric challenges around the globe (or in India): -

a. The "Prosthopedia" platform would also be an open-source arena for unbiased patient reviewed and ranked implant and procedure centric literature and information, across multiple languages with the use of illustrative imageries, for the pristine and blemish free patient level awareness and knowledge regarding the various aspects of arthroplasties, implants and patient rights.

b. The "Prosthopedia" platform might also provide for the listing of the variety of hip and knee implants(initially), as commercially and clinically available for utilization, across the global quadropoly brands and the local manufacturers, for the patients to directly review and rate them, and possibly purchase them, against a valid proof of requirement.

c. The "Prosthopedia" platform should also allow for the manufacturer and regulatory authorities to directly track and inform end-user patients, regarding any manufacturing defect/hazards, or any other red flags for the immediate resolution and widest coverage at once.

d. The "Prosthopedia" platform will feature a real-time dashboard, that would present and highlight reported arthroplasty procedures and implant usage characteristics on a live status, reported either by the patient/patient family, or the arthroplasty performing institute.

The possible benefits of the "Prosthopedia" platform for both the patient and implant manufacturer circles are highlighted through the following slide excerpts of the original idea presentation: -



Figure 7.1.1 :- ***Illustrative Demonstration of the Benefits of the "Prosthopedia" App/Web Platform to the Global and Local Patient Community.***



Figure 7.1.2 :- ***Illustrative Demonstration of the Benefits of the "Prosthopedia" App/Web Platform to the Implant Manufacturer, Regulator and Supplier Community.***

MODULE – VIII

“Final Conclusion.”

Final Conclusion

- On a general basis, the global patient community troubled with various sorts of hip and knee diseases, are receiving and opting for an arthroplasty-based resolution to the problem, now more than ever.

- While, some nations from across the globe with a 'first-world', state-of-the art healthcare system and infrastructure has an arthroplasty registry database operating, some equally important nations are noted to be without it. Though, the presence of such a registry doesn't equate or rationalize the prevalent practices to be of accurate order, but such a practice of maintaining records, might just be tool, should there be an implant failure driven health-care hazardous emergency in any foreseeable future, they would be desperately wishing for.

- The majority practice globally is to upgrade to the modern practices standard, like utilizing cementless fixations in greater proportion for non-complicated procedures, than cemented ones, for hip arthroplasties, but some sections prevail wherein legacy conventional practices are attributed with greater confidence and importance than the newer ones, as it is the case for Sweden.

- While hip arthroplasties on a broad perspective seems to be well tolerated and received, some of knee arthroplasties performed in the recent years, which is further fuelled by the speeding numbers of knees gets replaced in much greater proportions than hips, indicate may involve a certain degree of non-necessitated and hurried procedures, for reasons best explainable by the concerned clinician cohort.

- The general practice during a implant failure crisis, involves a chain of hierarchy, from the implant manufacturers to regulatory authorities to hospitals/surgeons and finally to end-user patients. This chain of passing intel, might unintentionally or intentionally corrode a portion of the initial message, which might influence the end-user patient's decision making at the hour of crisis. Therefore, this research as a part of its final outcome conceives the idea of a patient-centric platform, wherein they can directly interact with the peer community, and also report their procedures, should their respective clinics miss-out on reporting them, and through this very platform, implant manufacturer/suppliers and the governmental regulatory bodies can directly track, inform and interact with the patients, for any requirements, and the chain vice-versa.

- This research proposes the platform as, "Prosthopedia", that might be the very revolution, global arthroplasty domain, not just needs, but has to definitely, undergo if not today, but certainly some time soon in the future.

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