An innovative approach to the diagnosis and management and prevention of instability in total knee joint arthroplasty using state of the art robotic technology

by

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Summary

Total knee arthroplasty (TKA) is a common and very successful surgical procedure in the treatment of osteoarthritis of the knee. Figures from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) have shown that over the last 3 decades the numbers of patients undergoing Primary Total Knee Arthroplasty has been progressively rising.

Approximately 52,000 Primary TKA procedures were performed in Australia in 2016. Total knee arthroplasty is accepted by the orthopaedic surgical community as the best surgical treatment available for the treatment of end stage osteoarthritis. However complications still occur and 2017 NJR figures show a revision surgery rate of approximately 5% at 10 years post-op.

The numbers of patients undergoing revision knee arthroplasty are on the rise. Since 2003 the number of Primary TKA's performed has increased by 115.1% and Revision TKA's have increased by 73.3 % in Australia. In 2016 from AOANJRR figures 4668 Revision Knee Arthroplasty procedures were performed. The estimated total cost of care for a Revision Knee arthroplasty procedure is 63,000 Australian Dollars. This means the annual cost to the healthcare system for this surgery nationally is approximately 294 million Australian dollars. Revision TKA surgery is invasive and has a high rate of complications for our patients. Revision for TKA instability is a significant problem with many patients failing within the first 3 years post-op and sustaining a high rate of re-revision surgery. In addition, as shown in our systematic review *Chapter 2,* the diagnosis and management of TKA instability is less well described in the published literature compared to other modes of failure.

The purpose of this thesis is to design a robust diagnostic approach to improve the. Diagnosis of TKA instability and reduce our rates of re-revision surgery. TKA revision for instability is used as a sentinel event to use the AOANJRR National registry data combined with a local Revision Registry to identify areas to improve our diagnostic and

management processes. Clinical outcomes are then then assessed, and innovations in Robotic technology reviewed to assess their impact in improving ligament balancing in primary TKA surgery with the potential to reduce failures for instability in the future.

In *Chapter 2* we performed a systematic review to evaluate what is known in the current published literature. Using the published data an evaluation was performed of the current understanding of when a patient's TKA fails due to instability. An evaluation was performed of the demographics and patient factors that lead to instability. Surgical and implant related factors were also assessed to draw any associations.

In *Chapter 3* the results from our systematic review were used to design and construct a standardized diagnostic algorithm for the failed or potentially failing total knee arthroplasty. Our ultimate aim is to use these processes to reduce the rates of revision for our patients with a significant reduction in further surgeries and a massive saving to the healthcare system. This algorithm was then evaluated to assess which criteria were the most reliable in diagnosing TKA instability allowing to reduce the number of patients undergoing revision surgery. Our literature review suggests this is the first attempt to do this with no previous studies published at this time.

In *Chapter 4* the data from our systematic review and a report from the National registry on our departments historic results were used to the design and implement a local revision knee arthroplasty registry. National registries already exist and are a very useful quality and research tool. However, revision surgery data is very granular, and the use of a local registry allows more detailed evaluation of trends over time. The local registry was then compared with national figures to evaluate how to improve our diagnostic and clinical processes. Our registry showed high revision rates for 'pain'. Patients were diagnosed through this pathway as either unstable, failing for another reason or not requiring further surgery. This local data was then analysed and compared with the national figures to improve our diagnostic and management process. This data can then be used in a feedback loop to suggest potential changes to the collection of national data. We have used our historic national data to evaluate a new robust and standardized diagnosis and management process.

In *Chapter 5* we reviewed our clinical experience with revision knee arthroplasty surgery to assess the post-op outcomes of our patients. Some published series suggest poor outcomes in patients revised for TKA instability compared to other reasons for revision and high rates of re-revision surgery. This study evaluated our re-revision rates and cross-referenced them with our historical and current results on the National AOANJRR registry. This showed that we had reduced our re-revision rates from 14.6 to 8.3%. However, PROMs score for our revision patients were low suggesting that despite a reduction in our re-revision rates prevention of revision surgery in the first place would be desirable for our patients.

In *Chapter 6* we evaluated the use in technology in improving ligament balancing in primary TKA surgery with the potential to reduce failures and revision TKA surgery for instability in the future. Computer assisted surgery has been proved in previous studies to reduce outliers in surgical accuracy and revision rates over time. This technology has now been modified with the introduction of Robotic TKA surgery systems. These have been designed to specifically improve the accuracy of ligament balancing. Our analysis shows that in primary TKA surgery the implants can be inserted with a high level of ligament balancing precision with the potential to reduce failures in the future.

In *Chapter 7* we discuss the implications of the work from this Thesis and how this can be used to improve patient outcomes. Finally, in *Chapter 8* we have reviewed and considered the possible future research that could stem from this thesis and enhance our understanding of the issues in TKA instability. A number of different technological systems are emerging that aim to improve either the alignment or ligament balancing in primary TKA surgery. Robotic techniques measure the size of ligament ‘gaps ‘to assess balancing and are highly accurate. However other systems now exist with pressure transducer capability to assess the force ligaments apply to the TKA prosthesis. The combination of simultaneous accurate Robotic implantation and measurement of ligament tension may offer enhanced ability to implant the TKR prosthesis in a way that best mimics the patient’s own biomechanics.

Our university biomechanics department has designed a specific gait lab system to assess the effects of TKA on the patients gait cycle and the abnormal force patterns they may experience in instability. This includes a unique stair climbing force vector array to evaluate the effects of Robotic assisted TKA patients against controls. Finally, the effects of these innovations on TKA revision rates can be assessed using the AOA registry system. The registry has shown that the improvements obtained in Computer assessed surgery have reduced revision rates in primary TKA surgery. This data however took 8 years to collect and assess therefore a similar review of Robotic TKA surgery and its results lies out with the time frame of this Thesis.

In summary this thesis has combined Local and National Registry data to improve clinical practice in revision TKA surgery. The development of a robust comprehensive local registry, diagnosis and management pathway has already had a dramatic effect on our clinical practice. To our knowledge, this is the first study to use combined registry data to determine a method to reduce re-revision rates in revision TKA surgery. Finally, the use of Robotic innovation and increases accuracy in knee ligament balancing may reduce the rates of failure in primary TKA surgery reducing our patients need for revision surgery in the first place.

Publications and presentations arising from this Thesis

Mid flexion instability as a mode of Failure in TKR, A Systematic Review
Wilson CJ, A Theodoulou, Damarell R & Krishnan J

Wilson CJ, Theodoulou & Krishnan J. Knee instability as the primary cause of failure following Total Knee Arthroplasty (TKA): A systematic review of the patient, surgical and implant characteristics of revised TKA patients. *2017 Sept (29) The Knee.*

APOA Congress	Melbourne March 2016 (Poster)
AOA SA Annual Meeting	Barossa August 2016 (Presentation)

Clinical Diagnosis of Instability in Total Knee Arthroplasty: Design and evaluation of a new diagnostic algorithm for the diagnosis of the unstable Total Knee Arthroplasty
Wilson CJ, Ford J & Quinn S & Krishnan J

Arthroplasty Society ASM	Noosa, June 2017 (Presentation)
AOA SA ASM	McLaren Vale, Aug 2017 (Presentation)
Flinders Research Week	FMC, September 2017 (Presentation)
ISTA Annual Congress	London October 2018 (Presentation)

Design & Construction of a formal Local Revision Knee Arthroplasty Registry

Wilson CJ,* A Visvanathan, *G Wong & Krishnan J

Published in *The Journal of Knee Surgery*	March 2020
AOA State Branch Meeting	Tonsley, Adelaide November 2016 (Presentation)

Arthroplasty Society ASM	Noosa, June 2017 (Presentation)
Flinders Research Week	FMC, September 2017 (Presentation)
Surgical Convocation	Victor Harbour October 2018 (Presentation)

Results of Revision Total Knee Arthroplasty due to Instability
Wilson CJ, Kelly J & Krishnan J

Arthroplasty Society ASM	Hobart May 2018 (Presentation)
ISTA Annual Congress	London October 2018 (Poster)

Accuracy of Bone Resection in MAKO Total Knee Robotic Assisted Surgery

Sires JD, Craik JD & Wilson CJ

Published in *The Journal of Knee Surgery*	November 2019
ISTA Annual Congress	London October 2018 (Presentation)
AOA SA Scientific Meeting	Adelaide Feb 2019 (Presentation)
Arthroplasty Society ASM	Noosa May 2019 (Presentation)
Australian Orthopaedic Association ASM	Canberra Oct 2019 (Presentation)

Validation of Accuracy and Gap Balancing in MAKO Total Knee Robotic Assisted Surgery

J Sires & Wilson CJ

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Arthroplasty Society ASM	Noosa May 2019 (Presentation)
Australian Orthopaedic Association ASM	Canberra Oct 2019 (Presentation)
AOA SA State Branch ASM	Adelaide Feb 2020 (Presentation)

Summary of Chapters

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List of Abbreviations

ADL	Activities of Daily Living
AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
BMI	Body Mass Index
CORR	Clinical Orthopaedics and Related Research
EPAS	Electronic Patient Archive System
FMC	Flinders Medical Centre
MeSH	Medical Subject Headings
MINORS	Methodological Index for Non-Randomised Studies
MRN	Medial Record Number
NJR	National Joint Registry
OA	Osteoarthritis
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROMs	Patient Reported outcome measures
PROSPERO	International prospective register of systematic reviews
TKA	Total Knee Arthroplasty
UKA	Unicompartmental Knee Arthroplasty

Declaration

I certify that this thesis does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university, and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

After commencing my candidature, I have designed all the studies and investigations included in this thesis. All studies were performed with ethical approval from the South Adelaide Clinical HREC and where appropriate the South Adelaide Local area health network Compliance committee.

In designing and performing the systematic review and clinical reviews I have consulted and involved staff from the Flinders University Library, students and research staff from the university. These are all included in the acknowledgments. The students and research staff have also offered me assistance in the collection of clinical and research data.

All clinical studies and the thesis text have been subject to review and scrutiny by my PhD supervisors.

Dr. Christopher Wilson

14/08/2020

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Specific thanks also go to Raechel Damarel from the Flinders University library for her Help and sharing her significant experience in how to design and conduct a systematic review and Richard Woodward from the Flinders University Statistics department for his help in ensuring the statistical calculations used were appropriate and accurate.

A very big thank you to my supervisors Professor Jegan Krishnan and Professor Rudi Jaarsma. Thank you for providing support and guidance throughout this work and for their continued motivation. I am most grateful for your time and patience with me throughout my canditure.

Finally, thank you very much to the patients who participated in the studies included within this thesis. They gave up their time while recovering from surgery to participate in our questionnaires and investigations.

Chapter One: Introduction

Aims

The overall aim of this thesis is to use knee instability as the sentinel event to develop a detailed system within my department to enhance the accuracy of diagnosis and quality of management for our patients. This system intends to reduce revision TKA rates and improve outcomes of revision surgery leading to a reduction in our re-revision surgery rates.

To evaluate the outcomes of this system the AOA national joint replacement registry information is used in combination with a local registry to provide improved and more detailed information on how this process has achieved these goals. The results of our systematic review suggest this is the first time this has been attempted.

In the prevention of TKA failure for instability this thesis aims to describe and evaluate the use of Robotic assisted surgery to improve ligament balancing in primary surgery and hopefully reduce the need for revision surgery in the first place.

In this work I intend to evaluate these processes and use the results to improve surgical outcomes, reduce complications and reduce the number of patients who return to theatre for further revision surgery. This would potentially lead to a reduction in the human cost of this condition and also a significant reduction in the financial burden on our service and healthcare system.

Research Questions

After performing and appropriate Systematic literature review relating to instability in TKA surgery the thesis aims to address the following research questions.

Research question 1 was to describe a new standardised clinical assessment of TKA instability

This question involves the design and evaluation of a new diagnostic algorithm for TKA instability, the methods of how this was done and its effects on our clinical practice. This question is addressed in *Chapter 3.*

Research question 2 was to design and evaluate a local revision arthroplasty registry.

These data are used to assess our current revision TKA surgery practice and assess how this data can be better collected and analysed to improve practice. Long term trends can be evaluated in the future. This question is discussed and addressed in *Chapter 4.*

Research question 3 was to evaluate the Clinical outcomes of our revision TKA surgery for instability.

Using data from our local registry a clinical review of our cases was performed. Local revision TKA was compared to and combined with national AOANJRR figures to evaluate effects of the changes our diagnostic algorithm has had on clinical practice. This question is addressed in *Chapter 5*

Research question 4 was to evaluate the potential of Robotic Assisted TKA surgery and its potential to reduce TKA instability.

Both computer assisted surgery and robotic assisted TKA surgery may allow surgeons to improve ligament balancing during surgery which may potentially reduce failures for TKA surgery. Data was collected on the accuracy of this technology in balancing knee ligaments intraoperatively. This question is addressed in *Chapter 6.*

Osteoarthritis

Causes and Incidence

Osteoarthritis is the most common degenerative condition affecting the musculoskeletal system in the general population. It causes progressive pain and loss of function causing patients to seek medical intervention in the form of pain management, physical therapy and when these conservative options are unsuccessful surgical intervention. It is estimated that 10% of the human population over the age of 60 years old are affected by significant clinical problems that can be attributed to OA[1.]

Osteoarthritis is defined as a condition characterised by focal areas of cartilage loss within synovial joints with associated hypertrophy of the bone and thickening of the joint capsule. The prevalence of disease is only an estimate as the patterns of symptoms and joint involvement vary. In addition, there are many people with radiographic evidence of OA but no significant clinical symptoms or disability[1].

Epidemiological research has used the concepts of Radiological OA, Symptomatic OA and Self-reported OA to define the disease when trying to quantify the incidence and prevalence of OA. Radiographic OA considers only the pathophysiological changes on radiographic images and is also subject to variation depending of the different radiological scoring systems used by different authors. Symptomatic OA is defined as patients with both radiological and clinical symptoms related to the joint pathology. Some authors also define self-reported OA based on patient's own information concerning a previous diagnosis of OA[1].

Unsurprisingly previous reports in the literature suggest a higher prevalence of radiographic OA compared to the other definitions. However, using self-reported OA as a guide the prevalence of osteoarthritis of the knee still varied between studies from 7.1 to 15 %[1]. Patients with osteoarthritis present with pain, swelling and limitation of their physical function. Commonly patients report pain when walking or descending stairs. The commonly describe pain rising from a chair and the pain may wake them from sleep. The need for a walking aid such as a stick or frame is also common. The joint is usually stiff

and sore and can grind, a term known as 'crepitus 'on clinical examination. Patients are usually tender around the joint line and in significant disease can also present with deformity of the affected joint. The diagnosis of osteoarthritis is usual made by detecting a combination of relevant symptoms, physical signs and X-ray findings.

Prevention and Conservative Treatment

Most patients will have tried some method of conservative management before seeking the opinion of a surgeon usually with the assistance of their general practitioner. Early arthritis symptoms are commonly managed with either simple analgesics or Non-Steroidal Anti-Inflammatory agents. These medications can reduce pain, improve function and either delay or prevent the need to consider surgical management[6]. In addition, many patients use medical therapies targeted at modulating the effects of the arthritis such as glucosamine or fish oils. These agents have shown some benefit for some patient's osteoarthritis symptoms[7] however a recent Systematic review showed no benefit over placebo[2].

In addition to management with medications patients are commonly advised to work at exercise therapy either on their own or with the assistance of a physiotherapist. In lower limb osteoarthritis the use of hydrotherapy is also useful. General advice on a healthy and especially weight loss will not only improve their general function it can reduce the stress though weight-bearing joints and allow patients to improve their function without the need to undergo surgical treatment[3,4].

It is generally accepted within the medical community that once the patient's symptoms or functional deficit is no longer responding to these measures it is appropriate to consider a surgical opinion and investigate what surgical options are available. The key issue with the decision to proceed with surgical management is usual based on deteriorating function, increasing pain, and a negative effect on the patient's ability to perform normal activities of daily living or symptoms that they feel are having an adverse effect on their quality of life.

Current Surgical Intervention

Surgical therapy for end stage osteoarthritis of the knee usually involves arthroplasty surgery. Other surgical management options are available including corrective osteotomy in younger patients and arthroscopic surgery[5].

In early OA of the knee some patients may benefit from arthroscopic knee surgery. Patients with early OA can benefit from debridement of their chondral damage and resection of any associated meniscal tears. This surgery is less invasive, the complications less severe and the recovery time shorter. Patients may request less invasive surgery or are apprehensive about the prospect of a TKA. However, although a common surgical practice the evidence for arthroscopic debridement is remains controversial. Randomised studies have suggested that in the presence of OA arthroscopy is no better than analgesia and physiotherapy[9].

Patients with OA restricted to only one compartment of the knee for example the medial compartment can benefit from surgery other than the TKA procedure. One example is Uni-compartmental knee arthroplasty (UKA). This involves resection and replacement of the damaged articular surface of the medial compartment only. This surgery comes with the benefit of conserving the bone and tissues in the unaffected compartments. However, the surgical indications for UKA are very specific and as a result this procedure is only performed in 5.7% of all knee replacement cases[10]. This surgery comes with a higher risk of early revision in the first 10 years. Approximately 15% of Unicompartmental knees have been revised by this time[11].

Patients with selective medial compartment OA can also be treated with a realignment osteotomy. This involves a corrective osteotomy to either the distal femur or proximal tibia. The abnormal mechanical axis created by OA wear is corrected to allow the patient to bear more weight through the normal cartilage in the unaffected compartment. This option is attractive to patients who are too young for TKA surgery or who have heavy manual jobs [5]. This surgery is performed in a selected group of patients and represents a small minority of all knee surgeries performed compared to the more common TKA's. For the purpose of answering our scientific questions my analysis has been directed towards

the issues affecting TKA patients. Total knee arthroplasty surgery is widely accepted amongst the orthopaedic surgical community as the gold standard for the treatment of osteoarthritis of the knee when non-surgical measures such as analgesics and physical therapy no longer control the patient's symptoms.

Total Knee Arthroplasty

Incidence & Demographics

Total knee arthroplasty is a surgical intervention, which aims to restore the function of a diseased knee joint. The main goals are to relieve pain, restore alignment, reproduce knee movement and balance knee ligaments. By achieving these aims the surgeon's goal is to restore the patient's clinical function similar to that obtained without the osteoarthritis disease process.

According to AOANJRR 2017 figures Osteoarthritis is the commonest diagnosis for patients undergoing TKA accounting for 97.6% of the cases of primary total knee arthroplasty procedures. Over 55,000 TKA procedures were performed in Australia in 2017 [12]. Current data from health funds suggests a total knee arthroplasty costs on average. $23,000. The total financial burden nationally for these procedures is therefore approximately 1.26 Billion AUS Dollars[15]. The numbers of cases performed continues to rise, with a 4.3% increase overall in 2017 compared to 2016[12]. In 70.5 % of these procedures, the surgery is performed in patients in the age range of 55- 75, only 6.6% of cases are performed in patients under 55 years of age[12]. Surgery remains more common in females accounting for 55.4% of cases [12]. Therefore, while accepted TKA as the gold standard of care for OA of the knee, this surgery is a significant financial burden on the healthcare service. In addition, with increasing patient life expectancy and increasing TKA numbers, with the majority of cases performed in patients under 75 years of age, the potential healthcare burden of revision surgery remains significant.

Basic Knee Anatomy

TKA surgery requires the surgeon to understand the basic anatomy of the knee and perform surgical resections that will not only allow the knee implant to replace the

damaged articular surfaced but also the surgeon to use those implants to restore the alignment an ligament balancing of the knee. Surgical instruments are designed to assist the surgeon in accurately measuring the knee alignment; thicknesses of bony resection required and assess ligament tensions to ensure they are correctly balanced. The basic bony, cartilage and ligamentous structures of the knee are shown in *Fig 1* below.

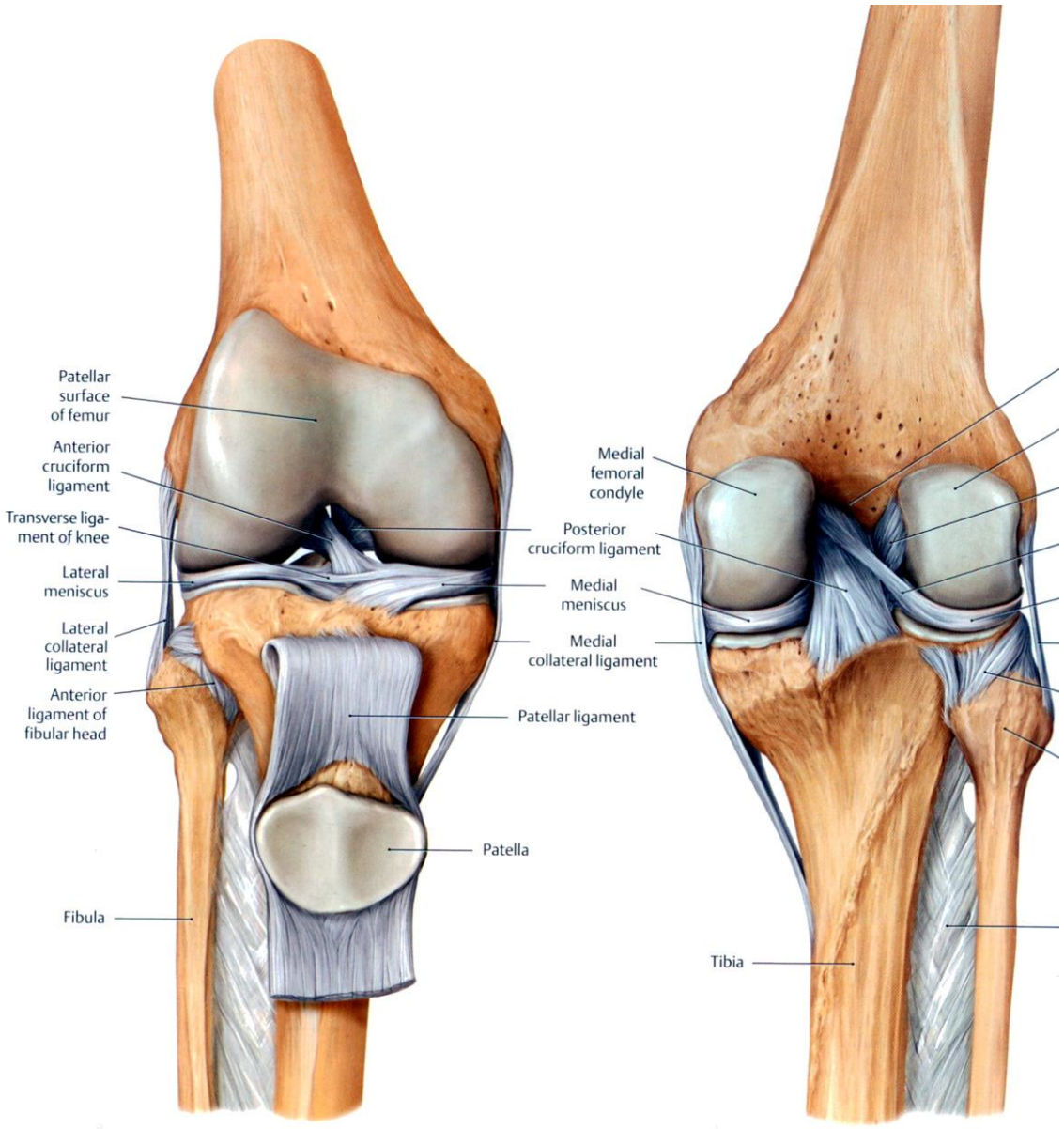


Fig 1. The anatomy of the human knee from in front and behind. The patella has been reflected to show the anterior cruciate ligaments and meniscal cartilages clearly. Reproduced from Physiopedia / www.physio-pedia.com/Knee, image has no non-commercial copyright restrictions.

Surgical Technique

Technically the diseased articular surfaces of the femur and tibia are resected within the knee joint. The removed bone and cartilage are then reconstructed using surgical prosthetic implants that are designed to mimic the smooth articulation present in a non-diseased joint. The Prosthetic implants are also designed to assist the surgeon to balance and recreate the normal ligament tensions that the patient requires to have a functioning stable knee.

The surgeon uses a step-by-step series of tools and 'jigs 'to measure each step of the surgical process and achieve the goals mentioned above. Surgical jigs can be supplemented by measurements taken using Computer navigation systems or Image based Patient specific technologies. For the purpose of this description, a conventional jig-based system is described.

Each patient has a slightly different alignment and morphology. The bones involved vary in size from patient to patient and must be accurately assessed and measured. In addition, the ligaments of the knee need to be 'balanced' to achieve normal knee stability and function (this will be discussed in more detail in *Chapter 3*). However, during surgery the technique must allow the surgeon to balance the knee joint and two 'gaps 'are used. These are termed the 'Flexion Gap 'and 'Extension Gap.' The extension gap is the space between the femur and tibia with the knee in full extension and the flexion gap is the same space with the knee flexed to 90 degrees. Both gaps are determined by the amount of bone resected and the tension of the patient's ligaments. This is summarised in *Figure 2* below.

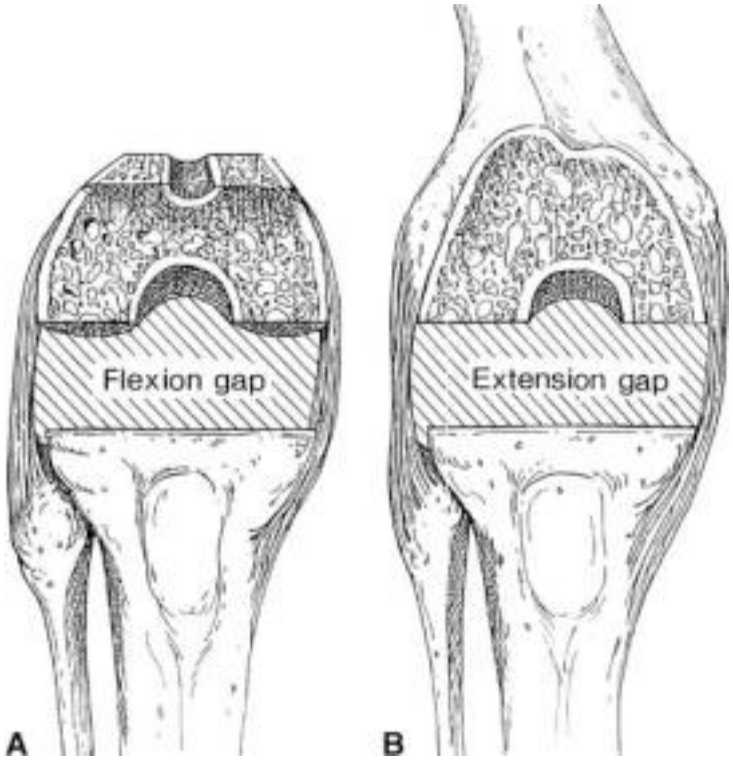


Figure 2, diagrammatic example of the Flexion gap A and Extension gap B showing in this case a symmetrical bone resection in both gaps. Reproduced with permission Griffin et al J Arthroplasty 2000.

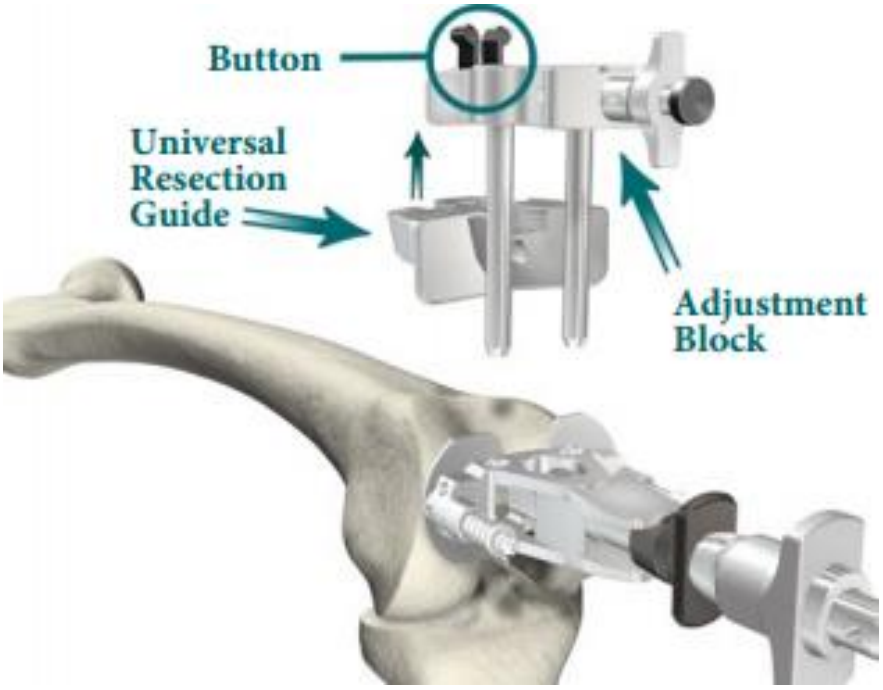
Total knee arthroplasty is performed in the operating theatre of a suitable hospital. Aseptic surgical techniques and adequate anaesthesia are used. The surgeon performs a midline incision through the skin over the knee joint. The deep tissues medial to the patella are excised and the patella reflected to allow adequate exposure of the articular surfaces. Abnormal soft tissue is excised, and preparation made to measure and perform the bony resections.

Prior to performing surgical cuts measurement jigs are used to assess the patient's alignment correcting for any deformity caused by the disease process. In the method described the bony alignment of the patients Femur and Tibia are used as reference guides. To begin the process an Intra-medullary guide rod is inserted down the Femoral Intra-medullary canal. Using a reference jig, the angle and thickness of the first femoral

cut is measured. This is called the Distal femoral cut; it should be parallel to the ground if the patient was in a weight bearing position. It is normally cut in 5 – 7 degrees of valgus in relation to the patient's Femoral Intramedullary alignment. The thickness of the cut is 8 – 10 mm to match the thickness of the femoral implant used.

Fig 3 Using drill and Intra medullary guides to use the femoral intra medullary alignment as a guide for femoral resections. Reproduced with permission from Stryker Triathlon surgical technique 2015.

The 'Distal cut surface' is then used as a reference to perform the rest of the femoral preparation. Using a sizing guide the patient's femur is measured and matched to a corresponding implant size, e.g. 2,3,4 etc. The appropriate 4 in 1 Femoral cutting block is then attached and matched to the patient's distal femoral rotation. The cuts are then checked and performed. This should allow the surgeon to resect all the remaining diseased articular surface and finish the femoral preparation to accept the final Femoral Implant.



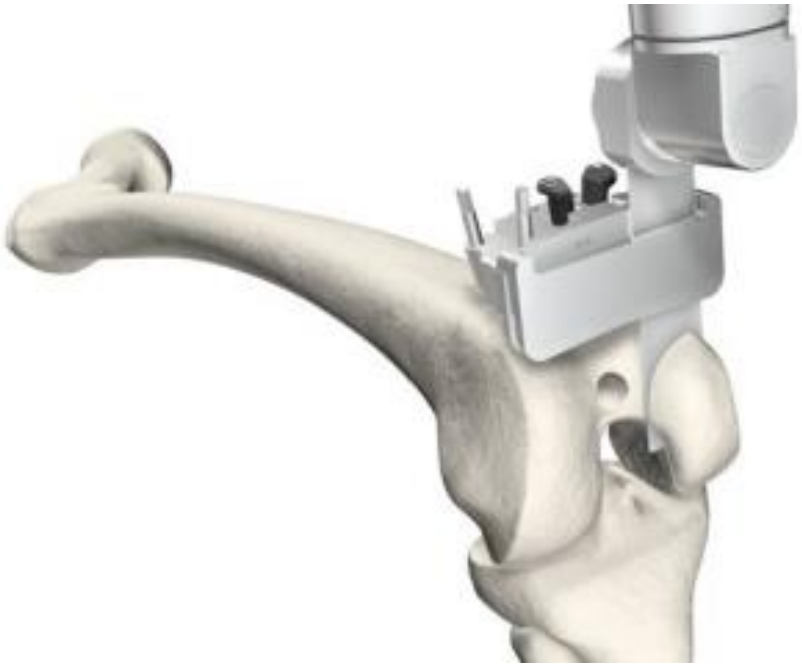


Fig 4a and 4b, the femoral intra medullary alignment is used to position the femoral resection guides. The resection is then measured a distal bone cut to match the thickness of the TKA femoral implant. Reproduced with permission from Stryker Triathlon surgical technique 2015.

Excess soft tissue and any remaining bony osteophytes are removed. A final assessment is made of the femoral preparation by applying a ‘trial ‘Femoral implant. This allows the surgeon to assess the accuracy of these steps before proceeding to the Tibial preparation.

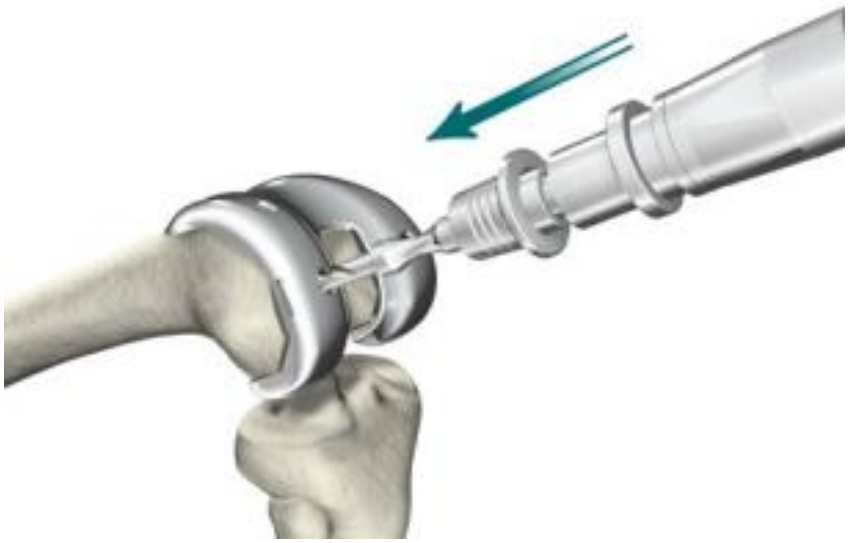


Fig 5, Surgeon checks fit of trial femoral implant and drills guide holes for femoral ‘pegs ‘that will control implant rotation. Reproduced with permission from Stryker Triathlon surgical technique 2015.

Tibial alignment jigs are used to assess the patient’s natural alignment. A long alignment rod Jig is applied around the patient’s ankle using the medial and lateral malleoli as reference points. The Tibial ankle clamps and proximal alignment rods allow placement of the Tibial cutting jig in parallel with the patient’s natural Tibial alignment. Most patients have a slight posterior Tibial slope and this is also taken into account.

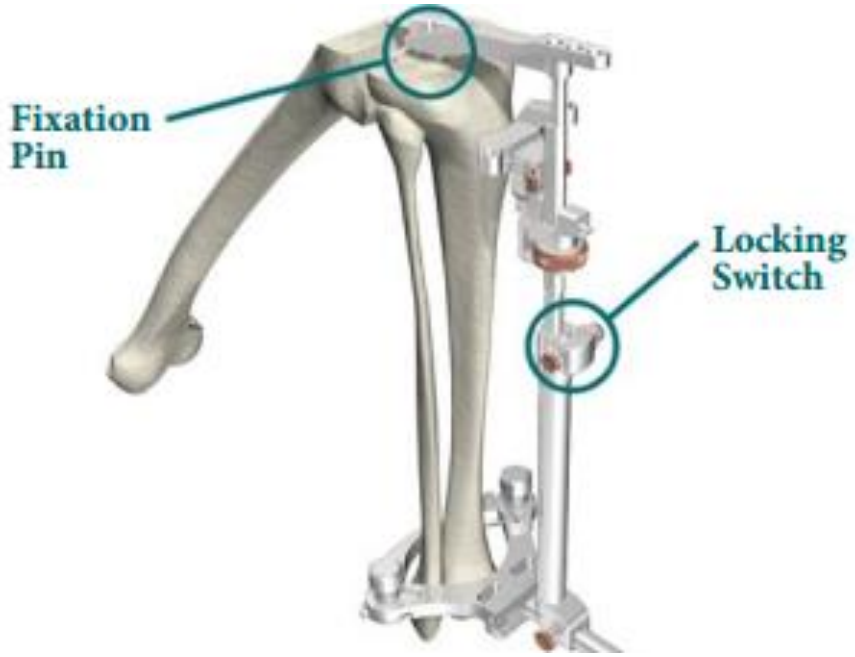


Fig 6 the extra medullary clamp and guide are used to measure the tibial alignment. Ankle clamps are passed around the patient's malleoli while a fixation pin is impacted into the tibia to allow accurate alignment and tibial flexion or 'slope' measurements to be made. Reproduced with permission from Stryker Triathlon surgical technique 2015.

Using the Tibial resection guide and a measurement stylus the position is measured to allow a resection of 9mm of bone of the proximal tibia in most cases. This resects the entire diseased articular surface and prepared the tibia at the correct thickness and alignment for insertion of the Tibial implant. The cut bone surface is removed, and any residual soft tissue or bone osteophytes resected. This is shown in *Figure 7* below.

The final Tibial preparation is completed using the Universal tibial template. This jig is applied to the Tibial cut surface and the appropriate size used to match the size of the patient's tibia. The correct tibia rotation is also assessed, and the tibia finished by making the appropriate keel cut. This step ensures the final and correct Tibial rotation is maintained and that the Tibial implant can be correctly secured in the patient's bone.

Fig 7 the tibia resection guide is appropriately positioned using the tibial alignment guides. The thickness of resection is measured and the tibia cuts made. Reproduced with permission from Stryker Triathlon surgical technique 2015.

Before final implantation the surgeon must assess the knees overall alignment and if the Flexion and Extension gaps are balanced. To perform this process a 'Spacer block' tool is inserted into the new knee joint in both full extension and 90 degrees of flexion. This block mimics the thickness of the final implant and allows the surgeon to ensure the tension is correct and symmetrical in both gaps. This device also allows the insertion of an alignment rod to ensure the final alignment of the patient's leg is satisfactory prior to insertion of the final implants.

For a final check Trial implants are inserted and the alignment checked again. The balance of knee ligament tension is checked again for the Flexion and Extension gaps using specifically designed 'spacer' blocks or jigs. In *Fig 8* below the extension gap is measured at 9mm. The Range of motion is checked to ensure it is adequate and that the patella tracks well thought the whole range. If all these steps are complete and satisfactory the

surgeon can insert the final implants with bone cement. Once insertion is satisfactory and complete the wound is closed in layers and dressings applied.

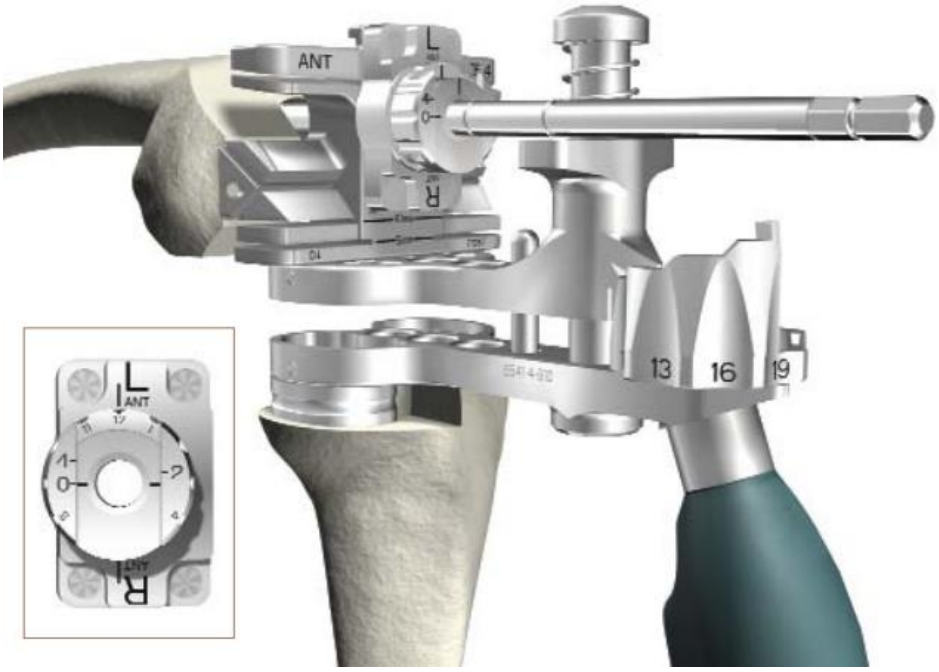


Fig 8 Ligament ' spacer blocks ' are used in both flexion and extension to assure the flexion and extension gaps of the knee are balanced before the final prosthesis is implanted. Reproduced with permission from Stryker Triathlon surgical technique 2015.

TKA Methods of Failure

TKA is widely accepted as the gold standard in the surgical management of osteoarthritis of the knee. Patients obtain good pain relief in the majority of cases and enjoy good restoration of their clinical function. In addition, using modern material and well tested implants patients can achieve good long-term results with less than a 5% revision rate by 10 years post op [16]. However not all patients are satisfied, and failures will occur leading to further pain, disability and the need for revision surgery.

The numbers of patients undergoing Revision knee arthroplasty are on the rise. Since 2003 the number of Primary TKA's performed has increased by 115.1% and Revision TKA's have increased by 73.3 % in Australia [17]. Revision knee arthroplasty is a significant

undertaking for our patients with both a higher morbidity and mortality related to Primary TKA. The financial cost of providing this care for the Australian Healthcare System is also significant. US estimates suggest as cost of approximately $74,000 per procedure [15]. It is not clear whether this is purely a reflection of the increasing numbers of Primary TKA's performed or whether other factors are involved.

According to NJR 2017 figures, the commonest reasons for revision TKA remain Loosening/ Lysis (25.9%), Infection (22.5%), Patello femoral pain (10.9%), Pain (8.6%) & Instability (7.3%). The full breakdown on reasons for revision is summarised in *Table 1* below.

Table KT11 Primary Total Knee Replacement by Reason for Revision (Primary Diagnosis OA)

Reason for Revision	Number	Percent
Loosening	5074	25.9
Infection	4412	22.5
Patellofemoral Pain	2143	10.9
Pain	1694	8.6
Instability	1429	7.3
Patella Erosion	992	5.1
Arthrofibrosis	689	3.5
Fracture	541	2.8
Malalignment	428	2.2
Lysis	389	2.0
Wear Tibial Insert	331	1.7
Metal Related Pathology	304	1.5
Incorrect Sizing	239	1.2
Other	962	4.9
TOTAL	**19627**	**100.0**

Table 1, the reason for Revision knee arthroplasty in all knees recorded until December 31st 2016. Table KT11 Page198, 2017 AOANJRR report.

Loosening/ Lyses progressively rises over time from index surgery while the other causes of failure are commonest in the first 4 years. This subject is discussed in much further detail in our systematic review of the published evidence included in *Chapter 2*.

Revision knee arthroplasty follows the same principles of trying to restore knee function, alignment and mechanics. However, in revision surgery the surgeon has also to consider the issues of addressing the pathological issue, safely removing the pre-existing implants with minimal harm and finally reconstructing the knee joint to restore the patient's

function. Knee revision is therefore inadvisable without first making a sound diagnosis of the pathology that has led to failure [18]. Once this has been achieved the surgeon needs to safely remove the implants with the minimum of host bone loss and then use revision instruments to reconstruct the knee, taking into account any pathological deformity or bone loss present.

Revision knee systems differ from primary knee arthroplasty systems in order to tackle these issues. They commonly include intramedullary instruments to assess the patient's normal alignment. In addition, the revision knee systems usually allow the surgeon to use metallic augments to build up and compensate for any bone loss present.

Ligament laxity may also be a problem and, in these situations the revision knee system may have different articulating mechanisms and hinges to enhance or replace ligament function. The choice to use these implants can be made by the surgeon during pre-operative planning or on the basis of findings in theatre. Once the original implants have been safely removed and the final bone preparation is made the surgeon can use a tension device or spacer blocks to ensure the ligaments in the knee joint are balanced and that the thickness of implant required is the same in both flexion and extension. This is shown in *figure 9* below.

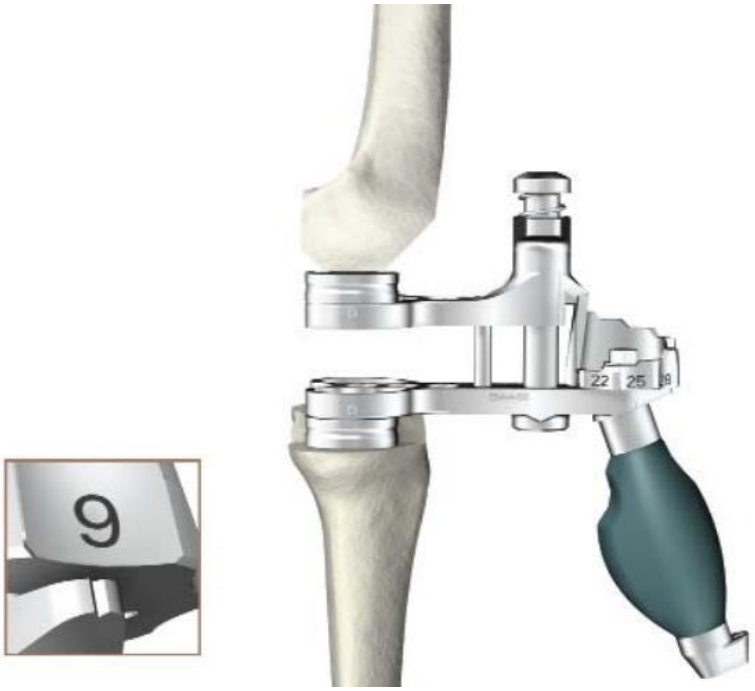


Fig 9, an adjustable tensioner device is used to assess the thickness of the extension gap. The surgeon can then check the knee ligaments are balanced and measure the thickness of implant required. In this example the adjustable device is suggesting a 9mm polyethylene insert would be the desirable thickness. Reproduced with permission from Stryker Triathlon surgical technique 2015.

In a complex revision scenario with significant bone loss it may not be possible to balance the knee. If persistent ligamentous instability is present despite using standard implants the surgeon can use implants, which stabilise the knee to assist with ligament function and knee balancing. If the ligamentous deficit is too severe a 'hinged 'revision knee implant can be used. This utilises a constrained articulation between the femur and tibia. In a difficult case this can completely replace the stabilising function of the patient's knee ligaments. An example of a hinged revision knee implant is shown below in *figure 10*.

Fig 10, a fully constrained Revision total knee implant. In this example a 'hinge' connects the femur and tibia allowing the implant to be used when severe ligamentous insufficiency is present. Reproduced with permission from Stryker Triathlon surgical technique 2015.

Australian Orthopaedic Association National Joint Replacement Registry

Since 1999 the AOA, with the help of surgeons and the Australian government, has collected data on primary and revision arthroplasty surgery nationally. This process has allowed the collection and analysis of data with large numbers, making it a very powerful tool both for the surveillance of the outcomes of prosthetic implants and in research related to arthroplasty surgery. Each year the registry provides reports on the results and revision rates for all implants used in Australia. Surgeons also are issued with individual reports to monitor and benchmarking their own practice, allowing for improvements to be made and to perform a comparative assessment. Implant manufacturers are supplied with the results of their own implants to allow them to update and maintain their quality and manufacturing processes in line with other products in use on the market.

In addition, surgeons can request specific reports to look at results for specific implants, time frames or even their own department in isolation. When compared to the large numbers in the national data base these reports can be used as powerful research and audit tools. As part of this thesis in *Chapter 4* we used historic local data and compared it with national trends to identify areas for improvement in our practice. These data were then compared with our local figures and subsequent reports on our figures to identify trends and effects from our changes to diagnosis and management.

The registry now holds data on over 602,000 TKA procedures [12]. Over the last year 55,000 new TKA procedures were added to the registry [12]. At an approximate cost of $23,000 per case the total burden on the health care system for these procedures is 1.26 Billion dollars a year, for the hospital stay and procedure alone[13]. By comparison the total budget to run the AOANJRR is only 2.3 Million dollars annually[19]. Therefore, if the data produced by the national registry leads to even small reductions in implant failures and subsequent revision surgeries the registry system can prove to be very cost effective [20].

Local Revision Joint Replacement Registry

One of the main strengths of the national registry is its size and the subsequent power of its data. Large numbers allow analysis to be performed with results that could not be obtained in one centre. In addition, these registries are very useful for the analysis of trends in data over time. This is an essential part of the registries function when performing surveillance of implants. Increased failure rates of a specific implant that may not be picked up in one centre can be more easily detected looking at larger numbers.

However, one of the weaknesses of these large systems is that they may not hold the level and detail of information that can be obtained at a local level. Revision surgery is very heterogeneous and at a national level it is difficult to store and analyse this level of detail. A smaller local revision may have fewer cases but allows the surgeon or researcher to collect and analyse data to a much higher level of detail. This may detect trends regarding information not collected in national systems. In *Chapter 4* we used our experience with the national registry and the results it provided for our historic cases to devise a local system allowing us to gather more in-depth figures. These can be used alongside national figures to ensure our practice is in check with national trends. In addition, this local information can be fed back to the national system to indicate additional analysis that could be undertaken at a broader scale.

Knee Instability in TKA

Knee Instability Definition

Knee instability is defined by a number of means; from the point of view of the surgeon this refers to a laxity in the patient's knee resulting in clinical symptoms. This can be caused by ligamentous laxity or injury, loosening of the components, failure or breakage of components and surgical error in relation to implant size or balancing of the soft tissues of the knee [8]. Furthermore, some implant designs have features that predispose to development of 'mid flexion instability' where the ligaments appear balanced at 0 and 90 degrees of flexion but become lax in the mid-range [21]. These patients can experience significant symptoms climbing steps or rising from a chair.

A review of The Australian AOANJRR reports in recent years shows that the percentage of all knee revision surgeries performed for TKA instability is rising. In the 2008 AOANJRR report, instability was the 9th most common reason for revision at 3.8%; [22] and in 2011 it was the 7th most common at 4.5% [23]. The 2018 report states that instability is the 5th most common reason at 7.8% [24]. It is unclear whether this is due to an increasing incidence or an increased awareness of the diagnosis. Recent work has debated whether these failures are related to surgical techniques or the actual design of the knee implants. The recent development of single radius implant designs hoped amongst other clinical issues to reduce the incidence of mid flexion knee instability. These implants work on the principle that the same amount of bone is resected from the distal and posteromedial femur. In combination with a minimal thickness of bone resection the knee would in theory move through its range of movement with the same tension on the Medial collateral ligament. If the knee is balanced with the medial collateral ligament in good tension mid flexion instability could be avoided. At this time this remains unclear if this implant design does reduce mid-flexion instability and one recent study suggested it had no effect at all [25].

In addition, we have observed a group of patients who are initially stable but become unstable over the first 3 years post-op. The cause of this problem is not yet known and will be investigated as part of the ongoing work in this thesis.

Causes of Knee Instability

The failure causing the patient's instability can be defined as either peri-operative, early or late. Early failures tend to occur in the first 3 years with late failure occurring several years later. Early failure tends to be caused by ligamentous injury of laxity while late failure is possibly due to delayed diagnosis of ligamentous laxity, attenuation of the knee ligaments or trauma. As part of our systematic review in *Chapter 2* we try to identify the causes of instability as a mode of failure looking at both early and late failures. Patients with significant symptoms may seek the opinion of a surgeon regarding revision knee arthroplasty. In our systematic review it was difficult to define the exact causes of failure from the published literature. What was clear was that instability cases failed very early

with the average time to revision surgery < 4 years after primary TKA surgery (*Table 4, Chapter 2*).

Diagnosis and Treatment of Knee Instability

Clinically instability is diagnosed by either clinical assessment, radiological assessment or a combination of both. Once the diagnosis is confirmed the surgeon must use a the patient's symptoms combined with their surgical history and indwelling implants to decide whether surgical intervention is beneficial. Many patients will tolerate mild instability without the need for surgical intervention. In addition, some patients may have medical issues making surgery riskier and some knee implants are easier to revise than others, depending on the implants specific design. Discussion around clinical cases and presentations within the Arthroplasty Society of Australia* suggested that there is a growing awareness amongst surgeons of Instability as a mode of implant failure and that these failures may be under diagnosed. In addition to patients who are developing mid flexion instability there may be a subgroup developing a form of 'acquired instability' after initially successful knee arthroplasty surgery. We assume with the limited evidence so far, this is due to chronic ligamentous failure months or years after the knee arthroplasty, but further work is required to prove if this is the case. While other common modes of failure including Aseptic Loosening and Prosthetic Infection have been studied extensively, there is a lack of published evidence in relation to Instability as a mechanism of failure. Therefore, the need to explore a more robust diagnostic process and Registry sub-analysis was required.

**Wilson CJ, Ford J & Quinn S & Krishnan J*	*Clinical diagnosis of Instability in the failing TKA. Evaluation of a new diagnostic algorithm.*	
Arthroplasty Society ASM	*Noosa QLD*	*Jun 17*

Clinical Experience with Knee instability

In *Chapter 3* we used the information from our systematic review and our initial historic Registry report to develop a standardised diagnostic and management pathway. The historic report is summarised in *Appendix 6*. This was designed to improve our clinical experience in both the diagnosis of and revision surgery for knee instability. In our department all patients suspected of having an unstable TKA are seen by a surgeon for routine clinical and radiographic assessment. If there is a significant concern that further surgery is required, the patients will undergo an examination under anaesthetic (EUA). This investigation involves both radiology and aspiration / injection of the knee. In addition, patients have routine bloods and if required scans performed to exclude prosthetic infection as the cause of failure. This diagnostic pathway is discussed in detail in *Chapter 3*.

During the EUA procedure the patient with an adequately relaxed the knee is x-rayed in 5 positions. The first is taken in the neutral position and represents a prosthetic knee as it would appear in a normal AP x-ray films. The surgeon can magnify the view and look for any evidence of asymmetry or loosening. The next 2 x-rays are taken in 20 degrees of flexion. This allows relaxation of the knee capsule and demonstrates the knees stability in the extension gap. In this position the surgeon applies a varus and then valgus force to look for signs of the knee joint opening or 'gapping.' In a normal prosthetic knee, the patient's joint will open between 2 and 5mm, which is easily seen on the screening, x-rays. Greater than 5mm of asymmetric gapping is usually considered pathological. The images are stored and can be used for further discussion or diagnostic purposes.

Two further images are taken at 90 degrees of flexion, these represent the flexion gap in the prosthetic knee. Again, a varus and then valgus stress is applied, and images recorded as before. The knee is then tested for anterior and posterior draw stability. In this test the surgeon holds the tibia firmly and directs an anterior and then posterior force on it while the knee is flexed to 90 degrees. Usually a primary knee implant is stable to the posterior stressing force. In normal circumstances the patient's knee will translate forward between 0 and 10mm on applying and anterior force. Greater than 10mm is usually

considered to be pathological. An example of the EUA fluoroscopic radiographs is shown in *Figure 18, Chapter 3*.

An aspiration of the knee is performed, and any fluid obtained is sent for microbiological culture and for microscopy to perform a white cell count. This test provides further evidence to confirm or rule out prosthetic infection as a cause of implant failure. Finally, an Intrinsic knee injection is performed using 10 mls of sterile local anaesthetic. The patient is then examined post-op to record if they obtained pain relief from the injection. An absence of post op pain relief is considered a negative test and suggests the patient's symptoms are coming from a source extrinsic to the knee and further assessment may be required before considering surgery. Extrinsic pain can come from other sources such as the lumbar spine, hip joint, and the tendons or muscles around the knee. All patients are reviewed in the surgeons consulting rooms and the results discussed before considering the final decision to proceed to revision arthroplasty surgery.

This process was designed to attempt to reduce our number of patients revised for 'pain 'and to obtain a more accurate diagnosis of the reason for revision prior to performing surgery. In addition, patients tested in this process may not proceed to revision TKA surgery. Patients may therefore avoid revision TKA surgery, who may be experiencing pain but do not have a good reason to undergo repeat invasive knee surgery. The results of this process are discussed in full in *Chapter 3*. There was no evidence of a similar formal diagnostic and review process in our systematic review suggesting this is the first attempt to combine registry data with a robust diagnostic algorithm in the diagnosis and management of the failing knee.

All patients who underwent revision TKA surgery were recorded in our local revision registry and a prospective clinical evaluation of our patients was performed to evaluate the outcomes of patents that have undergone revision TKA surgery. The local registry involved a prospective collection of the revision knee arthroplasty procedures performed in our department. All patients' results were crosschecked twice by the author to look for errors or duplications. These patients had all been evaluated using our diagnostic algorithm prior to revision surgery. An Ad Hoc report was then requested and obtained

from the AOANJRR to allow comparison of this prospective data and compare these findings with our historic AOANJRR results. This report is summarised in *Appendix 7.* In *Chapter 4* the national registry results show that patients who have gone through our diagnostic process are more likely to undergo less invasive revisions. These patients may have fewer complications, cost our department less financially and have a lower risk of returning for further revision TKA surgery.

The Local Registry gives us a significantly more detailed account of the patient's characteristics and the type of surgery required allowing for comparison to the AOANJRR registry. This local registry is discussed in detail in *Chapter 4*. It will continue on prospectively beyond the scope of this thesis to allow us to continue to monitor trends into the future. In addition, its information can be fed back to the national registry in a 'feedback loop 'to allow modifications in its data collection and encourage the uptake of similar systems both nationally and internationally.

Clinical Results in Revision Surgery

In *Chapter 5* we evaluate our outcomes prospectively for patients who have come through this whole process. Using these results, we hope to gain further understanding of the outcomes for our patients after they have experienced revision TKA surgery. All patients were cross checked by the AOANJRR national registry to ensure they had not been re-revised in other centres. Our re-revision rates were then cross checked with an AOA registry cross analysis of all revision procedures performed prior to the introduction of our standardised algorithm. This report is summarised in *Appendix 8*.

This showed that since this algorithm was implemented, we had reduced or re-revision rates from 14.6 to 8.3% although it is impossible to say that this reduction is an effect of the algorithm alone or due to changes in technique in our primary TKA surgery over time. Hopefully the algorithm has reduced the number of our patients requiring revision surgery and it has also reduced the financial burden these surgeries have on our local health care service. To evaluate clinical outcomes Oxford scores were collected as Patient

reported outcome measures (PROMs). These were lower than expected suggesting there are still issues with patients function after revision TKA surgery despite reducing the revision rate. This highlights the need to reduce revision surgery rates in the first place. This is discussed further in *Chapter 6.*

Robotic technology and ligament balancing in TKA Surgery

In *Chapter 6* we evaluated the use in technology in improving ligament balancing in primary TKA surgery with the potential to reduce failures and revision TKA surgery for instability in the future. Computer assisted surgery (CAS) has been proved in previous studies to reduce outliers in surgical accuracy and revision rates over time [26]. Computer Navigated (CAS) TKA surgery uses digital referencing instead of 'Jigs' to map out the size of the patient's bones and the abnormal alignment to allow the surgeon to correct the alignment during the procedure and check that the alignment is correct before implanting the final prosthesis. The Navigation system uses fixed points or 'Trackers' to reference the position of the patient's bones in space with a reference and display system. Initial registration is performed to allow the computer system to map out the patients pre surgical alignment. The surgeon then uses a digital reference device or 'pointer 'to map out the surface of the patients knee joint. This process is known in CAS surgery as 'Registration'. An example of this process is shown in *Figure 11* below. This is cross referenced with the patient's alignment data and a 'Morph 'of the patient's knee is generated. The system uses a database of Morphs previously saved in its database for this final step, the Morph that most closely resembles the patients knee data is used. Therefore, in these systems this is an accurate estimate not exact representation of the patient's anatomy. Using this digital model, the surgeon can plan and execute the cuts with a high level of accuracy. These cuts are then checked with trial implants to ensure the correct alignment and implant size has been achieved.

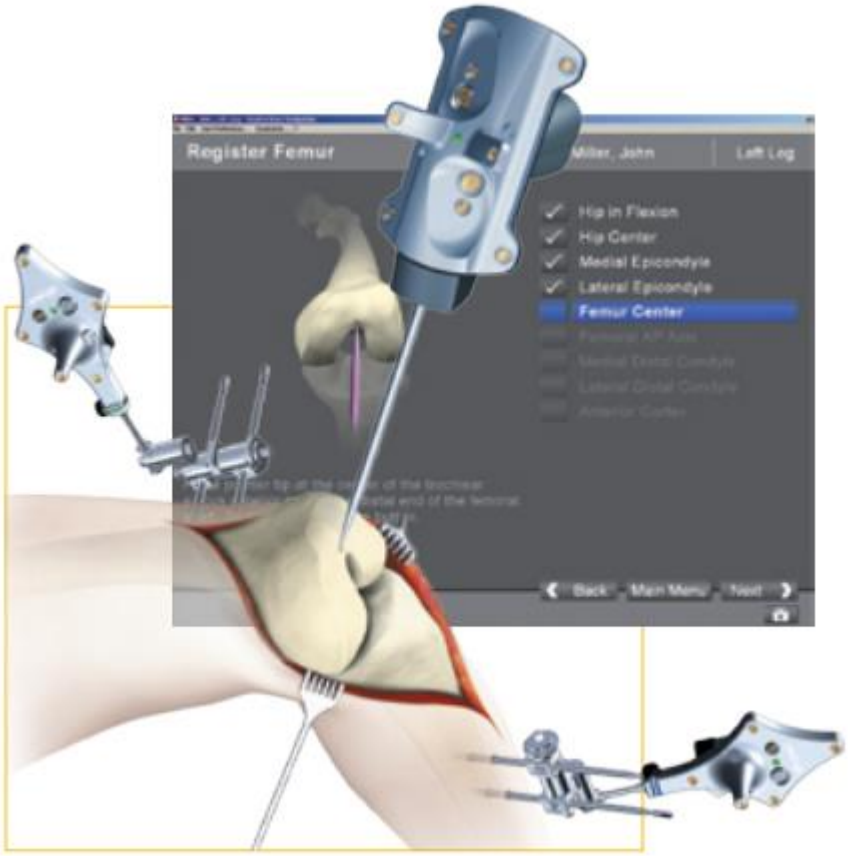


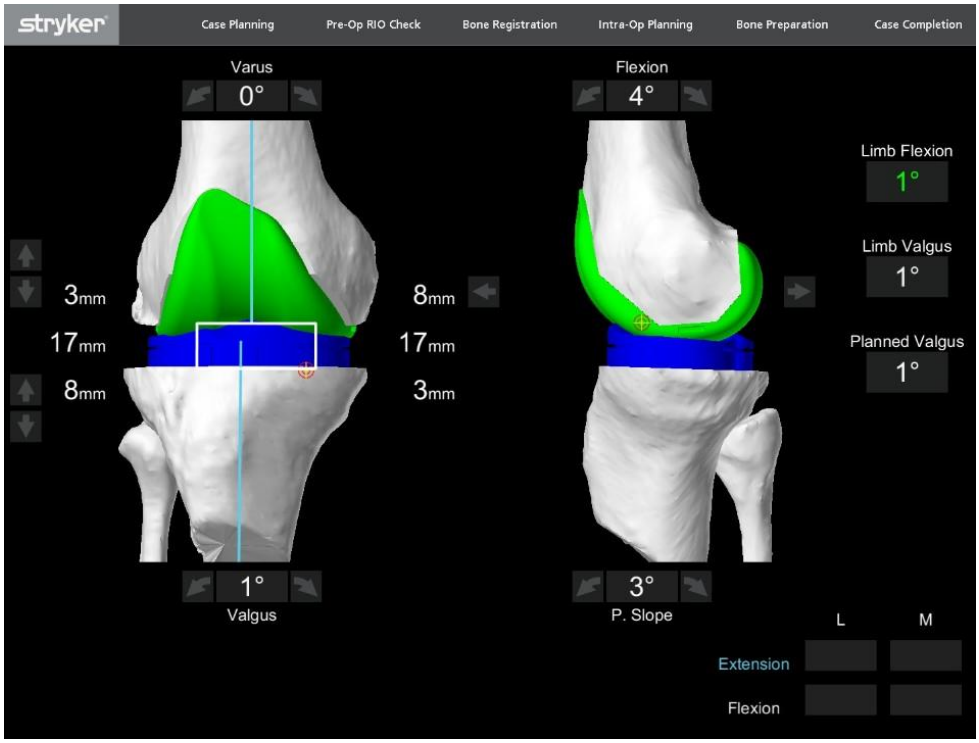
Figure 11 Mapping of the patient's knee during CAS Total Knee arthroplasty surgery.[67]

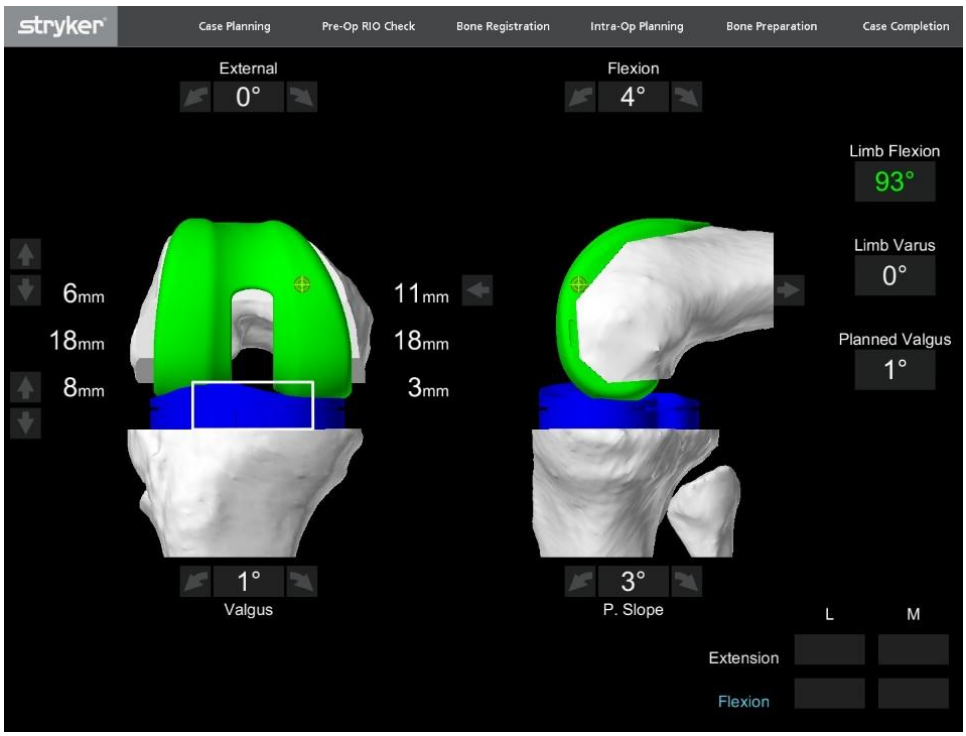
Reproduced with permission from Stryker

The CAS TKA method has been used for years to assist surgeons reproduce the patient's normal alignment and therefore improve the function in their knee. However, overtime implant companies have upgraded the functionality and software driving these systems. Surgeons can now use the CAS software to measure, and correct, the abnormal ligament flexion and extension gaps before performing bone cuts. In this process the surgeon can also check the alignment in both the coronal and sagittal plane before making the decision to insert the definitive implants. However, the CAS kinematic testing can allow checks to me made to ensure the flexion and extension gaps are symmetrical. In addition, the laxity of the patient's ligament s can be kinematically assessed throughout the range of movement. The knee is passed through a ROM with trackers and trial implants in place. The surgeon can feel and measure any laxity of asymmetry before committing to final implantation.

In our routine surgical practice, I have used CAS surgery for routine primary TKA surgery and for the last 4 years have now used the Kinematic balanced technique. The aim of this change has been to attempt to reproduce the patient's biomechanics and also reduce the risk of instability due to surgical error. AOANJJR report data on these cases under my care shows a revision rate of 0% at 4 years with this technique.[70]

Robotic surgery uses similar principles to CAS surgery however, the MAKO system uses enhanced software. In addition to assessing alignment the surgeon can estimate the best position to perform bone cuts to allow optimal balancing of the patient's ligaments and balance the flexion and extension gaps. The system also uses data from a pre-op CT combined with intra-operative mapping to accurately assess the exact shape and position of the patient's knee without relying on standardised 'morphs 'in the systems data base. By using this technology in the way, the knee can be implanted in the position that provides the best Kinematic Ligament balancing for the patient's knee without necessarily implanting the knee in a 'Neutral 'Mechanical alignment. The knee can be inserted in for example 2 degrees of Varus on purpose which represents an abnormal mechanically aligned knee while the ligament balancing and therefore Kinematic Alignment has been optimised. When considering kinematic balancing using the Robotic assisted TKA system the surgeon also has the choice to look at the patient's gap balancing and laxity before performing any surgery and then before making any bone cuts. An example of this planning and balancing capability is shown in *Figures 12 a and b* below.





Figures 12 a and b, Gap balancing data from the MAKO robotic system before surgical bone cuts are performed. Reproduced with permission from Stryker

In *Chapter 6* we evaluate our data regarding accuracy in bone cuts, implant positioning and ligament 'gap' balancing in TKA surgery. Using robotic we assess the ability of new surgical technology to perform these actions with a higher level of accuracy than previous surgical methods. In addition, the surgeon has the ability to plan these surgical procedures using data specific to each patient prior to commencing surgery. Our analysis shows that in primary TKA surgery the implants can be inserted with a high level if ligament balancing precision with the potential to reduce failures in the future.

Data published from the AOANJRR national registry has shown reduced revision rates in cases where computer assisted surgery has been performed to improve surgical accuracy [26]. However further research will be required to assess the long-term effects of robotic surgery and whether its improved accuracy of ligament balancing leads to a reduction in failure rates for TKA instability in the long term.

Chapter Two: A systematic review of the published literature, causes of instability in TKA

This Chapter Contains Material from:

Wilson CJ, Theodoulou & Krishnan J. Knee instability as the primary cause of failure following Total Knee Arthroplasty (TKA): A systematic review of the patient, surgical and implant characteristics of revised TKA patients. *2017 Sept (29) The Knee.*

Introduction

Background

Revision total knee arthroplasty (TKA) is a significant undertaking for patients with both higher morbidity and mortality in comparison to primary TKA[29]. In recent years, there has been an increase in patients reporting symptoms relating to knee instability; similarly, the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) has reported rising rates of revision for knee instability. In the 2008 AOANJRR report, instability was identified as the 9th most common reason for all revisions, at 2.9%[30]. In 2011, this increased to the 7th most common cause, at 5.8%[31], and most recently, the 5th most common reason for revision at 7.3% in 2017[32]. It is unclear whether this trend is due to an increasing incidence, or an increased awareness of the diagnosis. Recent work has also debated whether these failures are related to surgical techniques or knee implant design, with the issue remaining unclear[33].

TKA instability can arise due component loosening, component breakage, polyethylene wear, ligamentous instability or surgical error in relation to implant size or balancing of the knee[34]. In addition, some implant designs may have features that predispose to development of 'mid flexion instability' where the ligaments appear balanced at 0° and

90° of flexion but become lax in the mid-range[35]. These patients can experience significant symptoms climbing steps or rising from a chair.

Discussion around clinical cases and presentations within the Arthroplasty Society of Australia (*June 2017*) have suggested that there is a growing awareness of instability as a mode of implants failure amongst surgeons. In addition to patients who are developing mid flexion instability, there may be a subgroup developing a form of 'acquired instability' after initially successful, knee arthroplasty surgery. With the limited evidence available, it is assumed that this is due to chronic ligamentous failure months or years after the knee arthroplasty procedure. While other common modes of failure such as aseptic loosening and prosthetic infection have been studied extensively, there is a lack of evidence in relation to instability as a mechanism of failure.

A number of definitions of knee instability exist in the literature. In addition, symptoms that present and appear to be caused by instability may also be due to a number of other factors including patellofemoral articulation, muscular weakness, component loosening, and infection[36]. It is important to define reasons for failure accurately to allow correct reporting of these TKA failures. An essential part of this literature review was to try and define a standardised description of TKA instability by evaluating how it has been described in previously published studies. In addition, as part of this review we have evaluated what clinical methods have been used to diagnose these failures and use this data to create a standardised diagnostic process.

With instability increasing as a cause of revision TKA, a clear understanding of the factors contributing to instability and subsequent revision is imperative. Recent AOANJRR figures consistently confirm that revision surgery not only reports higher rates of complication, but also poses a greater risk for further Re-revision surgery. Such evidence highlights the need to enhance our understanding of how to achieve the optimal outcome at the primary procedure and reduce the patient's risk of entering a descending spiral of multiple surgeries.

An assessment of an unstable knee has been recently described by Petrie and Haidukewych[37] and Cottino and others[38]. The use of clinical and radiological assessment is considered in these papers to obtain the correct diagnosis. A combination of both assessments is required to accurately confirm the diagnosis of instability and to exclude other diagnoses, which may elicit a different treatment approach. In the present review we assessed whether the published literature supported this recommendation and considered how the results available could enhance our understanding of these diagnostic issues in clinical practice.

Time to Failure

The AOANJRR data suggests that most TKA implants are expected to last more than 10 years. A well-functioning primary implant has an approximately 5% chance of failure by 10 years post-op[32]. The most common reasons for revision were loosening, infection patellofemoral pain, pain and instability. Overall 2.7% of TKA's implanted for OA will fail by 3 years and 3.6% by 5 years [32]. Therefore, despite the fact that failure rates are low of the knees that fail many do so early. The AOANJRR is a powerful source of Australian data, providing yearly cumulative percentage revision rates in consideration of various factors, such as implant type.

The present review explored the international literature on knee instability to investigate time to failure following primary TKA. Time to failure is an essential factor in our understanding of an unstable knee, as patients with early knee failure are at greater risk of higher complication rates and re-revision surgery prematurely in their surgical journey.

Patient Characteristics

Failure of primary knee arthroplasty has been more commonly reported in a younger patient cohort of ≤ 75 years of age[33]. Patients over 75 years of age have a cumulative failure rate of 2.9% at 10 years post op. This failure rate gets higher with diminishing age. Patients aged 55 – 64 years old have a failure rate of 7.0% while patients younger than 55 years old at the time of primary surgery have a cumulative revision rate of 10.8% at 10

years. This effect of age is summarised in *Figure 13* below. A younger cohort is consequently more likely to require further surgery over time, emphasising the need for further investigation of specific modes of failure. Evidence on patient characteristics such as age, gender and Body Mass Index (BMI) were investigated in this review to screen for potential correlation between patient characteristics and instability failure.

Figure KT10 Cumulative Percent Revision of Primary Total Knee Replacement by Age

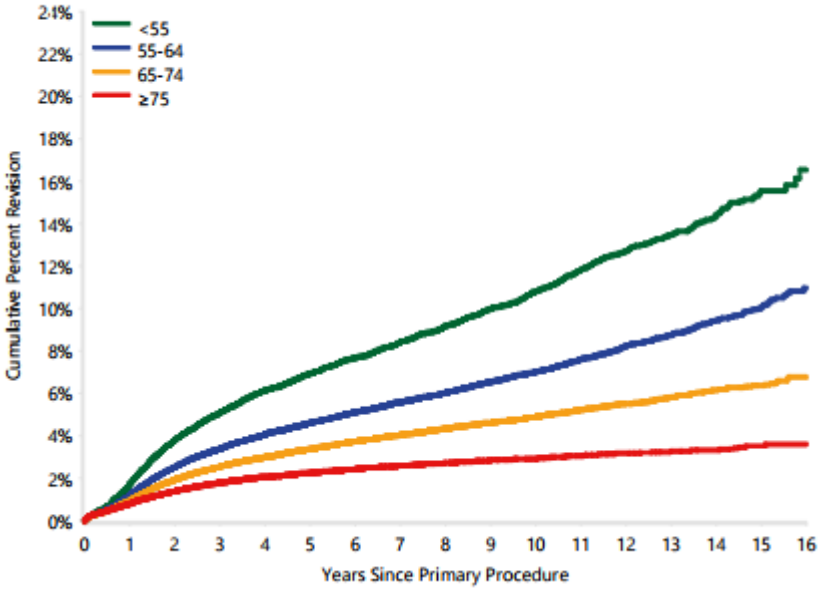


Fig 13, Cumulative revision of primary TKA prosthesis by age of patient at time of surgery. Reproduced with permission from the AOANJRR. Figure KT13, Page 199 2017 Annual report.

<u>*Surgical Technique*</u>

Chang et al[40] described that prevention of knee instability through the use of appropriate prostheses and technique was paramount. Although current interest in the orthopaedic community is focused on failures of specific implants, Chang et al[40] emphasised the importance of surgical technique and appropriate intraoperative gap balancing, over implant use, when attempting to reduce risk of failure. Given current evidence, this review considered literature on both surgical technique and implant type, to determine their influence of knee instability and TKA failure.

The aim of this review was to systematically assess the current evidence available regarding knee instability after TKA to identify the patient, surgical and implant characteristics of primary TKA patients revised for knee instability.

More specifically, the primary objectives were *to consider literature that describes knee instability as the primary cause of failure of primary TKA to determine:*

1. *time to failure between primary TKA and revision TKA;*
2. *patient characteristics, surgical technique or implant type used in patients revised due to knee instability.*

Secondary objectives were to i*dentify the methods of diagnosis of Knee instability*

Materials and Methods

The Cochrane Library and PROSPERO were screened for published protocols or reviews related to the topic of interest, of which none were identified. Our review was then registered online with PROSPERO (Registration Number CRD42015019898) to prevent duplication of work by other centres. The review was performed on the basis of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[41].

Search Strategy

We conducted a sensitive and comprehensive search for published and unpublished studies relevant to the review question. Searches were restricted to studies published in English within the past 10 years.

Orthopaedic implant companies regularly update and modify their implants as advances in design and engineering lead to improvements in results and quality. Following an initial screen of the literature it was apparent that older articles referred to knee implants no longer in use in the current market. Furthermore, surgical techniques have developed significantly over the last 10 years compared to previous methods. As a result, it was essential to impose a search date limit so articles identified and reviewed would be relevant to current clinical practice.

Before developing the final search strategy, a preliminary scoping search of Ovid Medline was conducted to identify relevant Medical Subject Headings (MeSH) and a wide range of synonymous text-words. A detailed, sensitive search strategy was then developed in this database before accurate translation for other databases. These databases were: *PubMed; Cochrane Database of Systematic Reviews, Central Register of Controlled Trials, EMBASE (OvidSP), CINAHL, Scopus,* and *Web of Science.* A database search strategy is available in *Table 2* below.

A simplified version of the database search strategy was used to find unpublished ('grey') literature. This search included web search engines Google (Advanced) and Google Scholar (Advanced), clinical trial registries, major theses catalogues, grey literature repositories (e.g. Open-Grey), and the websites of significant conferences and organisations. The candidate endeavoured to contact authors wherever additional data or clarification was required.

Ovid MEDLINE Search Strategy
MeSH Terms
Arthroplasty, Replacement, Knee/ Knee prosthesis/ Causality/ or Precipitating factors/ or Risk factors/ Joint instability/ (Knee joint/ or Knee/) and Arthroplasty/
Free Text Terms
(TKA? or TKR?).tw. (Knee* adj4 (replacement* or arthroplast* or prosthe*)).tw. (Stable or stabili* or instabili* or unstable or destabili* or constrain* or balanc* or imbalanc* or unbalanc*).tw. (Aetiology or Adverse effects).fs. (Causalit* or causati* or cause* or ?etiolog* or risk* or precipitat* or predispos* or multifactor* or multi-factor*).tw
/ MeSH/Subheading combination; * Search Term Truncation

Table 2 *Search Strategy summary*

Eligibility/Selection Criteria

Systematic search results were merged in the reference management software program, EndNote, and duplicate articles removed. Titles and abstracts were screened for eligibility based on the inclusion and exclusion selection criteria by a single author [CW]. Full-text articles were then retrieved for titles and abstracts that were deemed relevant, or where

eligibility was unclear. Eligibility of the full-text articles was reviewed by two authors independently [CW, AT], and any disagreement between authors was further deliberated until consensus was reached. Articles were selected in accordance with the following inclusion criteria: (1) Any articles referring to instability in post-operative primary TKA patients; (2) Articles reporting on revision TKA due to instability; (3) Articles published or available between 2005 to 30th March 2015.

Articles were excluded in accordance with the following exclusion criteria: (1) The term 'instability' was identified by review authors to define other pathologies such as aseptic implant loosening or loosening/dislocation failure of mobile bearing knees; (2) Articles reported on atypical knee implants (i.e. Unicompartmental or Partial Knee Arthroplasty); (3) Articles described historical implants no longer in use in Australia or globally; (4) Articles which refer to revision of components previously revised; (5) No data relevant to knee instability as a cause of revision in title or abstract.

Critical Appraisal

The Methodological Index for Non-Randomised Studies (MINORS) instrument was used to assess the methodological quality and risk of bias of non-randomised surgical studies included in the review. MINORS is a validated, 12 – item critical appraisal tool for assessment of quality of comparative or non-comparative non-randomised surgical studies[42]. Items are scored as *0 (not reported)*, *1 (reported but inadequate)* and *2 (reported and adequate),* with an ideal score of 16 for non-comparative and 24 for comparative studies[42]. Case reports were not critically appraised.

Data Extraction

Two authors [CW, AT] independently extracted the data from all eligible articles. Data extraction was piloted on 3 articles before use independently. Data extracted included *age, gender, BMI, primary implant design and surgical technique, time to revision, revision type and prosthesis, diagnostic testing for instability, cause for instability (traumatic or non-traumatic), instability type (chronic or acute) and reported dislocation.*

Disparities in data extraction were discussed, reviewed and resolved.

Data Analysis

Quantitative data for continuous variables including *time to failure* and *age* were pooled in a statistical meta-analysis using the Comprehensive Meta-Analysis (Version 3.3.070). Effect sizes were expressed as weighted mean differences with 95% confidence intervals, and a random effects model was used. As included studies reported mean *time to revision* with the variance measure of range, ranges were converted to standard deviations to allow for meta-analysis calculation, using, "Standard Deviation Estimator" implemented in PASS 14 Power Analysis and Sample Size Software (2015. Dichotomous data was analyzed descriptively using percentages and ratio.

Results

Systematic Search

The database and grey literature searches identified a total of 1841 unique articles. Following initial abstract screening, 252 articles were retrieved for full-text assessment, of which 42 met the selection criteria. A number of included articles did not report sufficient information relevant to the primary objective of this review. As such, corresponding authors or institutions of 25 selected articles were attempted to be contacted for further data. Despite efforts, the authors of three articles were uncontactable. Data was deemed unattainable if a response was not received within 6 weeks following initial contact. All authors were contacted 2 times to try and obtain this additional data. Eventually 17 articles were consequently withdrawn due to a lack of author response. A total of 22 articles were included in the qualitative synthesis, a breakdown of article selection can be found in *Fig. 14* below.

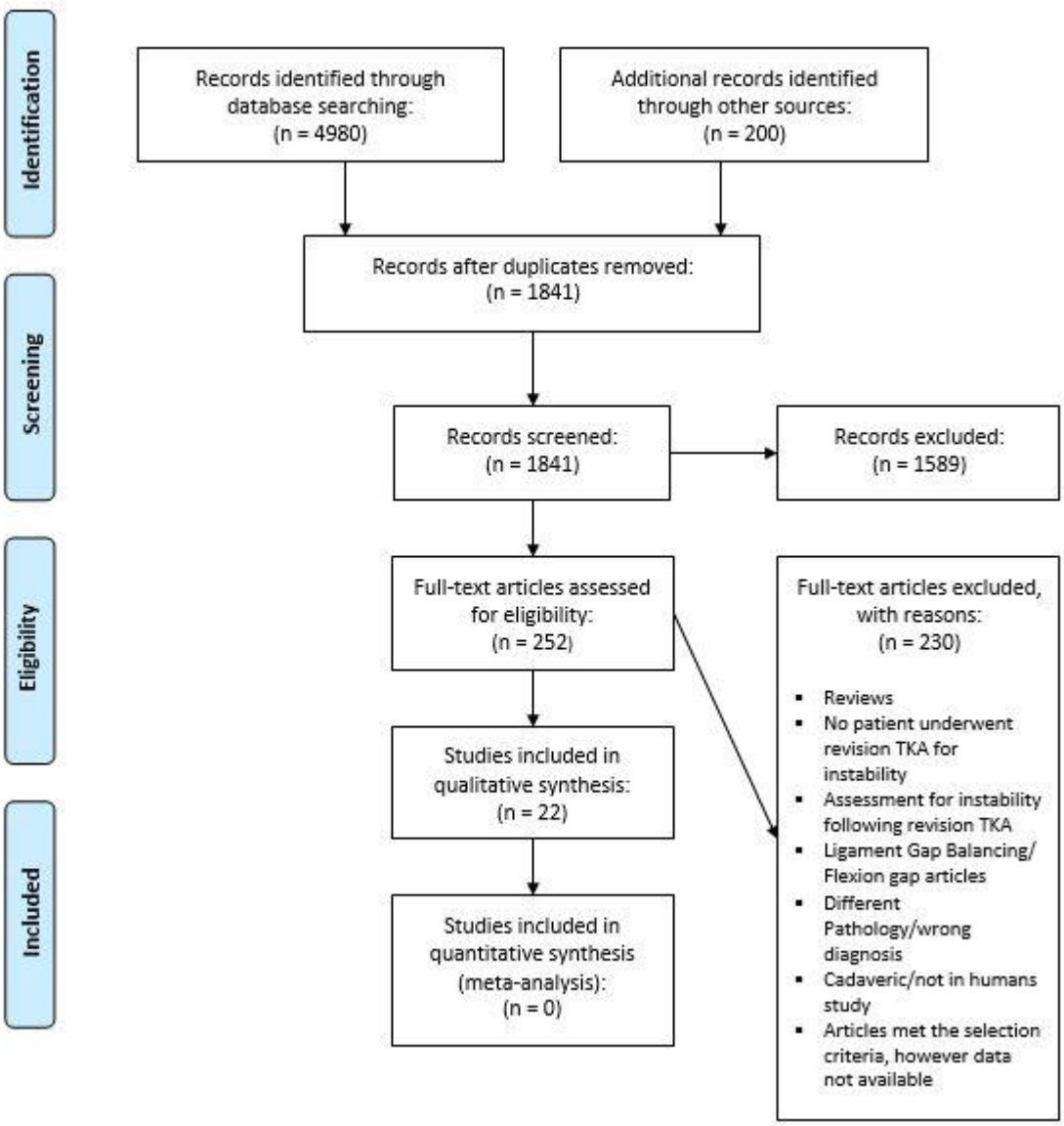


Figure 14. *PRISMA Flow Diagram summarising process for Article Selection*

A description of the characteristics of included studies is also provided in *table 3* below.

First Author, Year	**Study Design**	**Number of knees revised for instability**	**Age** (Yrs.) *(min – max)*	**Gender** *(M: F)*	**Time to Revision** (*Months) (min – max)*	**Primary TKA Implant Design** *(CR : PS)*
Schwab, J. H., 2005[43]	RCS	10	67 (51 – 79)	8 : 2	27 (8 – 59)	0 : 10
Scott, R. D., 2005[44]	PCS	6	NR	NR	NR	6 : 10
Firestone, T. P., 2006[45]	RCS	109	64 (39 – 86)	57 : 48	38.4 (8 – 60)	81 : 28
Girard J., 2009[46]	RCS	2	NR	NR	16.5 (15 – 18)	0 : 2
Raab, G. E., 2009[47]	Retrospective Comparative Study	42	61.8 (40 – 86)	20 : 20	NR	NR
Unnanuntana, A., 2010[48]	Case Report	1	47	0 : 1	21	1 : 0
Villanueva, M., 2010[49]	RCS	6	68.7 (65 – 73)	1 : 5	43.6 (6 – 120)	5 : 1
Arnout, N., 2011[50]	Case Reports	4	(53 – 73)	0 : 4	NR	NR
Hosaka, K., 2011[51]	RCS	2	78 (73 – 83)	0 : 2	31.2 (2.4 – 60)	NR
Koskinen, E., 2011[52]	RCS	10	70 (57 – 87)	0 : 10	51.6 (12 – 156)	10 : 0
Mayle, R. E., 2012[53]	RCS	1	NR	0 : 1	16	NR
Bieger, R., 2013[54]	RCS	13	67 (55 – 79)	3 : 10	43 (4 – 82)	NR
Kasahara, Y., 2013[55]	Retrospective Comparative Study	13	76 (60 – 89)	1 : 12	91 (4 – 240)	NR
Tay, K. S., 2013[56]	RCS	3	NR	NR	41.1	NR
Van Kempen, R. W., 2013[57]	PCS	23	66.1 (45.4 – 86.4)	11 : 12	NR	NR
Abdel, M. P.,	RCS	60	65 (43	27 : 33	NR	41 : 19

2014[58]			– 82)			
Hamilton, D. F., 2014[59]	Prospective CCS	25	70.3 (49 – 85)	11 : 14	52.8 (36 – 84)	24 : 1
Kannan, A., 2014[60]	RCS	37	62 (40 – 82)	13 : 24	NR	24 : 13
Song, I. S., 2014[61]	RCS	24	71 (52 – 85)	4 : 18	82.5 (14 – 228)	14 : 10
Flierl, M. A., 2014[62]	Case Report	1	NR	0 : 1	3	1 : 0
DePuy Synthes, 2014[63]	Case Reports	4	76.3 (64 – 89)	1 : 0	64.5 (6 – 168)	1 : 1
Springer, B. D., 2015[64]	Case Report	1	62	1 : 3	24	0 : 1

NR = Not reported; TKA = Total Knee Arthroplasty; PS = Posterior Stabilised; CR = Cruciate Retaining
Study Designs: RCS: Retrospective Case Series; PCS: Prospective Case Series; CCS: Case Control Study;

Table 3: *Characteristics of Included Studies*

Study Quality

All studies were assessed for quality; however, there was no quality restrictions imposed for inclusion in the review. The majority of the 22 articles included were of a case series study design (15) and a retrospective nature (19). Further study designs included a single case-control study (1), retrospective comparative studies (2) and case reports (4). The MINORS mean score for study quality was low at 9.11 (range, 6 – 18).

Time to Failure

Time to failure between primary TKA and revision TKA was described in 16 of the 22 included articles, of which reported on a total of 374 knees revised for instability. Of these 16 articles, 5 were unable to be included in the meta-analysis as 4 were case reports and 1 did not report a time to failure range. The remaining 11 articles reported on

a total of 218 knees and demonstrated a weighted mean time to failure of 44.7 months (95% CI [33.8, 55.7]) (*Table 4*).

Patient Characteristics

Of the 22 articles included, 19 reported a gender distribution, with approximately 16.4% more females revised for instability than males (*Table 4*). It must be noted some articles reported the number of knees revised for instability and the gender distribution, without specifying the gender of bilateral patients, causing a discrepancy between total the number of knees and total number of males and females reported in this review.

A total of 88 revised knees revised for instability reported BMI, with only 1 patient identified with a BMI ≥ 40. The mean age at time of revision surgery was reported in 16 of 22 included articles. Of these 16, 2 were unable to be included in the meta-analysis as they were of a case report study design. The remaining 14 articles reported on a total of 378 knees and demonstrated a mean age of 67.6 years at time of revision surgery (95% CI [65.38, 69.75]) (*Table4*).

Table 4. Time to Failure and Characteristics of patients revised for Instability

	Units	*Results*
Time to Failure *(n_k= 218; n_a= 11)*	Weighted Mean 95% CI	44.7 months 95% CI [33.8, 55.7]
Gender *(n_k=386; n_a= 19)*	M : F	158 : 220
BMI *(n_k=88; n_a=5)*	BMI < 40 : ≥ 40	87 : 1
Age at Time of Revision Surgery *(n_k=378; n_a=14)*	Weighted Mean 95% CI	67.6 years 95% CI [65.38, 69.75]

n_k = number of knees revised for instability reported for each parameter

n_a = number of articles that reported the parameter

Surgical Technique and Implant Type

Primary TKA

Osteoarthritis was the principle indication leading to primary TKA in patients that later required revision for instability. The conventional surgical technique was the main technique employed for the primary TKA, however this was only reported in 4 of the included articles (15 knees). None of the included articles provided specific data regarding the effect of CAS or PSI surgery.

In comparison to the Posterior Stabilized (PS) implant design; the Cruciate Retaining (CR) implant was used 70.7% of the primary TKA procedures that were subsequently revised for instability (*Table 5*). However, this may just reflect the fact that CR knees are more commonly used in primary surgery.

Revision TKA

A total of 10 articles reported the type of revision, with the majority of patients requiring a total revision (77.4%), that being revision of both the femoral and tibial components. A constrained or semi-constrained revision prosthesis was more commonly used in patients revised for instability, in comparison to unconstrained (*Table 5*)

Knee Instability: Diagnosis, Cause and Type

Of the 22 included articles, 15 reported the diagnostic approach used to determine instability. The majority of articles (12) used a combination of both radiographic and clinical testing, while 3 only used clinical assessment. A number of articles (6) also reported the cause of instability, with 9 categorized as traumatic and 58 non-traumatic, reported in a total of 67 revised knees. Authors also categorized the type of instability as either chronic or acute. A mere 3 articles reported the type of instability, with 23 chronic and 3 acute cases identified. A total of 5 articles (51 knees) reported on dislocation rates. A dislocation was reported in 12 of the 51 knees revised for instability (23.5%). It is not clear from the different accounts if these are due to subluxation, PS post 'jump' or true dislocation of the knee prosthesis.

Table 5. Characteristics of Surgical Technique and Implant			
Primary TKA		*N*	
Indication for Primary TKA	Osteoarthritis	118	
(n_k =120; n_a= 8)	Rheumatoid Arthritis	2	
Surgical Technique	Conventional	14	
(n_k =15; n_a=4)	Minimal Invasive Surgery	1	
Implant Design	Posterior Stabilized	86	
(n_k =294; n_a=14)	Cruciate Retaining	208	
Revision TKA		*N*	*(%)*
Type of Revision	Complete Revision (T+F)	106	*(77.4)*
(n_k =137; n_a=10)	Femoral Only	6	*(4.4)*
	Tibial Only	4	*(3.8)*
	PE Insert Only	18	*(13.1)*
	Femoral and PE Insert	1	*(0.7)*
	Patella and PE Insert	2	*(1.5)*
Revision Prosthesis	Constrained	35	*(35.0)*
(n_k =100; n_a=7)	Semi – Constrained	44	*(44.0)*
	Standard/Unconstrained	21	*(21.0)*

N = number; PE = Polyethylene

n_k = number of knees revised for instability reported for each parameter

n_a = number of articles that reported the parameter

Discussion

The aim of this review was to systematically assess the current evidence available regarding knee instability after TKA to identify time to failure between primary and revision TKA. In addition, we considered the patient characteristics, surgical technique and implant type used in patients revised due to knee instability.

Not only has instability been identified as cause of revision knee arthroplasty but also a cause for early revision after primary TKA surgery. Our findings of the relevant literature identified that on average, patients underwent revision for instability at 44.7 months (95% CI [33.8, 55.7]) following primary TKA. With 95% of primary knees surviving for more than 10 years in Australia[65], patients and surgeons expect greater longevity from TKA surgery than ever before. Our results highlight that current evidence reports knee instability as a cause of early failure and subsequent revision knee surgery. Early revision has shown the potential to instigate a downward spiral for the patient. The cumulative risk re-revision surgery for all revisions of a known primary knee is 17.4% over the following 5 years[66], demonstrating the grave clinical implications of an unstable knee.

Patient Characteristics: Age, BMI and Gender

In regard to gender distribution, females demonstrated a slightly higher incidence of revision compared to males. This finding is consistent with AOANJRR figures, which report greater revision rates for females across all causes[67], and is consistent with our local clinical experience where females more commonly require early revision for instability.

Average age at primary TKA was low, with patients undergoing the procedure in their mid-sixties. This result is consistent with Australian national data, which suggests revision rates are higher in patients who are less than 75 years of age when the primary knee surgery was performed[33].

Finally, our data suggests that BMI was not a relevant patient characteristic with regards to revision, however this was reported in a very few numbers of articles and inferences cannot be concluded.

Surgical Technique and Primary Implant Design

Of the 4 studies commenting on surgical technique only one study was performed using a MIS technique, while all other revised knees were performed using conventional instruments. Of the two implant designs, the majority of revised knees had received a CR design, however, this may simply be due to greater use of this implant type. When reviewing the 10 most common knee implants used in Australia in 2014, 76% were CR designs while 24% were PS[68]. In the majority (77.4%) of cases reported a total revision of

all original components was performed. A variety of minor revisions were reported with exchange of, for example, just the polyethylene inserts of the femoral component.

In our clinical practice the use of polyethylene exchange is common as surgeons are concerned about the need for further revisions, especially in our younger patients. This practice is supported by AOANJRR results that suggest the when we look at revision of patients who's known primary surgery was for OA and subsequently have a 1st revision TKA surgery < 5 years post op have a much higher risk of re-revision surgery ay 5 years post revision (17.7%) [69]. However, patients in this diagnostic group who undergo their first revision 5 years or more after primary TKA surgery have a re-revision rate of only 8.9% at 5 years [69]. Patients who undergo their first revision at less than 5 years post primary and have a minor revision surgery have lower re revision rates compared to Major or Major partial TKA revisions [70]. As most revisions for knee instability occur in the first 5 years, a more conservative approach may be more supported given the greater risks of re-revision.

Diagnostic Approach for TKA Instability

A combination of clinical assessment and radiological assessments were most commonly used to diagnose instability, highlighting adherence to recommended practice[29,34]. The most important diagnostic factor is always the clinical history. Patients with symptomatic instability, particularly in flexion, report a common series of symptoms including a feeling of insecurity in the knee without frank giving way, difficulty with stairs, recurrent knee swelling and anterior knee pain[39].

Conclusions

The published literature on TKA failure due to instability following primary TKA surgery concludes that most patients fail early (< 4 years post op) and have high rates of subsequent revision knee surgery. In addition, these revisions were frequently reported in a younger patient cohort and most commonly in female patients. Furthermore, this pattern of early revision surgery at a younger age also leads to a high rate of re-revision surgery highlighting the grave implications of an unstable knee

In response to these conclusions we designed a local revision registry to accurately record our reasons for revision and analysis the previous primary TKA surgery performed in patients who required revision. Data collection and analysis was also performed on patient characteristics to attempt to identify any factors that could be addressed to reduce the risk of TKA failure for our patients in the future. In addition, we designed a standardised diagnostic algorithm to improve our diagnostic accuracy of the failing knee and potentially reduce the rate of re-revision surgery for our patients in the future. These issues are discussed fully in *Chapters 3 and 4.*

Chapter Three: Clinical Diagnosis of Instability in TKA:

Design and evaluation of a new diagnostic Algorithm for the diagnosis of the unstable total knee Arthroplasty

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This Chapter Contains Material from:

Visvanathan A, Jackman E Krishnan J & Wilson CJ.

Design, Construction & Early Results of a Formal Local Revision Knee Arthroplasty Registry

The Journal of Knee Surgery March 2020.

Introduction

Background

Total Knee Arthroplasty (TKA) surgeries as previously described are primarily done to improve knee function and to achieve pain relief.[72] However loosening, infection, persistent pain and instability are significant factors that contribute to reduced patient satisfaction and a slower return to normal daily functional activities.[72,73,74,75, 77,78] As shown in *Chapter 1* revision knee arthroplasty is commonly performed in the first 5 years after the Primary procedure and the risks of Re-Revision are significant. The key factor that determines whether a surgery is successful in obtaining a satisfactory outcome is an accurate pre-op diagnosis and using this to prepare a definitive management plan or plans prior to performing the patient's surgery [79]. Conservative Revision surgery can be performed where possible, to reduce patient's complications and financial cost. Loosening, instability, infection and pain are common reasons for revision surgery [80]. In addition, postoperative stiffness has been found to be a relatively common complication following TKA, with an estimated occurrence up to 20% being reported in the literature,-[76] with most studies reporting an average occurrence of 1.3% to 11% .[79] In 2017 AOA Registry figures however, stiffness only accounts for 3.5% of revisions[80].

The accepted options for improving postoperative stiffness in TKA surgeries are manipulation under anaesthesia (MUA), arthroscopic arthrolysis, surgical debridement, and revision arthroplasty.[72, 76] MUA, otherwise known as examination under anaesthesia (EUA), has often been suggested as the first step in managing postoperative stiffness, [77] however there has been debate as to the timing of this intervention and the subsequent effectiveness of this procedure in improving ROM at the knee.[72] Furthermore, recent studies have suggested an associated between MUA and the risk of requiring further revision [72]. In our department we try to avoid using MUA as an intervention and instead aim to establish the cause of the patient's pain or stiffness before proceeding to surgical intervention. Currently, there is no standardised guideline to help assist a clinician in determining whether a patient should undergo TKA revision surgery, with most decisions based on a clinician's experience and clinical judgement. In our systematic review in *Chapter 2* only 12 articles in the published literature commented on using a combination of clinical assessment and radiological assessment to diagnose instability.[81] There was however a lack of objective results in these papers that could be used by meta-analysis to draw any firm conclusions on how to standardise the diagnostic pathway.

Aims: Indications for a Standardised Pathway

The use of a standardised pathway may reduce misdiagnosis of the reason for a patient's symptomatic TKA. In our experience MUA procedures are uncommon due to the complications and poor clinical outcomes summarised above. However, the MUA procedure was adapted to an atraumatic technique designed to diagnose the reason for failure rather than to try and treat it. For simplicity we have described it as EUA (Examination under Anaesthetic) not as manipulation.

The aim of this study was to design, implement and evaluate our own diagnostic algorithm for the diagnosis of instability and other causes that lead to failure and subsequent revision surgery. This aims to bridge the gap found in our systematic review of diagnostic methods to combine Clinical Assessment, Serology, Dynamic Radiological Assessment, Microbiology and Intrinsic pain testing (Injection) in one standardised pathway for all patients. By improving the accuracy of diagnosing these problems we aim to improve the outcomes of Revision TKA

surgery. Patients who do not require further surgery could be identified sparing them the risks associated with what can become a very complex surgical intervention.

Methods

Design of a Standardised Pathway

After review of the studies selected in *Chapter 2,* our historic AOA registry results and discussion with our consultant team we began working on the design of a diagnostic algorithm. The main aim was to produce a reliable and reproducible system where the reason for TKA failure can be diagnosed. The second aim was to exclude all patients with extrinsic pain e.g. referred pain from the Lumbar Spine. From our literature review in *Chapter 2* previous studies have shown poor correlation with knee aspiration results and the diagnosis of infection or instability.[82,83]

Chatoo et al reported the success of a thorough assessment of the spine and hip with diagnostic injections in these areas to exclude intrinsic pathology. They suggested the use of diagnostic knee injections to aid the diagnostic process but did not report or reference using this technique in their paper.[84] From our systematic review and review of the available literature this technique has not been described. The decision was therefore made to add an intra-articular 'Intrinsic knee injection 'to the diagnostic algorithm to evaluate if this assisted in the exclusion of extrinsic sources of pain. Clinical assessment may also have a low level of diagnostic accuracy, *Simpson et al* suggested finding quantifiable methods for defining instability clinically for mid-flexion instability but did not report intra-operative assessment of instability.[85] The use of fluoroscopy in theatre to assess knee instability has been previously described by multiple authors in our systematic review. Hirshmann et al describe a validated process where the knee is measured in flexion and extension under varus and valgus stress. The describe separation of more than 5mm as pathological. This was therefore adopted in our diagnostic algorithm.[86]

Using the information from our review in *Chapter 2*, the decision was made to design a diagnostic method that could use and allow the combination and evaluation of these

multiple diagnostic tools to provide as much information as possible, and assist the surgeon in planning most appropriate approach for the patient's surgery. Finally, the pathway had to structured be as efficient as possible for the patient and allow unnecessary scans and tests to be avoided. The pathway involving clinical examination, blood tests, dynamic fluoroscopy with Examination under Anaesthetic (EUA), knee aspiration and Intrinsic Knee Injection is summarised in *Figure 15* below.

Evaluation of the Standardised Diagnostic Pathway

In this study, we examined the medical records of 45 patients who had undergone EUA's at a single hospital centre for post-operative complications following a primary TKA. All procedures were performed by the senior author between April 2014 and March 2016 inclusive. The patients had all been clinically evaluated using our standard diagnostic algorithm and their data recorded in our Local Revision Register described in *Chapter* 3.

Ethical approval for our analysis was first obtained from the South Adelaide Human Research Ethics committee (*SAC HREC EC00188*). Approval was granted for application number *OFR # 434.15* prior to collection or analysis of patient data. Patients were identified from our electronic patient healthcare records system (EPAS) that had undergone our assessment protocol for a potentially failed TKA, and who met the inclusion criteria of having a primary TKA in situ which was being considered for some form of revision surgery.

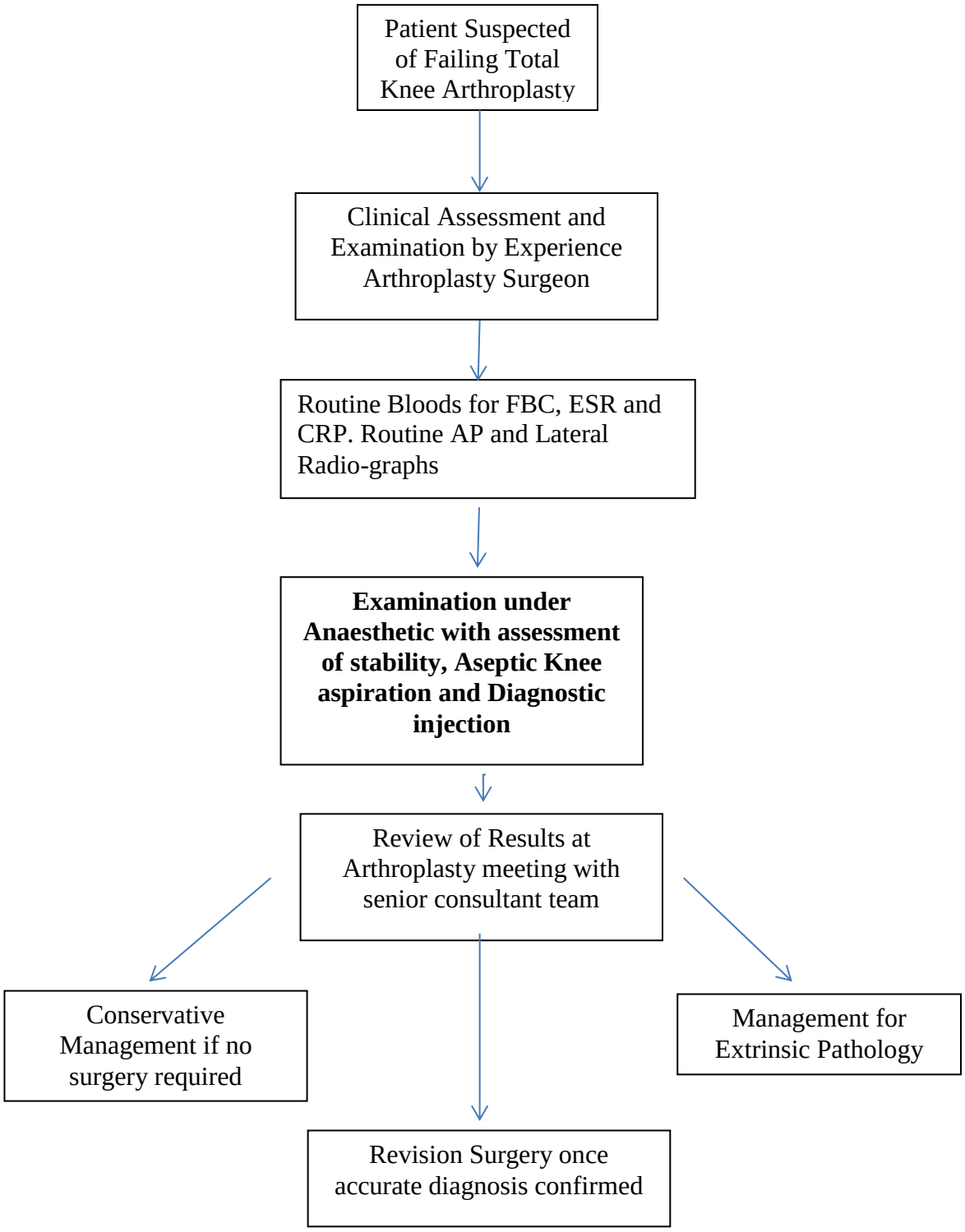


Figure 15, Diagnostic Algorithm for the potentially failing knee arthroplasty

Process of Diagnostic Pathway

All patients were reviewed by an experienced revision arthroplasty surgeon and had routine history and clinical examination. As part of the standardised work-up for each patient, blood tests were done to examine a patient's haemoglobin levels, white cell count, absolute neutrophil count, C-reactive protein levels, and erythrocyte sedimentation rate. The results of these blood tests were recorded. In addition, routine knee radiographs were taken to look for implant wear or loosening. Two revision arthroplasty specialists were present at the review clinic and cases were discussed as required. Where possible Nuclear isotope bone scanning was not routinely used unless specifically indicated to reduce the radiation dose to our patients as in our clinical experience as we have had had issues with equivocal results in the past. However, in cases where the specialists felt the investigation would assist in answering a specific question they were also used.

Patients were then booked for an EUA assessment where the patient undergoes Dynamic Fluoroscopic assessment. This allows the surgeon to feel, quantify and record for the record and instability of the prosthetic joint. The EUA parameters reviewed included anteroposterior (AP) movement of the knee joint, the degree of Varus and Valgus instability, synovial fluid aspirate for bacterial culture, synovial fluid cell count and Intrinsic knee injection. Five standardised fluoroscopic radiographs are taken and these are also saved in the patient's record on our electronic radiology system (PACS). One x-ray is taken in the neutral position like a standard AP radiograph. In 20 degrees of flexion the films are taken with a Varus then a Valgus stress to assess the stability of the extension gap of the knee. Varus and Valgus stress radiographs are then taken in 90 degrees of flexion to assess the flexion gap. Stress opening of more than 5 mm was considered pathological and less than 5 mm considered within normal physiological limits. The anterior and posterior drawer tests are performed with the knee in 90 degrees of flexion. An example of an EUA fluoroscopic image is shown in *Figure 16* below. Again, more than 5mm of drawer was considered pathological and less than 5 mm within normal limits. The knee is then extended and, under aseptic technique, is aspirated and any fluid sent for microbiological culture and a cell count. Finally, for a diagnostic test of intrinsic knee pain 10 mls of 0.75% Naroprim local anaesthetic is injected into the knee. After the procedure the patient is mobilised and asked if they feel any difference in their pain. A significant improvement in pain is required for a

positive result of intrinsic knee pain. For each case the results of EUA and blood tests were then discussed within the senior consultants at our weekly arthroplasty planning meeting. Once agreement was reached a suitable diagnosis was recorded for each patient, as well as whether a revision surgery was indicated, the surgical plan and potential implant options noted. The patients in both our Public and Private theatres all went through the same process and were then booked when appropriate for Revision Arthroplasty Knee surgery with two experience specialists present. All the patients included in the study had a follow-up clinic where the results were discussed and the patient was offered either revision surgery or conservative management, as per the consensus reached during the senior consultant meetings. The results were recorded and summarised using an *Excel* ™ spreadsheet. The data was analysed using Wilcoxon ranksum, Fisher's exact tests and logistic regression models. Correlations were drawn between EUA findings and the eventual need for revision surgery. Other parameters evaluated included patients Age, Gender and BMI and also basic blood tests and cell counts in fluid aspirated from the knee joint. The study design and methodology was constructed using the STROBE guidelines to simplify the structure and enhance the clarity of how the results are presented.[87]

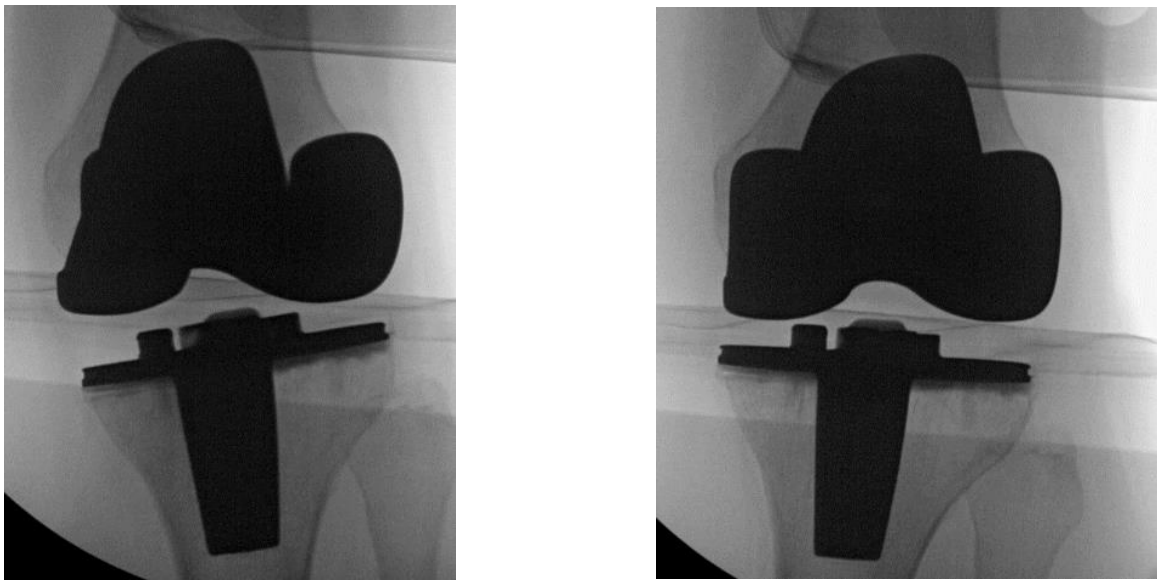


Figure 16, EUA stress fluoroscopy showing abnormal joint opening > 5mm with Valgus then Varus stress in the extension gap.

Statistical methods

The primary outcome was whether a revision had occurred or not. Differences in sample attributes in *table 6* were analysed by t-tests, Wilcoxon ranksum or chi-squared tests as appropriate. Differences in proportions in revision according to AP, varus or valgus status in *table 7* were assessed using Fisher's exact test. The cumulative incidence of revision by cause was modelled for our data and visually compared to that in the AOA national joint registry Logistic regression was used to simultaneously assess the effect of these predictors on revision status. The Hosmer-Lemeshow statistics revealed no evidence of model violation. Results are presented as odds ratios (OR) with 95% confidence intervals. A p-value of less than 0.05 (two-tailed) was considered to be statistically significant. All analyses were performed using Stata 14.2 (StataCorp, College Station, Texas) The Data for our cumulative revision surgery rates and indications for revision surgery were taken from an Ad Hoc report requested for the AOA National joint registry.[88]

Results

Patients Demographics

Results were available for 45 patients in total, which was a complete data set for the study period. With respect to our EUA findings there was no significant difference in the values for Haemoglobin, White cell count or Aspirate cell count for whether patients proceeded to revision surgery or not. The demographics of these patients are summarised in *table 6* below. There was no significant difference in gender, age or BMI between patients who did or did not have varus instability on EUA. For simplicity we have reviewed these figures against Varus Instability as this finding had the strongest association with whether the patient proceeded to revision surgery.

	Stable Varus	Unstable Varus	P-value for difference
Female Gender n (%)	10(62.5)	12(41.4)	0.18
Age (years), mean(sd)	72.8(8.2)	70.8(10.7)	0.51
BMI (kg/m^2) mean(sd)	30.4(7.1)	31.5(3.9)	0.57

Table 6, Demographic results for all patients evaluated.

There was an even spread in the percentage of revision between both males and females which is an interesting finding as Primary knee arthroplasty is much more common in females.[88] There was little variation in the BMI or relative risk of revision surgery between either gender.

Comparison Between Local and National Registry figures

When analysing our local revision registry figures and ad-hoc report was obtained from the AOANJRR. The results of this report suggested the indications for revision surgery in our centre have not historically been unusual compared with national figures. This is summarised in *Figure 17* below. [86] However as discussed in Chapter 4 when the AOA registry data is broken down in more detail there were historically high rates of revision TKA surgery for 'Pain 'and 'Patello-femoral Pain' in our department compared to national figures. Instability is the 4th Most common reason for revision TKA surgery in our historical figures with a slightly higher cumulative incidence compared to the results for other hospitals. [86]

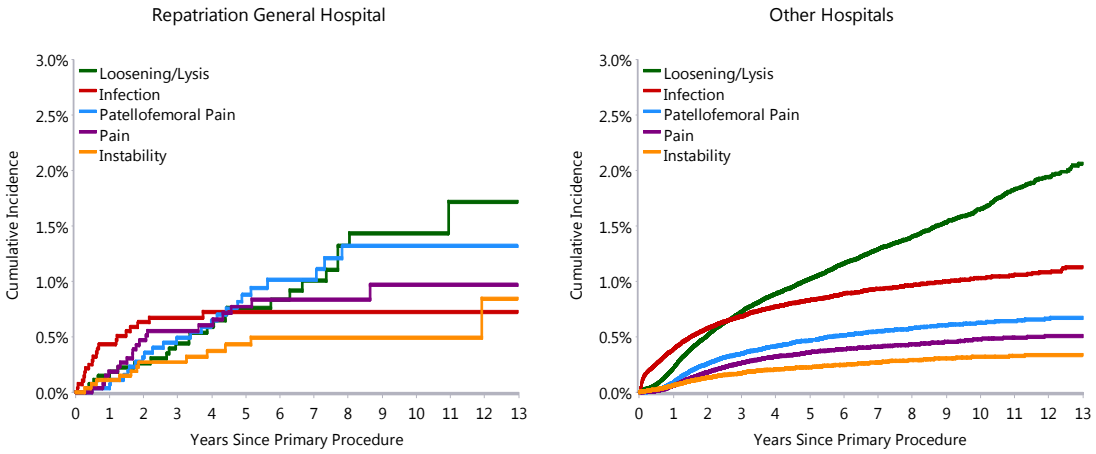


Figure 17: *Cumulative of Incidence Revision Total Knee Arthroplasty by Diagnosis. Reproduced from AOANJRR Ad Hoc report 1667.*

Analysis of Blood Parameters

Analysis of the Red Cell count and White cell count of knee joint aspirate showed no significant difference between patients who eventually underwent revision surgery. The mean blood CRP value for patients who underwent revision surgery was lower at 3.2 vs 7.1

in patients treated surgically. This may be of clinical relevance but the difference was not statistically significant (p=0.33). A similar pattern was shown with ESR with patients who underwent revision had a lower value of 11.1 while those treated conservatively y had a higher value of 21.5. This difference was again not statistically significant (p=0.08). It is possible with respect to ESR inflammatory markers the lack of significance is a type 2 error due to the small sample size.

Joint Aspirate Cell counts

Attempt to analyse the effect of cell counts and whether revision was eventually required Were unhelpful in this series. When comparing groups 11/22 patients who did not require revision TKR surgery had a normal / low White Cell Count (WCC) while 11/22 were raised. There was no significance in the correlation with Aspirate WCC and eventual revision surgery (p>0.302). When comparing Red Blood Cell (RBC) counts on aspirate 8/22 patients who did not require revision TKA surgery had a negative RBC count while 14/22 were significantly raised (p>0.436)

Dynamic Radiological Assessment

With regards radiological instability there was a more dramatic difference between patients who proceeded to revision surgery. Instability in either Anterio-posterior (AP), Varus or Valgus was associated with a higher incidence of revision surgery. This was statistically significant for all 3 groups in chi-squared analysis (*table 7*).

Parameter	Revision No	Revision Yes	P-value for difference
AP Stable†	18/22	2/22	<0.001
Varus Stable	15/22	1/22	<0.001
Valgus Stable	17/22	9/22	0.016

† The AP status was not recorded 2 subjects.

Table 7, The relationship between radiological findings and whether revision surgery was performed.

When AP, varus and valgus status were entered into a logistic regression model with revision as the outcome only varus status remained significant OR = 20.0 (95%CI 1.48, 275.4), p = 0.024 that is, those with positive varus status were approximately 20 times more like to undergo a revision. The effect of varus status on revision was also independent of age and gender in a separate logistic regression, OR = 49.9 (95%CI 5.3, 469.2), p=0.001.

Discussion

This study was designed as part of our process to improve patient outcomes and increase quality control. We have moved from a traditional model of individual treating surgeons to a team-based approach. It is hoped that this will lead to improvements in our patient's outcomes not only in the unstable TKA but also in all modes of implant failure. The results of this study summarise the EUA findings for the first 3 years of this standardised process to evaluate what factors we should focus on with regards to predicting which patients are likely to require revision knee arthroplasty surgery and which patients should be spared the potential complications of invasive surgery.

On review of our figures synovial aspirate cell counts have not revealed an association with whether a patient requires revision surgery or not. Inflammatory markers do not show a strong association, patients who do progress to surgery have on average a lower count on either CRP or ESR. As a result of these findings we have evolved our algorithm after consultation with our dedicated Infectious Diseases (ID) team. Joint fluid aspirates were sent for culture, which they suggested may have under diagnosed prosthetic infections. This factor is discussed in more detail in a separate study. After consultation with our ID team the EUA technique was modified to include Arthroscopy. All patients now have 5 deep tissue biopsies taken for prolonged culture and one for Histopathology in addition to the usual joint aspiration. Our ID team perform prolonged cultures on the deep tissue obtained in the hope of reducing our false negatives for prosthetic infection and detecting atypical organisms, which may be slower to culture and therefore could be missed in routine

analysis. Arthroscopic assessment allows the surgeon to assess the implant visually and look for any potential abnormalities. *Figure 18* below shows examples of the views obtained and synovial biopsies being undertaken. The surgeon and look for signs of purulence of synovitis. Beep tissue biopsies are safe and easy through this technique. As part of a separate study patients will also have joint aspirates tested with Synovasure™ Alpha Defensin screening technology (*Zimmer Australia*) a biomarker produced by white blood cells that is specific to chronic implant infection.

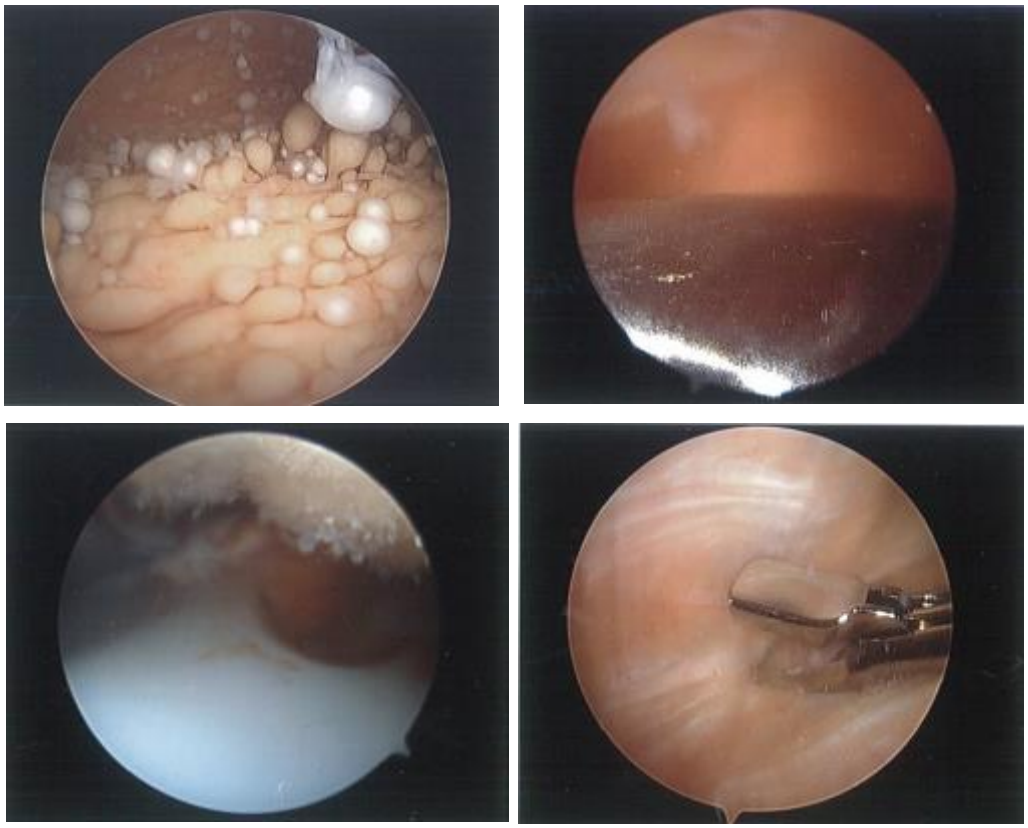


Figure 18 Arthroscopic views of the knee during EUA showing clockwise synovitis associated with polyethylene wear, femoral and tibial implants & biopsy of deep tissue / knee synovium

Our results suggest that Instability findings on Fluoroscopic screening have been the most reliable indicator of the need for Revision surgery by far. Patients who fail due to instability tend to fail early after their primary TKA surgery.[87] This finding is therefore very useful in improving the effectiveness of our diagnostic process.

As part of our ongoing process as described in *Chapter 4* all patients results were added to our local revision hip and knee registry to help evaluate the effects of our diagnostic pathway and provide ongoing monitoring of the reasons for revision and the type of surgery performed. Historical results had shown that pain had been a common indication for revision surgery in the past while our current algorithm had reduced this indication from to 36.7% to 13.9% of cases.[87] Stiffness was also an uncommon indication for revision surgery at only 2.8%. The commonest indication for revision in our Revision registry was instability at 33.3% and 13.9% patients underwent revision for prosthetic infection. In addition, this registry has shown that 47% of our patients undergo 'Minor Revisions' with lower complication rates and less financial expense to the hospital. AOANJRR figures also suggest that these patients who undergo less invasive revision surgery are at a lower risk of re-revision surgery in the first 5 years compared with Total TKA revisions.[87]
This study has limitations. The sample was chosen as a convenience sample of all presentations at the Repatriation General Hospital between April 2014 and March 2016 and may not be representative of the larger community. The sample size was small, so non-significant associations may be Type 2 errors.

Conclusions

Our results confirm it is possible to set up a standardised diagnostic and management pathway for Revision TKA surgery. Patient's diagnosis is evaluated and confirmed by a revision team instead of by one surgeon. Diagnostic parameters of aspirate counts and inflammatory markers can be unpredictable while radiological examination for varus instability is much more reliable. As a result of the results described above our algorithm has been enhanced to include routine arthroscopy and deep tissue samples. The management of infections is now discussed at monthly meetings with our dedicated ID team to improve the quality and co-ordination of antibiotic management.

The combination of this rigorous approach with ongoing review of our results in a local revision knee arthroplasty has led to lower rates of revision surgery for pain. Our diagnostic pathway will hopefully lead to enhanced accuracy of diagnosis for our patients and potentially reduced rates of re-revision for our patients ongoing.

Chapter Four: Design & construction of a formal local revision knee arthroplasty registry

This Chapter Contains Material from:

Visvanathan A, Jackman E Krishnan J & Wilson CJ.

Design, Construction & Early Results of a Formal Local Revision Knee Arthroplasty Registry

The Journal of Knee Surgery March 2020.

Introduction

Background

The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) maintains a record of joint replacements and revisions, providing an unsurpassed resource for orthopaedic surgeons.[89] This system was first established in 1999 following the success of the Swedish National Joint Registry.[89] These primary registries have been highly applauded for identification of high risk surgical implants and methods to improve patient outcomes. They are also a very powerful research tool.

Originally the AOANJRR collected data on the outcomes of primary arthroplasty procedures. Since 2014 it has reported results on revision arthroplasty procedures with a focus on lower limb arthroplasty at a national level. However, revision arthroplasty surgery is very heterogeneous and therefore data collected is more complicated with more surgical and implant variety compared with primary surgery. It is a nationwide registry and assessing the exact type of revision surgery performed at a specific hospital, implants used, site and the cohort of patients that it treats is difficult. However, in revision surgery these details are important. The Registry provides specific analysis on request but the large variation in detail with revision surgery makes some analysis challenging.[90] As part of the development and improvement of our local data collection our department decided to design and develop a

locally based registry focus on the work of our own hospital. As part of this thesis the registry was planned and the steps put in place to collect, store and analyse the necessary data.

Potential Benefits

When developing a new registry, a clear goal needs to be defined as to its purpose and an assessment of it appropriate to achieve this purpose.[93] The development of a local revision lower limb registry aims to create a valuable resource to the Department of Orthopaedic Surgery as a tool for improved data collection. The level of detail that is recorded locally is much higher than can be achieved nationally and may potentially help to identify factors that may predict patients at high-risk of revision in the future, ultimately optimizing patient outcome.[90,91,92] In our centre as per standard care, the collection of devices, surgical and demographic patient data is performed, however compiling this information and maintaining a formal register of revisions had not been previously established. The importance of understanding any confounding or predictive factors of device revision may aid in identifying high-risk patients. In this thesis we describe the registry process in *Chapters 4* and evaluated our outcomes in *Chapter 5*. The evaluation of these results aims to prove that the use if our local registry will improve the quality of our service in the long term. In addition, this data can be compared with national data and trends.

Validity

To be useful in scientific research a registry has to be both Valid and accurate. The AOANJRR reports are edited by a highly qualified board of senior orthopaedic surgeons. The data is then reviewed prior to publication by a larger group of surgeons to ensure it is valid and describing data and issues relevant to current orthopaedic practice. It reports its data is highly accurate with complete data sets for over 97.8% of all joint arthroplasty surgeries are reported for its analysis each year. In addition, its staff cross check cases with other government data bases and local hospitals to minimise any loss of data in its analysis.[94] The data and results from the local registry were reviewed by our local consultant group and discussed with a group of experts at the Arthroplasty Society* to ensure we were measuring information that was valid and describes relevant to current orthopaedic practice. The

process was then peer reviewed including discussion of its Validity and published in The Knee. Data was collected from our theatre booking schedule then cross referenced with hospital paper records and our digital EPAS system to ensure no patients or data was missed. The information was then cross checked by hand by the senior author to ensure the accuracy of the data with respect to both errors and emissions.

**Clinical Diagnosis of Instability in the failing TKA, Evaluation of a new diagnostic algorithm.*

Wilson CJ presented at, Arthroplasty Society ASM, *June 2017*

Aims

We aim to design and manage a new Local revision TKA registry. Using this data we hope to illustrate potential predictors of poor results in TKA surgery, such as patient-specific or device-associated factors. Data collected can also be analysed for audit and quality control purposes to enhance continuous quality improvement within our service. Therefore, a comprehensive electronic data set was created to record information on all revision cases ongoing. These data can then be analysed to determine any potential correlation between patient characteristics, implant type and reason for revision and outcomes. This is particularly focused on the presence of comorbidities and body mass index (BMI). This will provide a comprehensive dataset in order to aid surgeons in making informed decisions and potentially identify high-risk patients or clear trends in the patients routinely treated. Of particular interest is the need for a qualitative assessment of the influence of device, comorbidities, including obesity, on revision risk and revision as a result of infection.

We designed, set-up and analysed a local registry that facilitates prospective collection of hip and knee revision data in order to maintain a quality of care and continuing surgeon education. This registry was set up at a specific time following on from a previous AOANJJR analysis of Revision TKA figures in our department. At the same time our standardised revision TKA algorithm was designed and implemented in our department. The results were then used to conduct a comprehensive analysis of the diagnosis and surgical management of knee revision surgery at the Repatriation General Hospital. With regards to knee instability the age, gender and surgical factors were analysed and compared with national

AOANJJR figures to evaluate of correlations could be made and to allow the ongoing evaluation and improvement of our diagnostic pathways.

The aim of this local registry is to collect and analyse data that will lead to improvements in our diagnostic algorithms, management processes and clinical outcomes for our patients. Any potential benefits or modifications can be fed back to the national registry in a ' feedback loop ' to potentially improve data collection or processing for all patients in the long term. The registry will be maintained on an ongoing basis to allow continuous collection of data and monitoring of our surgical outcomes.

Methods

Study Design

To plan and implement a new registry it is necessary to identify the key stakeholders and build a registry team. In the initial set up the team comprised of the Principle author, the local Nurse practitioner and a dedicated research student. A full-time research administrator was added to the team later. Once team was set up and after discussion about the feasibility of data collection and management discussed the design of the data collection process was finalised. The study was then reviewed and approved by our local Human Research Ethics Committee, (SAC HREC EC00188) - *Approval number: 506.15*. This approval is summarized in *Appendix 3*.

To set up the registry, all patients who underwent a revision lower limb arthroplasty between April 2014 to December 2015 were identified from the surgery booking lists. The start date of April 2014 was chosen as the hospital moved to a wholesale change in-patient records system. Traditional paper records were terminated and all information moved to a new Electronic Patient Archive System (EPAS). Starting from this point allowed all data to be obtained from one records system and avoid the complications of trying to source and review patient records from more than one system. The patient's data was then cross-checked with departmental booking staff and theatre records to ensure no cases were

missed. As all the data was de-identified and patients were not directly contacted Ethics approval was gained without the need to obtain consent from the patients.

Data Collection process

The database was set up specifically to record the patient demographics, significant comorbidities, and primary arthroplasty history including time of surgery, the type of primary implant and the hospital where the initial surgery was performed. Details of the revision arthroplasty including bone defects, type of and reason for revision, peri and postoperative complications, and prosthetic components details. Postoperative complications, readmissions and repeat surgeries were assessed directly from day of surgery to 3 months post op. This data is routinely collected by our hospital quality service. To capture revision surgeries after this time data was cross checked with the national AOANJRR.

Microsoft excel ^{Tm} software was used to compile data in a logical form and allow easy analysis and identification of patterns. All data was then backed up to avoid loss of information. Patients EPAS records and paper theatre records were used to collect and summarise relevant patient characteristics, type of revision performed, and known complications. This was then cross-checked to prevent duplication, avoid the loss of relevant data and to ensure the correct description was used for diagnosis, type of revision and implant types. The data was also cross-checked for any errors and to look for ways to improve the accuracy and reliability of the data collection.

Data Storage and Analysis

The patients' MRN number was used to access their files on the electronic patient administration system (EPAS) and fill in the columns, primarily from admission notes, surgical note, and discharge note and where applicable, the ICU admission note. The data was cross checked against any existing paper files/records with the operating theatre and booking staff to ensure no details were missed. Upon completion of the registry for 2014-2015, the patients were De-identified and allocated a study number. Percentages of data were calculated from the database and compared to the findings published in the 2014 and

2015 Annual Reports AOANJRR reports and a specific *ad hoc report 1167*. This report was requested for this purpose and summarised all results from our hospital prior to 2014 to allow comparisons to be made between surgeries performed in the past and those in our current treatment pathway, summarised in *Chapter 3*. After this initial data collection and analysis, the Registry data was collected prospectively ongoing to allow further analysis of results and trends in the future. When summarised and analysed data was grouped into levels 1 – 4 as described by Gliklich et all. These levels of data are summarised in *Figure 19* below.

TABLE I Proposed Hierarchy of Data Elements for Arthroplasty Registries

General Data Elements by Level
Level I
Patient identifiers (identifying numbers, name, national register identification, sex, and date of birth)
Date of procedure
Primary diagnoses for the procedure
Type of procedure
Medical device information (catalog and lot numbers)
Surgeon identifier
Hospital identifier
Level II
Patient comorbidities
Body mass index
Patient ethnicity or race
General health status of patient at time of surgery
Surgical techniques
Surgical prophylaxis
Intraoperative complications
Level III
Patient-reported outcomes
Clinical and/or functional outcome assessments
Patient socioeconomic status
Costs of surgery
Level IV
Radiographic assessments

Figure 19 Data Element by level, Extracted from Inacio MCS et al JBJS (AM) 2016[76]

Reproduced with permission from JBJS (AM)

Results

Demographics

In the period from April 2014 to December 2015, a total of 36 knee revision arthroplasty procedures were performed at the Repatriation General Hospital (RGH). Of these, 25 were 1st revision knee replacement, 10 were further revisions of knees previously revised. The mean age of patients was 71.1 years old with females forming the majority of the patient population at 67%. However, many patients had their primary Knee Arthroplasty at a young age with the average being only 62.5 years old. It is also worthy of note that 47.2% of patients had a previous hip or knee arthroplasty performed in another joint. In addition, 61% of patients had a history of hypertension and 41.7% has some form of lipid dysfunction, 36% were Ex-smokers. 52.8% of the patients had a BMI of ≥30kg/m^2 with a mean of 31.8. The demographic results for all patients are summarised in *Table 8* below. This would be described as level 2 data in the hierarchy of data elements [95].

Table 8: Patients demographics at the point of revision knee arthroplasty (n=36)	
Characteristics	Value
Age, mean (SD), yrs	71.1 □ 10.4
Sex, no. (%) of patients	
Male	12 (33)
Female	24 (67)
Comorbidities, no. (%) of patients	
Hypertension	22 (61.1)
Diabetes Mellitus	3 (8.3)
Hypercholesterolemia/ Hyperlipidaemia	15 (41.7)
Hypothyroidism	6 (16.7)
Previous Arthroplasty	
Hip	3 (8.3)
Knee	13 (36.1)
Ankle	1 (2.8)
Smoking status, no. (%) of patients	
Never smoked	22 (61.1)
Ex-smoker	13 (36.1)
Currently smoking	1 (2.8)
Body Mass Index (BMI), mean (SD), kg/m^2	31.8 (5.0)
No. (%) of patients	
≥ 30kg/m^2	19 (52.8)
< 25kg/m^2	0

Table 8: Key demographics and significant comorbidities total number and percentages of revision knee arthroplasties at the RGH from April 2014 – December 2015.

Historic RGH Registry Results

Prior to analysing our current results, we requested and reviewed the previous results for our centre supplied to us by the AOANJRR team. This report number 1667 is included in full detail in *Appendix 6*. Our overall revision rate for TKA surgery seems to be similar to the average figures for all Australian hospitals [96]. This is summarised below in *Figure 20.*

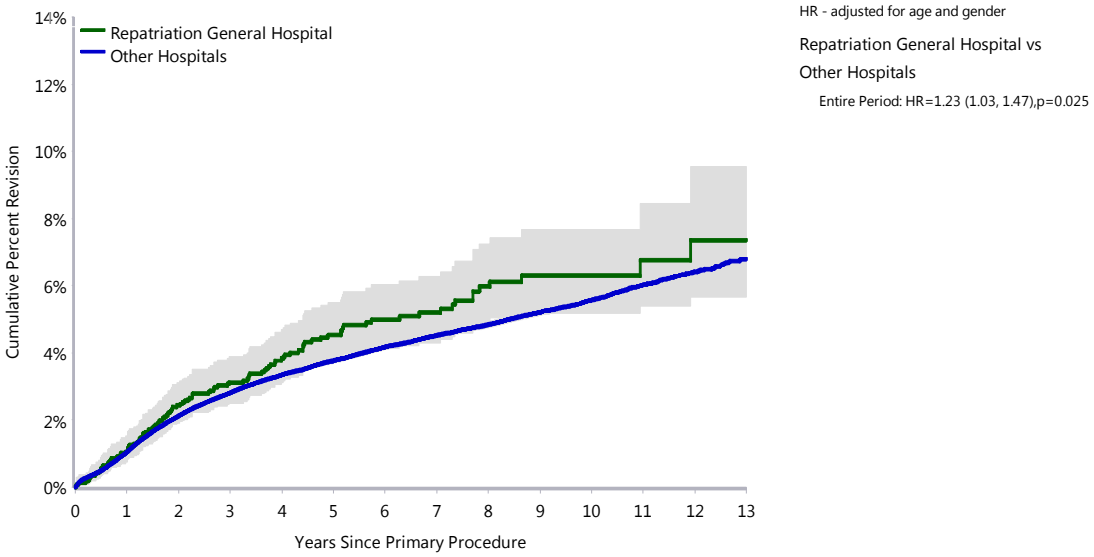


Figure 20, Revision rate for the Repatriation General Hospital for all causes.

In addition, our revision rates over time appeared to follow the national trend for both loosening and infection. However, there were a worrying high number of knee revisions performed for either patella femoral pain or 'pain'. As part of our diagnostic process it was felt that pain should be a diagnosis of exclusion after a rigorous process to establish what the patient's true diagnosis was. In addition, we felt that isolated patellar revision should not be performed as commonly and only after other diagnosis such as instability or loosening have been thoroughly excluded. Our previous trends from this report subdivided by all indications are shown in *Figure 21* below.

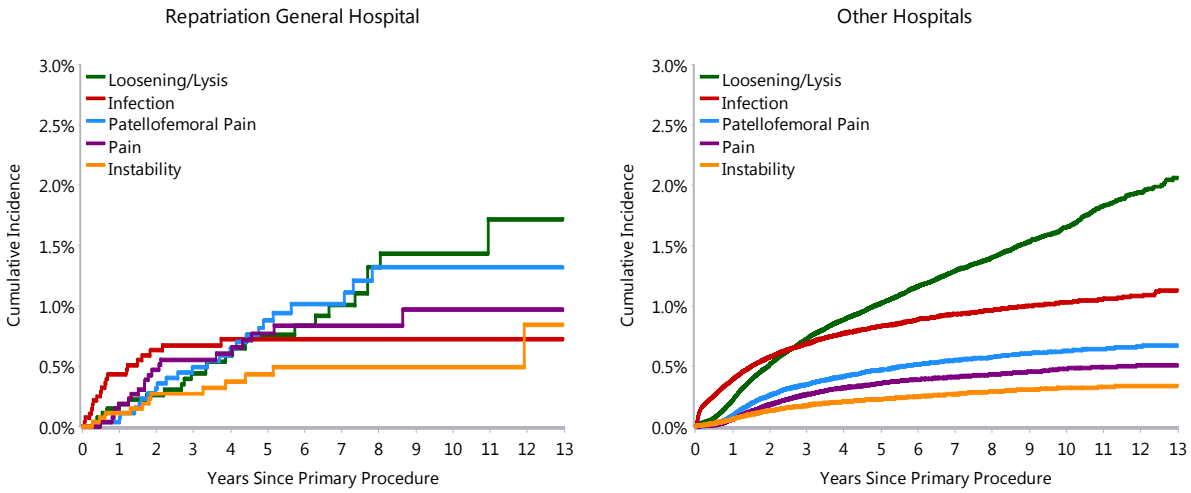


Figure 21: *Cumulative Incidence of Total Knee Revision by Diagnosis & Hospital*

A more detailed breakdown of this is shown in *Figure 22* below with a combined with a combined revision percentage for both 'Patello-femoral pain' and 'pain' of 36.7%. This accounts for the revision of 1.5% of all primary TKA procedures performed in our hospital. This compares with only 21.2% for all hospitals in Australia or revision of 0.7% of all primary TKA procedures performed nationally.

	Repatriation General Hospital			Other Hospitals		
Revision Diagnosis	**Number**	**% Primaries Revised**	**% Revisions**	**Number**	**% Primaries Revised**	**% Revisions**
Loosening/Lysis	25	0.9	20.8	3963	1.0	29.2
Infection	19	0.7	15.8	3020	0.8	22.3
Patellofemoral Pain	24	0.8	20.0	1641	0.4	12.1
Pain	20	0.7	16.7	1230	0.3	9.1
Instability	12	0.4	10.0	822	0.2	6.1
Arthrofibrosis	3	0.1	2.5	483	0.1	3.6
Patella Erosion	2	0.1	1.7	422	0.1	3.1
Fracture	4	0.1	3.3	352	0.1	2.6
Malalignment	2	0.1	1.7	310	0.1	2.3

Figure 22, detailed breakdown of historic reasons for TKA revision by surgical indication.

Comparison of Current with historic results

When comparing these results with our current local registry figures we can demonstrate that the most common reasons for doing a revision knee replacement are Radiological Instability (33.3%), prosthetic infection (13.9%) and pain (13.9%). Comparing to The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

statistics in their 2017 Annual report, the most common reasons for doing this procedure are: loosening/lysis (25.9%), infection (22.5%) and patello femoral pain (10.9%). *Table 9* shows the further breakdown of the reasons for revision knee arthroplasty of the 36 patients at RGH compared to this annual report. For clarity we have described our diagnosis and reason for revision in the same categories used in AOANJRR reports. These data would be classed as level 1 data elements.[76]

Reason for revision	Total Number	Percentage	AOANJRR
Instability	12	33.3	7.3
Pain/ Patellofemoral Pain	4	13.9	19.5
Infection	5	13.9	22.5
Loosening /Lysis	4	11.1	25.9
Metal related pathology	1	2.8	1.5
Wear tibial insert	7	19.4	1.7
Fracture	1	2.8	2.8
Arthrofibrosis	1	2.8	3.5

Table 9: *Clinical indication for revision TKA surgery in Local Revision Registry compared to 2017 AOANJRR Annual report.*

Although pain is still a common diagnosis, this is still an improvement on our previous audit figures. The historic report number 1667 from the AOANJRR in 2015 showed Pain as the reason for diagnosis in 36.7% of cases.[96] Our rates of revision for both Pain and Patellofemoral pain combined are now 13.9% which is less than the national figures of 19.5%. It is not possible from this data to determine if this reduction in revisions in our local figures is due to the use of our Diagnostic algorithm in isolation of in there has also been an increase in the use of patella resurfacing in our primary procedures as well. The cases covered in this report were performed in our department up to 2013, the introduction of our new diagnostic algorithms came in after this time and will be discussed in more detail in *Chapter 3*. Therefore one of our aims with this new diagnostic process was to improve the pre-operative diagnosis of the failing TKA. Another was to try to reduce revision procedures in patients that could be potentially managed non-operatively. As a result, revisions for pain have reduced from 36.7% to 13.9% with these results suggesting the fact that the algorithm is improving diagnostic accuracy. Further discussion of these results is also included in detail

in *Chapter 3*. Our local registry results for both tibial insert wear and loosening differ from the national registry but their combined total is similar at 30.5% vs. 27.6% of cases respectively. It is not clear from these data if this represents a difference in surgical practice or simply a difference in how accurately our revisions are coded in our National joint registry forms. The diagnosis of instability is much higher in our local series than in the national figures. This is an interesting result as the awareness and diagnosis of instability is increasing in recent years. In our department we have an interest in the management of TKA instability. Analysis of the trends in our data over the next few years will be helpful to assess if this is due to a recent number of local referrals or if our diagnostic algorithms lead to a higher number of cases being diagnosed as instability while they are diagnoses as a different reason for failure elsewhere. These reasons for revision are also shown in *figure 23* below to demonstrate their relative numbers.

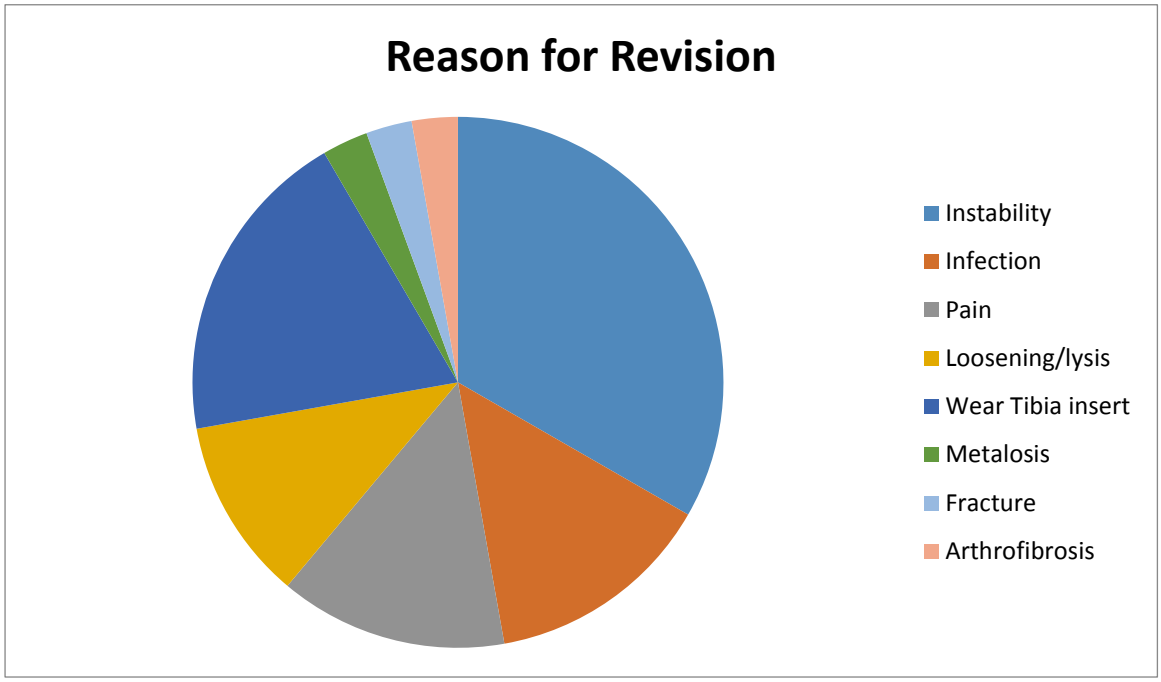


Figure 23: *Pie chart showing the relative distribution of the indications for revision surgery.*

The type of revision performed was then also analysed. When comparing our historical results to the National registry we found that there was alarmingly high numbers of revisions of the Patellar component alone compared to other hospitals at that time. Our local Patellar revision figures were twice those on the national registry at 39.2 % and 20.9 % respectively. This raised the concern that these patients may have been misdiagnosed as

patellar pathology while another clinical indication had not been accurately diagnosed. In addition, there was the concern that these patients may go on to have a further re-revision procedure due to diagnostic inaccuracy. The comparison of our historic types of revision procedures locally are shown in comparison to national Registry results in *figure 24* below.

	Repatriation General Hospital			Other Hospitals		
Type of Revision	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
TKR (Tibial/Femoral)	21	0.7	17.5	3433	0.9	25.3
Patella Only	47	1.6	39.2	2842	0.7	20.9
Insert Only	13	0.5	10.8	2817	0.7	20.8
Tibial Component	9	0.3	7.5	1470	0.4	10.8
Insert/Patella	11	0.4	9.2	1220	0.3	9.0
Femoral Component	9	0.3	7.5	864	0.2	6.4
Cement Spacer	9	0.3	7.5	795	0.2	5.9
Removal of Prostheses	1	0.0	0.8	72	0.0	0.5
Minor Components				37	0.0	0.3
Reinsertion of Components				8	0.0	0.1
Cement Only				7	0.0	0.1
Total Femoral				3	0.0	0.0
N Revision	**120**	**4.2**	**100.0**	**13568**	**3.4**	**100.0**
N Primary	**2870**			**393602**		

Figure 24: *Type of Revision of Primary Total Knee Replacement by Hospital (All Diagnoses)*

<u>Types of Revision Surgery performed</u>

When comparing our current figures to the national annual reports the number of Total revisions performed was similar. We performed total revision surgery in 33.3% of cases compared to 25.6% in the 2017 national report. In addition, 47.2% of our patients underwent a 'Minor' revision of the Polyethylene inserts and Patellar button compared to only 10.0% in the national figures. This result does represent a change in our department practice in recent years. There have been concerns for some time in the joint registry that TKR revision patients have a high rate of re-revision in less than 10 years. In addition, Total revision TKR patients have been shown to have a significantly higher rate of complications compared to 'minor 'or more conservative revision surgery[97]. Re-revision rates at 5 years are 15% at 5 years according to the 2017 annual report. This is significantly higher failure rate than primary knees which currently have a 4% failure rate at 5 years. This is

summarised in *Figure 25* below. The current annual registry results confirm the issues that not only do revised knees fail early but they mostly fail in the first 5 years. This is summarised *Figure 26* below. This stresses the need to not only avoid revision surgery where possible but also to improve diagnosis and management of these failing TKA's to try and reduced the rates of re-revision failure for our patients in the future.

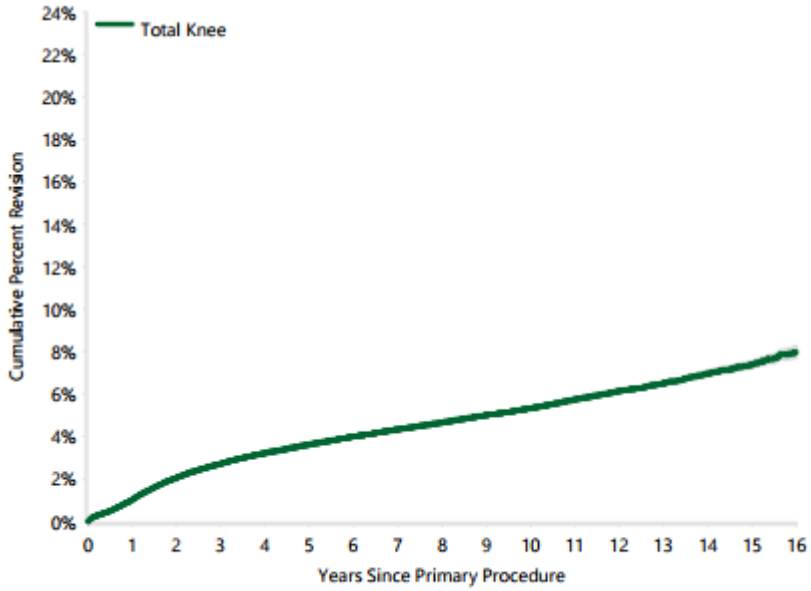


Figure 25: *Cumulative Percent Revision of Primary total knee replacement (Primary Diagnosis OA) Reproduced from AOANJRR 2017 Annual report Figure KT8 Page 197.*

As a result, we have tried to be more conservative and retain well-fixed and well-positioned metal implant. Hopefully this practice will lead to a reduction in complications for our patients and is likely to lead to a significant cost saving for our hospital. This practice has been supported by the 2015 AOANJR figures, which have shown a high rate of re-revision for these patients in the first 5 years after index revision surgery [98]. In addition, patients who undergo a total revision have a re-revision rate of 24.3% at 10 years while those who have a more conservative revision with insert exchange and patella resurfacing have a lower re-revision rate of 21.4%[99]. Patients who undergo an isolated insert only revision have the highest rate of re-revision surgery at 29.7% at 10 years[99]. In the 2017 report patients who undergo a minor revision have the lowest rates of re-revision in the long term at 20% with revision of the insert and patella doing better than insert revision alone. Partial revision

when one of the metal implants is changed has the highest re revision rate of 24 % at 10 years. This continues to support our practice of using more conservative revisions where possible. This type of revision surgery works well with lower complication rates, financial cost and potentially without poorer patient outcomes.

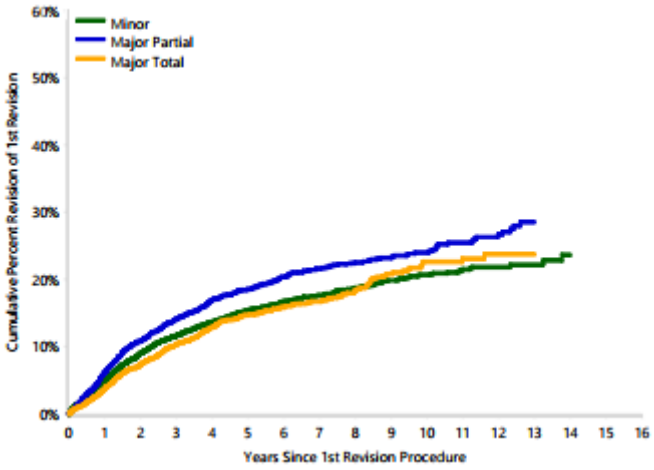


Figure 26: *Cumulative Percent Revision of 1st Revision of known Primary total knee replacement by Class of 1st Revision (Primary Diagnosis OA) Reproduced from AOANJRR 2018 Supplementary revision knee report Figure R11 Page 17.*

The most common type of knee revision recorded in our registry involved a Polyethylene exchange and patella button (47.2%), followed by total revision (33.3%) and insertion of spacer for prosthetic infection (13.9%). This is different from the AOANJRR statistics in 2015 where the most common type of revision done was all components (48.3%), tibial insert (14.3%) and patella only (10.8%). In addition, our new diagnostic algorithm has shown a significant reduction in the numbers of isolated patellar resurfacing with our figs falling from 39.2% to 8.3%. This comparison of local registry results and national results at the same time period (2015) represents a success from our program as patients are not being subjected to an unnecessary patellar revision where the cause of their pain may be either extrinsic to the knee or be caused by a different diagnosis. The types of revision surgery performed are summarised in *Table 10* below.

Type of revision	Total Number	Percentage	AOANJRR
Poly exchange +/- Patella	17	47.2	21.3
Total	12	33.3	48.4
Infection Spacer	5	13.9	20.4
Patella button alone	3	8.3	10.8
Femoral component only	1	2.7	3.9
Tibial component only	0	0	7.4

Table 10: *Reasons for revision knee arthroplasty total number and percentages at the RGH from April 2014 – December 2015 and percentages from AOANJRR 2015 annual report.*

Co-morbidities

Given that 25 out of the 36 revision knee arthroplasty was the first revision, we calculated that the time since the primary knee arthroplasty was 6.96 years (95% CI 4.39 to 9.53). This is similar to our results in *Chapter 2* where over 90% of TKA arthroplasties are expected to survive for over 10 years while those that do fail tend to do so early. There was no significant difference between the time to first revision between males and females ($p=0.715$). Interestingly, patients with a pre-existing condition of hypertension had a significantly shorter time to their first knee revision procedure (3.8 years) compared to those without hypertension (11.7 years) when adjusted for age, gender, height and weight ($p<0.05$). The clinical relevance of this result with this small series is unclear. However, there was no relationship between any other co-morbidity and the time to revision procedure. This is summarised in *Table 11* below.

Comorbidities	Mean (SD)	p-value	p-value (adjusted for age, gender, height and weight)
Hypertension		0.005	0.002
Yes	3.8 (3.3)		
No	11.7 (6.7)		
Diabetes Mellitus		0.425	0.386
Yes	3.5 (3.5)		
No	7.3 (6.4)		
Hypercholesterolemia/ Hyperlipidaemia		0.459	0.250
Yes	5.8 (4.7)		
No	7.7 (7.1)		
Hypothyroidism		0.601	0.899
Yes	8.5 (8.2)		
No	6.7 (6)		
Previous Arthroplasty (any)		0.063	0.148
Yes	9.2 (7.3)		
No	4.6 (3.8)		
Previous Hip Arthroplasty		0.328	0.556
Yes	10.3 (8.3)		
No	6.5 (6.0)		
Previous Knee Arthroplasty		0.169	0.190
Yes	9.3 (7.5)		
No	5.4 (4.9)		
Smoking status (between groups)	-	0.348	0.356

Table 11: *Effects of comorbidities on time (years) to first knee revision (n=25) Level 2 data*[76]

Discussion

Summary

This study in summary involved the design of a Local Revision Registry and the compilation of data of all revision lower limb arthroplasties conducted at the RGH from 2014-2015. No system is perfect and some data for a few patients was missing in the patient database. However, ideally a registry should have no missing data and therefore effort was made to retrieve any missing data through EPAS files, administration, patient booking diaries and paper surgical history records. By checking these resources all patients who underwent revision surgery in that time frame were identified. Our Local hospital registry has been proven to be useful for audit and quality control tool. It can provide an important insight into patient characteristics, implant type and association of comorbidities with revision risk and type.[95] Ongoing research involving certain characteristics and trends identified from the

register will help improve patient care and health outcomes at the RGH. More than 63% of the revision arthroplasties were performed on female patients, which roughly correlate with our figures in our literature review in *Chapter 2*. This might suggest a higher risk of revision for female patients however in the 2015 National figures females made up 56% of all primary TKA procedures performed with therefore more females 'at risk' of revision surgery.[100] From these small numbers is not possible to say if this shows a definite increase in risk or a reflection on a higher percentage of female patients undergoing primary TKA surgery. Figures from the registry were compared with the AOANJRR statistics to identify differences in the hospital's patient population vs. the national trends of orthopaedic patients.

Obesity is common in our patients, (52.8%) undergoing knee revision were classified as obese, with a BMI greater than 30. There is some evidence to suggest that obese patients may be have a higher revision risk post lower limb arthroplasty; however, more research is required to confirm the premise.[101] Cardiovascular disease (CVD) was also prevalent in more than 70% of the patients who underwent revision knee or hip arthroplasties. High incidence of CVD may be due to the average revision lower limb arthroplasty patient age being 73 years and due to obesity. It is however a significant issue when considering surgical and anaesthetic risk for the patient undergoing surgery.

Another common patient characteristic was presence of bilateral knee primary arthroplasty. Since a common cause for primary arthroplasty is osteoarthritis, it is expected that it would affect multiple joints and therefore patients may require multiple arthroplasties. Data about the diagnosis/reason for primary knee and hip arthroplasty for revision patients in this register is incomplete; but current literature shows that osteoarthritis is the leading reason for primary lower limb arthroplasty.[102] It is not possible from this data set to evaluate at this time any reason why patients who undergo more than one primary arthroplasty procedure are more likely to undergo revision surgery. Further prospective data collection may help evaluate this association further, however, this may be difficult if the cause is multifactorial. Additionally, 30.5% of knee revision arthroplasties had previously been revised which suggests that a revision arthroplasty may put a patient at risk for a subsequent re-revision

which is strongly supported by the AOANJRR data on re-revisions summarised in *Figure 26* above.

The classification of type of revision was based on the new prosthesis implanted. In accordance with AOANJRR reporting revisions are classified as Major Total, where both the femoral and tibial implants are revised. Major Partial, where only one of the femoral or tibia implants is revised or Minor where the main metal implants are retained. Data from the AOANJRR 2015 and now 2017 reports shows that using Minor Revisions where appropriate patients could have less invasive surgery with no increase on long term re-revision rates.[99] The AOANJRR classification is summarised on *Figure 27* below.

This has been part of a wholesale move in our practice to *Conservative Revision* for both Hip and Knee surgery. The Conservative hip pathway has also had significant benefits but is outside the scope of this thesis. [102,103] However, in addition our local registry we also classified poly liner exchange +/-patella and isolated patella button surgery were categorised separately as part of assessing whether our Diagnostic algorithm described in *Chapter 4* has led to a significant reduction in revision surgery for patella femoral pain. Performing a patellar revision in combination with insert revision has been shown in AOANJRR data to have a lower re-revision rate compared to insert revision alone. This is summarised in *figure 28* below.

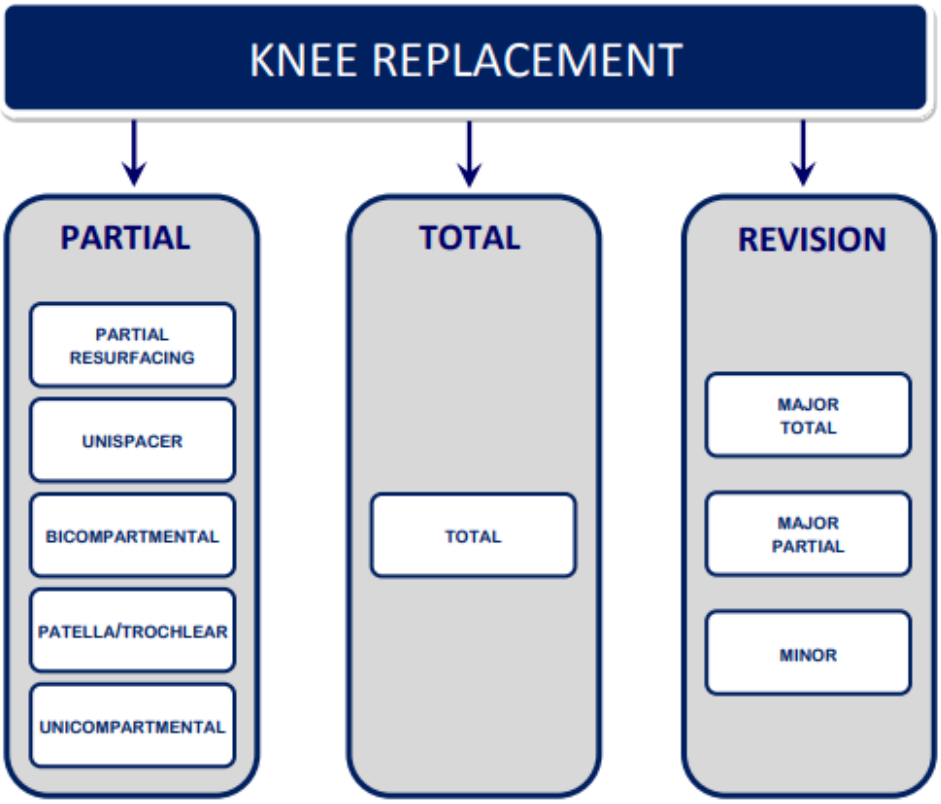


Figure 27 Categories of knee arthroplasty revision. Reproduced from AOANJRR 2015 Report page 132

AOANJRR 2017 figures confirm that these minor revisions have similar re-revision rates to more invasive procedures however as previously described have a significantly lower complication rate for patients. Surgical time is much shorted and the implant cost financially will be significantly less. More detailed analysis of these issues may be possible using this local registry but is not possible with the figures currently available.

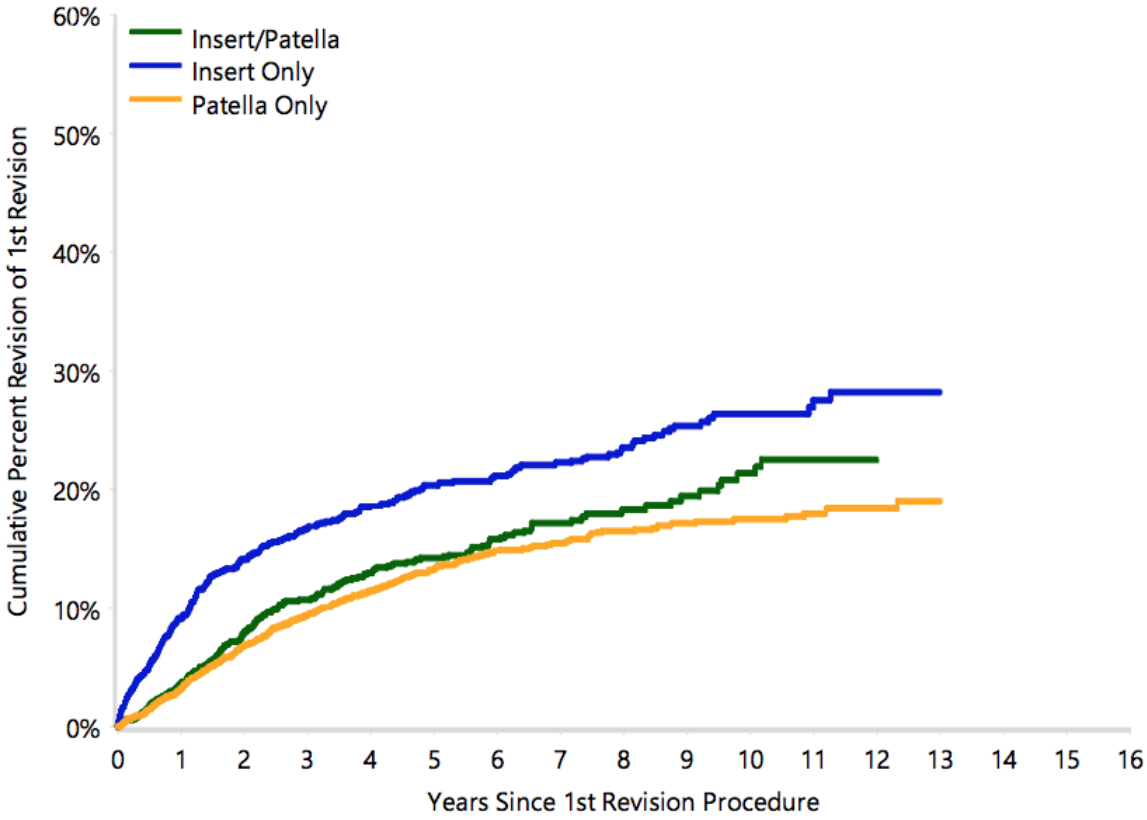


Figure 28: *Cumulative Percent Revision of Minor 1st Revision of Known Primary total knee replacement by type of 1st Revision (Primary Diagnosis OA, excluding 1st revision for infection*) Reproduced from AOANJRR 2018 Supplementary report. Figure R15 Page 19.

Conservative revision

The figures for the different types of revision knee arthroplasty were interestingly not all consistent with the AOANJRR 2015 percentages. The most frequently performed revision knee arthroplasty at the RGH was found to be poly liner exchange with/without patellar resurfacing or replacement (47.2%) and the second most common type of revision was a total knee replacement (33.3%). These figures are almost reversed in the National registry with Total revision at 48.4% and Poly exchange and patella sitting at only 21.3%. This also represents a significant shift from our historic figures where Poly liner exchange +/- Patella was only 16.7%.[96] However, these figures reflect the wholesale change in the way revision TKA surgery is managed in our department since 2014. Despite these changes and the introduction of our standardised diagnostic and management algorithm the overall rates of

Major and Minor revisions did not change. These data are summarised in *figure 29* below. Our routine pathway is discussed in more detail in *Chapter 3*. In this pathway all patients are subjected to a standardised and robust diagnostic process. The investigations and clinical scenarios are then discussed at weekly arthroplasty meetings attended by a number of our experienced clinicians before the final surgical plan is arranged and then implemented. Care is taken to identify patients where total revision is not required and to source old records and order implants to facilitate this process.

We feel this process may put our department 'ahead of the game 'in comparison to overall National trends and may lead to an increase in more Conservative Revision Knee Arthroplasty surgery in the future. The two main benefits to patients are that those who undergo 'minor' revision surgery may have significantly lower complication rates compared to those who undergo Total revision TKA and a lower rate of re-revision surgery[81]. The potential cost saving to the hospital is obvious with a shorter surgical time and a smaller number of implants requiring purchase. With the ongoing collection of our registry data over time we hope to confirm these trends with both a reduction in costs for our department and in the human costs of complications and re-operations for our patients.

Results at RGH from 1 September 1999 to 31 December 2013 (AOANJRR ad hoc 1167)	**Results in the local registry April 2014 to December 2015**
Reason for revision:	*Reason for revision:*
20.0% Patellofemoral pain	33.3% Instability
16.7% Pain	13.9% Pain
Type of revision performed:	*Type of revision performed:*
39.2% Patella revision	47.2% Insert exchange +/- Patella
10.8% Insert exchange	8.3% Patella revision
9 .2% Insert + patella exchange	
= 59.2% Minor revision	**= 55.5% Minor revision**
17.5% Tibia + femur exchange	33.3% Tibia + femur exchange
7.5% Tibia exchange only	2.7% Femur exchange
7.5% Femur exchange only	
= 32.5% Major revision	**= 36.0% Major revision**

Figure 29 Comparison of Historical revisions compared to revisions in our local registry.

Indications

It is always difficult to define a single reason for revision and patients can present with multiple indications such as pain and instability in the same patient. The admission notes and surgical notes and clinical records were all used to identify the causes of revision knee arthroplasty surgery. The results were then re checked by another member of the surgical team to try and identify any inaccuracies or duplications. The results showed that instability (33.3%), Infection (13.9%) and Pain (13.9%) were the top three reasons for revision knee arthroplasty. This does not correlate with the recent 2015 National report that suggested that Loosening and Lysis was the most common reason at 38.0%. The reasons for this discrepancy are not entirely clear but the application of our conservative management process would explain the discrepancies. While it is possible that other factors may be involved such as surgeon bias or changes in how operations are coded, our current Re-revision rates have reduced since the introduction of algorithm and conservative process have been shown to have an effect on patient outcomes. Instability had remained one of the top 5 reasons for revision in the AOA 2017 report at 7.3% of cases. Our figures are higher at 33.3% but it is unclear whether this is due to under diagnosis in general while our Diagnostic process includes radiographic EUA testing to try and accurately identify instability in the failing TKA patient. As part of our long-term prospective data collection we hope to ascertain if this is an abnormally high result or simply due to a more rigorous assessment methods. Many of our revision patients are referred from other centres that do not perform as much revision surgery. The local departmental interest in this topic may have led to more referrals for instability from other surgeons in comparison to the national average. This would require comparison with the results from other Tertiary referral centres to see how they compare.

Limitations

The current patient set analysed is quite small with only 36 patients of which only 25 were 1st revisions and it is difficult to evaluate significant differences. However this number is comparable with that found in other Revision TKA studies. In our systematic review of the published literature the average number of patients per study was only 27. Despite this our local registry has proved to be a very valuable tool that without doubt will be of great benefit to our department and the broader orthopaedic community. Prospective data

collection of this registry will allow more specific audits of larger patient populations and patient follow-up.[91,92] A registry will also eliminate bias that may otherwise be present when selecting revision arthroplasty patients for a specific study based on inclusion and exclusion criteria at the RGH. [91,92] This local registry comprises of a much higher specificity of detail in comparison to national AOANJRR. We currently gather Level 1 and 2 data but future work is underway to add patient reported outcome measures (PROMs) to the current data set. This registry will then include level 3 data as well and is discussed in further detail in *Chapter 5*. [76] Ongoing prospective data collection and further analysis in the future to will hopefully continue to improve clinical health outcomes at the RGH and may possibly have wider implications.[102]

Conclusions

This study created a local orthopaedic registry and collected data on all revision lower limb arthroplasties performed at the RGH from April 2014 to December 2015. The current frequency of types and reasons for revision arthroplasty were identified. The Local registry provides data in a much higher level of detail than in the National AOANJJR registry. The prospective data is easy to access and analyse, it will be used to monitor the trends in the management of a complex subset of arthroplasty patients and the quality of service our department provides and monitor trends in patient management over time.

To our knowledge this is the first study in Revision TKA surgery that compares and combines our Local historical results, current Local Registry results and the National Registry results. Using this information, we have found that our department has been able to improve quality and hopefully diagnostic accuracy. By combining this analysis with the implementation of our Diagnostic and Management algorithm fewer patients are treated for 'pain 'or 'patella-femoral pain' and therefore hopefully undergoing surgery with a more robust diagnostic and management plan. In addition a higher number of patients may undergo more Conservative Revision surgery in the future due to the patients with knee pain being more accurately diagnosed. These patients may be subjected to fewer complications and according to recent AOANJRR reports have a lower chance of returning for re-revision surgery.[92] As a result of this finding further work is under development of the

concept of ‘conservative revision ‘ to allow us to keep working on better outcomes for our patients with less risk. Both these factors will also lead to a significant reduction in financial cost to our department. If this system and its results were extrapolated out to a national level the cost saving could pay the annual budget for the AOA joint registry 3 times over.

Chapter Five: Prospective results of Knee Revision Arthroplasty Surgery in patients with instability.

Introduction

Background

Revision total knee arthroplasty (TKA) procedures are increasing in number. According to the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) 2016 annual report, there have been 48,502 revisions since 2003, with revision procedures accounting for 8.2% of all knee replacement operations. The overall rate of revision TKA has not increased in relation to primary TKA suggesting this increase is related to increasing primary TKA procedures over time.[104] During that time frame, the number of revision procedures occurring annually has increased 82.9%, with an annual increase of 0.7% from 2013 to 2014.[104] Revision TKA are commonly complex procedures, they often endure higher complication rates compared to primary surgery. In addition, these procedures commonly occur in younger patients and within 5 years of the initial TKA.[105] Similarly, research has shown that patients that undergo a revision TKA have a high rate of a re-revision procedure within the first 5 years.[106] The underlying reasons for revision TKA procedures vary, with instability accounting for 7.3% according to AOAJNRR.[104] However, according to the literature, instability can account for up to 22% of revision procedures[107], and can present numerous hurdles, as the underlying cause of instability may not be easily identified.[105] Identifying the cause of instability can be difficult, with the onus lying upon the individual surgeon. Once identified, the surgeon must balance the flexion and extension gaps using revision tools and modified implants. Where required constrained implants can be used to assist this process but not at the expense of adequate gap balancing, in order to appropriately treat the instability. [108] Revision tools and jigs can be used to kinematically balance the knee while minimising bone loss.

Review of Patients managed by our Diagnostic Algorithm

In our department we have designed and validated a specific diagnostic and management process aid in the clinical care of the patient with TKA failure. This diagnostic algorithm is described in detail in *Chapter 3*. Its introduction has led to a wholesale change in practice in our department. The results of *Chapters 3 and 4* show it has a fundamental effect on our results with improved accuracy in management and an increase in more conservative TKA revision surgery.[106] Our systematic review described in *Chapter 2* shows there is no current standardised guideline for surgeons to follow to determine whether a revision TKA procedure should take place. This work has been presented both Nationally and Internationally with good feedback from other revision specialists, formal discussion of these issues at the Arthroplasty Society of Australia in June 2017 was met with positive feedback and strong support. Some of the leading surgeons in this group are now adopting similar practice in their own centres. In this study our standard diagnostic algorithm was applied to all patients, ensuring that all patients who received revision TKA procedures for instability underwent the same diagnostic work-up prior to the procedure. Despite numerous studies evaluating revision TKA outcomes, no study has focused on the subjective, patient-based outcomes post revision TKA procedures completed solely due to instability. We have used instability as the sentinel event to investigate this issue but the diagnostic and management methods can be extrapolated to all indications in the failing TKA. The aim of this study is to determine the effectiveness of our diagnostic algorithm for those patients undergoing revision TKA for instability by assessing objective patient reported outcomes, as well as rates of re-revision via the AOANJRR for those patients post-op.

Materials & Methods

Patients

All revision cases performed by the principal author for instability at the Repatriation General Hospital between April 2014 and December 2016 were reviewed. Data was collected prospectively then reviewed retrospectively as part of this Thesis to assess their clinical outcomes. Patient's data was collected from patient electronic records, intra-

operative data, and the hospital electronic database that highlighted instability as the reason for the revision procedure. All patients went through our diagnostic algorithm as described in *Chapter 3*. All patients who underwent revision procedures for reasons other than instability were not included in this study; however their outcomes have been assessed in another study that is outside the scope of this thesis. Similarly, patients whom had multiple revision procedures on the same knee were excluded, as the results would not represent their primary revision procedures. The knees were revised using the Stryker Total Stabilised knee system. This system is currently in use in our service and has good results survivorship.[109]

A new cutting guide was introduced to improve restoration of the joint line combined with balancing the flexion and extension gaps during surgery called the Trial Cutting Guide (TGC). This allows the surgeon to cinematically balance the knee before making the final bone cuts and hopefully improves ligament balancing for the surgeon during the revision procedure. Prior to using this system, a surgical observation was arranged with Dr S Zelicoff in New York, USA was arranged to ensure the technique was adapted appropriately. The TGC guide system is shown in *figure 3*0 below.

Assessment Methods/ TGC technique

All patients were assessed using our standardised diagnostic algorithm as described fully in *Chapter 3*. Prior to undergoing revision surgery, the results of the clinical assessment and these standardised investigations were discussed with the whole arthroplasty team to ensure an accurate diagnosis was made, an appropriate surgical plan formed and the appropriate implants ordered. All patients deemed to require a revision procedure were conducted by the principal author were recorded in our local revision registry and subsequently followed up an AOANJRR Ad Hoc report on all cases, to determine if re-revision procedures had taken place since the initial revision TKA. This was confirmed by Ad Hoc report 2257, which is summarised in *Appendix 7* below. During the revision surgery procedure all patients had their knees kinematically balanced by the senior author in an attempt to correct the instability pattern that had led to revision surgery in the first place. The Stryker TS knee system was already our implant of choice but the TGC cutting guide system was also used as it is specifically designed to assist with intra- operative kinematic

balancing giving the surgeon an excellent assessment of how well the patients ligaments are balance prior to making bone cuts and implanting the definitive prosthesis.

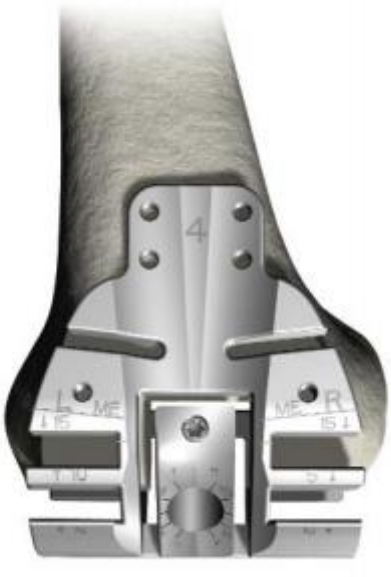


Figure 30, TCG femoral cutting guide allowing ligament balancing and assessment of augmentation before bone cuts are made.

Clinical Follow up

The Oxford Knee Score (OKS) was sent out to the revised patients to be completed. The OKS was chosen, as it is an objective, patient reported questionnaire proven to be useful in evaluating knee function both pre- and post-TKA.[110] Its reproducibility and sensitivity to clinically significant changes made it an important resource for this study to evaluate, assess, and score individual patient progress and overall outcomes. Criteria for functional outcome were defined by the OKS and summarised in *figure 31* below. All results were cross-checked by the in-house statistician.

OKS CRITERIA	Oxford Knee Score
Normal Function	40-48
Acceptable	30-39
Poor Function	20-29
Unacceptable	0-19

Figure 31: Functional outcome result as defined by the oxford knee score.

Consent

The South Australian Southern Health Networks Ethics Committee approved the undertaking of this study *OFR 436.15 - HREC/15/SAC/401.* Patients were then contacted and mailed subjective, patient-reported questionnaires (Oxford Knee Score) to be completed and returned. The patients were also sent a letter outlining the purpose of the study so that informed consent could be given, as well as a pre-paid envelope to which to return the completed survey. Patients who consented to the study and wished to participate returned the questionnaire as outlined.

Registry

All patient records were reviewed to look for evidence of re-revision surgery. In addition, an Ad Hoc report was requested from the AOANJJR joint registry to ensure no patients had been revised in other centres without our knowledge. In addition, a further report was obtained to assess re-revision rates within our department prior to the introduction of our diagnostic algorithm to assess whether or not this led to a reduced rate of re-revision surgery for our patients. This report 2418 is summarised below in *Appendix 8*. The study design and methodology was constructed using the STROBE guidelines to simplify the structure and enhance the clarity of how the results are presented.[87]

Results

Basic Demographics

26 patients were identified between April 2014 and December 2016 inclusive. Of the 26 identified patients, 25 had revision knee procedures, one was found to have had a primary TKA, and one was found to have completed the questionnaire incorrectly. These patients were excluded from this study, leaving a total of 24 patients. Of the 24 questionnaires sent out, 19 were returned. 17 out of the 19 patients who returned questionnaires were found to have met all inclusion criteria or returned a complete data set.

GENDER	TOTAL (n)	Mean AGE (Years ± SD)	Mean TIME SINCE PROCEDURE (Months ± SD)
Male	7	69.00 ± 10.35	38.25 ± 18.06
Female	10	66.30 ± 9.73	28.18 ± 18.20

*Table 12: All included patients average age and time since procedures as per gender. *Time since procedure calculated as the gap between the 'date of procedure' to the date the survey was mailed out.*

Re-revision Rates

Our historical Re-revision rates were cross checked with AOANJRR Ad Hoc report 2418 which analysed all cases performed in our department prior to the introduction of our Diagnostic algorithm. In this report 3553 TKA cases were cross checked of which 163 were revised. By cross checking all further revisions we found our historical Re-revision rate was 10.4% at 2 years and 12.4% at 3 years. This report number 2418 is listed in full in *Appendix 8*. These figures are summarised in *figure 32* below.

In our current series two out of 24 patients (8.33%) had further revision procedures on the same knee confirmed via the adhoc AOANJRR report 2257 summarised in *Appendix 7*. The follow up time for all patients being approximately 3 years. It is difficult to run a statistical review of these figure with only 24 patients but it clearly shows a reduction in Re-revision rate from 12.4 to 8.3% at 3 years post op.

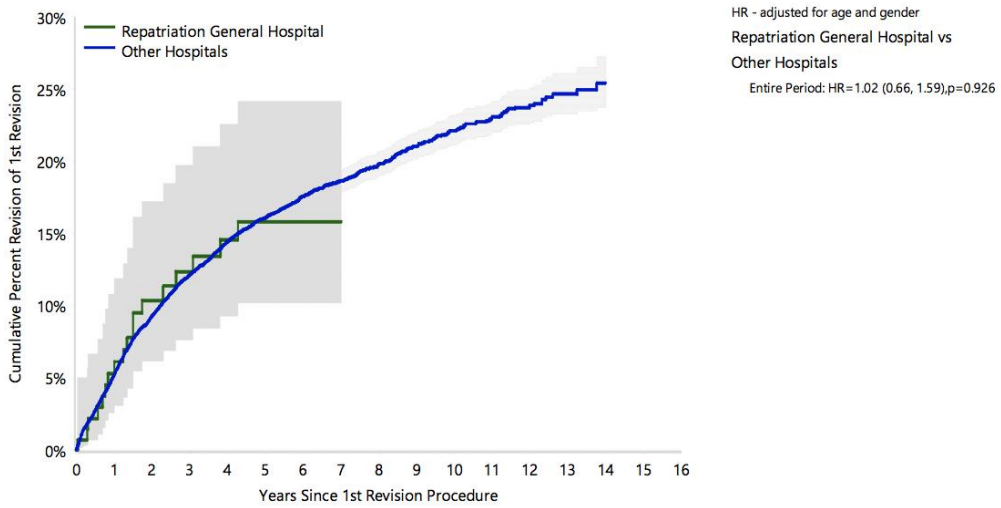
CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Repatriation General Hospital	5.3 (2.6, 10.8)	10.4 (6.1, 17.2)	12.4 (7.6, 19.7)	14.6 (9.3, 22.5)	15.8 (10.2, 24.2)
Other Hospitals	5.2 (4.9, 5.6)	9.3 (8.8, 9.8)	12.1 (11.6, 12.7)	14.4 (13.8, 15.1)	16.1 (15.4, 16.8)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Repatriation General Hospital	15.8 (10.2, 24.2)	15.8 (10.2, 24.2)			
Other Hospitals	17.5 (16.8, 18.3)	18.6 (17.9, 19.4)	19.8 (19.0, 20.6)	21.0 (20.1, 21.9)	22.1 (21.1, 23.1)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital						
Other Hospitals	23.1 (22.0, 24.2)	23.8 (22.7, 25.1)	24.6 (23.3, 26.1)	25.4 (23.7, 27.2)		

Figure 32: Table 15: Yearly Cumulative Percent Revision of 1st Revision of Primary Total Knee Replacement by Primary Hospital (All Diagnoses, Excluding 1st Revision for Infection)

In addition, when reviewing our historical Re-revision rates, it was important to show that they were not high in comparison to other hospitals. Therefore, not only has our re-revision rate been reduced, but it has been reduced when compared to results that were similar to the Australian average at that time. It was possible to run statistics showing our historical re-revision rate was no different than that obtained in all other Australian hospitals at that time. When adjusted for age and gender there was no significant difference with a p=0.926. This is summarised in *Figure 33* below.



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Repatriation General Hospital	139	117	96	84	71	59	49	43
Other Hospitals	15506	13022	10847	9017	7387	5948	4611	3541

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital	35	20	14	10	7	4	0	0	0
Other Hospitals	2729	2008	1408	930	592	295	127	30	6

Figure 33: Cumulative Percent Revision of 1st Revision of Primary Total Knee Replacement by Primary (All diagnosis excluding first revision for infection)

These figures confirm that our historic figures for Re-revision surgery were comparable for national figures at the time. The use of our diagnostic algorithm and revision with the TCG kinematic balancing technique has therefore reduced our Re-revision rate which was

acceptable compared to the national figures to an even lower rate with potentially reduced complications for our patients and a reduced financial burden on our healthcare system.

Oxford Knee Scores

The OKS questionnaire was completed subjectively by the patients with no influence nor input from the authors. 17 out of 19 questionnaires were included, as one patient had undergone a re-revision procedure, and one had completed the questionnaire incorrectly. Of the 17 returned, 7 were males and 10 were females. The average Oxford Knee Scores for males and females were 22.86 ± 6.10 and 13.30 ± 5.33 respectively. The results are summarised in *Figure 34* below. The PROMs results reported show poor function scores for all patients. As these patients have been regularly followed up and have not requested further surgery it is not clear if these low oxford knee scores are due poor pre-op functional status, the function in their revised knee or due to a general decrease in their function over time. Further studies are underway in our department using Oxford Knee score, Forgotten joint score and satisfaction scores. These are being collected pre-op and up to 1-year post op to help clarify this issue.

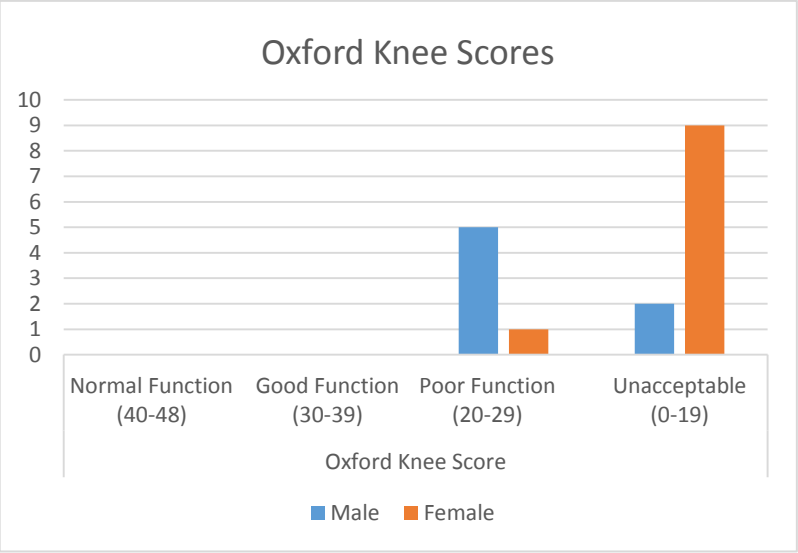


Fig 34: Oxford Knee Score outcomes as per functional classification

Discussion

Historical results in our department suggested that pain was the most common indication for revision surgery, accounting for 36.7% of all cases. However, our new diagnostic algorithm saw the number of revision procedures being performed within our local revision registry for pain drop from 36.7% to 13.9% of all cases.[106] The most common indication proved to be instability, accounting for 33.3% of all primary indications for revision procedures.[106] Similarly, positive instability findings on the intra-operative fluoroscopic radiographs during the EUA showed a high correlation with the incidence of revision surgery.[106] Self-reported knee instability has been defined as a 'sensation of buckling, shifting, or giving away of the knee.[111,112] The MARKER study which followed 323 participants for 6/12 post-TKR and assessed for instability, found that 32% of patients whom self-reported pre-op instability, retained that instability 6/12 post-operatively.[113] Self-reported knee instability remains scarce, as it is rarely sought by health professionals who provide rehabilitation to those undergoing TKR.[111]

Patient-specific characteristics/factors are important to understand and include general or local neuromuscular disorders, hip or foot deformities, and obesity. Some patients can have a mildly unstable knee and have no pain at all while other patients who are unstable can present with pain or with functional difficulty such as climbing stairs. As a result of these variations we decided to include in our diagnostic algorithm; a thorough objective assessment of knee stability which can be recorded radiographically. The knee is assessed for varus-valgus laxity in 20^0 flexion, and 90^0 of flexion to assess the extension and flexion 'gaps. AP laxity should also be assessed with an anterior and a posterior draw test. In addition, all patients have what we have termed an 'Intrinsic Knee Injection' where an intra-op injection of local is performed and the patient is examined during mobilisation. A negative test raises the concern that their pain is coming from and extrinsic source e.g. the Hip or Lumbar Spine. When validating our algorithm, we found a negative intrinsic injection test was found in 30% of patients who were subsequently recommended that revision surgery was not recommended.[106] These patients underwent further investigations to diagnose and treat extrinsic cases for pain including lumbar spine disease, hip disorders and chronic pain disorders.

Patients deemed appropriate for surgery were then revised using the TGC system designed specifically to assist with the balancing of the knee before any bone cuts are made. This streamlines the surgical process and allows the surgeon to be confident the knee imbalance has been corrected before resecting bone and testing with traditional trial implants. The system was used in this series to address the patient's knee instability and potentially reduce the risk of re revision due to poor correction. Interestingly our patients reported relatively low oxford knee scores. It is unclear whether this represents a low general level of function in these patients for other reasons or whether they have adapted to a low level of function after a long treatment course for their knees including multiple knee surgeries.

Re-revision is a significant issue for TKA patients. In the recent 2016 AOANJJR report 16% of patients have undergone a re-revision procedure by the 5-year mark.[104] This is excluding cases revised for infection, so this poor result may not only be poor but the patients with the worse expected post op results have already been excluded from the analysis. This is summarised in *figure 35* below.

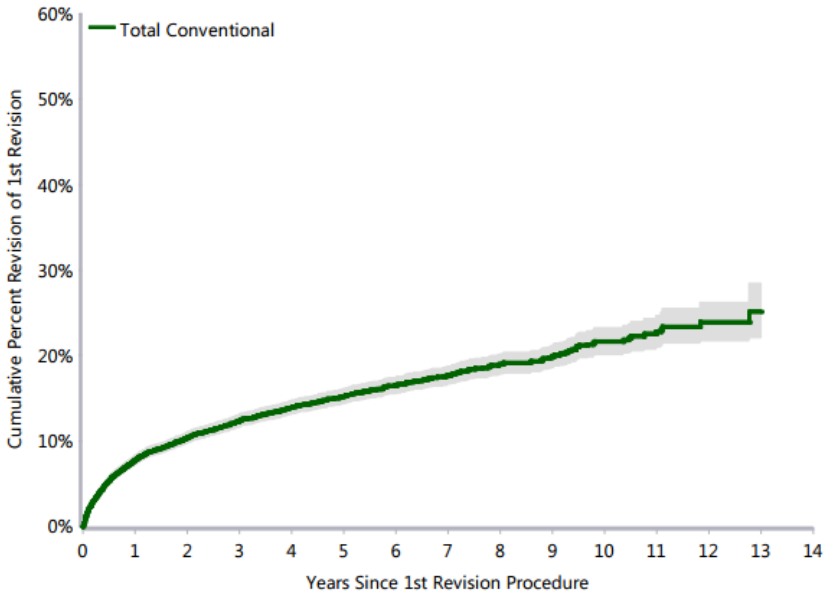


Figure 35: Cumulative percent revision of first revision of primary total conventional knee replacement (primary diagnosis osteoarthritis, excluding first revision for infection)[104]

Our results are short term with just under 4 years follow up. However, after reviewing our local records and cross referencing with the AOANJJR ad hoc reports only 8.33% of our patients have been re-revised. In addition, this revision rate is lower than our own historical

figures with a Re-revision rate of 12.4% at 3 years rising to 14.6% at 4 years. This suggests that with a rigorous diagnostic and management process it may be possible not only to improve our diagnostic accuracy for our patients, we can also reduce the risk of re-revision surgery for them in the future. In addition, many failing revision TKA patients fail and undergo subsequent re-revision early stressing the need to break this cycle of multiple complex procedures for our patients.

The combination of our diagnostic algorithm and the use of the TGC cutting guides to improve intra-operative kinematic ligament balancing may also have an effect on the post-op results. The improved balancing may lead to less re-revision for recurrent instability or due to loosening secondary to poor balancing and increased stress on the implant / bone interface. However further follow up of these cases is ongoing to ensure this is in fact the case.

Conclusions

In this study the results show that using our diagnostic algorithm for patients undergoing revision TKA for instability we can reduce Re-revision rates for our patients. By utilising AOANJRR resources we have shown our re-revision rates are now well below Australian national figures and improved compared to our own historic results. Our PROMs reported are lower than expected highlighting the fact that avoiding revision TKA surgery in the first place is desirable for our patients. The use of Computer assisted and Robotic assisted TKA surgery to try and achieve this aim is discussed in more detail in *Chapter 6*.

However, this system may allow more accurate diagnosis of instability and other methods of TKA failure allowing the correct surgical management for our patients. Further long-term review of the cases in our registry is ongoing.

Chapter Six: Robotic Gap Balancing in TKA Surgery

This Chapter Contains Material from:

Sires JD, Craik JD & Wilson CJ.

Accuracy of Bone Resection in MAKO Total Knee Robotic Assisted Surgery

The Journal of Knee Surgery Nov 2019.

Sires JD & Wilson CJ

Validation of Accuracy and Gap Balancing in MAKO Total Knee Robotic Assisted Surgery

The Journal of Knee Surgery March 2020.

Introduction:

As described in the previous chapters patients with TKA instability are younger, fail early, have high re-revision rates and poor PROMs scores after revision TKA surgery. Therefore, the issue of prevention of TKA instability in the first place is of importance. We have described the process through which patients are more thoroughly diagnosed and managed for their failing knee to prevent surgery in patients who could be managed conservatively and try to avoid revision surgery for the incorrect diagnosis.

Using the new diagnostic algorithm, we have shown that up to one third of patients are spared from unnecessary surgery for pain extrinsic to the knee and refined our procedure to enhance the diagnosis of instability and prosthetic infection. Through the design of the Local Revision registry and comparison of data compared with Local Historic and National results we have shown that more conservative revision surgery can be performed compared to national trends with lower complication rates for our patients and hopefully lower re-revision rates and significantly reduced cost. Finally, with our prospective evaluation and registry review we have shown lower re-revision rates for our patients compared to before and after the implementation of this process. However many patients feel they have low

functional scores compared to their peers and any Revision TKA surgery has still the potential of complications.

Therefore, it seems logical to focus on how to prevent TKA instability from occurring in the first place. In conventional TKA surgery instruments were used to perform measured resections of bone and correct the osteoarthritic limb from and abnormal to a normal mechanical alignment. Computer navigation, patient specific instrumentation, and more recently robotic assisted arthroplasty techniques have been developed to improve implantation accuracy. The introduction of newer surgical techniques has potentially increased the complexity of TKA surgery at the same time as improving both accuracy and reproducibility of TKA implant positioning. However, controversy exists on whether the aim of the TKA technique is to use these technologies to produce a knee in neutral mechanical alignment or to implant the prosthesis in a position that produces a knee with balanced flexion and extension gaps irrespective of mechanical alignment. As a result, there is a growing shift amongst arthroplasty surgery surgeons to move away from mechanical alignment. Mechanical alignment is based on a combination of population averages and the ideal that the ideal patient has an overall mechanical alignment of zero degrees. However, a gap balancing technique is more tailored towards the ideal alignment position for each individual patient.

**Wilson CJ, Ford J & Quinn S & Krishnan J*	*Clinical diagnosis of Instability in the failing TKA. Evaluation of a new diagnostic algorithm.*	
Arthroplasty Society ASM	*Noosa QLD*	*Jun 17*

Mechanical Alignment

As described in *Chapter 1* surgeons have used a variety of instruments and tools or jigs over the years in the execution of these procedures. Traditional techniques were described as 'measured resection' where jigs are used to resect a specific thickness of bone. This bone and any defects caused by the OA disease process are then reconstructed using the shape and thickness of the prosthetic implant. This process is demonstrated in *Figs 4b and b* in *Chapter one*. In addition, the implants were inserted in a 'neutral' or Zero degrees mechanical alignment with relation to the patient's hip, knee and ankle. The logic behind this process was that a knee would function mechanically better if the leg was restored to a neutral mechanical alignment. In addition, earlier studies had shown that knees will survive

longer with fewer revisions due to aseptic loosening if the knee was implanted with the leg in a neutral mechanical alignment with an error of less than +/- 3 degrees in relation to Varus and Valgus.[114] The mechanical alignment can be measured pre and post-op with either Long leg radiographs or CT scans. The use of long leg x-rays has been shown to be reproducible allowing surgeons to plan and verify how accurate the mechanical alignment has been restored.[115] An example of long leg X-ray measurement is shown in *Figure 36* below.

However not all patients can be assumed to be in neutral alignment in the absence of OA in the Hip or Knee joint. There is a wide variety of 'normal 'mechanical alignment in our population even in the absence of disease.[116] Patients may not even have the same mechanical alignment in each of their legs. Therefore, restoring the patient to a neutral mechanical alignment may not be restoring them to their own normal mechanics at all. Measured resection and mechanical alignment techniques may therefore fail to produce not only normal mechanics of the knee but also normal balance in the ligament tensions within their joints.

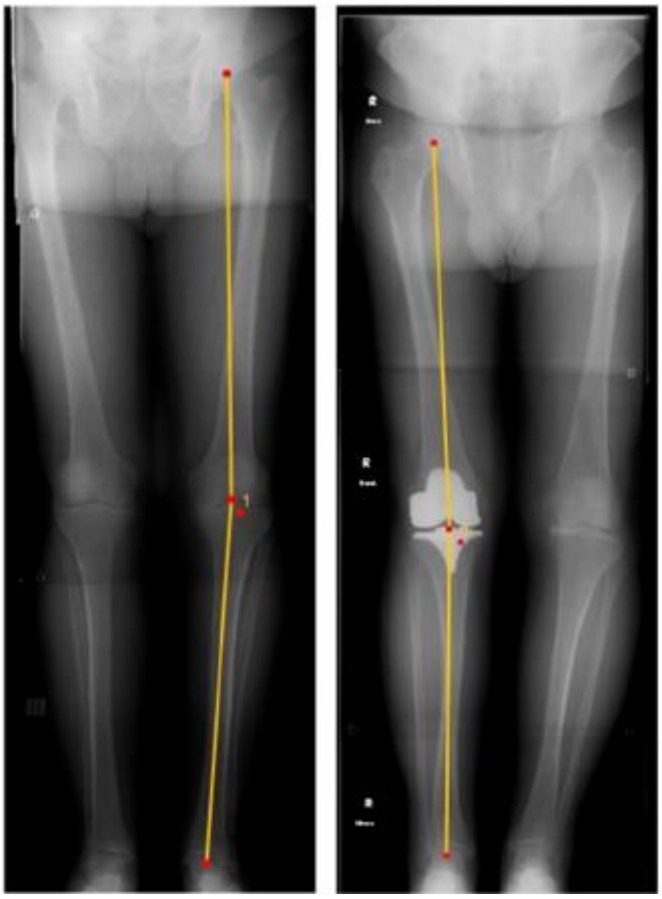


Figure 36, Example of Varus Mechanical alignment in a pre-op long leg x-ray and near 'Neutral 'mechanical alignment post-op [117]

Despite improvements in Implant technology and accuracy of placement if the surgical implants instability remains a significant reason for failure in TKA surgery. The systematic review in *Chapter 2* included data from the 2015 AOANJRR report. Since that report the 2017 report has been published. This shows that Instability remains a significant problem and is currently the 5th commonest reason for revision surgery. This is shown in *Figure 37 below.* Data from that report looks at how knees fail not just in total but as we have described how knees fail over time from index TKA surgery. In *Figure 38* below we show from registry data that not only does instability remain a significant reason for failure, most of these failures continue to occur in the early post op period with most of the later failures being causes by Aseptic loosening.

Table KT7 Primary Total Knee Replacement by Reason for Revision

Reason for Revision	Number	Percent
Loosening/Lysis	4990	28.1
Infection	3985	22.5
Patellofemoral Pain	2059	11.6
Pain	1535	8.7
Instability	1194	6.7
Patella Erosion	772	4.4
Arthrofibrosis	611	3.4
Fracture	486	2.7
Malalignment	403	2.3
Wear Tibial Insert	290	1.6
Metal Related Pathology	286	1.6
Incorrect Sizing	222	1.3
Other	897	5.1
TOTAL	**17730**	**100.0**

Figure 37 Reasons for revision of Primary Total Knee Arthroplasty. AOANJJR 2017 report.

Kinematic Balancing

The concept of Kinematic Alignment was introduced with the idea of restoring the patient's anatomy to a mechanical axis which matches normal for them and restores their mechanics and ligament tensions closer to normal. This involves moving away from pure mechanical measurements and implanting patients in positions that allow better balancing of their ligaments despite the limb being malaligned in for example slight Varus. Using tensioning devices such as that shown in *Figure 9*, *Chapter 1* the surgeon relies on the patient's ligament tension, balanced in both the flexion and extension gaps to decide what position the implant will sit in and moving away from the previous concept of producing neutral alignment then releasing ligaments, perhaps unnecessarily, to balance the gaps.

While working through the new diagnostic and management algorithm, from review of recent studies and after Discussion with other groups of surgeons both in Australia and overseas I have changed my routine surgical technique in primary TKA surgery to move towards a Kinematic balancing approach. Interestingly when reviewing the data in *Chapter 2* on the published literature with relation to TKA instability there was not a lot of information

on the use of technology in ligament balancing and its relationship with prevention of instability of the knee. Discussions with these surgical groups have focused on how the use of technological aids such as Computer Navigation Assisted surgery and Robotic Assisted surgery to improve Interestingly the accuracy of Kinematic balancing which may help patients feel better with a more ‘ normal ‘ feeling knee and may reduce their risk of instability and therefore failure.

**Validation of Accuracy and Gap Balancing in MAKO Total Knee Robotic Assisted Surgery*
J Sires & Wilson CJ
Arthroplasty Society ASM Noosa May 2019

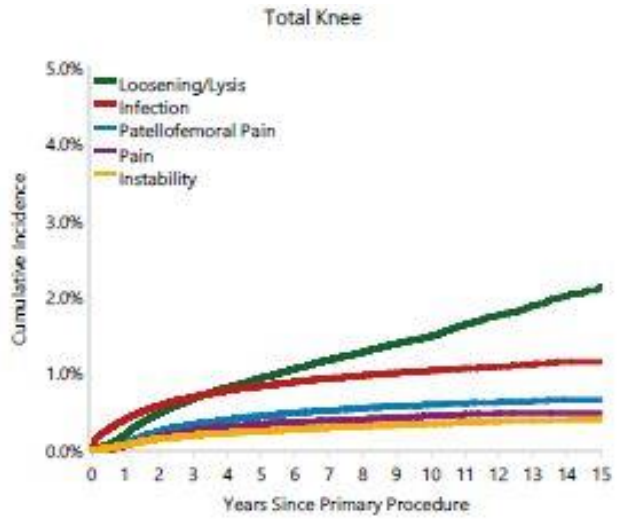


Figure 38 Cumulative Incidence by Revision Diagnosis in Primary Total Knee Arthroplasty. AOANJJR 2016 report.[104]

<u>Computer Navigated TKA surgery.</u>

Computer Navigated (CAS) TKA surgery uses digital referencing instead of ‘Jigs’ to map out the size of the patient’s bones and the abnormal alignment to allow the surgeon to correct the alignment during the procedure and check that the alignment is correct before

implanting the final prosthesis. The Navigation system uses fixed points or 'Trackers' to reference the position of the patient's bones in space with a reference and display system. Initial registration is performed to allow the computer system to map out the patients pre surgical alignment. The surgeon then uses a digital reference device or 'pointer 'to map out the surface of the patients knee joint. This process is known in CAS surgery as 'Registration'. This is cross references with the patient's alignment data and a 'Morph 'of the patient's knee is generated. The system uses a database of Morphs previously saved in its database for this final step, the Morph that most closely resembles the patients knee data is used. Therefore, in these systems this is an accurate estimate not exact representation of the patient's anatomy. Using this digital model, the surgeon can plan and execute the cuts with a high level of accuracy. These cuts are then checked with trial implants to ensure the correct alignment and implant size has been achieved.

The CAS TKA method has been used for years to assist surgeons reproduce the patient's normal alignment and therefore improve the function in their knee. However, the overtime implant companies have upgraded the functionality and software driving these systems. Surgeons can now use the CAS software to measure the abnormal ligament flexion and extension gaps before performing bone cuts. The alignment check is shown in *Figure 39* below. In this process the surgeon can check the alignment in both the coronal and sagittal plane before making the decision to insert the definitive implants.

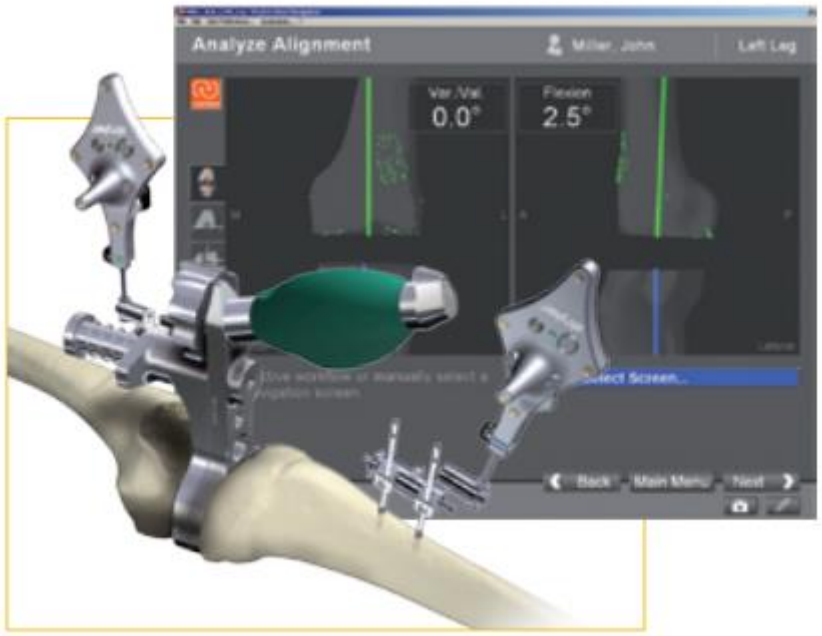


Figure 39 Final alignment check using trackers and a knee gap balancing device before implantation of the definitive prosthesis.[118]

In addition, the surgeon can estimate the best position to perform bone cuts to allow optimal balancing of the patient's ligaments and balance the flexion and extension gaps. By using this technology in the way, the knee can be implanted in the position that provides the best Kinematic Ligament balancing for the patient's knee without necessarily implanting the knee in a 'Neutral 'Mechanical alignment. The knee can be inserted in for example 2 degrees of Varus on purpose which represents and abnormal mechanically aligned knee while the ligament balancing and therefore Kinematic Alignment has been optimised.

When considering kinematic balancing using CAS the surgeon also has the choice to look at the patient's gap balancing and laxity before this final step. As previously discussed, these technologies can be used to allow a knee prosthesis to be implanted in a neutral mechanical alignment. However, the CAS kinematic testing can allow checks to me made to ensure the flexion and extension gaps are symmetrical. In addition, the laxity of the patient's ligament s can be kinematically assessed throughout the range of movement. The knee is passed through a ROM with trackers and trial implants in place. The surgeon can feel and measure any laxity of asymmetry before committing to final implantation. This test is shown below in *Figure 40*.

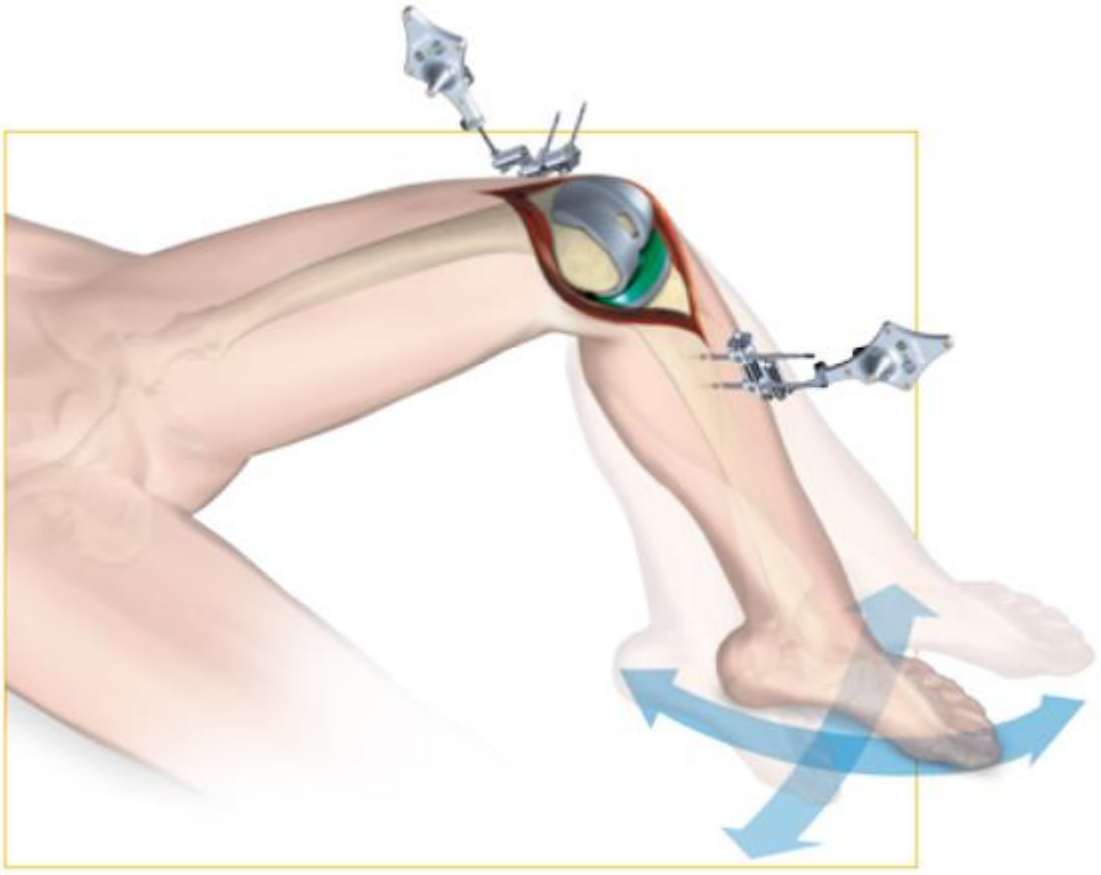


Figure 40 Kinematic assessment of the patient's ligament laxity and gap balancing using the CAS navigation trackers and trial implants throughout the patients ROM.[118]

Clinical Assessment of Kinematic Alignment Balancing in TKA surgery.

In arthroplasty surgery one of the difficulties with outcomes assessment is the number of patients and time required to evaluate whether an innovation in surgical technique has had a significant effect on patients' outcomes or not. These evaluations can take years and require large numbers of patients to obtain significant results. The use of CAS in TKA surgery has been steadily increasing over the last 10 years. In 2016 30% off all TKA surgery recorded in the AOA registry was performed using a CAS technique.[120] Despite this increasing uptake and the reduction in alignment errors and outliers achieved using this technique it has taken time to show a significant difference in patients clinical results[121] or where failure and

revision surgery is used as an end point. The registry has been collecting and now reporting on these failure rates and in the current 2018 figures shows a significant reduction in revision rates in patients < 65 years old whose surgery has been performed with or without the CAS technique (p<0001). This is shown in *Figure 41* below.

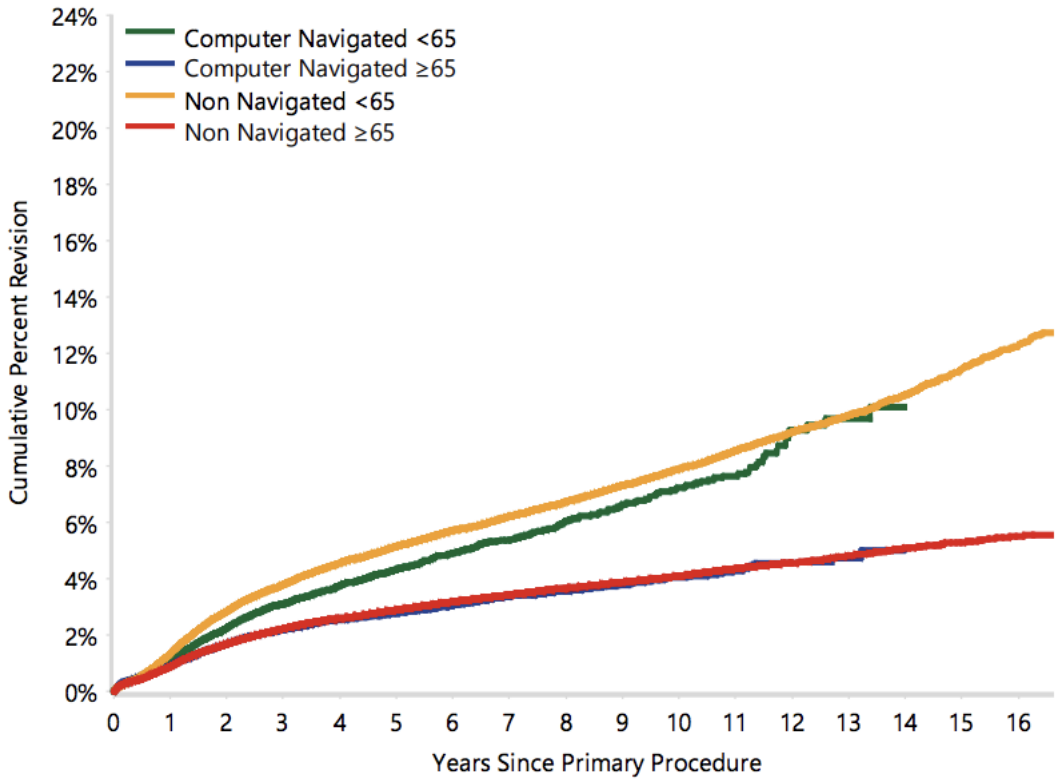


Figure 41 Cumulative percent Revision of Primary total knee replacement by Computer Navigation and Age (Primary Diagnosis OA) [119]

In our routine surgical practice, I have used CAS surgery for routine primary TKA surgery and for the last 4 years have now used the Kinematic balanced technique. The aim of this change has been to attempt to reproduce the patient's biomechanics and also reduce the risk of instability due to surgical error. With regards future research a gait analysis study is planned to look at the gait patterns of these primary TKA patients but this work is outside the scope and time frame of this thesis.

Robotic TKA surgery.

The MAKO total knee robotic-arm assisted surgery (Stryker Kalamazoo, Michigan) uses a pre-operative plan based on a computed-tomography scan of the patient's knee, as well as 3D planning to size and orientate implants, as well as allowing for dynamic balancing of flexion and extension gaps. This can be evaluated in the surgeon's office before surgery takes place and fine-tuned intra-operatively when real time bone mapping data is added. An example of a pre-op plan showing the potential implant position and bone cuts is shown in *figure 42* below. This technology may allow the surgeon to perform more accurate and reproducible bone resection, therefore leading to a more accurate final mechanical alignment compared to what the surgeon aimed for during pre-operative planning.

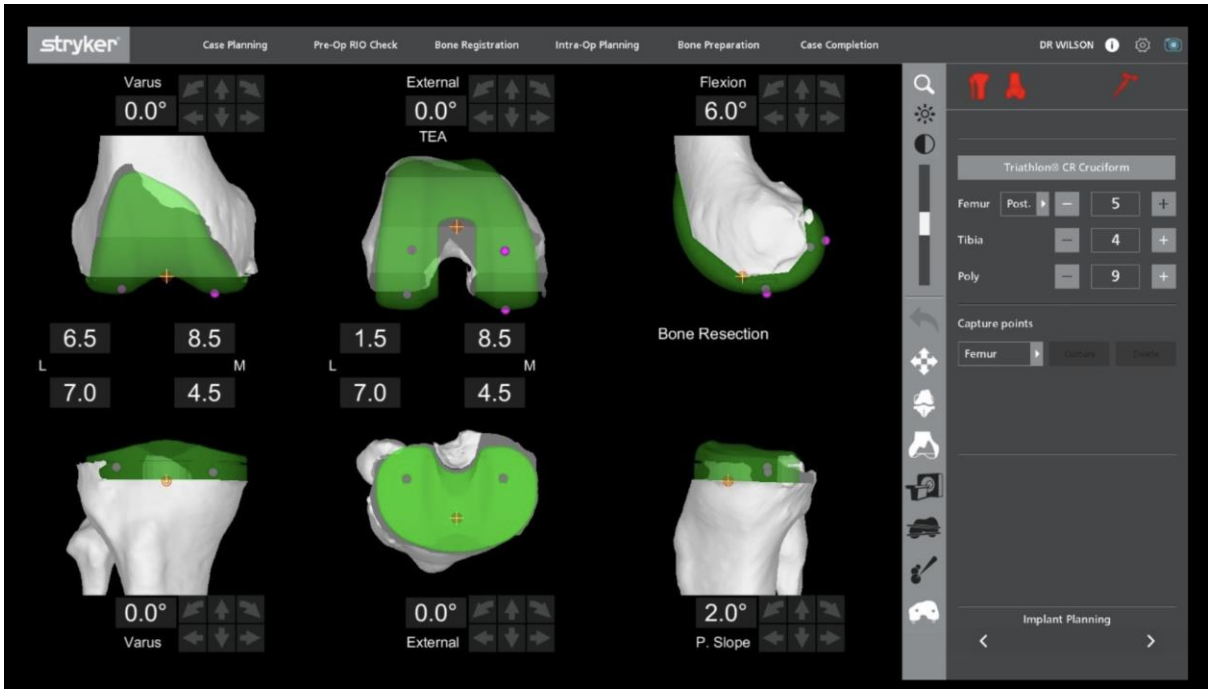


Figure 42 Pre-op planning of robotic bone resections before surgery has taken place. Reproduced with permission from the authors own surgical series

In addition, the surgeon can use intra-operative mapping similar to the CAS technique to confirm the patient's morphology and estimate any asymmetry in the patient's flexion and extension gaps. Changes are then made to the pre-op plan to confirm the ideal implant

position to allow gap balancing to occur, all before the surgical bone cuts are made. The final gap balancing position is then confirmed with 'trial' components before the surgeon accepts the final implant position. An example of the intra operative balancing is shown in figure 43 below where a patient's extension gap is imbalanced prior to correction being made.

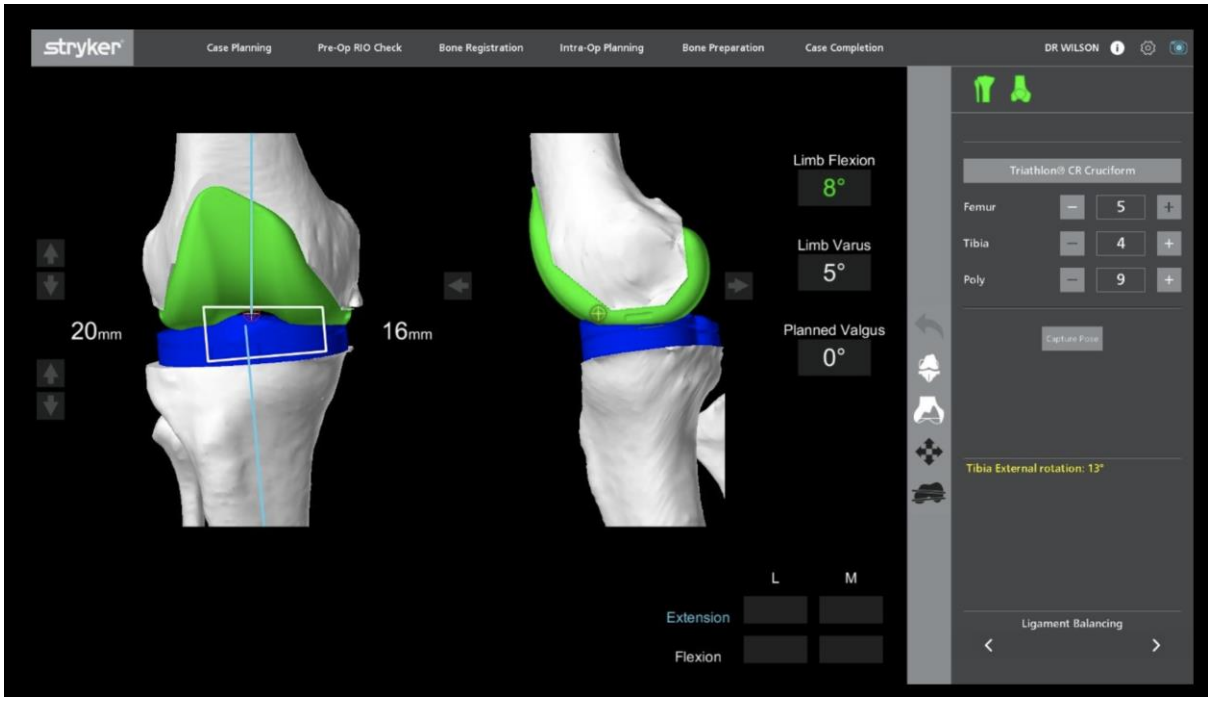


Figure 43 Intra-op gap balancing showing asymmetry of the extension gap. Reproduced with permission from the authors own surgical series

Although data is limited, robotic-assisted devices have shown to have increased implantation accuracy, mechanical axis alignment and soft tissue preservation. A study by Hampp et al [121] using MAKO total knee robotic arm assisted surgery found improved accuracy and precision in achieving pre-planned implant positioning in cadaveric knees compared to conventional TKA. Limited data exists on the MAKO total knee system, which was released in 2017, unlike the uni-compartmental version which has shown a significant improvement in implantation accuracy, pain and short-term outcomes [122,123]. Its gap balancing capabilities may lead to the reconstruction of a more stable knee at the end of

surgery. Recent studies have shown that balancing the patient's flexion and extension gaps with less than 2 mm of difference leads to improved PROMs scores.[124]

This technology clearly requires a significant investment in surgical hardware for a hospital or orthopaedic department. The unit is also large and its footprint has to be dialled into the floor plan of a surgeon's theatre set up. An example of the surgical robot is shown in *Figure 44* below.

Figure 44 Example of surgical 'Robot 'with is motorised arm for orientation of surgical tools in space. Reproduced with permission from Stryker [125]

The aim of this study was to determine if the MAKO robotic total knee system can be used to accurately balance the flexion and extension gaps in TKA surgery allowing the surgeon to reconstruct a more 'stable 'knee.

Methods:

The MAKO robotic-arm Assisted TKA's system was introduced to our hospital in 2018. Prior to our first surgical case, a team of three surgeons underwent intensive training and mentorship on the technique. All three surgeons were established TKA surgeons with experience with computer assisted TKA and the Triathlon implant (Stryker Kalamazoo, Michigan). This study included the public cases from the three surgeons, as well as the private cases of one surgeon forming a series of 40 consecutive TKA's using the MAKO system and Triathlon Total Knee implant between April to December 2018. This included all of our learning curve as well as the initial case performed. Ethics approval was obtained prior to commencing the research from our local HREC, number AUD/19/SAC/77, summarised in *Appendix 1*.

Before analysing our gap balancing data a pilot analysis was performed to assess the accuracy of bone cut in our hands using the MAKO robotic system. Surgeons after performing each bone cut would perform a validation check for each of the distal femoral, anterior femoral and tibial cuts. The bone cut values were found to be highly accurate with most cuts less than 1 degree or one mm from the pre-surgical plan. These results are summarised in *Table 13* below.

Overall, the accuracy of both femoral and tibial bone resection was high, with 95% of cuts being $\leq$ 1mm of the plan. Additionally, we found a small tendency for the anterior femur and tibial cuts to undercut the bone, however this was minimal. Furthermore, the precision of bone resection was high for all three bone resections, represented by low standard deviations of 0.30, 0.27 and 0.33 respectively. 24 knees had a final limb coronal alignment recorded. Mean absolute difference in final limb coronal alignment was 0.83° (0.80), with 75.00% being $\leq$1.00° of the plan and 100% being $\leq$3.00° of the plan.

		Mean	Root Mean Squared (Absolute) (mm)	Max Error (mm)	% ≤1° or ≤1mm
Distal Femur cut(n=28)					
	Deep	-0.05 (0.45)	**0.35 (0.30)**	1.10	96%
	Valgus	-0.20 (0.53)	**0.49 (0.30)**	1.00	100%
	Flexion	-0.12 (0.72)	**0.55 (0.49)**	1.80	75%
Anterior femur cut (n=26)					
	Depth	-0.44 (0.33)	**0.48 (0.27)**	1.10	96%
	Internal	0.42 (0.55)	**0.58 (0.39)**	1.50	85%
	Flexion	0.30 (0.44)	**0.44 (0.30)**	1.20	96%
Tibia cut (n=27)					
	Depth	-0.29 (0.40)	**0.37 (0.33)**	1.10	93%
	Valgus	-0.11 (0.86)	**0.62 (0.61)**	2.40	85%
	P Slope	-0.23 (0.71)	**0.62 (0.42)**	1.80	85%

Table 13 Intraoperative values of patients' bone cuts captured by the MAKO robotic system by mean value, absolute values and standard deviations.

These values were presented and discussed at the recent Arthroplasty society of Australia annual scientific meeting where it was agreed the system delivers surgical bone resections with a very high level of accuracy*.

**Wilson CJ & Sires J.* *Accuracy of Bone Resection in MAKO Total Knee Robotic Assisted Surgery*
Arthroplasty Society ASM *Noosa QLD* *May 19*

Power Calculation

Prior to beginning the analysis, a power calculation was performed and cross checked with our local statistics department. As previously discussed, patients whose gaps are balanced within 2mm have superior PROMs scores. As discussed, our initial review robotic accuracy suggested bone cuts are made with high precision to approximately 0.4mm*. Due to this high level of accuracy we decided to establish whether the MAKO achieves balanced gaps of ≤1mm. To establish whether the MAKO achieves balanced gaps of ≤1mm a non-inferiority power analysis of differences was undertaken with a margin of 1.00mm. A total of 18 patients were required to achieve a power of 80% (a=0.0025). Our study group was

therefore adequately powered. The power calculation was cross checked with Professor Richard Woodman, our University statistician to ensure the data was adequately powered before proceeding. A summary of his calculations is included below.

Non-Inferiority Power Analysis of Differences in a 2x2 Cross-Over Design

Numeric Results for Non-Inferiority T-Test (H0: Diff >= NIM; H1: Diff < NIM)
Higher Means are Worse

Power	N	Non-Inferiority Margin (NIM)	Actual Difference (D)	Significance Level (Alpha)	Beta	Standard Deviation (SdPaired)
0.91586	6	1.000	0.000	0.02500	0.08414	0.540
0.93371	8	1.000	0.200	0.02500	0.06629	0.540
0.86668	10	1.000	0.400	0.02500	0.13332	0.540
0.83879	18	1.000	0.600	0.02500	0.16121	0.540
0.80541	60	1.000	0.800	0.02500	0.19459	0.540
0.80541		1.000	1.000	0.02500	0.19459	0.540
1.00000	2	2.000	0.000	0.02500	0.00000	0.540
1.00000	2	2.000	0.200	0.02500	0.00000	0.540
1.00000	2	2.000	0.400	0.02500	0.00000	0.540
0.99528	6	2.000	0.600	0.02500	0.00472	0.540
0.97684	6	2.000	0.800	0.02500	0.02316	0.540
0.91586	6	2.000	1.000	0.02500	0.08414	0.540

Statistical tests

Data presented is means and standard deviations. 95% Confidence intervals were calculated for the absolute differences in medial and lateral gaps. Confidence intervals were also calculated for the absolute difference between trial and final implantation gaps. These were considered balanced to within ≤1.00mm if they did not cross 1.00mm. Paired t-test was used to assess whether a significant difference was present between measurements, with an alpha value set at 0.025.[126,127,128,129]

TKA surgery was performed with a medial para-patellar approach, with a majority being cruciate retaining. Femoral and tibial registration pins were inserted allowing intraoperative dynamic tracking, allowing calculation of knee gaps and coronal alignment via the MAKO system software. Surgeons recorded the planned bone resections after bone cuts were

made, they were checked and recorded using a verification probe provided with the MAKO system and saved as screen shots for each measurement. Previous Cadaver studies have suggested a high level of accuracy using this device to validate bone cuts.[130]

The gap balancing figures for the extension and flexion gaps were both measured and recorded as screen shots at 3 time points. Firstly, before bone cuts were made, secondly during insertion and assessment of trial TKR components and thirdly after the definitive prosthesis were implanted. The data was recorded at each stage by the surgical team and stored to allow analysis later. Gap data was analysed and compared within each of the 3 groups with the assumption that a difference of less than 1mm in any one gap set was within acceptable limits. If confidence intervals did not cross 1.00 there were considered balanced within 1mm. Data was then compared between the 3 groups to assess any difference between pre-op values and trial implant values then between trial implant values and final implant values.

Results:

A total of 40 patients had their gap balancing data captured using the MAKO system software. The mean age was 70.3 years old (SD 9.49) range 50 – 93 years. Regarding gender 29 patients were female (72.5%), 50% of knees were left side and 50% were right sided. The patients in this series consisted of our first 40 cases performed with the MAKO robot and included all comers with no diagnosis excluded.

Pre-bone cut data showed a difference in the patient's extension and flexion gap values. These values are clearly recorded before surgical correction has been performed or any osteophytes removed. The gaps are therefore expected to be imbalanced at this stage with 37.2% of extension gaps balanced and only 9.1% of flexion gaps balanced. These results are summarised in *table 14* below.

	Medial Gap	Lateral Gap	ABS difference	Range	Balanced (% within 1mm)
Extension	16.35 (2.60)	17.70 (3.17)	3.25(3.01)	0 → 11	40.0% (16/40)
Flexion	14.85 (2.53)	15.88(3.86)	3.98(2.63)	0 → 12	10.0% (4/40)

Extension: 95% Confidence Interval: 3.25 ± 0.93 (2.32 to 4.18) (p=0.053) paired t-test
Flexion: 95% Confidence Interval: 3.98 ± 0.82 (3.17 to 4.79) (p=0.177) paired t-test

Table 14 Intraoperative values of patients' flexion and extension gaps captured by the MAKO robotic system before any bone cuts or corrections are made.

After all bone cuts were made and osteophytes were removed, trial implants were inserted and the surgeons recorded the patient's flexion and extension gaps to ensure correction of any gap balance was adequate. If further correction or bone resection was required it was then performed and these values re checked. The data used shows the final balancing figures accepted by the surgeons before proceeding. This stage 97.6% of all gaps were balanced within 1mm. The mean difference between each value was only 0.4mm with a confidence interval of 0.54 suggesting no difference. Using a paired t-test to compare the extension gaps values and flexion gaps values $p > 0.05$ in both groups confirming there was no significant difference between the values. This data is summarised in *table 15* below.

	Medial Gap	Lateral Gap	ABS Difference	Range	Balanced (% within 1mm)
Extension	19.20(1.33)	19.43(1.28)	0.38 (0.53)	0 → 2	97.5% (39/40)
Flexion	18.18(1.09)	18.40(1.18)	0.43 (0.54)	0 → 2	97.5% (39/40)

Extension 95% Confidence Interval: 0.38 ± 0.16 (0.22 to 0.54) (p = 0.027) paired t-test
Flexion 95% Confidence Interval: 0.43 ± 0.17 (0.26 to 0.60) (p=0.037) paired t-test

Table 15 Intraoperative values of patient's flexion and extension gaps captured by the MAKO robotic system after all bone cuts and corrections with trial implants in place.

Finally, the gap balancing data was compared between the trial implant values and the values obtained with the final TKA prosthesis in situ. There was no significant difference between the values with mean differences ranging from -0.1 to 0.2mm and no confidence intervals greater than 1.00. suggesting no significant difference. More than 90% of all absolute values were within 1mm. Again, all p values were > 0.05 suggesting no significant difference. These results are summarised in *table 16* below.

	Trial	**Final Implant**	**ABS Difference**	**Range**	**% within 1**
Extension					
Medial	19.15 (1.95)	19.20(1.33)	0.54 (0.59)	0→2	97.50% (39/40)
Lateral	19.25 (1.11)	19.43(1.28)	0.56 (0.66)	0→2	90.00% (36/40)
Flexion					
Medial	18.28 (0.89)	18.18(1.09)	0.56 (0.66)	0→4	92.7% (37/40)
Lateral	18.43(0.77)	18.40(1.18)	0.69 (0.78)	0→3	95.1% (38/40)

Extension medial: 95% Confidence Interval: 0.54 ± 0.18 (0.36 to 0.72) (p=0.700) paired t-test
Extension lateral: 95% Confidence Interval: 0.56 ± 0.21 (0.36 to 0.77) (p=0.213) paired t-test
Flexion medial: 95% Confidence Interval: 0.56 ± 0.21 (0.36 to 0.77) (p=0.472) paired t-test
Flexion lateral: 95% Confidence Interval: 0.69 ± 0.24 (0.45 to 0.93) (p=0.881) paired t-test

Table 16 Intraoperative values of patient's flexion and extension gaps captured by the MAKO robotic system comparing trial implant and the final prosthetic implants.

Discussion

Overall, our pilot results show that the accuracy of both femoral and tibial bone resection was high, with 95% of cuts being ≥1mm of the plan. Additionally, we found a small tendency for the anterior femur and tibial cuts to undercut the bone, however this was minimal. Furthermore, the precision of bone resection was high for all three bone resections, represented by low standard deviations of 0.30, 0.27 and 0.33 respectively.

Minimal data existed on the accuracy of bone resection in the MAKO total knee system, with one study involving 6 cadaveric specimens showing greater accuracy and precision as compared to conventional TKA.[121] This study adds to this evidence using real patients and a larger sample size. A systematic review by Fu[131] showed implantation accuracy for neutral knee of 0° is measured when looking at arthroplasty techniques, however the surgeons in this study did not necessarily aim for this. This is because the ligament balancing capabilities of this technology were used, and this may have resulted in a patient having a planned varus or valgus knee.

Our results suggest the system can deliver accurate bone cuts and well-balanced gaps. Non-inferiority and paired t-test analysis show the gaps produced are within 1mm which is better than clinically recommended values.[124] The fact that the gap values are symmetrical is statistically significant using these tests. Overall, this technology provides the surgeon with the option to obtain mechanical alignment or focus on ligament balancing and/or kinematic alignment. The accuracy in achieving planned bone resection and final limb coronal alignment using the MAKO Robotic-Arm Assisted technology is high.

However, our main interest is in whether the use of this robotic technology will help improve gap balancing during primary TKA surgery and therefore potentially reduce instability. In our literature review in Chapter 2 it was suggested that some patients may have a knee prosthesis implanted which is initially stable and becomes unstable with time due to attrition of the knee ligaments [81]. However previous studies in this review have

shown that TKA instability is commonly due to surgical error [81]. Accurate gap balancing should therefore reduce the risk of TKA failure due to instability and potentially reduce the risk for revision surgery. Studies have shown that gaps balanced to less than 2mm improve patient's outcome scores [81]. In this series 95% of gaps are balanced within 1mm with no cases gaps greater than 2mm suggesting the system has a high level of accuracy. In addition, there was little difference between the trial implant gap measurements and final prosthesis measurements with > 90% of measurements within 1mm. This study did not include any info on Patient reported outcomes. However previous studies have shown improved PROMs scores when the gap balancing values are better or less than 2mm[124]. Further research by *Wilson et al* has shown significantly improved Oxford knee scores comparing Robotic with non robotic knees in the same centre with the same implants.[136]

These 40 cases include all of the surgeons learning curve including case number one. This suggests that with adequate training to use the system it can deliver accurate gap balancing power with a high level of reliability.

Conclusions

In this study we have evaluated the accuracy of the MAKO robotic system and its ability to produce accurate and reliable balanced gaps. With studies showing that TKA instability can be due to surgical error and revision TKA surgery having poor PROMs scores and a high re-revision rate the use of this technology to reduce failures seems promising. Further PROMs studies and long-term registry analysis will be required to evaluate if this innovation leased to improved patient outcomes and reduce rates of revision TKA surgery in the future.

Chapter Seven: Discussion of results

Chapter 1 - Introduction

In this chapter we provide an overview of the overall findings of the thesis. Osteoarthritis is the commonest chronic condition affecting mature adults. Surgical management has well recognised results with the ability to restore function and relieve pain. As a result, 53,000 TKA procedures were performed in 2016 in Australia, with an approximate cost to the healthcare system of over 1.2 billion Australian dollars. Primary TKA surgery increases year by year and subsequently Revision TKA surgery is also on the increase. Revision procedures have a significant complication rate and a high financial cost to the healthcare system approx. 63,000 Australian dollars per case. The technical details of TKA and Revision TKA surgery are explained to clarify points described later.

The Australian joint registry (AOANJRR) is a powerful instrument used nationally to collect data on Arthroplasty surgery and its failures on a National level. It has been very successful in monitoring the results of orthopaedic implants and protecting patients by identifying failures. However, it is also a very powerful research tool and can be used to investigate research questions far beyond the data summarised in its national reports. Instability is described as a reason for TKA failure and Revision TKA surgery. It is poorly defined and described in the literature but is known to lead to early failure and early Revision surgery. Instability remains the 5th most common reason for TKA failure.

The overall aim of this thesis is to use knee instability as the sentinel event in a process where AOA national joint replacement registry information is used in combination with a local registry to provide improved information on how to reduce unnecessary revisions and reduce our re-revision surgery rates and therefore reduce the financial burden for our healthcare system. The local registry can then be used as a feedback loop to the national registry system to stimulate improvements in data collection ongoing. In addition, the key discussion points and recommendations relating to surgical management are made. The background the work is summarised and reasons for the research undertaken.

Chapter 2 - Systematic Review of the Published Literature, causes of instability in TKA

The systematic review of the published literature showed the results of all papers published on Revision surgery for instability of the TKA for the last 10 years. It was surprising to find that out of all the orthopaedic literature there were only 22 articles that reported any results for analysis. Orthopaedic results commonly focus on 10-year data and based on the latest joint registers worldwide, the revision rate for the total knee arthroplasty is approximately 12% over a period of 10 years (*Labek G et al*). However, in our review the results for TKA failure due to instability time to failure was reported in 11 articles. These suggest these patients fail early with a mean time to failure of only 44.7 months. In addition, patients who failed were young with an average age at revision surgery of 67.6 years. These findings are of significant concern as the Mean age for a primary TKA in Australia is 68.6 years (AOA NJJR 2016, page 200). The patients in our instability series are therefore having their second procedure at a relatively young age. As shown in *Chapter 4* these young patients have a higher complication rate compared to primary TKA patients and a high rate of re-revision in the first 5 years. This raises the issue that prevention of TKA failure due to instability may be of greater benefit to future patients than improving the quality or revision or 'salvage 'surgery. Patients with a BMI > 40 did were not shown to be at increased risk of revision surgery with only one case reported out of 88 cases reported in relation to BMI. The review did not show any difference in revision rate in relation to male or female gender.

The review showed that most patients who were revised had a Total revision meaning a revision of all components (77.4%). In addition, 79% had revision to components with either partial or total constraint. This finding compounds the issues caused by the patients having a lower than average age at time of surgery. The aggressive surgery they had undergone comes with both a high risk of surgical complications and a high risk of re-revision surgery. Figures from the AOANJJR report a re-revision rate of 30% in the first 5 years after these Total revision procedures. In addition, these procedures require a large amount of theatre time and have a high cost per patient treated. Those issues are discussed further in *Chapter Four*.

Overall the review identifies the serious nature of instability as a method of failure in TKA surgery. The patients fail younger, have potentially high-risk revision surgery early and have

a high risk of re-revision surgery in the short term highlighting the grave implications of an unstable knee. The review therefore reinforces the need to better understand the issues in ligament balancing and how to address them. For those patients who already have an unstable knee a more robust diagnostic and management pathway is required which is the basis for our new pathway discussed in *Chapter 3*.

Chapter 3 – Clinical assessment and diagnosis of Instability – Evaluation of a new diagnostic algorithm.

In this study the aim was to construct, describe and evaluate our diagnostic algorithm for the failing knee arthroplasty. The study was designed after our systematic literature review and a review of our historic registry results with the intention of standardising and improving the accuracy of diagnosis for our patients. In our literature review there was a common message in many papers that the accurate diagnosis of the reason for TKA failure is essential in obtaining a good outcome from revision surgery. Despite this were a number of varied descriptions of how to diagnose instability on the failing TKA with some authors describing a clinical method, some a radiological method but few combining both. As a result, we designed a standardised and reproducible pathway for all failing knees in our clinic including those with instability. Patients would undergo a standardised clinical examination, blood tests and x-rays. A standardised EUA assessment was also devised and performed. The results were reviewed by the whole arthroplasty team to ensure consensus regarding the diagnosis and to assist in the development of the surgical plan. Surgeries were then performed with 2 specialists present both of whom have significant experience in revision surgery. The main aims of the study were to evaluate the algorithm, improve diagnostic quality for our patients. This would also hopefully reduce the rates of complications or re-revision for our patients and prevent them from undergoing unnecessary procedures.

Once the algorithm was designed it was rolled out to all potential revision cases in our department with the final point of control being our weekly planning meeting where the consultant group reviews the surgical plan for the next week's cases and allows appropriate implants to be arranged. Patients who went through this system were entered into our local revision registry, which continues to gather data beyond the scope of this thesis.

The initial 45 patients who went through this process were included in the study. Their electronic records were reviewed to assess their blood results, EUA findings and eventual diagnosis and or need for revision surgery. All EUA findings were recorded in the patient's case record and the EUA radiographic films saved on our digital archive system. Finally, an Intrinsic joint injection was performed and the patients examined post op for pain to exclude patients with an extrinsic pain source such as the Hip or Lumbar spine. Interestingly age, gender or BMI did not have an effect on EUA instability or the need for revision surgery. The even spread of revisions between males and females is particularly interesting as Primary TKA surgery is much more common in females. Factors such as joint aspirate white cell count and red cell count had no impact on the patients need for surgery. The CRP blood test was lower in patients who required surgery as was the ESR which was a surprising finding. Surgeons routinely perform these tests before revisions surgery, however our findings suggest a lower (negative) result is unhelpful in deciding whether surgery is required or not. Radiological instability was more predictive. The best EUA factors were Anterior- Posterior Drawer test and Varus instability test. Both had a P value < 0.001 when predicting whether surgery was needed for instability.

This study successful described the design and results of our algorithm. The process has been modified since to include the help of our local infectious disease's clinicians in the diagnosis and management of failure due to prosthetic infection. In addition, as part of the EUA procedure all patients now have deep tissue biopsies for infection and as part of a separate study some patients have had synovial fluid tested for infection biomarkers using the Synovasure^{tm} Alpha Defensin biomarker testing system. To our knowledge this is the first study to design and evaluate a standardised and comprehensive diagnostic and management pathway for revision TKA surgery. The results of this pathway are recorded in and monitored by our local Revision registry to assess ongoing trends and issues. The results of this registry are discussed in *Chapter 4*.

Chapter 4 – Design and evaluation of a Local Revision Arthroplasty Registry

In *Chapter 4* we discuss how the appropriate diagnosis and management of the Revision TKA is an essential part of the care of our patients. However, it is also essential to monitor the results of this treatment both to evaluate and trends in surgical results and to facilitate a constant and evolving process, which continuously improves patient outcomes. The national AOANJJR provides useful data on the survivorship of Revision TKA surgery and describes the worryingly high rates of Re-revision surgery for TKA patients. However, Revision TKA surgery is a much more heterogeneous area than primary TKA surgery. A more detailed local review of data and outcomes is therefore of great value. Data can be collected to a much higher level of detail and complexity allowing evaluation not possible in the National figures. In addition, as shown in *Chapter 2* unlike THA surgery knees tend to fail earlier, which allows local trends to be collected and monitored without having to collect 15 years of data to get a meaningful answer. In this study the National registry was however used for an important comparison. Each year the AOANJJR provides a summary report for all Arthroplasty surgery in Australia. Due to the large-scale nature of the data requiring collected and analysis each year's summary report shows data for surgery up to the year before with the 2012 report showing data on cases performed up to the end of 2011 and so forth. On request the AOANJJR will provide specific data on a specific group of patients in what is referred to as an *Ad Hoc* Registry report. Such a report was therefore requested for all hip and knee data at our centre from 2013 back to the beginning of AOANJJR data collection. This would allow a meaningful comparison of all historic data up to the time when our new models of diagnosis and management were introduced. By comparing the historic AOANJJR data with our local registry this study shows the differences these changes have made on our local management and also allows comparisons to be drawn with the current National summaries showing current trends throughout the country.

When reviewing the *Ad Hoc* report on our local historic figures there were two main concerns. Firstly, while our most common indication for Revision TKA was Loosening and lysis our next 2 indications were 'patello-femoral pain' and 'pain'. In the National figures up to 2013 these 2 indications were much less common. We were concerned that this may represent a poorer level of diagnostic accuracy with the potential for an elevated incidence

of Re-revision surgery in these patients. In our Literature review in *Chapter 2* anterior knee pain is described as a common symptom in TKA instability. Is therefore possible that in the past some of these patients were being miss diagnosed and therefore miss treated. Therefore, one of the main aims of our Local registry was to review if firming up our diagnostic and management methods led to a reduction in the rate of surgery for these 2 indications. Secondly the commonest type of revision surgery in our historic figures was revision of the Patella button only. In our local centre this had accounted for 39.2% of all revision cases while the National figures at that time showed a rate of only 20.9 %. We felt that this was part of the same diagnostic problem and hoped that our new methods would lead to a reduction in this rate of surgery and bring it down to a level more in line with current national figures.

Although the number of cases is small the Local registry was also designed to evaluate in more detail what type of patients are more commonly revised and to allow prospective analysis of these results as trends over time. When reviewing the current results in the local registry gender did not seem to have much effect on the risk of revision. Female patients accounted for 67% of all revisions, which is almost identical to the percentage of patients undergoing primary TKA surgery [54]. In addition, BMI did not seem to be a relevant factor. The average BMI of a revision patient was 31.8 kg/m^2, which is again very similar to our figures for primary TKA surgery. It has been suggested in many papers that a higher BMI leads to a higher risk of revision TKA surgery. However, our results are more in line with those in our systematic review in *Chapter 2*, which suggests BMI, is not a major risk factor.
However, the age of our patients was low at 71.1 years. In addition, the average age of these patients was only 62.5 years old at the time of their primary TKA surgery (*Wilson et al and NJJR 2015*). This result is of much more practical concern. We have shown in *Chapter 3* that patients who undergo revision surgery are at a high risk of re-revision surgery in less than 5 years. If our patients are undergoing their initial surgery younger then they are clearly at a higher risk of further complications and therefore functional impairment at a younger age. This highlights the need to get the diagnosis right first time and reduce the risk of further potentially harmful surgeries. Interestingly 61% of revision patients had a history of hypertension and 47.2% had a previous hip or knee arthroplasty performed in another joint. It is not possible from this small series to conclude if this is an important association

regarding the risk for revision TKA surgery of if these are simply common findings in our routine patients. As the Local registry prospectively grows further evaluation of these associations may be more practical.

In this study our current figures demonstrate that the most common local reason for doing a revision knee replacement is Radiological Instability (33.3%), this being a combination of ligamentous instability and instability due to imbalanced flexion or extension gaps. The Diagnosis of 'Pain 'has reduced dramatically. The combination of 'Pain' and 'Patello- femoral Pain' into one group was only 13.9%. A significant reduction on 36.7% in our historic figures and more in line with current national figures of 6.7%. Infection was the indication in 13.9% of cases, which is also similar to current national figures of 21%. These results suggest we have achieved our aim of a reduction in cases performed for pain. It will however require ongoing prospective collection of our Local figures to evaluate if this change in practice leads to a reduction in our re-revision rates in the future.

Our results on the type of Revision surgery are interesting but for different reasons. One of our main aims was to look at the incidence of Patellar button revision alone. In our historic figures 39.9% of all revisions in our centre were of the patellar button alone. The current local registry results show that our rate has fallen dramatically to 8.3% which is more in line with 2015 AOANJJR figures showing a rate of 10.8%. This is hopefully a relevant finding suggesting our more accurate diagnostic methods are leading to more appropriate revisions strategies with the 'default' treatment of Patella button revision being reserved for very specific cases only. Another interesting finding is that our rate of 'Minor revision' remains high and is higher than national figures. When you exclude the patella button cases 'Minor revisions' involve either revision of the polyethylene insert only or its revision in combination with patellar button revision. These two are commonly combined to reduce the possibility of further re-revisions if they are done independently. Our Local registry shows a rate of minor revision of 47.2% verses current National figures of 21.3%. This may be one of the most relevant findings with respect to our ongoing patient care. Patients who undergo these 'Minor revisions' have been shown not only to have significantly lower surgical complication rates but also AOANJRR figures also suggest that these patients who undergo less invasive revision surgery are at a lower risk of re-revision surgery in the first 5

years. Minor revisions are also a significantly smaller financial burden on the local healthcare system as the implant cost is significantly reduced.

Overall this study is a useful indicator that not only has the work in this thesis enhanced our knowledge of Instability as a cause for failure in TKA surgery our enhanced understanding of how to manage and diagnose our patients may leads to significantly better short and long term outcomes for our patients in the future. This is discussed in further detail in *Chapter 3.* It is also to our knowledge the first study combining both Local and National registry data to address a specific mode of failure in TKA surgery and use this data to improve diagnosis and reduce revision failures, which could lead to re-revisions. Our clinical results from this work are discussed in *Chapter 5*.

Chapter 5 – Prospective evaluation of the outcomes of revision TKA for instability.

In this study we reviewed the results of patients who had undergone revision knee arthroplasty for instability of the knee. This paper closes the journey of the thesis as these patients have all gone through the diagnostic algorithm described in *Chapter 3* and their surgical management is recorded and followed up through the revision registry described in *Chapter 4*. All patients were performed by myself or under my care and were revised to the Stryker TS revision implant. This system uses a new guide called the TCG or trial guide cutting system which is designed to allow the surgeon to balance the knee before making the final bone cuts and will hopefully improve accuracy and streamline the process of revision TKA surgery for instability and for other indications.

The patients therefore were identified in the clinic as potentially unstable and then the diagnosis confirmed by our new algorithm. The case was discussed at our arthroplasty meeting by a committee of surgeons to confirm the diagnostic plan and the implants required and the surgery was then performed. Post op all patients were identified using our Revision registry and the records assessed for evidence of re-revision surgery. This finding was strengthened by using Ad Hoc AOANJJR reports to confirm no additional revisions were performed in other centres without our knowledge and compare our current re-revision

rates historic rates before the implementation of this algorithm. Oxford knee scores were obtained either in writing or over the phone to assess the patient's functional status. The mean follow up was 28 months for females and 39 months for males.

It was unexpected that many of the patients had low oxford scores. All our patients are regularly followed up and no patients have requested re-revision outside the cases reported. It is unclear if this finding is due to other joints affecting the results of the score or general deconditioning of the patients included. Our female patients are slightly younger than our male patients and the male patients have on average longer follow up, we are not able to deduce why from the data available.

The main finding of this paper related to re-revision rates and is one of the key issues regarding our outcomes as a whole. As we have seen in our results of *Chapter 4* the local revision registry confirms that the use of our new diagnostic algorithm has led to a focus on conservative revision TKA surgery and less revision surgery for 'pain 'as the diagnosis. In this series our re-revision rate is only 7.69% at 4 years post-op. This comes from a small series however national re-revision rates for TKA patients are 12 % and 16% for 3 and 4 years post-op respectively. In addition, a larger series from our centre, pending publication, showed a re-revision rate of only 6.5% for all diagnosis at 4 years. Although further study and longer follow up is required these results suggest that that following this pathway leads to not only patients avoiding unnecessary surgery, they undergo less invasive surgery with a lower risk of re-revision surgery in the years to come. The work in this chapter combined data from Local clinical research, Historic National Registry Data, Local Registry Data and Current National Data. To our knowledge this is the first attempt to do so in Revision TKA surgery. Through discussions with other surgeons and at the 2017 ASM of the Australian Arthroplasty Society this standardised process is now spreading and being taken up by other units in Australia.

However, when assessing PROMs scores for these patients, Oxford knee scores are surprising low. This suggests that some patient's while happy to live with their knee and do not require further revision surgery do wish they had a higher level of function from their knee. Despite our success in reducing re-revision rates these patients reported results

suggest there is still a need to try and prevent TKA failure from instability in the first place. As discussed in Chapter 2 our literature review shows that failure due to instability is multi-factorial. However, the one factor a surgeon can influence is the accuracy if surgical implantation and improved balancing of the knee gaps and therefore the patient's ligaments. This has been explored in our department using computer navigated knee technology[123]. However, the recent introduction of Robotic gap balancing technology has enhanced surgeon's ability to plan and then implant the TKA prosthesis with a higher level of accuracy and better ligament balancing. This is discussed further in *Chapter 6*.

Chapter 6 – Robotic Gap Balancing in TKA Surgery

In this chapter we reviewed the use of Robotic surgical technology to improve the balancing of the flexion and extension gaps in primary TKA surgery. This allows the surgeon to accurately balance the knee ligaments and reduce the risk of instability due to surgical inaccuracy or error. Our results in the previous chapters clearly show that avoiding TKA failures in the first place is more desirable than finding the best solutions once they have failed.

Robotics surgery uses technology similar to CAS combined with pre-op CT scans to program the system with accurate data regarding the patient's knee anatomy and alignment. The system also uses a surgical arm to deliver the bone cuts with a high level of accuracy. Our results show that using the Robotic technique the surgeon can perform bone cuts to fractions of a millimetre and that in 100% of cases the knee was implanted in > 3 degrees from the planned alignment. This enhanced accuracy will help surgeons reduce technical errors which should reduce failures and revisions in general. Registry based studies have shown that using CAS to reduce outliers leads to a reduction in failures and revisions in TKA surgery.

Robotic surgery gives the surgeon enhanced ability to plan the primary TKA procedure and implant the knee in a position where their gaps and therefore ligaments are balanced. The pre-op plan shows the patients unique ligament 'imbalance 'and allows templating of the

surgical correction required. During surgery dynamic data is recorded allowing the final assessment of the ligament imbalance to be calculated and corrected. Finally, the system confirms that the correction has been delivered before the prosthesis is implanted.

Our results show that the final ligament gaps are delivered with less than 1mm difference between the gaps and that this result is statistically significant. Previous clinical studies have recommended gaps are balanced with less than 2mm of difference, however, the system is allowing the prosthesis to be implanted with a much higher level of accuracy. Finally, when comparing the trial implant gap values with definitive implanted prosthesis values the mean difference is 0.2 mm with standard deviations less than 1.0 suggesting the system reproduces accurate final results after deliver and execution of the surgical plan. In this study we have evaluated the accuracy of the MAKO robotic system and demonstrated its ability to produce accurate and reliable balanced gaps. Further PROMs studies and long-term registry analysis will be required to evaluate if this innovation leased to improved patient outcomes and reduce rates of revision TKA surgery in the future.

Chapter Eight: Future research arising from this Thesis

Introduction

Background

With high revision rates in younger patients and revisions occurring early the issue of prevention of TKA instability is an important issue in orthopaedic surgery. The work in this Thesis has progressed through the clinical issues and features of TKA instability. Improvements in the diagnosis and management of instability and lead to increased diagnostic accuracy, reduced surgical complications and failures requiring re-revision surgery. Using local and national registries surgical trends can be measured and analysed over time to ensure quality of primary and revision surgery continues to improve for patients. Using PROMs, the final clinical outcomes of patients can be analysed and have shown in this Thesis to be poorer than expected after Revision TKA surgery. Technology can be used to increase surgical accuracy and ligament balancing in primary TKA surgery and potentially reduce failures due to TKA instability for future patients.

The next research step is to evaluate the effects of these interventions and prove if they lead to better long-term outcomes for patients in the long term. This can be evaluated by validating the effect that these balancing technologies have on the patient's ligaments and the effect this has on failures and revision surgery. This work is beyond the scope and time frame of this thesis however plans are already underway within our department for the research to be undertaken. Our main areas of focus are summarised below.

Gait Analysis

Introduction

Patients with TKA instability commonly complain of difficulty ascending stairs and a feeling that they cannot 'trust' their knee. This may be related to abnormal gait patterns or issues

with muscle coordination that lead to either unpleasant symptoms or inefficiency of muscle contraction. Therefore, the research hypothesis for this project is that patients with an unstable TKR will demonstrate abnormal gait and muscle coordination patterns.

To quantify this issue more objectively a study has been designed to evaluate if these abnormal patterns or related forces can be identified. In collaboration with our local biomechanics department a specific gait lab rig has been designed and constructed to allow assessment of a patients gait pattern both during in normal walking and during stair climbing or descent.

The aim of this study is to evaluate what gait and muscle coordination abnormalities occur in these patients compared to TKA patients who asymptomatic and a third group that are robotically balanced and asymptomatic. These patterns may also allow an estimation of the inefficiencies in their muscular function which lead patients to seek further surgical intervention.

Methods

We from previous studies estimate approximately 20 patients will be required for each group to be adequately powered. This sample size exceeds the sample size used by the 80% of the studies of gait in TKR patients[133], which therefore it is adequate for capturing salient motion features for this population. Gait analysis will be performed in the new Rehabilitation and Motion Analysis Laboratory, which is located at the Tonsley Campus of Flinders University. This purpose built 84 sqm facility is fully operational, features a flexible configuration to maximise utility, and is approved for use on orthopaedic patients.

Three groups, comprising twenty participants each (symptomatic and asymptomatic TKR patients), will be recruited from the Flinders Medical Centre arthroplasty department. An application for Ethical approval has sought prior to recruiting patients for the study.

All participants will undergo a clinical and radiological assessment of the implant, in robotic cases gap balancing parameters will already be recorded. In the symptomatic group instability will have been diagnosed using our algorithm described in Chapter 3.

All participants will undergo a gait analysis assessment of motion, muscle activity and ground reaction forces during the execution of common activities of daily living with different levels of difficulty. Participants will be instrumented using reflective skin-mounted markers located at relevant anatomical positions and surface electromyography sensors placed over the major superficial lower-limb and back muscles. The marker set will be based on a well-established protocol developed and used within our group for gait analysis experiments (Martelli *et al.*, JBiomech 2015). The marker's trajectory will be recorded using the available 10-camera Vicon system (Vicon Bonita 10, 1MP Optical Camera, 250 fps), during walking at a self-selected speed, walking fast, running, stair ascent, stair descent, sitting on and then rising from a chair. The muscle electrical activity at the erector spinae, gluteus maximus, gluteus medius, rectus femoris, vastus medialis, vastus lateralis, semimembranosus, semitendinosus, gastrocnemius lateralis, gastrocnemius medialis and tibialis anterior will be collected from both legs using the wireless 16-channel EMG system available in the lab (Trigno Wireless EMG, Delsys Inc., Natick, USA). Ground reaction forces will be recorded using the 4 force platform system available (AMTI OR6-7-1K-SYS Force Platforms). Additional measurements will include a static pose used as reference, simple movements about a single joint axis and maximal voluntary contraction measurements of each principal muscle group using a hand-held dynamometer. Motion and electromyography measurements will be processed to extract the joint angles and the envelope of the muscle electrical activity. The study hypothesis will be tested using a student t-test (< 0.05). If found to be significantly different, symptomatic and asymptomatic data will be compared using regression analysis. An example of a patient under analysis is shown in *figure 45* below.

Figure 45: *Study participant wearing skin reflective markers crossing one of the force platform systems.*[134]

Discussion

Greater understanding of the abnormal forces occurring in the unstable TKA may enhance our knowledge of how to prevent these failures occurring. In addition results in Chapter 5 have shown that surgical revision for these patients has poor outcomes with regards patients PROMs scores. With enhanced understanding of the abnormal biomechanics occurring new treatment options using non-surgical interventions such as physical therapy may help to improve the quality of life and function of patients with an unstable TKA without the need to resort to revision TKA surgery.

This work could therefore be of great assistance not only in preventing TKA failures but in increasing our capability to treat patients who are already symptomatic with potentially less complications. The project also represents the strong collaboration between our department of orthopaedics and department of biomechanics which has produced a large amount of interesting research and teaching opportunities for our staff and students so far.

Pressure transducer Analysis

The use of CAS and robotic systems measure alignment and ligament gaps in absolute geometric values. Alignment is described in degrees and ligament gaps in millimetres. However knee ligaments are balanced when the tension between the ligaments is balanced. Using tensioning devices such as that shown in *Figure 8*, *Chapter 1* the surgeon assesses the patient's ligament tension to ensure they are balanced in both the flexion and extension gaps. This will dictate what position the implant will sit in and moving away from the historical concept of producing neutral mechanical alignment then releasing ligaments, perhaps unnecessarily, to balance the gaps. When performing these checks using CAS the

system gives feedback on the best position to produce this balance with respect to knee alignment. This is shown below in *Figure 46.*

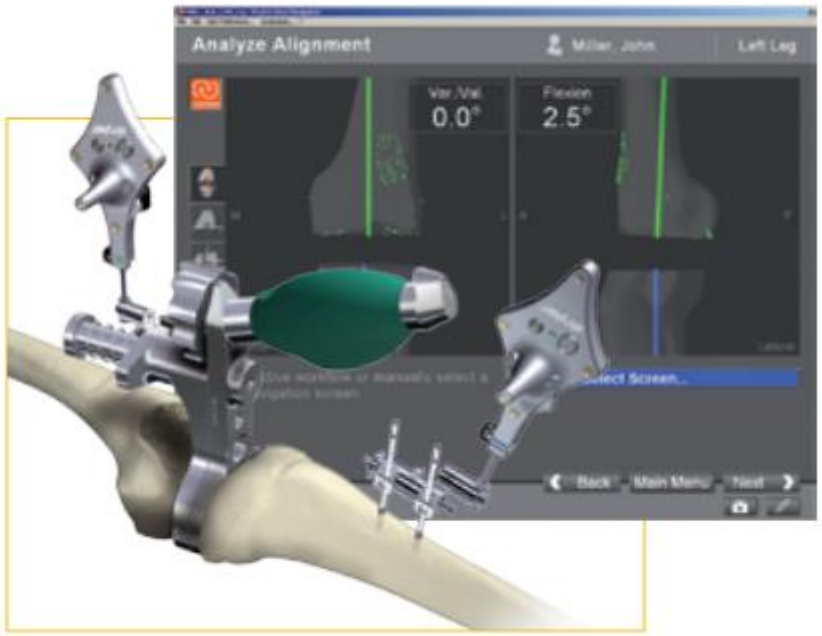


Figure 46: *Final alignment check using trackers and a knee gap balancing device before implantation of the definitive prosthesis. Reproduced with permission from Stryker.*

Robotic systems produce similar results for the surgeon with regards intra-operative feedback. Although these results have a higher level of accuracy and reproducibility compared to CAS they are still geometrical measurements and do not give any feedback on absolute ligament tension.

Surgical tension devices have increased in popularity which can allow the surgeon to assess the ligament tension as a force in Newtons instead of a measurement in millimetres. These devices contain transducer sensors which allow real time measurement of these tensions during surgery. An example of these sensors incorporated into knee trial implants is shown in *figure 47* below.

Figure 47: *Trial Knee inserts containing in built pressure transducers to allow real time feedback of knee joint pressure. Reproduced with permission by Zimmer.*

During live surgery surgeons can perform their usual bone cuts using either conventional, CAS or robotic tools to obtain their planned optimal alignment. During the trailing procedure the transducer device can be used to check medial and lateral knee compartments pressures which are used as a measure of adequate bone resection and ligament tension. An example of how the sensor and knee implants link together is shown in *figure 48* below.

Figure 48*: Trial Knee inserts with pressure transducers can be used with trial or definitive components during live surgery. Reproduced with permission by Zimmer.*

The sensors then send live feedback via wireless signal to a display monitor which the surgeon can use to ensure the knee compartments are in equal tension. This can then be checked in 10 degrees extension, 45 degrees flexion and 90 degrees flexion gaps to ensure the ligaments are balanced throughout the range of knee movement. An example of the display obtained in theatre is shown in *Figure 49* below showing the pressures are almost identical and therefore the ligaments in this example are in equal tension.

Figure 49: *Live surgical display of tensions in the medial and lateral compartments of the knee. Reproduced with permission by Zimmer.*

Discussions regarding the results in Chapter 6 on this thesis at the recent Arthroplasty of Australia Annual meeting commended the high level of accuracy obtained when robotic gap balancing is performed*. As the next step in understanding this process the recommendation was to try and combine robotic gap balancing measurements with sensor pressure measurements in the same patients to try and enhance our understanding of how these technologies can be used in combination. Discussions are underway with the implant companies involved to devise a study protocol which can achieve this aim and allow us to begin our ethical application process.

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This research may allow surgeons to use these technologies to improve how we balance knees in TKA surgery and potentially allow prosthetic knees to be implanted in a position and tension where the knee ligaments function in the same way as a native human knee.

This would improve the accuracy of TKA surgery which may help patients feel better with a more 'normal 'feeling knee and may reduce their risk of instability and therefore failure.

Registry Based analysis

Introduction

Long term analysis of patient outcomes with regards revision surgery requires both large numbers and long term follow up. The use of computer navigation surgery (CAS) has shown a reduction in outliers and errors. Over time this has led to increased adaptation of the CAS technique by surgeons who have been reassured by its increased accuracy. However it takes time to follow up these patients for long enough to show a significant difference in revision rates. A recent publication from the AOANJRR registry showed that using CAS leads to a reduction in revision rates, however it took 9 years of registry follow up to deliver this significant result[26]. In this study revision rates were reduced for all reasons for patients under the age of 65 years old. When considering loosening as the reason for revision there was a significant reduction in revision rates for all patients (*p=0.001*). Data from AOANJRR reports clearly shows that loosening is the commonest reason for revision therefore the reduction of these failures is of great clinical importance. The different rates of revision by diagnosis are shown in *Figure 50* below.

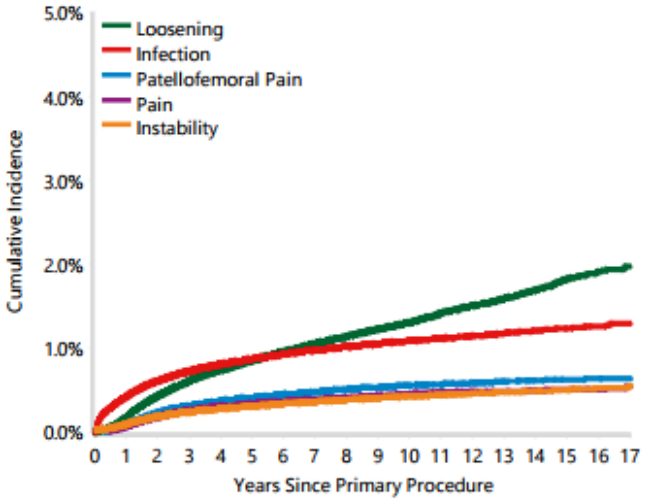

Figure 50: *Cumulative Incidence by Revision Diagnosis in Primary Total Knee Arthroplasty. AOANJJR 2018 report.*[135]

Ongoing analysis from the registry may show over time that the improved ligament balancing capabilities of the gap balancing system may help reduce revision rates over time. This technology has only been in routine use in Australia for the last 2 years. If the time frame is similar to the CAs experience then data collection with have to continue for some time before a significant improvement in failures, if any, can be shown.

Prospective Robotic TKA Registry

In an attempt to evaluate the effects Robotic gap balancing techniques on revision rates in a level of detail that has not been performed before we have now set up a system where detailed registry analysis will be prospectively performed. This work will be part of a multicentre study in Australia New Zealand, which will attempt to obtain the numbers and power to try and demonstrate any significant improvements with this technology. A regional registry has been set up to record data and evaluate all robotically implanted TKA cases throughout Australia and New Zealand. In addition to the usual outcome measures recorded in the AOANJRR registry this project will collect detailed information on patients' demographics, pre-op deformities, surgical corrections performed, type and size of implants used, surgical time and alignment corrections achieved.

By prospectively collecting data from a number of centres this study should generate adequate numbers to allow strong conclusions to be made on how these techniques may potentially improve patient outcomes. Hopefully the results will show reduced the rates of TKA failure with lower numbers of patients requiring revision surgery for instability and potentially other causes of failure in the future.

Our team has applied for Ethical approval for this study to allow collection of prospective data which will be shared with the regional registry. Data from this regional registry will be used as tool to combine with National registry data in a similar way to the work described in Chapter 4 in this thesis. This will be the first attempt to our knowledge to do so on this scale and with this level of detail. This will provide larger numbers to improve patient outcomes

and feed back to the National registry in a process that will also encourage enhanced and improved data collection in the long term.

It is estimated that this work will take approximately 5 years taking well outside the scope of this Thesis.

Chapter Nine: Conclusions

In this thesis I have explored an interesting journey through the diagnosis, management and potentially prevention of TKA instability of the knee. The whole process has evolved over a period of almost 5 years and has revolutionised the treatment of our patients within our centre. It has combined clinical data with local and national registry data in a way that has not been attempted before in revision TKA surgery. Arthroplasty surgery can offer patients a significant improvement in their quality of life with long lasting effects for years to come. However, it can also significantly impair quality when complications lead to further surgery and functional impairments that can affect our patients for years to come or even permanently.

In this journey we started with a review of the literature confirming that revision for TKA instability is a significant problem with unanswered issues. Patients are revised early and many are young at the time of their first revision surgery. In addition, many have to undergo re-revision surgery in the first 5 years post-op. This was therefore chosen as the Sentinel Event for this surgical Thesis. In addition, our local historical data from the AOANJRR registry has shown that in the past many patients have undergone surgery for vague diagnosis such as 'pain 'and it is not surprising that some of these patients have come back for re-revision surgery.

Using this historical data and our literature review a robust, standardised and re-producible diagnostic process was constructed for the benefit of all our patients. The development of a local revision registry has allowed more detailed assessment and follow up of our outcomes and will continue to do so prospectively for years to come. This can also combine with and be fed back to national registry processes to improve and modify data collection and analysis. Review of our revision rates has shown that not only has this work improved out level and detail of diagnostic accuracy the use of a structured diagnostic and management pathway has shown a reduction in our re-revision surgery rates which is of huge benefit to our patients. This could have potentially huge benefits in both human cost and in financial cost to our healthcare service with each revision TKA surgery costing on average $63,000.

However the patient clinical results of our patients suggest that prevention of revision TKA surgery in the first place would be of the most benefit to them.

With the evolution of surgical techniques to enhance ligament gap balancing during surgery we can aim to reduce surgical error and its effect on TKA instability. Our results have shown a high level of accuracy using robotic techniques to perform ligament gap balancing. This evolution in our management process and enhanced accuracy of execution may have a profound effect on improving the outcomes of our patients in the future.

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J Knee Surg. 2019 Mar;32(3):239-250.

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Appendixes

Appendix 1

MAPT Questionnaire for assessing functional impairment in a patient with Hip or Knee dysfunction.

Questionnaire has been removed due to copyright restriction. Available online from: https://www.health.qld.gov.au/__data/assets/pdf_file/0024/374424/hip_knee_chhsd.pdf

Appendix 2

Oxford Knee score Questionnaire for Pain and Functional Impairment.

Removed due to copyright restriction.

Removed due to copyright restriction.

Appendix 3

Ethics Approvals for studies performed as part of this thesis.

Office for Research

Flinders Medical Centre / The Flats F6/F8
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Final approval for ethics application

08 December 2015

Dear Dr Wilson

This is a formal correspondence from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188). This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." No hard copy correspondence will be issued.

Application Numbers: 506.15

Title: Quantitative analysis of revision lower limb arthroplasty at RGH and initiation of a formal Revision Arthroplasty Registry

Chief investigator: Dr Christopher Wilson

Public health sites granted ethical approval: Repatriation General Hospital

The Issue: The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) have reviewed and provided ethical approval for the above application. The approval extends to the following documents/changes:

- SAC HREC Clinical Audit Application form dated 03 December 2015

Approval Period: 08 December 2015 to 08 December 2016

Please read the terms and conditions of ethical approval below, as researchers have a significant responsibility to comply with reporting requirements and the other stated conditions.

For example, the implications of not providing annual reports and requesting an extension for research prior to approval expiring could lead to the suspension of the research, and has further serious consequences.

Please retain a copy of this approval for your records.

TERMS AND CONDITIONS OF ETHICAL APPROVAL
Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions.

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below.

Researchers have a significant responsibility to comply with the *National Statement 5.5.* in providing the SAC HREC with the required information and reporting as detailed below:

1. **It is the policy of the SAC HREC not to provide signed hardcopy or signed electronic approval letters**, as our office is moving to electronic documentation. The SAC HREC office provides an unsigned electronic PDF version of the study approval letter to the Chief Investigator/Study Manager via email. These email approvals are generated via the email address research.ethics@health.sa.gov.au which can be linked back to the SAC HREC.
2. **If University personnel are involved in this project**, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. **Compliance** with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
4. To **immediately report to SAC HREC** anything that may change the ethical or scientific integrity of the project.
5. **Report Significant Adverse events (SAE's)** as per SAE requirements available at our website.
6. **Submit an annual report on each anniversary of the date of final approval** and in the correct template from the SAC HREC website.
7. **Confidentiality** of research participants MUST be maintained at all times.
8. A copy of the **signed consent form** must be given to the participant unless the project is an audit.
9. Any **reports or publications derived from the research** should be submitted to the Committee at the completion of the project.
10. All requests for **access to medical records** at any SALHN site must be accompanied by this approval email.
11. To **regularly review the SAC HREC website** and comply with all submission requirements, as they change from time to time.
12. The researchers agree to use **electronic format** for all correspondence with this department.

Kind Regards

Anna Pantelidis
Administration Officer, Office for Research

On behalf of
Professor David Gordon, Chair, SAC HREC

Office for Research

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Government of South Australia
SA Health
Southern Adelaide Local Health Network

Extension Request to Ethics Approval: Approved

4 July 2017

Dr Chris Wilson
Consultant Surgeon
Orthopaedic Surgery
Repatriation General Hospital
Daws Road
DAW PARK SA 5041

Dear Dr Chris Wilson

OFR Number:	506.15
Project title:	Quantitative analysis of revision lower limb arthroplasty at RGH and initiation of a formal Revision Arthroplasty Registry
Chief Investigator:	Dr Chris Wilson

Ethics Approval Period: 03 July 2017 – 03 July 2018

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethics approval for this extension which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research*

Public health sites approved under this application:

- Repatriation General Hospital

The below document/s have been reviewed and approved:

- Annual review and extension request form dated 16 May 2017

TERMS AND CONDITIONS OF ETHICS APPROVAL

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
2. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
3. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
4. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
5. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.

6. Confidentiality of research participants MUST be maintained at all times.
7. A copy of the signed consent form must be given to the participant unless the project is an audit.
8. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
9. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
10. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
11. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.

For any queries about this matter, please contact Philip Morgan or Petrina Kasperski on (08) 8204 7433 or via email to Health.SALHNOfficeforResearch@sa.gov.au.

Yours sincerely

Paula Davies
Assistant Director, Office for Research

Office for Research

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Government of South Australia
SA Health
Southern Adelaide Local Health Network

Final approval for ethics application

30 October 2015

Dear Dr Wilson

This is a formal correspondence from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188). This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." No hard copy correspondence will be issued.

Application Numbers: 434.15

Title: Retrospective study on patients who have undergone Examination under Anaesthetic (EUA) also known as Manipulation under Anaesthesia (MUA) following Total Knee Replacement (TKR)

Chief investigator: Dr Chris Wilson

Public health sites granted ethical approval: Repatriation General Hospital

The Issue: The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) have reviewed and provided ethical approval for the above application. The approval extends to the following documents/changes:

- SAC HREC Clinical Audit Application Form dated 12 October 2015
- Letter of Support from Head of Department – A/Professor Graham Mercer dated 02 October 2015

Approval Period: 30 October 2015 to 30 October 2016

Please read the terms and conditions of ethical approval below, as researchers have a significant responsibility to comply with reporting requirements and the other stated conditions.

For example, the implications of not providing annual reports and requesting an extension for research prior to approval expiring could lead to the suspension of the research, and has further serious consequences.

Please retain a copy of this approval for your records.

TERMS AND CONDITIONS OF ETHICAL APPROVAL
Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions.

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below.

Researchers have a significant responsibility to comply with the *National Statement 5.5.* in providing the SAC HREC with the required information and reporting as detailed below:

1. **It is the policy of the SAC HREC not to provide signed hardcopy or signed electronic approval letters**, as our office is moving to electronic documentation. The SAC HREC office provides an unsigned electronic PDF version of the study approval letter to the Chief Investigator/Study Manager via email. These email approvals are generated via the email address research.ethics@health.sa.gov.au which can be linked back to the SAC HREC.
2. **If University personnel are involved in this project**, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. **Compliance** with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
4. To **immediately report to SAC HREC** anything that may change the ethical or scientific integrity of the project.
5. **Report Significant Adverse events (SAE's)** as per SAE requirements available at our website.
6. **Submit an annual report on each anniversary of the date of final approval** and in the correct template from the SAC HREC website.
7. **Confidentiality** of research participants MUST be maintained at all times.
8. A copy of the **signed consent form** must be given to the participant unless the project is an audit.
9. Any **reports or publications derived from the research** should be submitted to the Committee at the completion of the project.
10. All requests for **access to medical records** at any SALHN site must be accompanied by this approval email.
11. To **regularly review the SAC HREC website** and comply with all submission requirements, as they change from time to time.
12. The researchers agree to use **electronic format** for all correspondence with this department.

Kind Regards

Anna Pantelidis
Administration Officer, Office for Research

On behalf of
Professor David Gordon, Chair, SAC HREC

Office for Research

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Government of South Australia
SA Health
Southern Adelaide Local Health Network

Amendment to ethics application approved

You are reminded that this letter constitutes ethical approval only for this amendment. If you are waiting on Site Specific Assessment (SSA) authorisation for your study, you must not commence this research project at any public Health site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

10 August 2016

Dr Chris Wilson
Department of Orthopaedics
Repatriation General Hospital
DAW PARK SA 5041

Dear Dr Wilson

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this amendment which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research.*

Application Number: OFR # 434.15

Title: Retrospective study on patients who have undergone Examination under Anaesthetic (EUA) also known as Manipulation under Anaesthesia (MUA) following Total Knee Replacement (TKR).

Chief Investigator: Dr Chris Wilson

Approval date: 04 August 2016

This amendment approval does not alter the current SAC HREC approval period for the study: 30 October 2015 to 30 October 2016

Public health sites approved under this application: Repatriation General Hospital

The below documents have been reviewed and approved:

- Project Amendment Application form dated 06 July 2016
- Clinical Audit Application form v2 dated 08 July 2016 (clean and tracked)
- Head of Department Support Letter – A/Prof Graham Mercer dated 02 October 2015

TERMS AND CONDITIONS OF ETHICAL APPROVAL
As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval covers the ethics component of the application. Please submit a copy of the approved amendment to the local RGO for acknowledgement
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
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5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
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12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.
13. Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

Yours sincerely

Paula Davies
Manager, Office for Research

Office for Research

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Flinders Drive, Bedford Park SA 5042
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Government of South Australia
SA Health
Southern Adelaide Local Health Network

Final approval for ethics application

You are reminded that this letter constitutes **ethical** approval only. **Ethics approval is one aspect of the research governance process**.
You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form has been authorised by the Chief Executive or delegate of each site.

07 December 2015

Dear Dr Wilson

This is a formal correspondence from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188). This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." No hard copy correspondence will be issued.

Application Number: 436.15 - HREC/15/SAC/401

Title: Outcomes of revision knee arthroplasty using the Stryker revision system

Chief investigator: Dr Christopher Wilson

Public health sites granted ethical approval: Repatriation General Hospital

The Issue: The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) have reviewed and provided ethical approval for the above application. The approval extends to the following documents/changes:

- SA Health Low and Negligible Risk Application dated 12 October 2012
- Letter of Invitation – To Participate
- Oxford Knee Score

Approval Period: 07 December 2015 to 07 December 2018

Please read the terms and conditions of ethical approval below, as researchers have a significant responsibility to comply with reporting requirements and the other stated conditions.

For example, the implications of not providing annual reports and requesting an extension for research prior to approval expiring could lead to the suspension of the research, and has further serious consequences.

Please retain a copy of this approval for your records.

TERMS AND CONDITIONS OF ETHICAL APPROVAL
Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions.

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below.

Researchers have a significant responsibility to comply with the *National Statement 5.5.* in providing the SAC HREC with the required information and reporting as detailed below:

1. **The approval only covers the science and ethics component of the application**. A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. **It is the policy of the SAC HREC not to provide signed hardcopy or signed electronic approval letters**, as our office is moving to electronic documentation. The SAC HREC office provides an unsigned electronic PDF version of the study approval letter to the Chief Investigator/Study Manager via email. These email approvals are generated via the email address research.ethics@health.sa.gov.au which can be linked back to the SAC HREC.
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12. To **regularly review the SAC HREC website** and comply with all submission requirements, as they change from time to time.
13. The researchers agree to use **electronic format** for all correspondence with this department.

Kind Regards

Anna Pantelidis
Administration Officer, Office for Research

On behalf of
Professor David Gordon
Chair, SAC HREC

Office for Research
Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Amendment to ethics application approved

You are reminded that this letter constitutes ethical approval only for this amendment. If you are waiting on Site Specific Assessment (SSA) authorisation for your study, you must not commence this research project at any public Health site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

24 May 2017

Dr Christopher Wilson
Consultant Orthopaedic Surgeon
Department of Orthopaedics
Repatriation General Hospital
216 Daws Road
DAW PARK SA 5042

Dear Dr Wilson

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this amendment which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research*.

Application Number: OFR 436.15 - HREC/15/SAC/401

Title: Outcomes of revision knee arthroplasty using the Stryker revision system

Chief Investigator: Dr Christopher Wilson

This amendment approval does not alter the current SAC HREC approval period for the study: 7 December 2015 to 7 December 2018

Public health sites approved under this application:

Repatriation General Hospital

The below documents have been reviewed and approved:

Ethics and governance

- Project amendment form – addition of MAPT – dated
- Low and negligible risk application form dated 08 May 2017
- MAPT questionnaire

TERMS AND CONDITIONS OF ETHICAL APPROVAL

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5*.

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval covers the ethics component of the application. Please submit a copy of the approved amendment to the local RGO for acknowledgement
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
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13. Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

Yours sincerely

A/Professor Bernadette Richards
Chair, SAC HREC

Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Final Approval for Ethics Application

07 May 2019

Dr Christopher Wilson
Orthopaedics and Trauma Surgery
Flinders Medical Centre

Dear Dr Wilson

OFR Number: 77.19
Project title: Analysis and Validation of MAKO Total Knee Robotic-Assisted Surgery.
Chief Investigator: Dr Chris Wilson

Ethics Approval Period: 28/04/2019– 28/04/2020

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) (EC00188) have reviewed and provided approval for this application which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007, updated 2018).*

You are reminded that this letter constitutes **Ethics** approval only. **Ethics approval is one aspect of the research governance process**.

You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form, has been approved by the Chief Executive or delegate of each site.

Public health sites approved under this application:

- Flinders Medical Centre

The below documents have been reviewed and approved:

Document	Version	Date
Audit based research form	1	24.04.2019
Data collection form	1	24.04.2019

Terms and Conditions of Ethics Approval:

SALHN has recently introduced site monitoring of authorised studies. This approval/authorisation is subject to participation in this monitoring process. You will be notified in advance if your site has been selected for an inspection
It is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval only covers the science and ethics component of the application. A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)* & the *Australian Code for the Responsible Conduct of Research (2018)*.
4. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
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For any queries about this matter, please contact The Office for Research on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au

Yours sincerely,

Professor Bill Heddle
Chair
Southern Adelaide Clinical Human Research Ethics Committee

Office for Research

Flinders Medical Centre
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Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Final Authorisation for Governance

Dr Christopher Wilson
Orthopaedic Consultant
Flinders Medical Centre
BEDFORD PARK SA 5042

Email Contact: Christopher.wilson@sa.gov.au
Sire0014@flinders.edu.au

Dear Dr Wilson

OFR Number:	77.19
HREC reference number:	AUD/19/SAC/77
SSA reference number:	AR/19/SAC/77
Project title:	Analysis and Validation of MAKO Total Knee Robotic-Assisted Surgery.
Principal Investigator:	Dr Christopher Wilson
Governance Authorisation Date:	**27.06.2019**

On the basis of the information provided in your Site Specific Assessment submission, I am pleased to inform you the SALHN Chief Executive Officer or delegate has granted authorisation for this study to commence at Flinders Medical Centre, SALHN.

The below documents have been reviewed and approved **subject to the terms and conditions** set out on the reverse of this page:

Document	Version	Date
Access Request Form		01.04.2019
SAC HREC Approval letter**	AUD/19/SAC/77	28.04.2019

Should you have any queries about this authorisation, please contact the Office for Research on 8204 6453 or via email: Health.SALHNOfficeforResearch@sa.gov.au quoting the OFR reference number.

Yours sincerely

Paula Davies
Director,
Research Operations

Date 1/7/19

TERMS AND CONDITIONS OF ETHICS AND GOVERNANCE APPROVAL

The Principal Investigator must ensure this research complies with the National Statement on Ethical Conduct in Human Research (2018) & the Australian Code for the Responsible Conduct of Research (2007 updated 2018) by immediately reporting to the Office for Research (OFR) anything that may change the ethics or scientific integrity of the project. Final approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. Confidentiality of research participants MUST be maintained at all times.
2. If the research involves the recruitment of participants, a signed copy of the 'Consent Form' must be given to the participant. Any changes to the Participant Information Sheet/Consent Form must be approved by the lead HREC prior to being used.
3. No promotion of a study can commence until final ethics and SALHN executive approval has been obtained. All advertisements/flyers need to be approved by the committee and media contact should be coordinated through the FMC media unit.
4. Non-SA Health researchers viewing confidential SALHN data are required to complete and sign a SALHN Confidentiality Disclosure Deed
5. All approved requests for access to medical records at any SALHN site must be accompanied by this approval letter.
6. If your study involves a tertiary institution, contact the University to ensure compliance with University requirements prior to commencement of this study. This includes any insurance and indemnification.
7. The PI must adhere to Monitoring and Reporting requirements for both ethics and governance which are available on the SALHN Research Website.
8. The PI must immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project
9. An annual report must be submitted to the SAC HREC and SALHN governance on each anniversary of the date of final approval. Please visit the Office for Research website for the current template.
10. Non-SA Health researchers coming onsite at SALHN must provide evidence of a recent (<3 years) screening check. It is the responsibility of the Principal Investigator to ensure any non-SA Health personnel who conducts or monitors research meets SA Health screening requirements as per the SA Health Criminal & Relevant History Screening Policy Directive before they access any SA Health site. The cost of any such screening is the responsibility of the individual accessing the site or their employer.
11. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
12. Once the research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.
13. SALHN site-monitoring of authorised studies - this approval/authorisation is subject to participation in this monitoring process. You will be notified in advance if your site has been selected for an inspection.

Please visit the SALHN Research website regularly and comply with all submission requirements as they may change from time to time.

****HREC reviewed documents listed on the approval letter are accepted as part of the site authorisation.**

Appendix 4

Ad Hoc Request for Registry report 2557 on the results of all Historic Knee Arthoplasty Cases

(OFFICE USE ONLY)
REQUEST ID:

Australian Orthopaedic Association
National Joint Replacement Registry

DATA RELEASE REQUEST FORM

The AOANJRR is a Declared Federal Quality Assurance Activity and is required by law to abide by certain requirements of the declaration. The AOANJRR must protect the confidentiality of the information it receives, and maintain high-level data security procedures. Only de-identified data can be released

TO COMPLETE THIS FORM IN WORD

- *Place the cursor in the required field*
- *Tab to move to the next field*
- *Click on check box to mark*
- *Once complete email the form to cturner@aoanjrr.org.au*

TO ACCESS THE CURRENT ANNUAL REPORT USE THE FOLLOWING LINK AND SELECT PUBLICATIONS FROM THE MENU
https://aoanjrr.sahmri.com

SECTION 1

CONTACT DETAILS:

DATE:	13-07-17
PRINCIPAL REQUESTER:	Joshua Kelly
POSITION:	Final Year Medical Student
TELEPHONE:	82769666 MOBILE: 0419212716
EMAIL: (INSTITUTIONAL/ORGANIZATIONAL)	kell0476@flinders.edu.au
ORGANISATION:	Repatriation General Hospital
ADDRESS:	216 Daws Road, Daw Park, SA, 5041
CONTACT PERSON:	Dr Chris Wilson

DATE REQUIRED BY:

The AOANJRR will endeavour to provide the report by the nominated date; however this is dependent on the available resources at the time of the request and the complexity of the analysis required.

Version 1.2
Approved 15 February 2017

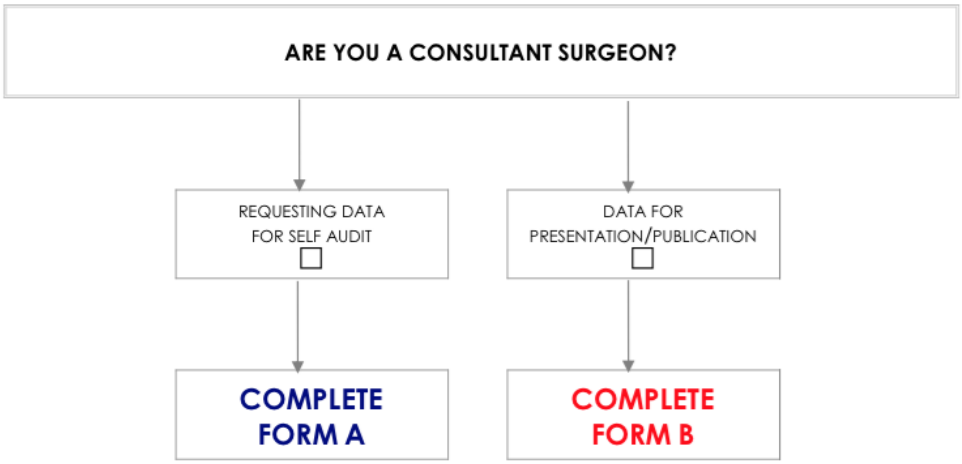
SECTION 2

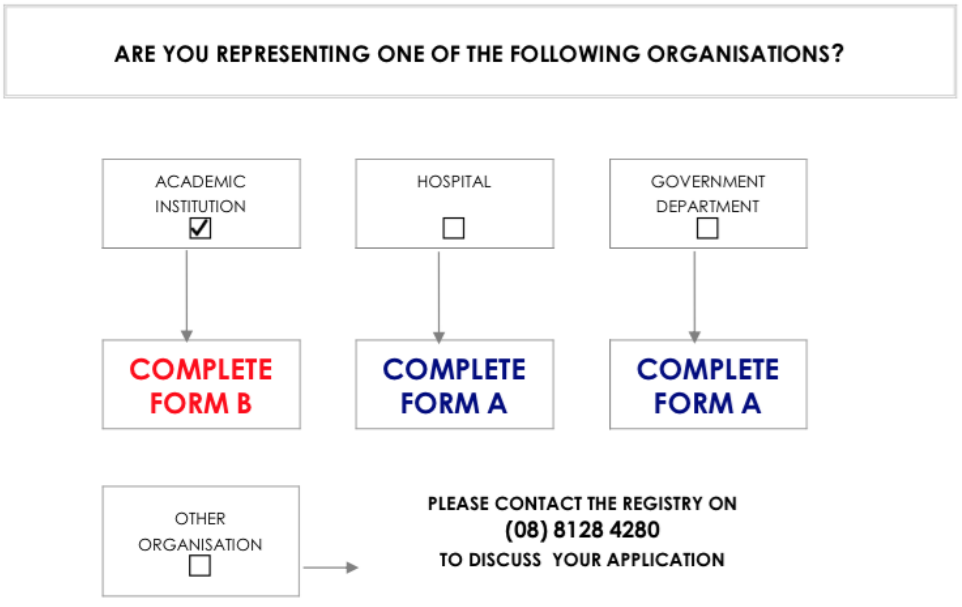
TYPE OF DATA REQUEST:

There are two types of data requests, each requires a different form to be completed: -

1. Requests seeking data analysis for an audit within a practice or organisation (Form A).
2. Requests seeking data analysis for a presentation or research project (Form B)

USE THE FOLLOWING GUIDE TO DETERMINE THE CORRECT FORM TO COMPLETE





FORM B

DATA RELEASE REQUEST FORM

(FORM B - PUBLICATIONS)

AOANJRR DATA FOR USE IN JOURNAL PUBLICATIONS

AOANJRR provides non-identifying data on request to surgeons and academic institutions to be used in the preparation of publications. The independence of data reporting, the correct interpretation and the quality of publications is crucial to ensure the integrity of the data and the credibility of AOANJRR.

Depending on the nature of the data provided, there are criteria for the involvement of AOANJRR in the manuscript preparation and publication. The AOANJRR currently identifies three different forms of ad hoc data:

1. a) Surgeons' personal data,
   b) Verification data related to ongoing clinical trials, and
   c) AOANJRR data (all other data).

2. **For ad hoc data report types a) and b)**

   The AOANJRR will not be involved in manuscript preparation or publication if the analysis is based on an individual surgeon's personal data or clinical trial verification data, unless requested.

3. **For ad hoc data report type c)**

   i. It is necessary for the AOANJRR to be involved in preparation and publication of a manuscript if the publication is based on analysis of the entire AOANJRR data or a subset of that data.
   ii. When the entire AOANJRR data is used, following consultation with the primary author, the AOANJRR Director and Deputy Directors will determine:
      - Authorship,
      - AOANJRR personnel involved in manuscript preparation, and
      - Contact person for the submission and review process of the manuscript.
   iii. At least one clinician from the AOANJRR and the relevant statistician will be included as authors and involved in the preparation of the manuscript.
   iv. AOANJRR manuscripts will be reviewed by the Academic Editorial Advisory Panel prior to submission.

4. **To ensure the quality of the data is maintained**

   i. It is anticipated that draft manuscripts will be provided within 12 months of receiving the ad hoc report;
   ii. If there is more than one request for the same data the initial requester will have 12 months from receipt of data to complete the required manuscript unless a formal extension has been approved. If a manuscript is not submitted the data may be provided to other requester(s).
   iii. The AOANJRR policy is that manuscripts must use the most up-to-date validated data.

The process of obtaining data through the AOANJRR Ad Hoc Request process provides the orthopaedic community with access to high quality data and support in manuscript development. Equally, this process ensures that the data integrity, analysis and reporting of all research papers based on AOANJRR data are of world class standard.

FORM B

ALL SECTIONS OF FORM B MUST BE COMPLETED

SECTION B1

REQUESTER/REQUESTING ORGANISATION:

Tick relevant box/es and provide details below

CONSULTANT SURGEON ☑ ACADEMIC INSTITUTION ☐

OTHER ☐ *PLEASE SPECIFY*

IDENTIFY WHO WILL HAVE ACCESS TO DATA:

SIGNATURE:

Dr Christopher Wilson - Consultant Orthopaedic Surgeon

SIGNATURE:

Joshua Kelly - Final Year Medical Student - Flinders University

SIGNATURE:

Dr Mariana Rego - Resident Medical Officer

SIGNATURE:

SECTION B2

JOURNAL/CONFERENCE DETAILS:

Complete details(where applicable)

TITLE OF PUBLICATION OR ABSTRACT: Outcomes of revision knee arthroplasty for patients with instability

PRINCIPAL AUTHORS: Dr Chris Wilson

Joshua Kelly

INTENDED JOURNAL: The Journal of Arthroplasty

CONFERENCE DETAILS: 5th Annual Meeting of the Canadian Arthroplasty Society

LOCATION: Toronto, Canada

DATE OF CONFERENCE: November 24th

ABSTRACT SUBMISSION DEADLINE: September 23rd

Please note: A draft abstract must be submitted at least 10 days prior to this date.

COMMENTS:

SECTION B3

DATA ANALYSIS:

Tick relevant box/es

DATA REQUIRED:

NATIONAL DATA ☐ STATE DATA ☑ NAME OF STATE: South Australia

Specify details of Other Data

OTHER DATA ☐

PROSTHESES OF INTEREST:

Revision Total Knee Replacements for Instability

USE THE CURRENT ANNUAL REPORT TO IDENTIFY TABLES AND FIGURES

TO ACCESS THE CURRENT ANNUAL REPORT USE THE LINK ON THE FRONT PAGE OF THE REQUEST FORM

SPECIFY DATA PERIOD REQUIRED IF DIFFERENT TO THE CURRENT ANNUAL REPORT :

2012 through 2016 inclusive

TABLE NUMBERS: KT7, KT11

FIGURE NUMBERS: KT7, KT11

Appendix 5

Ad Hoc Request for Registry report 2418 on the results of Revision Knee Arthoplasty Cases

(OFFICE USE ONLY)
REQUEST ID:

Australian Orthopaedic Association
National Joint Replacement Registry

DATA RELEASE REQUEST FORM

The AOANJRR is a Declared Federal Quality Assurance Activity and is required by law to abide by certain requirements of the declaration. The AOANJRR must protect the confidentiality of the information it receives, and maintain high-level data security procedures. Only de-identified data can be released

TO COMPLETE THIS FORM IN WORD

- *Place the cursor in the required field*
- *Tab to move to the next field*
- *Click on check box to mark*
- *Once complete email the form to cturner@aoanjrr.org.au*

TO ACCESS THE CURRENT ANNUAL REPORT USE THE FOLLOWING LINK AND SELECT PUBLICATIONS FROM THE MENU
https://aoanjrr.sahmri.com

SECTION 1

CONTACT DETAILS:

DATE:	20/12/2017
PRINCIPAL REQUESTER:	Dr Christopher Wilson
POSITION:	Ortho Consultant
TELEPHONE:	0416564557 MOBILE: 0416564557
EMAIL: (INSTITUTIONAL/ORGANIZATIONAL)	Christopher.wilson@sa.gov.au
ORGANISATION:	Flinders Medical Centre
ADDRESS:	C/o Orthopaedic Department
	Flinders Medical Centre
	Flinders Drive SA 5042
CONTACT PERSON:	Dr Christopher Wilson

DATE REQUIRED BY:

The AOANJRR will endeavour to provide the report by the nominated date; however this is dependent on the available resources at the time of the request and the complexity of the analysis required.

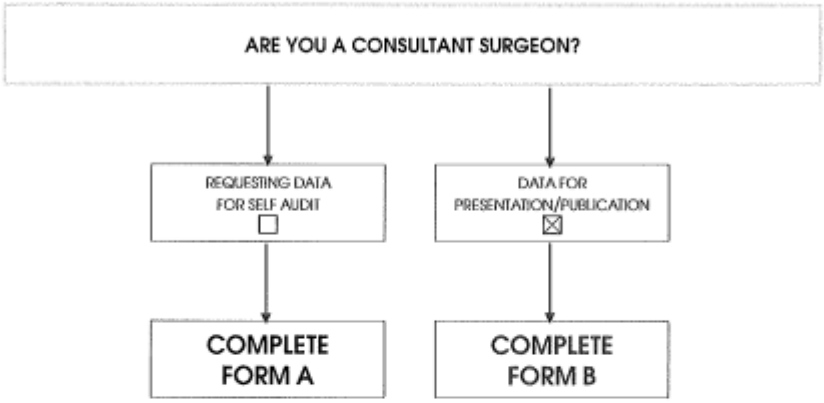
SECTION 2

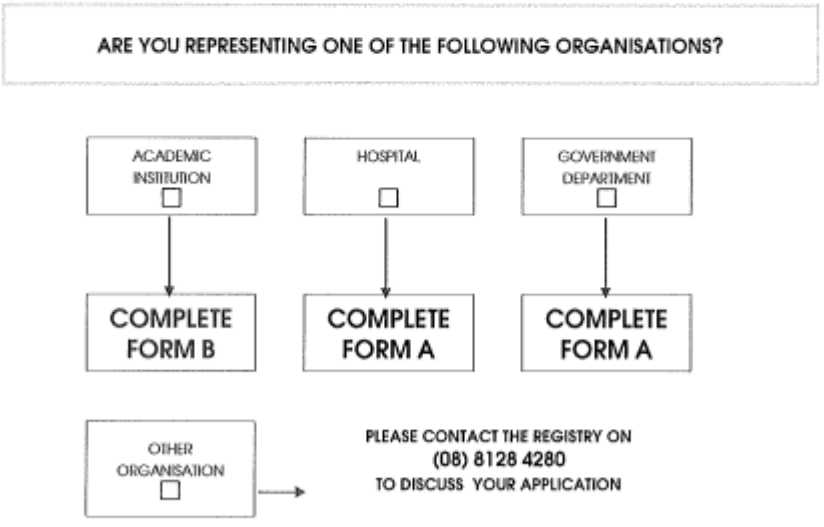
TYPE OF DATA REQUEST:

There are two types of data requests, each requires a different form to be completed: -

1. Requests seeking data analysis for an audit within a practice or organisation (Form A).
2. Requests seeking data analysis for a presentation or research project (Form B)

USE THE FOLLOWING GUIDE TO DETERMINE THE CORRECT FORM TO COMPLETE





FORM B

DATA RELEASE REQUEST FORM

(FORM B - PUBLICATIONS)

AOANJRR DATA FOR USE IN JOURNAL PUBLICATIONS

AOANJRR provides non-identifying data on request to surgeons and academic institutions to be used in the preparation of publications. The independence of data reporting, the correct interpretation and the quality of publications is crucial to ensure the integrity of the data and the credibility of AOANJRR.

Depending on the nature of the data provided, there are criteria for the involvement of AOANJRR in the manuscript preparation and publication. The AOANJRR currently identifies three different forms of ad hoc data:

1. a) Surgeons' personal data,
   b) Verification data related to on-going clinical trials, and
   c) AOANJRR data (all other data).

2. **For ad hoc data report types a) and b)**

The AOANJRR will not be involved in manuscript preparation or publication if the analysis is based on an individual surgeon's personal data or clinical trial verification data, unless requested.

3. **For ad hoc data report type c)**
   i. It is necessary for the AOANJRR to be involved in preparation and publication of a manuscript if the publication is based on analysis of the entire AOANJRR data or a subset of that data.
   ii. When the entire AOANJRR data is used, following consultation with the primary author, the AOANJRR Director and Deputy Directors will determine:
      - Authorship,
      - AOANJRR personnel involved in manuscript preparation, and
      - Contact person for the submission and review process of the manuscript.
   iii. At least one clinician from the AOANJRR and the relevant statistician will be included as authors and involved in the preparation of the manuscript.
   iv. AOANJRR manuscripts will be reviewed by the Academic Editorial Advisory Panel prior to submission.

4. **To ensure the quality of the data is maintained**
   i. It is anticipated that draft manuscripts will be provided within 12 months of receiving the ad hoc report;
   ii. If there is more than one request for the same data the initial requester will have 12 months from receipt of data to complete the required manuscript unless a formal extension has been approved. If a manuscript is not submitted the data may be provided to other requester(s).
   iii. The AOANJRR policy is that manuscripts must use the most up-to-date validated data.

The process of obtaining data through the AOANJRR Ad Hoc Request process provides the orthopaedic community with access to high quality data and support in manuscript development. Equally, this process ensures that the data integrity, analysis and reporting of all research papers based on AOANJRR data are of world class standard.

FORM B

ALL SECTIONS OF FORM B MUST BE COMPLETED

SECTION B1

REQUESTER/REQUESTING ORGANISATION:

Tick relevant box/es and provide details below

CONSULTANT SURGEON ☒ ACADEMIC INSTITUTION ☐

OTHER ☐ *PLEASE SPECIFY*

IDENTIFY WHO WILL HAVE ACCESS TO DATA:

Dr Christopher Wilson SIGNATURE: DR CHRIS WILSON 23/12/2017

SIGNATURE: X

SIGNATURE: X

SIGNATURE: X

SECTION B2

JOURNAL/CONFERENCE DETAILS:

Complete details(where applicable)

TITLE OF PUBLICATION OR ABSTRACT: Part of work on PhD thesis

PRINCIPAL AUTHORS: Dr Christopher Wilson

INTENDED JOURNAL:

CONFERENCE DETAILS: Arthroplasty Society ASM

LOCATION: Hobart

DATE OF CONFERENCE: May 2018

ABSTRACT SUBMISSION DEADLINE: Feb 2018

Please note: A draft abstract must be submitted at least 10 days prior to this date.

COMMENTS:

SECTION B3

DATA ANALYSIS:

Tick relevant box/es

DATA REQUIRED:

NATIONAL DATA ☐ STATE DATA ☐ NAME OF STATE:

OTHER DATA ☒

Specify details of Other Data

Review of re- revision data on all TKR patients from report 1667

PROSTHESES OF INTEREST:

All TKR patients

USE THE CURRENT ANNUAL REPORT TO IDENTIFY TABLES AND FIGURES

TO ACCESS THE CURRENT ANNUAL REPORT USE THE LINK ON THE FRONT PAGE OF THE REQUEST FORM

SPECIFY DATA PERIOD REQUIRED IF DIFFERENT TO THE CURRENT ANNUAL REPORT :

TABLE NUMBERS: N/A

FIGURE NUMBERS: N/A

ADDITIONAL ANALYSIS:	Re – revision rates for all Revision TKR patients in report 1667 both in total and by specific revision diagnosis. Some of these patients have been revised and the details on Revision rates are included in report 1667 Can you review the data to see how many from this Group of Revision TKR Patients have been Re-revised

SECTION B4

RESEARCH PROJECT:

HYPOTHESIS:

As part of my PhD thesis I have been working on the diagnosis of the failing knee and How to accurately diagnose the cause of failure. Previous annual Registry reports have clearly shown high rates of Re-revision surgery in Revision TKR.

All patients now go through our standardised diagnosis and management algorithm prior to revision surgery being performed designed to improve our diagnostic accuracy and reduce our rates of Re-Revision surgery in the future.

In this work our aim is to evaluate whether patients who have gone through this process have a reduced the rate of Re-revision surgery.

BACKGROUND INFORMATION:

Report 1667 contains information on TKR patients and their revision rates up to 2013.

The revision rates and reasons for revision are clearly shown in this report.

After 2013 we used this registry data as a guide to change our diagnostic & management pathway for all TKR patients managed by the Repatriation Hospital Arthroplasty team.

Analysis has already been performed on patients who have gone through this pathway from 2013 onwards and re-revision rates at 4 years are just under 10 %. Further follow up of these patients and their Re-Revision rates is on-going.

PRIMARY OBJECTIVES OF YOUR INVESTIGATION:

To establish the rates of Re-Revision in our current Revision TKR patients who have gone through our new revision algorithm since 2013.

In addition to use registry data from the Repatriation hospital from up to 2013 to evaluate if our re-revision rates have improved using our new algorithm both for all patients and by specific revision diagnosis.

The patients for this analysis are all within the group in report 1667.

OFFICE USE ONLY

ETHICS APPROVAL IS REQUIRED FOR THIS REQUEST **YES** ☐ **NO** ☐

SECTION B5

PRINCIPAL INVESTIGATOR:

NAME:	**Dr Christopher Wilson**
POSITION:	**Ortho Consultant**
ORGANISATION/UNIT:	**Flinders Medical Centre**
SIGNATURE:	Dr Christopher Wilson
DATE:	**20/12/2017**

DETAILS OF OTHER PERSON/S INVOLVED IN THE RESEARCH PROJECT:

NAME:
POSITION:
ORGANISATION/UNIT:

NAME:
POSITION:
ORGANISATION/UNIT:

NAME:
POSITION:
ORGANISATION/UNIT:

NAME:
POSITION:
ORGANISATION/UNIT:

NAME:
POSITION:
ORGANISATION/UNIT:

NAME:
POSITION:
ORGANISATION/UNIT:

NAME:
POSITION:
ORGANISATION/UNIT:

PLEASE ATTACH A LIST OF ADDITIONAL INVESTIGATORS IF REQUIRED

To facilitate a timely turnaround of requests please ensure that all relevant sections of the Form are completed in full. Incomplete requests will be returned to the requester for completion and resubmission prior to review by the AOANJRR Data Review Committee.

YOU HAVE COMPLETED FORM B – DO NOT COMPLETE FORM A

PLEASE EMAIL THE REQUEST FORM TO CYNTHIA TURNER, AOANJRR MANAGER AT THE EMAIL ADDRESS ON THE FRONT PAGE OF THE FORM

Appendix 6

Results of Registry report 1667 on the results of Revision Knee Arthoplasty Cases

Australian Orthopaedic Association
National Joint Replacement Registry

AD HOC REPORT
(FORM A – HOSPITAL REPORT)

REQUEST ID	PRINCIPAL REQUESTER	POSITION	ORGANISATION	CONTACT
1667	Graham Mercer		Repatriation General Hospital SA	Graham Mercer

DATE REQUESTED:	1/5/2015
DATE APPROVED FOR RELEASE:	1/7/15

DETAILS OF ANALYSIS PROVIDED

Hospital Start Date:	1 September 1999
Specific Data Period:	Procedures from 1 September 1999 to 31 December 2013

Comments:

- Primary total conventional hip replacement procedures using metal/metal prostheses with head size larger than 32mm have been excluded from the comparator. Primary total conventional hip replacement procedures at the Repatriation General Hospital have been analysed with and without procedures using metal/metal prostheses with head size larger than 32mm.

Data which can be potentially identifying are not provided by AOANJRR. In this analysis, the requested data detailed below is not included in the report:

- Public hospitals have not been provided as a comparator according to AOANJRR standard practice. All other hospitals have been provided instead.

Approved:	Professor Stephen Graves AOANJRR Director	2/7/15

Disclaimer:	*The AOANJRR has taken every care to ensure that the data supplied are accurate but does not warrant that the data are error free and does not accept any liability for errors or omissions in the data provided.*

Primary Knee Replacement

Table 52: Repatriation General Hospital Primary Knee Replacement by Class (All Diagnoses)

Class	Number	Percent
Total Knee	2870	83.3
Revision	421	12.2
Unicompartmental	143	4.1
Patella/Trochlear	10	0.3
Bicompartmental	2	0.1
Unispacer	1	0.0
TOTAL	**3447**	**100.0**

Primary Unispacer Knee Replacement

Table 53: Primary Diagnosis of Primary Unispacer Knee Replacement by Hospital

	Repatriation General Hospital	Other Hospitals
Primary Diagnosis	N	N
Osteoarthritis	1	39

Table 54: Revision Rates of Primary Unispacer Knee Replacement by Hospital (All Diagnoses)

Hospital	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Repatriation General Hospital	1	1	0	217.41 (5.50, 1211)
Other Hospitals	30	39	139	21.64 (14.60, 30.90)
TOTAL	**31**	**40**	**139**	**22.29 (15.15, 31.64)**

TABLE 55

Reasons for Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

% Primaries Revised: This shows the proportional contribution of each revision diagnosis as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of being revised for that diagnosis. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

% Revisions: The number of revisions for each diagnosis is expressed as a percentage of the total number of revisions. This shows the distribution of reasons for revision within a group but cannot be used as a comparison between groups.

Table 55: Revision Diagnosis of Primary Unispacer Knee Replacement by Hospital (All Diagnoses)

	Repatriation General Hospital			Other Hospitals		
Revision Diagnosis	**Number**	**% Primaries Revised**	**% Revisions**	**Number**	**% Primaries Revised**	**% Revisions**
Pain				7	17.9	23.3
Loosening/Lysis				5	12.8	16.7
Progression Of Disease				5	12.8	16.7
Synovitis				4	10.3	13.3
Implant Breakage Tibial				3	7.7	10.0
Incorrect Sizing				1	2.6	3.3
Infection				1	2.6	3.3
Malalignment				1	2.6	3.3
Osteonecrosis				1	2.6	3.3
Prosthesis Dislocation	1	100.0	100.0	1	2.6	3.3
Wear Tibial				1	2.6	3.3
N Revision	**1**	**100.0**	**100.0**	**30**	**76.9**	**100.0**
N Primary	**1**			**39**		

TABLE 56

Type of Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

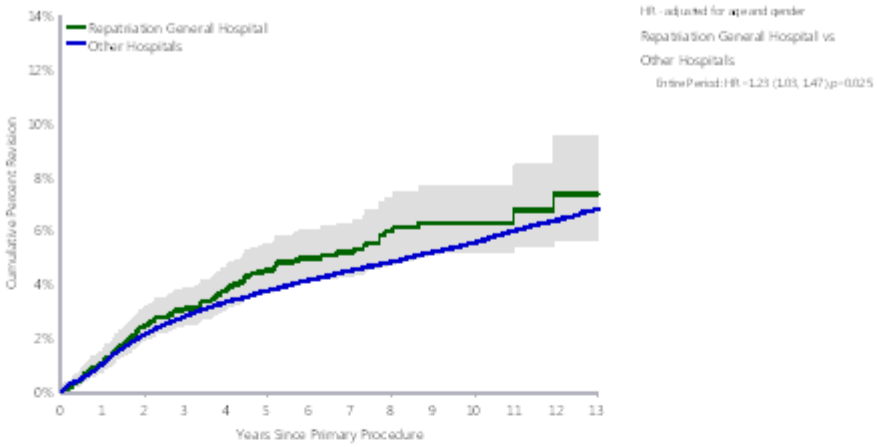
% Primaries Revised: This shows the proportional contribution of each type of revision as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of having that type of revision. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

% Revisions: The number of revisions for each type of revision is expressed as a percentage of the total number of revisions. This shows the distribution of types of revision within a group but cannot be used as a comparison between groups.

Table 56: Type of Revision of Primary Unispacer Knee Replacement by Hospital (All Diagnoses)

	Repatriation General Hospital			Other Hospitals		
Type of Revision	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
UKR (Uni Tibial/Uni Femoral)	1	100.0	100.0	19	48.7	63.3
TKR (Tibial/Femoral)				7	17.9	23.3
Unispacer				4	10.3	13.3
N Revision	**1**	**100.0**	**100.0**	**30**	**76.9**	**100.0**
N Primary	**1**			**39**		

Figure 15: Cumulative Percent Revision of Primary Total Knee Replacement by Hospital (All Diagnoses)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs
Repatriation General Hospital	2870	2579	2254	1983	1632	1350	1025	806	639	467	318	203	147	62
Other Hospitals	393602	343132	294793	250280	209366	173030	139477	110075	83868	60222	40343	23595	10247	2458

TABLE 79

Reasons for Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

% Primaries Revised: This shows the proportional contribution of each revision diagnosis as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of being revised for that diagnosis. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

% Revisions: The number of revisions for each diagnosis is expressed as a percentage of the total number of revisions. This shows the distribution of reasons for revision within a group but cannot be used as a comparison between groups.

Table 79: Revision Diagnosis of Primary Total Knee Replacement by Hospital (All Diagnoses)

	Repatriation General Hospital			Other Hospitals		
Revision Diagnosis	**Number**	**% Primaries Revised**	**% Revisions**	**Number**	**% Primaries Revised**	**% Revisions**
Loosening/Lysis	25	0.9	20.8	3963	1.0	29.2
Infection	19	0.7	15.8	3020	0.8	22.3
Patellofemoral Pain	24	0.8	20.0	1641	0.4	12.1
Pain	20	0.7	16.7	1230	0.3	9.1
Instability	12	0.4	10.0	822	0.2	6.1
Arthrofibrosis	3	0.1	2.5	483	0.1	3.6
Patella Erosion	2	0.1	1.7	422	0.1	3.1
Fracture	4	0.1	3.3	352	0.1	2.6
Malalignment	2	0.1	1.7	310	0.1	2.3
Metal Related Pathology				245	0.1	1.8
Wear Tibial Insert				217	0.1	1.6
Incorrect Sizing	1	0.0	0.8	187	0.0	1.4
Bearing Dislocation	1	0.0	0.8	108	0.0	0.8
Patella Maltracking	6	0.2	5.0	84	0.0	0.6
Implant Breakage Tibial Insert				71	0.0	0.5
Prosthesis Dislocation				64	0.0	0.5
Synovitis				55	0.0	0.4
Implant Breakage Patella				46	0.0	0.3
Implant Breakage Tibial				34	0.0	0.3
Osteonecrosis				27	0.0	0.2
Implant Breakage Femoral				20	0.0	0.1
Tumour	1	0.0	0.8	10	0.0	0.1
Wear Patella				8	0.0	0.1
Wear Tibial				8	0.0	0.1
Heterotopic Bone				4	0.0	0.0
Wear Femoral				3	0.0	0.0
Incorrect Side				2	0.0	0.0
Patella Dislocation				1	0.0	0.0
Other				131	0.0	1.0
N Revision	**120**	**4.2**	**100.0**	**13568**	**3.4**	**100.0**
N Primary	**2870**			**393602**		

Figure 16: Cumulative Incidence Primary Total Knee Replacement by Hospital (All Diagnoses)

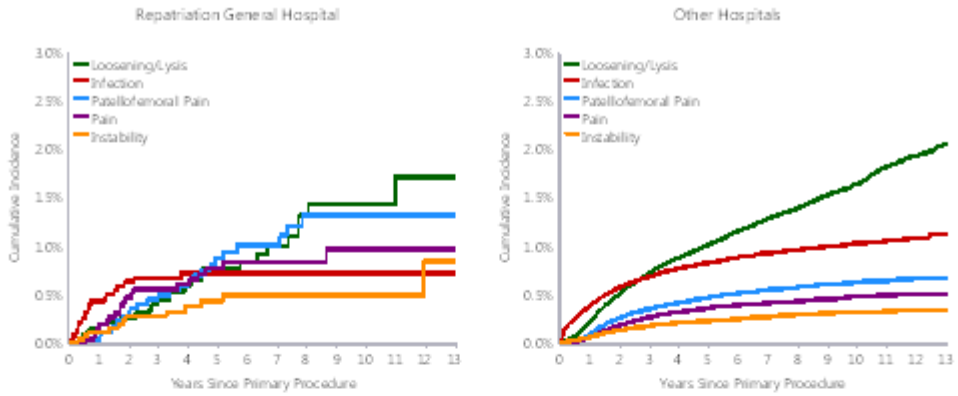


TABLE 80

Type of Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

% Primaries Revised: This shows the proportional contribution of each type of revision as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of having that type of revision. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

% Revisions: The number of revisions for each type of revision is expressed as a percentage of the total number of revisions. This shows the distribution of types of revision within a group but cannot be used as a comparison between groups.

Table 80: Type of Revision of Primary Total Knee Replacement by Hospital (All Diagnoses)

	Repatriation General Hospital			Other Hospitals		
Type of Revision	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
TKR (Tibial/Femoral)	21	0.7	17.5	3433	0.9	25.3
Patella Only	47	1.6	39.2	2842	0.7	20.9
Insert Only	13	0.5	10.8	2817	0.7	20.8
Tibial Component	9	0.3	7.5	1470	0.4	10.8
Insert/Patella	11	0.4	9.2	1220	0.3	9.0
Femoral Component	9	0.3	7.5	864	0.2	6.4
Cement Spacer	9	0.3	7.5	795	0.2	5.9
Removal of Prostheses	1	0.0	0.8	72	0.0	0.5
Minor Components				37	0.0	0.3
Reinsertion of Components				8	0.0	0.1
Cement Only				7	0.0	0.1
Total Femoral				3	0.0	0.0
N Revision	**120**	**4.2**	**100.0**	**13568**	**3.4**	**100.0**
N Primary	**2870**			**393602**		

Appendix 7

Results of Registry report 2257 on the results of Revision Knee Arthoplasty Cases

NATIONAL JOINT REPLACEMENT REGISTRY

27 July 2017

Dr C Wilson
C/- Ms M Rego
Repatriation General Hospital
216 Daws Road
DAW PARK SA 5041

Dear Dr Wilson,

Re: AOANJRR Data Request
Request ID: 2257

Further to your data request received 30 June 2017, please find attached the report.

These data are for procedures undertaken between 1 September 1999 and 30 June 2017 and notified to the AOANJRR. The AOANJRR has taken every care to ensure the data supplied are accurate.

The data released to you may only be used for the purposes outlined in the original request form. The data cannot be used for publication unless it was indicated on the form and the AOANJRR has already approved it. It is also AOA approved Policy that AOANJRR staff assist in preparing and writing the manuscript(s). Please make sure the necessary arrangements have been made before commencing preparation of a manuscript.

If you have any questions about the data or any other AOANJRR related issues please feel free to contact me.

Yours sincerely,

STEPHEN GRAVES

AUSTRALIAN ORTHOPAEDIC ASSOCIATION

NATIONAL JOINT REPLACEMENT REGISTRY

27 July 2017

Dr C Wilson
Repatriation General Hospital
216 Daws Road
DAW PARK SA 5041

Dear Dr Wilson,

Re: AOANJRR Data Request
Request ID: 2264

Further to your data request received 13 July 2017, please find attached the report.

These data are for procedures undertaken between 1 September 1999 and 31 December 2015 and notified to the AOANJRR. The AOANJRR has taken every care to ensure the data supplied are accurate.

The data released to you may only be used for the purposes outlined in the original request form. The data cannot be used for publication unless it was indicated on the form and the AOANJRR has already approved it. It is also AOA approved Policy that AOANJRR staff assist in preparing and writing the manuscript(s). Please make sure the necessary arrangements have been made before commencing preparation of a manuscript.

If you have any questions about the data or any other AOANJRR related issues please feel free to contact me.

Yours sincerely,

STEPHEN GRAVES

Australian Orthopaedic Association
National Joint Replacement Registry

AD HOC REPORT
(FORM B – DATA FOR PUBLICATION/PRESENTATION)

REQUEST ID	PRINCIPAL REQUESTER	ORGANISATION	CONTACT PERSON
2257	Chris Wilson	Repatriation General Hospital	Mariana Rego

DATE REQUEST RECEIVED:	30/6/17
DATE APPROVED FOR RELEASE:	26/7/17

DETAILS OF ANALYSIS PROVIDED

Specific Data Period:	Procedures from 1 September 1999 - 30 June 2017

Dr C Wilson provided 31 unique procedures to be matched. All of these were matched to an AOANJRR procedure.
Of the 31 procedures, 3 have been subsequently revised and 4 are now deceased. All of the subsequent revision, were performed by Dr C Wilson.

Data Use Conditions:

- The data of the AOANJRR are the intellectual property of the AOA.
- The AOANJRR is the custodian of AOANJRR data and consequently has the responsibility to ensure that the quality of the data is maintained and that it is used and interpreted appropriately.
- It is necessary for the AOANJRR to be involved in preparation and publication of a manuscript if the publication is based on analysis of AOANJRR data or a subset of that data.
- At least one clinician from the AOANJRR and the relevant statistician from SAHMRI are to be included as authors.
- The data provided may be used for presentation at the discretion of the requester however if it is to be presented at a major national or international meeting the abstract must be submitted to AOANJRR for approval at least 10 days prior to the deadline.
- The AOANJRR must be acknowledged as the source of data in any publication/presentation in which the AOANJRR is significantly involved.
- The manuscript must be approved by the AOA Academic Editorial Advisory Panel prior to submission.
- A copy of the published material must be supplied to the AOANJRR.

Approved:	Professor Stephen Graves AOANJRR Director	27/7/17

Disclaimer:	*The AOANJRR has taken every care to ensure that the data supplied are accurate but does not warrant that the data are error free and does not accept any liability for errors or omissions in the data provided.*

Appendix 8

Results of Registry report 2418 on the results of Re-Revision of Revision Knee Arthoplasty Cases

NATIONAL JOINT REPLACEMENT REGISTRY

25 January 2018

Dr Chris Wilson
Flinders Medical Centre
C/O Orthopaedic Department
Flinders Medical Centre
Flinders Drive SA 5042

Dear Chris,

Re: AOANJRR Data Request
Request ID: 2418 (follow up to 1667)

Further to your data request received 30 December 2017, please find attached the report.

These data are for procedures undertaken between 1 September 1999 and 31 December 2016 and notified to the AOANJRR. The AOANJRR has taken every care to ensure the data supplied are accurate.

The data released to you may only be used for the purposes outlined in the original request form. The data cannot be used for publication unless it was indicated on the form and the AOANJRR has already approved it. It is also AOA approved Policy that AOANJRR staff assist in preparing and writing the manuscript(s). Please make sure the necessary arrangements have been made before commencing preparation of a manuscript.

If you have any questions about the data or any other AOANJRR related issues please feel free to contact me.

Yours sincerely,

STEPHEN GRAVES

Director - Professor Stephen Graves | Deputy Directors - Richard de Steiger, Peter Lewis, Ian Harris | Manager – Cynthia Turner

AOA National Joint Replacement Registry | SAHMRI, North Terrace, Adelaide SA 5000
T +61 8 8128 4280 E cturner@aoanjrr.org.au | www.aoa.org.au

Australian Orthopaedic Association
National Joint Replacement Registry

AD HOC REPORT
(FORM B – DATA FOR PUBLICATION/PRESENTATION)

REQUEST ID	PRINCIPAL REQUESTER	ORGANISATION	CONTACT PERSON
2418	Chris Wilson	Flinders Medical Centre	Chris Wilson

DATE REQUEST RECEIVED:	30/12/2017
DATE APPROVED FOR RELEASE:	25/01/2018

DETAILS OF ANALYSIS PROVIDED

Specific Data Period :	Procedures from 1 September 1999 - 31 December 2016

Data Use Conditions:

- The data of the AOANJRR are the intellectual property of the AOA.
- The AOANJRR is the custodian of AOANJRR data and consequently has the responsibility to ensure that the quality of the data is maintained and that it is used and interpreted appropriately.
- It is necessary for the AOANJRR to be involved in preparation and publication of a manuscript if the publication is based on analysis of AOANJRR data or a subset of that data.
- At least one clinician from the AOANJRR and the relevant statistician from SAHMRI are to be included as authors.
- The data provided may be used for presentation at the discretion of the requester. However, if it is to be presented at a major national or international meeting the abstract must be submitted to AOANJRR for approval at least 10 days prior to the deadline.
- The AOANJRR must be acknowledged as the source of data in any publication/presentation in which the AOANJRR is significantly involved.
- The manuscript must be approved by the AOA Academic Editorial Advisory Panel prior to submission.
- A copy of the published material must be supplied to the AOANJRR.

Approved :	Professor Stephen Graves AOANJRR Director	DATE: 25/01/2018

Disclaimer:	*The AOANJRR has taken every care to ensure that the data supplied are accurate but does not warrant that the data are error free and does not accept any liability for errors or omissions in the data provided.*

Request 2418 - C Wilson

Table 1: Primary Diagnosis of Primary Total Knee Replacement by Hospital

Primary Diagnosis	Repatriation General Hospital		Other Hospitals	
	N	Col%	N	Col%
Osteoarthritis	3460	97.4	530742	97.6
Rheumatoid Arthritis	63	1.8	7479	1.4
Other Inflammatory Arthritis	15	0.4	2690	0.5
Osteonecrosis	11	0.3	1766	0.3
Tumour	2	0.1	671	0.1
Fracture	.	.	329	0.1
Chondrocalcinosis	1	0.0	19	0.0
Osteochondritis Dissecans	.	.	1	0.0
Other	1	0.0	157	0.0
TOTAL	**3553**	**100.0**	**543854**	**100.0**

Table 2: Revision Rates of Primary Total Knee Replacement by Hospital (All Diagnoses)

Hospital	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Repatriation General Hospital	163	3553	22266	0.73 (0.62, 0.85)
Other Hospitals	20063	543854	3116692	0.64 (0.63, 0.65)
TOTAL	**20226**	**547407**	**3138958**	**0.64 (0.64, 0.65)**

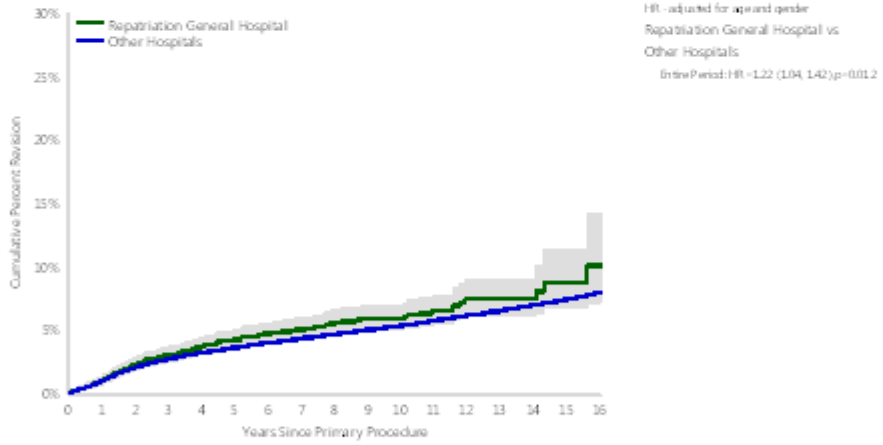
Table 3: Yearly Cumulative Percent Revision of Primary Total Knee Replacement by Hospital (All Diagnoses)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Repatriation General Hospital	1.0 (0.7, 1.4)	2.3 (1.8, 2.9)	3.0 (2.5, 3.7)	3.7 (3.1, 4.4)	4.3 (3.6, 5.1)
Other Hospitals	1.0 (1.0, 1.1)	2.1 (2.0, 2.1)	2.7 (2.7, 2.8)	3.2 (3.2, 3.3)	3.6 (3.6, 3.7)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Repatriation General Hospital	4.7 (4.0, 5.6)	5.0 (4.3, 5.9)	5.5 (4.7, 6.5)	5.9 (5.0, 6.9)	5.9 (5.0, 6.9)
Other Hospitals	4.0 (3.9, 4.1)	4.3 (4.3, 4.4)	4.7 (4.6, 4.8)	5.0 (5.0, 5.1)	5.4 (5.3, 5.4)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital	6.5 (5.5, 7.8)	7.4 (6.1, 9.0)	7.4 (6.1, 9.0)	7.4 (6.1, 9.0)	8.8 (6.7, 11.4)	10.1 (7.2, 14.2)
Other Hospitals	5.8 (5.7, 5.9)	6.2 (6.1, 6.3)	6.5 (6.4, 6.7)	7.0 (6.9, 7.1)	7.4 (7.2, 7.6)	8.0 (7.7, 8.3)

Figure 1: Cumulative Percent Revision of Primary Total Knee Replacement by Hospital (All Diagnoses)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Repatriation General Hospital	3553	3273	2928	2644	2329	2023	1736	1431
Other Hospitals	543854	482796	423582	369928	320258	273664	230026	190071

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital	1175	878	680	511	358	228	149	103	47
Other Hospitals	155076	123159	95550	71507	50512	33277	19229	8178	1907

TABLE 4

Reasons for Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

% Primaries Revised: This shows the proportional contribution of each revision diagnosis as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of being revised for that diagnosis. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

% Revisions: The number of revisions for each diagnosis is expressed as a percentage of the total number of revisions. This shows the distribution of reasons for revision within a group but cannot be used as a comparison between groups.

Table 4: Revision Diagnosis of Primary Total Knee Replacement by Hospital (All Diagnoses)

	Repatriation General Hospital			Other Hospitals		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Loosening	36	1.0	22.1	5181	1.0	25.8
Infection	24	0.7	14.7	4557	0.8	22.7
Patellofemoral Pain	29	0.8	17.8	2174	0.4	10.8
Pain	21	0.6	12.9	1702	0.3	8.5
Instability	23	0.6	14.1	1450	0.3	7.2
Patella Erosion	8	0.2	4.9	998	0.2	5.0
Arthrofibrosis	3	0.1	1.8	694	0.1	3.5
Fracture	5	0.1	3.1	574	0.1	2.9
Malalignment	2	0.1	1.2	443	0.1	2.2
Lysis	1	0.0	0.6	395	0.1	2.0
Wear Tibial Insert	1	0.0	0.6	343	0.1	1.7
Metal Related Pathology				310	0.1	1.5
Incorrect Sizing	1	0.0	0.6	244	0.0	1.2
Bearing Dislocation	1	0.0	0.6	143	0.0	0.7
Patella Maltracking	7	0.2	4.3	141	0.0	0.7
Implant Breakage Patella				103	0.0	0.5
Implant Breakage Tibial Insert				93	0.0	0.5
Synovitis				75	0.0	0.4
Prosthesis Dislocation				58	0.0	0.3
Implant Breakage Tibial				52	0.0	0.3
Osteonecrosis				47	0.0	0.2
Implant Breakage Femoral				31	0.0	0.2
Wear Patella				21	0.0	0.1
Tumour	1	0.0	0.6	16	0.0	0.1
Wear Tibial				9	0.0	0.0
Heterotopic Bone				6	0.0	0.0
Wear Femoral				3	0.0	0.0
Incorrect Side				2	0.0	0.0
Progression Of Disease				2	0.0	0.0
Patella Dislocation				1	0.0	0.0
Other				195	0.0	1.0
N Revision	**163**	**4.6**	**100.0**	**20063**	**3.7**	**100.0**
N Primary	**3553**			**543854**		

Figure 2: Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement by Hospital (All Diagnoses)

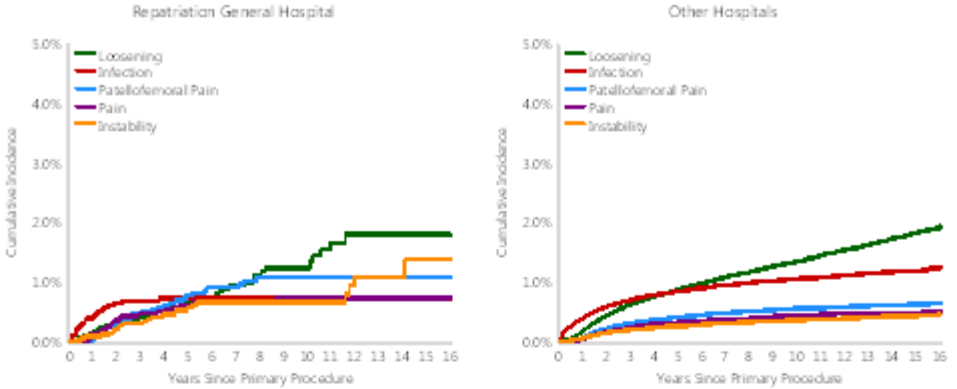


TABLE 5

Type of Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

% Primaries Revised: This shows the proportional contribution of each type of revision as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of having that type of revision. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

% Revisions: The number of revisions for each type of revision is expressed as a percentage of the total number of revisions. This shows the distribution of types of revision within a group but cannot be used as a comparison between groups.

Table 5: Type of Revision of Primary Total Knee Replacement by Hospital (All Diagnoses)

	Repatriation General Hospital			Other Hospitals		
Type of Revision	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
TKR (Tibial/Femoral)	30	0.8	18.4	5175	1.0	25.8
Insert Only	20	0.6	12.3	4350	0.8	21.7
Patella Only	58	1.6	35.6	4083	0.8	20.4
Insert/Patella	25	0.7	15.3	1993	0.4	9.9
Tibial Component	9	0.3	5.5	1949	0.4	9.7
Femoral Component	9	0.3	5.5	1184	0.2	5.9
Cement Spacer	11	0.3	6.7	1132	0.2	5.6
Removal of Prostheses	1	0.0	0.6	114	0.0	0.6
Minor Components				51	0.0	0.3
Total Femoral				12	0.0	0.1
Cement Only				11	0.0	0.1
Reinsertion of Components				9	0.0	0.0
N Revision	**163**	**4.6**	**100.0**	**20063**	**3.7**	**100.0**
N Primary	**3553**			**543854**		

Table 6: Revision Rates of Repatriation General Hospital Primary Total Knee Replacement by Components Used (All Diagnoses)

Femoral Component	Tibial Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
PFC Sigma CR	PFC Sigma	19	866	4218	0.45 (0.27, 0.70)
PFC Sigma CR	MBT	25	300	2731	0.92 (0.59, 1.35)
PFC Sigma CR	MBT Duofix	0	11	119	0.00 (0.00, 3.10)
Vanguard CR	Maxim	7	203	1067	0.66 (0.26, 1.35)
Vanguard CR	Vanguard	9	254	1427	0.63 (0.29, 1.20)
Attune CR	Attune	4	322	320	1.25 (0.34, 3.20)
Genesis II CR	Genesis II	14	218	1397	1.00 (0.55, 1.68)
Genesis II CR	Profix Mobile	1	20	129	0.78 (0.02, 4.32)
Genesis II CR	Legion	0	1	7	0.00 (0.00, 55.27)
Maxim	Maxim	16	184	1552	1.03 (0.59, 1.67)
AGC	AGC	11	154	1616	0.68 (0.34, 1.22)
Profix	Profix	9	150	1339	0.67 (0.31, 1.28)
LCS CR	MBT	2	70	506	0.40 (0.05, 1.43)
LCS CR	MBT Duofix	1	44	353	0.28 (0.01, 1.58)
LCS CR	LCS	0	3	38	0.00 (0.00, 9.71)
BalanSys	BalanSys	8	116	1187	0.67 (0.29, 1.33)
Triathlon CR	Triathlon	8	113	643	1.24 (0.54, 2.45)
Score	Score	1	68	123	0.82 (0.02, 4.54)
Genesis II PS	Genesis II	4	60	464	0.86 (0.23, 2.21)
Genesis II PS	Legion	0	2	14	0.00 (0.00, 27.30)
PFC Sigma PS	PFC Sigma	4	50	338	1.18 (0.32, 3.03)
PFC Sigma PS	MBT	1	12	110	0.91 (0.02, 5.08)
Series 7000	Series 7000	2	50	395	0.51 (0.06, 1.83)
Genesis II Oxinium PS	Genesis II	1	45	357	0.28 (0.01, 1.56)
Genesis II Oxinium PS	Legion	0	2	17	0.00 (0.00, 21.65)
Scorpio CR	Series 7000	5	44	463	1.08 (0.35, 2.52)
Nexgen CR Flex	Nexgen	0	33	311	0.00 (0.00, 1.19)
Journey Oxinium	Journey	4	32	235	1.70 (0.46, 4.36)
Nexgen LPS Flex	Nexgen	4	31	290	1.38 (0.38, 3.53)
Triathlon PS	Triathlon	0	15	132	0.00 (0.00, 2.80)
Genesis II Oxinium CR	Genesis II	0	11	69	0.00 (0.00, 5.37)
Legion CR	Genesis II	0	11	20	0.00 (0.00, 18.02)
Legion PS	Genesis II	0	9	11	0.00 (0.00, 34.65)
Attune PS	Attune	0	6	6	0.00 (0.00, 61.86)
Optetrak-CR	Optetrak	1	6	60	1.67 (0.04, 9.29)
Triathlon PS	Triathlon	0	5	16	0.00 (0.00, 23.30)
ACS	ACS Fixed	0	4	10	0.00 (0.00, 37.42)
Scorpio PS	Series 7000	0	3	34	0.00 (0.00, 10.87)
Vanguard PS	Maxim	0	3	8	0.00 (0.00, 48.33)
Duracon	Duracon	0	2	20	0.00 (0.00, 18.68)
Nexgen LCCK	Nexgen	0	2	8	0.00 (0.00, 46.00)
Profix Oxinium	Profix	0	2	18	0.00 (0.00, 20.80)
Unity Knee	Unity Knee	0	2	6	0.00 (0.00, 66.47)
Vanguard PS	Maxim	1	2	10	10.51 (0.27, 58.58)
AMK	AMK	0	1	8	0.00 (0.00, 47.69)
Coordinate	Coordinate Ultra	0	1	8	0.00 (0.00, 47.36)
Evolution	Evolution	0	1	3	0.00 (0.00, 110.9)

Femoral Component	Tibial Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
HMRS	HMRS	1	1	3	38.33 (0.97, 213.5)
Mets	Mets	0	1	1	0.00 (0.00, 355.5)
Natural Knee II	Natural Knee II	0	1	17	0.00 (0.00, 22.21)
Nexgen CR	Nexgen	0	1	16	0.00 (0.00, 23.68)
Nexgen RH	Nexgen	0	1	8	0.00 (0.00, 49.17)
Oss	Oss	0	1	6	0.00 (0.00, 59.86)
PFC Sigma FS	MBT	0	1	1	0.00 (0.00, 413.3)
Rpcc	Rpcc	0	1	4	0.00 (0.00, 99.51)
S-Rom	S-Rom	0	1	4	0.00 (0.00, 99.00)
TOTAL		**163**	**3553**	**22266**	**0.73 (0.62, 0.85)**

Table 7: Yearly Cumulative Percent Revision of Repatriation General Hospital Primary Total Knee Replacement by Components Used (All Diagnoses)

Femoral Component	Tibial Component	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
PFC Sigma CR	PFC Sigma	0.6 (0.2, 1.4)	1.3 (0.7, 2.3)	1.7 (1.0, 2.8)	2.4 (1.5, 3.8)	2.4 (1.5, 3.8)
PFC Sigma CR	MBT	2.0 (0.9, 4.4)	3.4 (1.8, 6.2)	4.8 (2.9, 7.9)	6.9 (4.5, 10.5)	8.4 (5.7, 12.2)
Vanguard CR	Maxim	1.5 (0.5, 4.5)	2.5 (1.1, 5.9)	2.5 (1.1, 5.9)	3.1 (1.4, 6.7)	3.1 (1.4, 6.7)
Vanguard CR	Vanguard	0.4 (0.1, 2.8)	2.0 (0.8, 4.7)	2.0 (0.8, 4.7)	2.4 (1.1, 5.3)	2.9 (1.4, 6.0)
Attune CR	Attune	1.0 (0.3, 3.2)				
Genesis II CR	Genesis II	0.9 (0.2, 3.6)	1.9 (0.7, 4.9)	3.4 (1.6, 7.1)	4.1 (2.0, 8.0)	5.6 (3.0, 10.2)
Maxim	Maxim	2.2 (0.8, 5.7)	4.4 (2.2, 8.7)	4.4 (2.2, 8.7)	4.4 (2.2, 8.7)	5.7 (3.1, 10.4)
AGC	AGC	0.6 (0.1, 4.5)	1.3 (0.3, 5.2)	2.7 (1.0, 7.0)	2.7 (1.0, 7.0)	3.4 (1.4, 8.0)
Profix	Profix	1.3 (0.3, 5.2)	2.0 (0.7, 6.1)	2.7 (1.0, 7.1)	4.1 (1.9, 9.0)	4.9 (2.4, 10.0)
LCS CR	MBT	0.0 (0.0, 0.0)	2.9 (0.7, 11.3)	2.9 (0.7, 11.3)	2.9 (0.7, 11.3)	2.9 (0.7, 11.3)
LCS CR	MBT Duofix	0.0 (0.0, 0.0)	2.4 (0.3, 15.7)	2.4 (0.3, 15.7)	2.4 (0.3, 15.7)	2.4 (0.3, 15.7)
BalanSys	BalanSys	0.0 (0.0, 0.0)	1.8 (0.4, 6.8)	2.6 (0.9, 8.0)	2.6 (0.9, 8.0)	4.5 (1.9, 10.5)
Triathlon CR	Triathlon	0.9 (0.1, 6.2)	3.0 (1.0, 9.0)	6.6 (3.0, 14.2)	6.6 (3.0, 14.2)	6.6 (3.0, 14.2)
Score	Score	1.7 (0.2, 11.4)	1.7 (0.2, 11.4)	1.7 (0.2, 11.4)		
Genesis II PS	Genesis II	1.7 (0.2, 11.2)	3.3 (0.8, 12.7)	5.1 (1.7, 14.9)	6.8 (2.6, 17.1)	6.8 (2.6, 17.1)
PFC Sigma PS	PFC Sigma	2.0 (0.3, 13.6)	6.2 (2.0, 18.0)	8.4 (3.2, 20.8)	8.4 (3.2, 20.8)	8.4 (3.2, 20.8)
Series 7000	Series 7000	2.0 (0.3, 13.6)	2.0 (0.3, 13.6)	2.0 (0.3, 13.6)	2.0 (0.3, 13.6)	2.0 (0.3, 13.6)
Genesis II Oxinium PS	Genesis II	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Scorpio CR	Series 7000	0.0 (0.0, 0.0)	2.4 (0.3, 16.1)	4.9 (1.2, 18.1)	4.9 (1.2, 18.1)	4.9 (1.2, 18.1)
Other (37)		0.4 (0.1, 3.0)	3.2 (1.5, 6.6)	4.2 (2.2, 7.9)	4.7 (2.5, 8.6)	4.7 (2.5, 8.6)

Femoral Component	Tibial Component	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
PFC Sigma CR	PFC Sigma	2.4 (1.5, 3.8)	2.4 (1.5, 3.8)	3.2 (1.7, 6.0)	3.2 (1.7, 6.0)	3.2 (1.7, 6.0)
PFC Sigma CR	MBT	8.4 (5.7, 12.2)	8.4 (5.7, 12.2)	8.8 (6.0, 12.7)	8.8 (6.0, 12.7)	8.8 (6.0, 12.7)
Vanguard CR	Maxim	3.1 (1.4, 6.7)				
Vanguard CR	Vanguard	2.9 (1.4, 6.0)	5.1 (2.5, 10.5)			
Attune CR	Attune					
Genesis II CR	Genesis II	7.9 (4.6, 13.4)	7.9 (4.6, 13.4)	7.9 (4.6, 13.4)	7.9 (4.6, 13.4)	
Maxim	Maxim	7.1 (4.1, 12.2)	7.1 (4.1, 12.2)	7.8 (4.6, 13.2)	7.8 (4.6, 13.2)	7.8 (4.6, 13.2)
AGC	AGC	4.2 (1.9, 9.1)	4.2 (1.9, 9.1)	5.2 (2.5, 10.6)	6.1 (3.1, 12.0)	6.1 (3.1, 12.0)
Profix	Profix	4.9 (2.4, 10.0)	5.7 (2.9, 11.1)	5.7 (2.9, 11.1)	5.7 (2.9, 11.1)	5.7 (2.9, 11.1)
LCS CR	MBT	2.9 (0.7, 11.3)	2.9 (0.7, 11.3)	2.9 (0.7, 11.3)	2.9 (0.7, 11.3)	
LCS CR	MBT Duofix	2.4 (0.3, 15.7)	2.4 (0.3, 15.7)	2.4 (0.3, 15.7)	2.4 (0.3, 15.7)	
BalanSys	BalanSys	4.5 (1.9, 10.5)	5.6 (2.5, 12.0)	5.6 (2.5, 12.0)	6.8 (3.3, 13.8)	6.8 (3.3, 13.8)
Triathlon CR	Triathlon	6.6 (3.0, 14.2)	8.1 (3.9, 16.4)	8.1 (3.9, 16.4)		
Score	Score					
Genesis II PS	Genesis II	6.8 (2.6, 17.1)	6.8 (2.6, 17.1)	6.8 (2.6, 17.1)	6.8 (2.6, 17.1)	6.8 (2.6, 17.1)
PFC Sigma PS	PFC Sigma	8.4 (3.2, 20.8)	8.4 (3.2, 20.8)	8.4 (3.2, 20.8)	8.4 (3.2, 20.8)	8.4 (3.2, 20.8)
Series 7000	Series 7000	2.0 (0.3, 13.6)	2.0 (0.3, 13.6)	6.0 (1.4, 23.2)	6.0 (1.4, 23.2)	6.0 (1.4, 23.2)
Genesis II Oxinium PS	Genesis II	2.6 (0.4, 16.8)	2.6 (0.4, 16.8)	2.6 (0.4, 16.8)	2.6 (0.4, 16.8)	2.6 (0.4, 16.8)
Scorpio CR	Series 7000	7.4 (2.4, 21.2)	7.4 (2.4, 21.2)	10.0 (3.9, 24.4)	10.0 (3.9, 24.4)	10.0 (3.9, 24.4)
Other (37)		5.3 (2.9, 9.3)	5.3 (2.9, 9.3)	5.3 (2.9, 9.3)	6.1 (3.5, 10.7)	6.1 (3.5, 10.7)

Femoral Component	Tibial Component	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
PFC Sigma CR	PFC Sigma						
PFC Sigma CR	MBT	8.8 (6.0, 12.7)	8.8 (6.0, 12.7)	8.8 (6.0, 12.7)			
Vanguard CR	Maxim						
Vanguard CR	Vanguard						
Attune CR	Attune						
Genesis II CR	Genesis II						
Maxim	Maxim	10.2 (6.1, 16.8)					
AGC	AGC	6.1 (3.1, 12.0)	7.4 (3.8, 14.0)	7.4 (3.8, 14.0)	7.4 (3.8, 14.0)	9.1 (4.8, 17.0)	
Profix	Profix	5.7 (2.9, 11.1)					
LCS CR	MBT						
LCS CR	MBT Duofix						
BalanSys	BalanSys	8.2 (4.1, 15.8)	8.2 (4.1, 15.8)				
Triathlon CR	Triathlon						
Score	Score						
Genesis II PS	Genesis II						
PFC Sigma PS	PFC Sigma						
Series 7000	Series 7000	6.0 (1.4, 23.2)	6.0 (1.4, 23.2)	6.0 (1.4, 23.2)	6.0 (1.4, 23.2)	6.0 (1.4, 23.2)	
Genesis II Oxinium PS	Genesis II						
Scorpio CR	Series 7000	10.0 (3.9, 24.4)	14.0 (5.9, 31.3)	14.0 (5.9, 31.3)	14.0 (5.9, 31.3)	14.0 (5.9, 31.3)	
Other (37)		7.7 (4.2, 13.7)					

Note: Only combinations with 40 or more procedures have been listed

Table 8: Revision Rates of PFC Sigma CR/PFC Sigma Primary Total Knee Replacement by Hospital (All Diagnoses)

Hospital	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Repatriation General Hospital	19	866	4218	0.45 (0.27, 0.70)
Other Hospitals	594	22222	140723	0.42 (0.39, 0.46)
TOTAL	**613**	**23088**	**144941**	**0.42 (0.39, 0.46)**

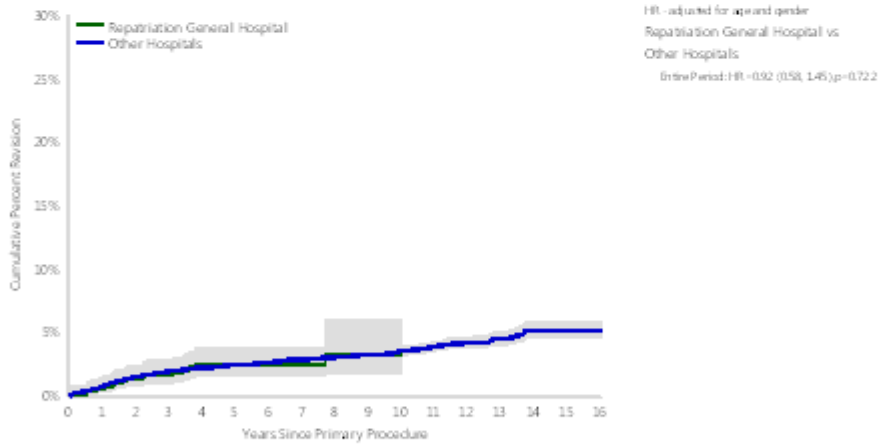
Table 9: Yearly Cumulative Percent Revision of PFC Sigma CR/PFC Sigma Primary Total Knee Replacement by Hospital (All Diagnoses)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Repatriation General Hospital	0.6 (0.2, 1.4)	1.3 (0.7, 2.3)	1.7 (1.0, 2.8)	2.4 (1.5, 3.8)	2.4 (1.5, 3.8)
Other Hospitals	0.7 (0.6, 0.9)	1.5 (1.3, 1.7)	1.9 (1.7, 2.1)	2.2 (2.0, 2.4)	2.4 (2.2, 2.6)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Repatriation General Hospital	2.4 (1.5, 3.8)	2.4 (1.5, 3.8)	3.2 (1.7, 6.0)	3.2 (1.7, 6.0)	3.2 (1.7, 6.0)
Other Hospitals	2.6 (2.4, 2.9)	2.8 (2.6, 3.1)	3.0 (2.7, 3.3)	3.2 (2.9, 3.5)	3.5 (3.2, 3.8)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital						
Other Hospitals	3.8 (3.5, 4.2)	4.2 (3.8, 4.6)	4.5 (4.0, 5.0)	5.1 (4.5, 5.9)	5.1 (4.5, 5.9)	5.1 (4.5, 5.9)

Figure 3: Cumulative Percent Revision of PFC Sigma CR/PFC Sigma Primary Total Knee Replacement by Hospital (All Diagnoses)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Repatriation General Hospital	866	844	792	640	491	360	260	170
Other Hospitals	22222	20878	19413	17391	15113	12761	10601	8576

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital	94	48	46	17	4	4	4	4	2
Other Hospitals	6990	5684	4451	3196	2118	1335	783	323	82

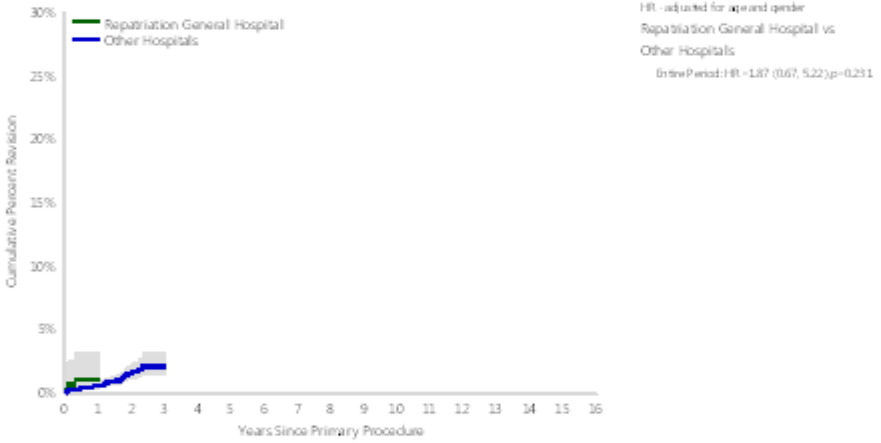
Table 10: Revision Rates of Attune CR/Attune Primary Total Knee Replacement by Hospital (All Diagnoses)

Hospital	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Repatriation General Hospital	4	322	320	1.25 (0.34, 3.20)
Other Hospitals	45	5370	6490	0.69 (0.51, 0.93)
TOTAL	**49**	**5692**	**6810**	**0.72 (0.53, 0.95)**

Table 11: Yearly Cumulative Percent Revision of Attune CR/Attune Primary Total Knee Replacement by Hospital (All Diagnoses)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Repatriation General Hospital	1.0 (0.3, 3.2)				
Other Hospitals	0.6 (0.4, 0.9)	1.5 (1.1, 2.2)	2.1 (1.4, 3.1)		

Figure 4: Cumulative Percent Revision of Attune CR/Attune Primary Total Knee Replacement by Hospital (All Diagnoses)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Repatriation General Hospital	322	155	33	0	0	0	0	0
Other Hospitals	5370	3028	933	80	0	0	0	0

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital	0	0	0	0	0	0	0	0	0
Other Hospitals	0	0	0	0	0	0	0	0	0

Table 12: Revision Rates of PFC Sigma CR/MBT Primary Total Knee Replacement by Hospital (All Diagnoses)

Hospital	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Repatriation General Hospital	25	300	2731	0.92 (0.59, 1.35)
Other Hospitals	235	5518	39392	0.60 (0.52, 0.68)
TOTAL	**260**	**5818**	**42123**	**0.62 (0.54, 0.70)**

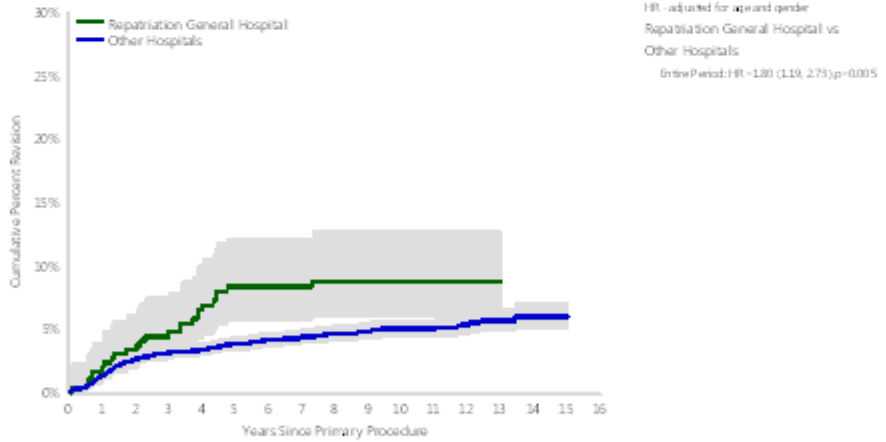
Table 13: Yearly Cumulative Percent Revision of PFC Sigma CR/MBT Primary Total Knee Replacement by Hospital (All Diagnoses)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Repatriation General Hospital	2.0 (0.9, 4.4)	3.4 (1.8, 6.2)	4.8 (2.9, 7.9)	6.9 (4.5, 10.5)	8.4 (5.7, 12.2)
Other Hospitals	1.3 (1.1, 1.7)	2.7 (2.3, 3.1)	3.1 (2.7, 3.6)	3.4 (3.0, 4.0)	3.8 (3.3, 4.4)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Repatriation General Hospital	8.4 (5.7, 12.2)	8.4 (5.7, 12.2)	8.8 (6.0, 12.7)	8.8 (6.0, 12.7)	8.8 (6.0, 12.7)
Other Hospitals	4.2 (3.6, 4.8)	4.4 (3.8, 5.0)	4.6 (4.1, 5.3)	4.8 (4.2, 5.5)	5.0 (4.4, 5.7)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital	8.8 (6.0, 12.7)	8.8 (6.0, 12.7)	8.8 (6.0, 12.7)			
Other Hospitals	5.1 (4.5, 5.8)	5.4 (4.6, 6.2)	5.7 (4.9, 6.6)	6.0 (5.0, 7.1)	6.0 (5.0, 7.1)	

Figure 5: Cumulative Percent Revision of PFC Sigma CR/MBT Primary Total Knee Replacement by Hospital (All Diagnoses)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Repatriation General Hospital	300	289	280	275	260	246	235	219
Other Hospitals	5518	5239	4951	4666	4202	3675	3243	2854

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital	205	174	142	107	73	46	23	11	0
Other Hospitals	2410	1785	1293	949	653	408	221	91	0

Revision of Primary Total Knee Replacement performed at Repatriation General Hospital

Table 14: Revision Rates of 1st Revision of Primary Total Knee Replacement by Primary Hospital (All Diagnoses, Excluding 1st Revision for Infection)

Hospital	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Repatriation General Hospital	20	139	678	2.95 (1.80, 4.56)
Other Hospitals	2241	15506	70072	3.20 (3.07, 3.33)
TOTAL	**2261**	**15645**	**70750**	**3.20 (3.07, 3.33)**

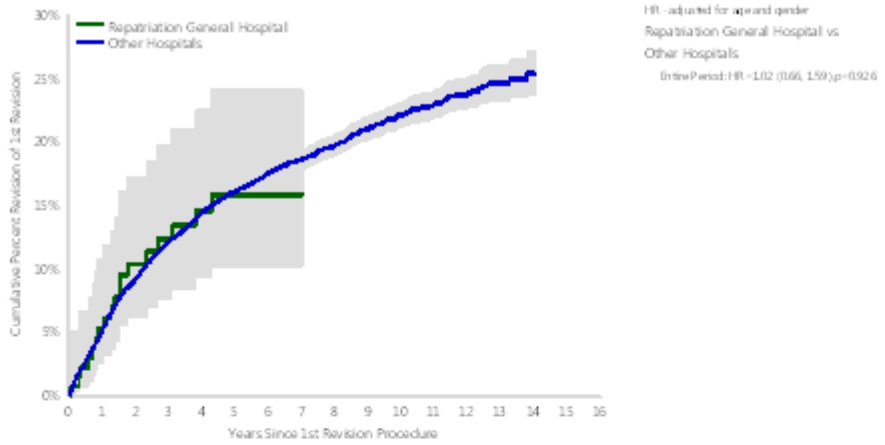
Table 15: Yearly Cumulative Percent Revision of 1st Revision of Primary Total Knee Replacement by Primary Hospital (All Diagnoses, Excluding 1st Revision for Infection)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Repatriation General Hospital	5.3 (2.6, 10.8)	10.4 (6.1, 17.2)	12.4 (7.6, 19.7)	14.6 (9.3, 22.5)	15.8 (10.2, 24.2)
Other Hospitals	5.2 (4.9, 5.6)	9.3 (8.8, 9.8)	12.1 (11.6, 12.7)	14.4 (13.8, 15.1)	16.1 (15.4, 16.8)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Repatriation General Hospital	15.8 (10.2, 24.2)	15.8 (10.2, 24.2)			
Other Hospitals	17.5 (16.8, 18.3)	18.6 (17.9, 19.4)	19.8 (19.0, 20.6)	21.0 (20.1, 21.9)	22.1 (21.1, 23.1)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital						
Other Hospitals	23.1 (22.0, 24.2)	23.8 (22.7, 25.1)	24.6 (23.3, 26.1)	25.4 (23.7, 27.2)		

Figure 6: Cumulative Percent Revision of 1st Revision of Primary Total Knee Replacement by Primary Hospital (All Diagnoses, Excluding 1st Revision for Infection)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Repatriation General Hospital	139	117	96	84	71	59	49	43
Other Hospitals	15506	13022	10847	9017	7387	5948	4611	3541

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Repatriation General Hospital	35	20	14	10	7	4	0	0	0
Other Hospitals	2729	2008	1408	930	592	295	127	30	6

Table 16: 2nd Revision Diagnosis of Primary Total Knee Replacement by Primary Hospital (All Diagnoses, Excluding 1st Revision for Infection)

	Repatriation General Hospital		Other Hospitals	
2nd Revision Diagnosis	N	Col%	N	Col%
Loosening	5	25.0	782	34.9
Infection	5	25.0	587	26.2
Instability	4	20.0	205	9.2
Pain	.	.	185	8.3
Arthrofibrosis	.	.	81	3.6
Malalignment	1	5.0	61	2.7
Patellofemoral Pain	1	5.0	43	1.9
Lysis	.	.	40	1.8
Metal Related Pathology	.	.	34	1.5
Wear Tibial Insert	3	15.0	28	1.3
Fracture	.	.	31	1.4
Prosthesis Dislocation	.	.	23	1.0
Incorrect Sizing	.	.	23	1.0
Bearing Dislocation	.	.	18	0.8
Patella Maltracking	.	.	17	0.8
Patella Erosion	.	.	14	0.6
Implant Breakage Femoral	.	.	10	0.4
Implant Breakage Patella	.	.	9	0.4
Implant Breakage Tibial Insert	.	.	8	0.4
Implant Breakage Tibial	.	.	8	0.4
Synovitis	1	5.0	6	0.3
Wear Patella	.	.	3	0.1
Heterotopic Bone	.	.	3	0.1
Wear Tibial	.	.	2	0.1
Osteonecrosis	.	.	2	0.1
Wear Femoral	.	.	1	0.0
Other	.	.	15	0.7
TOTAL	**20**	**100.0**	**2239**	**100.0**

Table 17: Type of 2nd Revision of Primary Total Knee Replacement by Primary Hospital (All Diagnoses, Excluding 1st Revision for Infection)

	Repatriation General Hospital		Other Hospitals	
Type of 2nd Revision	N	Col%	N	Col%
TKR (Tibial/Femoral)	6	30.0	1014	45.3
Insert Only	6	30.0	406	18.1
Cement Spacer	3	15.0	190	8.5
Tibial Component	2	10.0	184	8.2
Patella Only	2	10.0	173	7.7
Femoral Component	1	5.0	172	7.7
Insert/Patella	.	.	66	2.9
Removal of Prostheses	.	.	20	0.9
Minor Components	.	.	12	0.5
Unclassified - No components	.	.	1	0.0
Cement Only	.	.	1	0.0
TOTAL	**20**	**100.0**	**2239**	**100.0**

Appendix 9

Permission from Stryker for use of Trathlon Knee images

Fwd: request from Dr Chris Wilson - for use of Stryker material for Phd

BC

Blizzard, Cameron
Fri 13/05/2016 01:34
To: Mr Chris Wilson (chriswilson42@hotmail.com)

Reply

You replied on 07/06/2016 22:29.

Hi Chris,
Please see below.

Green light!!!!

Would you like me to email you the design rationale, and the surgical protocol?

Cameron Blizzard
Stryker Orthopaedics
0424 006 016
Sent from my iPhone

Begin forwarded message:

From: "Millard, Natascha" <natascha.millard@stryker.com>
Date: 13 May 2016 at 9:06:02 AM ACST
To: "Blizzard, Cameron" <cameron.blizzard@stryker.com>
Subject: FW: request from Dr Chris Wilson - for use of Stryker material for Phd

Hi Cameron,

This is what I had sent Chris. I was awaiting answered to the below.

If he just wants to reference publically available information, that's fine he can do that without our permission as long as he references appropriately.

If he just wants to reference publically available information, that's fine he can do that without our permission as long as he references appropriately.

Let me know if there is more I can do here?

Thanks,
Natascha

From: Millard, Natascha
Sent: Tuesday, 15 March 2016 9:12 PM
To: 'chris' <chriswilson42@hotmail.com>
Subject: RE: request from Dr Chris Wilson - for use of Stryker material for Phd

Hi Dr Wilson,

Apologies for my delayed reply.

If I understand correctly you are just seeking a copy of our surgical protocol for Triathlon? Do you have any specific additional questions?

If it is just the surgical protocol I will source this and send through. If there are more detailed questions, I will be able to send these through to our head of research at our manufacturing division, however I will need further information about the use of the information i.e. an outline of your research question and objectives.

Thanks in advance for this further clarification,
Kind regards,
Natascha

Natascha Millard
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F: +61 2 9467 1010
M: +61 412 216 446
natascha.millard@stryker.com

Appendix 10

Permission from AOANJRR to use figures and tablesin this thesis

Hi Chris,

I checked with the AOANJRR Directors and they have approved your request to use the figures for your chapter. They do not need to review your chapter. You may need to seek ethics permission/advice from Southern Adelaide Health Service's Orthopaedic Group if you haven't done so already.

Please note the Registry requirements for referencing data:

- Tables and figures must be reproduced in full and unaltered from the AOANJRR publication.
- References to the Registry must be correct.

I have attached the email to Geraldine Wong outlining the data reproduction requirements with regards to her paper which may be of assistance.
Let me know if there's anything further I can help you with.

Best wishes,
Sophie

Dr Sophie Rainbird
Research Coordinator
Australian Orthopaedic Association National Joint Replacement Registry

Location:
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Appendix 11

Reprints of Publications arising from this thesis

Contents lists available at ScienceDirect

The Knee

Knee instability as the primary cause of failure following Total Knee Arthroplasty (TKA): A systematic review on the patient, surgical and implant characteristics of revised TKA patients

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ABSTRACT

Background: The aim of this review was to systematically assess the current evidence available regarding knee instability after TKA to identify time to failure between primary and revision TKA. In addition, we considered the patient, surgical and implant characteristics of primary TKA patients revised for knee instability, and investigated methods used for knee instability diagnosis.

Methods: A systematic search of six databases and the unpublished literature was performed. Studies referring to instability in post-operative primary TKA patients, reporting on revision TKA due to instability, and published or available between 2005 to 30-Mar-2015 were eligible for inclusion. Quantitative data for continuous variables were pooled in statistical meta-analyses.

Results: A total of 1841 unique studies were identified, 42 of which met the selection criteria and a total of 22 studies included in the review. Time to failure between primary and revision TKA was 44.7 months (95% CI [33.8, 55.7]), and the weighted mean age at time of revision surgery was 67.6 years (95% CI [65.38, 69.75]). A gender distribution was identified, with approximately 16.4% more females revised for instability, however this was unable to be corrected for the baseline population. The majority of studies used a combination of radiographic and clinical testing to diagnose knee instability.

Conclusion: Research on knee instability following primary TKA reported early failure and subsequent revision knee surgery. The need for revision due to instability was frequently reported in a younger patient cohort and most commonly in female TKA patients. Early revision at a younger age highlights the severe implications of an unstable knee.

1. Introduction

Revision Total Knee Arthroplasty (TKA) is a significant undertaking for patients with both higher morbidity and mortality in comparison to primary TKA [1]. In recent years, there has been an increase in patients reporting symptoms relating to knee instability; similarly, the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) has reported rising rates of revision for knee instability. In the 2008 AOANJRR report, instability was identified as the ninth most common reason

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for all revisions, at 2.9% [2]. In 2011, this increased to the seventh most common cause, at 3.4% [3], and more recently, the sixth most common reason for revision at 3.9% [4]. It is unclear whether this trend is due to an increasing incidence, or an increased awareness of the diagnosis. Recent work has also debated whether these failures are related to surgical techniques or knee implant design, with the issue remaining unclear [5].

Instability can arise from component loosening, component breakage, polyethylene wear, ligamentous instability or surgical error in relation to implant size or balancing of the knee [6]. In addition, some implant designs have features that predispose to development of 'mid flexion instability' where the ligaments appear balanced at 0° and 90° of flexion but become lax in the mid-range [7]. These patients can experience significant symptoms climbing steps or rising from a chair.

Discussion around clinical cases and presentations within the Arthroplasty Society of Australia has suggested that there is a growing awareness of instability as a mode of implant failure amongst surgeons. In addition to patients who are developing mid flexion instability, there may be a subgroup developing a form of 'acquired instability' after initially successful, knee arthroplasty surgery. With the limited evidence available, it is assumed that this is due to ligamentous failure months or years after the knee arthroplasty procedure. While other common modes of failure such as aseptic loosening and prosthetic infection have been studied extensively, there is a lack of evidence in relation to instability as a mechanism of failure.

A number of definitions of knee instability exist in the literature. Instability may refer to the whole knee or may be used interchangeably with the term 'loosening', which more appropriately refers to a specific component and its fixation to the bone. In addition, symptoms that present and appear to be caused by instability may also be due to a number of other factors including patellofemoral articulation, muscular weakness, component loosening, and infection [8].

With instability increasing as a cause of revision TKA, a clear understanding of the factors contributing to instability and subsequent revision is imperative. Recent AOANJRR figures consistently confirm that revision surgery not only reports higher rates of complication, but also poses a greater risk for further surgery. Such evidence highlights the need to enhance our understanding of how to achieve the optimal outcome at the primary procedure, and reduce the patient's risk of entering a descending spiral of multiple surgeries.

An assessment of an unstable knee has been recently described by Petrie and Haidukewych [9] and Cottino and others [10]. The use of clinical and radiological assessment is considered in these papers to obtain the correct diagnosis. A combination of both assessments is required to accurately confirm the diagnosis of instability and to exclude other diagnoses, which may elicit a different treatment approach. In the present review we assessed whether the orthopaedic literature supported this recommendation, and considered how the results available could enhance our understanding of these diagnostic issues in clinical practice.

1.1. Time to failure

The AOANJRR data suggests that a significant proportion of knees that fail and require revision surgery do so at an early stage [4]. TKA implants are expected to last more than 10 years in the majority of cases, however most failures occur before this time [4]. The most common reasons for early revision were infection, instability and periprosthetic fracture. The AOANJRR is a powerful source of Australian data, providing yearly cumulative percentage revision rates in consideration of various factors, such as implant type. The present review explored the international literature on knee instability to investigate time to failure following primary TKA. Time to failure is an essential factor in our understanding of an unstable knee, as patients with early knee failure are at greater risk of higher complication rates and re-revision surgery prematurely in their surgical journey.

1.2. Patient characteristics

Failure of primary knee arthroplasty has been more commonly reported in a younger patient cohort of ≤70 years of age [4]. A younger cohort is consequently more likely to require further surgery over time, emphasising the need for further investigation of specific modes of failure. Evidence on patient characteristics such as age, gender and Body Mass Index (BMI) were investigated in this review to screen for potential correlation between patient characteristics and instability failure.

1.3. Surgical technique

Chang et al. [11] described that prevention of knee instability through the use of appropriate prostheses and technique was paramount. Although current interest in the orthopaedic community is focused on failures of specific implants, Chang et al. [11] emphasised the importance of surgical technique and appropriate intraoperative gap balancing, over implant use, when attempting to reduce risk of failure. Given current evidence, this review considered literature on both surgical technique and implant type, to determine their influence of knee instability and TKA failure.

The aim of this review was to systematically assess the current evidence available regarding knee instability after TKA to identify the patient, surgical and implant characteristics of primary TKA patients revised for knee instability.

More specifically, the primary objectives were *to consider literature that describes knee instability as the primary cause of failure of primary TKA to determine*:

1. *time to failure between primary TKA and revision TKA*;
2. *patient characteristics, surgical technique or implant type used in patients revised due to knee instability*.

The secondary objective was to *identify the methods of diagnosis of knee instability*.

2. Materials and methods

The Cochrane Library and PROSPERO were screened for published protocols or reviews related to the topic of interest, of which none were identified. Our review was then registered online with PROSPERO (Registration Number CRD42015019898) to prevent duplication of work by other centres. The review was performed on the basis of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [12].

2.1. Search strategy

We conducted a sensitive and comprehensive search for published and unpublished studies relevant to the review question. Searches were restricted to studies published in English within the past 10 years.

Orthopaedic implant companies regularly update and modify their implants as advances in design and engineering lead to improvements in results and quality. Following an initial screen of the literature it was apparent that older articles referred to knee implants no longer in use in the current market. Furthermore, surgical techniques have developed significantly over the last 10 years compared to previous methods. As a result it was essential to impose a search date limit to ensure studies identified and reviewed would be relevant to current clinical practice.

Before developing the final search strategy, a preliminary scoping search of Ovid Medline was conducted to identify relevant Medical Subject Headings (MeSH) and a wide range of synonymous text-words. A detailed, sensitive search strategy was then developed in this database before accurate translation for other databases. These databases were: *PubMed; Cochrane Database of Systematic Reviews, Central Register of Controlled Trials, EMBASE* (*OvidSP*), *CINAHL, Scopus*, and *Web of Science*. A database search strategy is available in Appendix A.

A simplified version of the database search strategy was used to find unpublished ('grey') literature. This search included web search engines Google (Advanced) and Google Scholar (Advanced), clinical trial registries, major theses catalogues, grey literature repositories (e.g. Open-Grey), and the websites of significant conferences and organisations.

Authors endeavoured to contact authors wherever additional data or clarification was required.

2.2. Eligibility/selection criteria

Systematic search results were merged in the reference management software program (EndNote X7, Thomson Reuters, New York, USA), and duplicate articles removed. Titles and abstracts were screened for eligibility based on the inclusion and exclusion selection criteria by a single author. Full-text articles were then retrieved for titles and abstracts that were deemed relevant, or where eligibility was unclear. Eligibility of the full-text articles was reviewed by two authors independently, and any disagreement between authors was further deliberated until consensus was reached.

Articles were selected in accordance with the following inclusion criteria: (1) Any articles referring to instability in post-operative primary TKA patients; (2) Articles reporting on revision TKA due to instability; (3) Articles published or available between 2005 to 30th March 2015.

Articles were excluded in accordance with the following exclusion criteria: (1) The term 'instability' was identified by review authors to define other pathologies such as aseptic implant loosening or loosening/dislocation failure of mobile bearing knees; (2) Articles reported on atypical knee implants (i.e. Unicompartmental or Partial Knee Arthroplasties); (3) Articles described historical implants no longer in use in Australia or globally; (4) Articles which refer to revision of components previously revised; (5) No data relevant to knee instability as a cause of revision in title or abstract.

2.3. Critical appraisal

The Methodological Index for Non-Randomised Studies (MINORS) instrument was used to assess the methodological quality and risk of bias of non-randomised surgical studies included in the review. MINORS is a validated, 12 – item critical appraisal tool for assessment of quality of comparative or non-comparative non-randomised surgical studies [13]. Items are scored as *0* (*not reported*), *1* (*reported but inadequate*) and *2* (*reported and adequate*), with an ideal score of 16 for non-comparative and 24 for comparative studies [13]. Case reports were not critically appraised.

2.4. Data extraction

Two authors independently extracted the data from all eligible studies. Data extraction was piloted on three studies before use independently. Data extracted included *age, gender, BMI, primary implant design and surgical technique, time to revision, revision type and prosthesis, diagnostic testing for instability, cause for instability* (*traumatic or non-traumatic*), *instability type* (*chronic or acute*) *and reported dislocation.*

Disparities in data extraction were discussed, reviewed and resolved.

2.5. Data analysis

Quantitative data for continuous variables including *time to failure* and *age* were pooled in a statistical meta-analysis using the Comprehensive Meta Analysis (Version 3.3.070). Effect sizes were expressed as weighted mean differences with 95% confidence intervals, and a random effects model was used. As included studies reported mean *time to revision* with the variance measure of range, ranges were converted to standard deviations to allow for meta-analysis calculation, using, "Standard Deviation Estimator" implemented in PASS 14 Power Analysis and Sample Size Software (2015) [14]. A patient-level weighted mean was calculated for the remaining continuous variable, BMI. Dichotomous data was analysed descriptively using percentages and ratio.

3. Results

3.1. Systematic search

The database and grey literature searches identified a total of 1841 unique studies. Following initial abstract screening, 252 studies were retrieved for full-text assessment, of which 42 met the selection criteria. A number of included studies did not report sufficient information relevant to the primary objective of this review. As such, corresponding authors or institutions of 25 selected studies were attempted to be contacted for further data. Despite efforts, the authors of three studies were uncontactable. Data was deemed unattainable if a response was not received within six weeks following initial contact, and 17 studies were consequently withdrawn. A total of 22 studies were included in the qualitative synthesis, a breakdown of study selection can be found in Figure 1 [15–36]. A description of the characteristics of included studies is also provided in Table 1.

3.2. Methodological quality of included studies

Studies were assessed for quality; however, there was no quality restrictions imposed for inclusion in the review. The majority of the 22 studies included were of a case series study design (15) and a retrospective nature (19). Further study designs included a single case–control study (one), retrospective comparative studies (two) and case reports (four).

For the 15 non-comparative studies the MINORS mean score was 8.2 (Min–Max: six to 12, out of 16) and 13.7 (Min–Max: 10–18, out of 24) for the three comparative studies.

3.3. Time to failure

Time to failure between primary TKA and revision TKA was described in 16 of the 22 included studies, of which reported on a total of 374 knees revised for instability. Of these 16 studies, five were unable to be included in the meta-analysis as four were case reports and one did not report a time to failure range. The remaining 11 studies reported on a total of 218 knees, and demonstrated a weighted mean time to failure of 44.7 months (95% CI [33.8, 55.7]) (Figure 2).

3.4. Patient characteristics

Of the 22 studies included, 19 reported a gender distribution, with approximately 16.4% more females revised for instability than males (Table 2). It must be noted that some studies reported the number of knees revised for instability and the gender distribution, without specifying the gender of bilateral patients, causing a discrepancy between the total number of knees and total number of males and females reported in this review. Furthermore, gender distribution was unable to be corrected for baseline populations, most commonly due to the design of included studies. Of the 19 studies, nine used revision for knee instability as a study inclusion criterion, and consequently, no data on the gender ratio of the primary TKA cohort was reported. Four studies solely considered a revised TKA study cohort, and a further four were of case report study designs. A mere two studies reported the gender ratio of the primary TKA cohort from which the revised instability subgroup was collected, of which the vast majority were female (88.8%).

The mean age at time of revision surgery was reported in 16 of 22 included studies. Of these 16, two were unable to be included in the meta-analysis as they were of a case report study design. The remaining 14 studies reported on a total of 378 knees, and demonstrated a mean age of 67.6 years at time of revision surgery (95% CI [65.38, 69.75]) (Table 2). A total of 88 revised knees reported BMI, with only one patient identified with a BMI ≥ 40 kg/m^2. The patient-level weighted mean BMI was 30.4 kg/m^2 (Min–Max: 19–61), however range was not reported for 1 study included in the calculation of the weighted mean.

3.5. Surgical technique and implant type

3.5.1. Primary TKA

Osteoarthritis was the principle indication leading to primary TKA in patients that later required revision for instability. The conventional surgical technique was the main technique employed for the primary TKA; however, this was only reported in

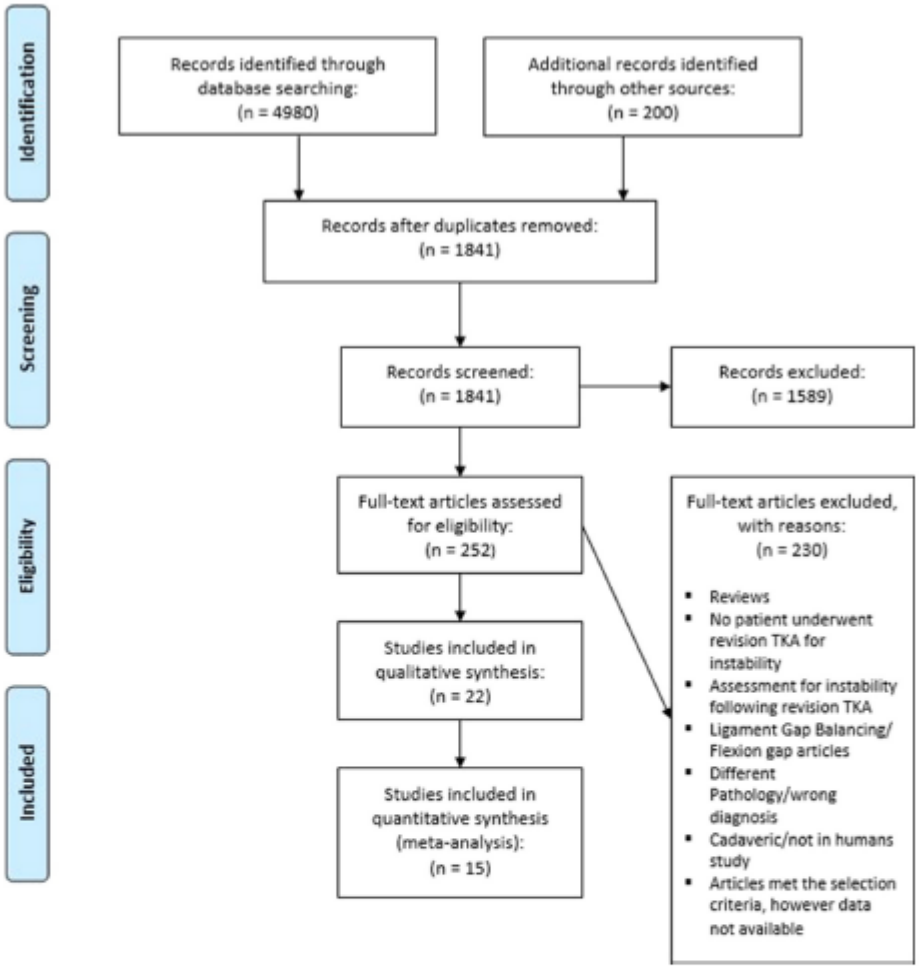

Figure 1. PRISMA flow diagram for study selection.

four of the included studies (15 knees). None of the included studies provided specific data regarding the effect of Computer – Assisted Surgery (CAS) or Patient Specific Instrumentation (PSI) surgery.

In comparison to the Posterior Stabilised (PS) implant design; the Cruciate Retaining (CR) implant was used in greater than double of the primary TKA procedures subsequently revised for instability (Table 3).

3.5.2. Revision TKA

A total of 10 studies reported the type of revision, with the majority of patients requiring a complete revision (77.4%). A constrained or semi-constrained revision prosthesis was more commonly used in patients revised for instability, in comparison to unconstrained (Table 3).

3.6. Knee instability: diagnosis, cause and type

Of the 22 included studies, 15 reported the diagnostic approach used to determine instability. The majority of studies (12) used a combination of both radiographic and clinical testing, while only three used clinical assessment. A number of studies (six) also reported the cause of instability, with nine categorised as traumatic and 58 non-traumatic, reported in a total of 67 revised knees. Authors also categorised the type of instability as either chronic or acute. A mere three studies reported the

Table 1
Characteristics of included studies.

First author, year	Study design	Number of knees revised for instability	Age (Yrs.) (min–max)	Gender (M:F)	Time to revision (months) (min–max)	Primary TKA implant design (CR:PS)
Schwab, J. H., 2005 [29]	RCS	10	67 (51–79)	8:2	27 (8–59)	0:10
Scott, R. D., 2005 [30]	PCS	6	NR	NR	NR	6:10
Firestone, T. P., 2006 [19]	RCS	109	64 (39–86)	57:48	38.4 (8–60)	81:28
Girard J., 2009 [21]	RCS	2	NR	NR	16.5 (15–18)	0:2
Raab, G. E., 2009 [28]	Retrospective comparative study	42	61.8 (40–86)	20:20	NR	NR
Unnanuntana, A., 2010 [34]	Case report	1	47	0:1	21	1:0
Villanueva, M., 2010 [36]	RCS	6	68.7 (65–73)	1:5	43.6 (6–120)	5:1
Amout, N., 2011 [16]	Case reports	4	(53–73)	0:4	NR	NR
Hosaka, K., 2011 [23]	RCS	2	78 (73–83)	0:2	31.2 (2.4–60)	NR
Koskinen, E., 2011 [26]	RCS	10	70 (57–87)	0:10	51.6 (12–156)	10:0
Mayle, R. E., 2012 [27]	RCS	1	NR	0:1	16	NR
Bieger, R., 2013 [17]	RCS	13	67 (55–79)	3:10	43 (4–82)	NR
Kasahara, Y., 2013 [25]	Retrospective comparative study	13	76 (60–89)	1:12	91 (4–240)	NR
Tay, K. S., 2013 [33]	RCS	3	NR	NR	41.1	NR
Van Kempen, R. W., 2013 [35]	PCS	23	66.1 (45.4–86.4)	11:12	NR	NR
Abdel, M. P., 2014 [15]	RCS	60	65 (43–82)	27:33	NR	41:19
Hamilton, D. F., 2014 [22]	Prospective CCS	25	70.3 (49–85)	11:14	52.8 (36–84)	24:1
Kannan, A., 2014 [24]	RCS	37	62 (40–82)	13:24	NR	24:13
Song, I. S., 2014 [31]	RCS	24	71 (52–85)	4:18	82.5 (14–228)	14:10
Hierl, M. A., 2014 [20]	Case report	1	NR	0: 1	3	1:0
DePuy Synthes, 2014 [18]	Case reports	4	76.3 (64–89)	1:0	64.5 (6–168)	1:1
Springer, B. D., 2015 [32]	Case report	1	62	1:3	24	0:1

NR = Not reported; TKA = Total Knee Arthroplasty; PS = Posterior Stabilised; CR = Cruciate Retaining.
Study Designs: RCS: Retrospective Case Series; PCS: Prospective Case Series; CCS: Case Control Study;

type of instability, with 23 chronic and three acute cases identified. Dislocation rate across included studies was unable to be appropriately investigated given the complication had been used as part of the selection criteria in some studies.

4. Discussion

The aim of this review was to systematically assess the current evidence available regarding knee instability after TKA to identify time to failure between primary and revision TKA. In addition, we considered the patient characteristics, surgical technique and implant type used in patients revised due to knee instability.

Not only has instability been identified as a significant cause of revision knee arthroplasty but also a leading cause for early revision. Our findings of the relevant literature identified that on average, patients underwent revision for instability at 44.7 months (95% CI [33.8, 55.7]) following primary TKA. With over 90.0% of primary knees surviving for more than 10 years in Australia [4], patients and surgeons expect greater longevity from TKA surgery than ever before. Our results highlight that

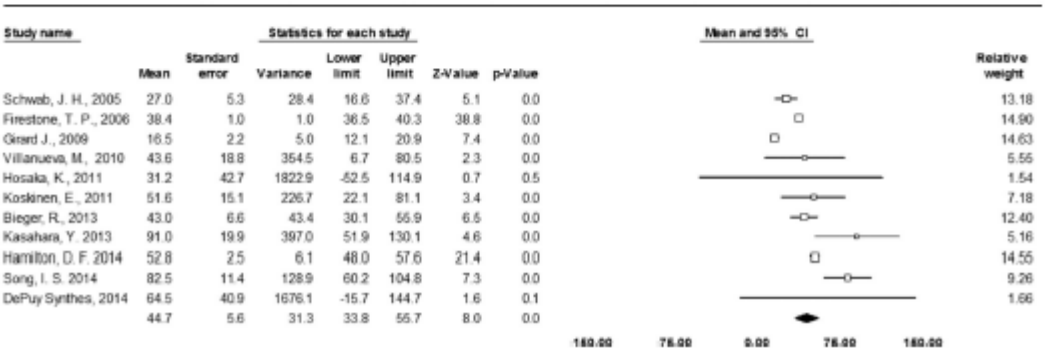

Figure 2. Forest plot of time to failure between primary TKA and revision TKA in months; CI: Confidence Interval.

Table 2
Time to failure and characteristics of patients revised for instability.

	Units	Results
Time to failure ($n_k = 218$; $n_s = 11$)	Weighted mean 95% CI	44.7 months 95% CI [33.8, 55.7]
Gender ($n_k = 386$; $n_s = 19$)	M:F	158:220
BMI ($n_k = 88$; $n_s = 5$)	BMI < 40:≥40	87:1
	Weighted mean[a]	30.4 kg/m^2
	Min–MAX[a]	19–61
Age at time of revision surgery ($n_k = 378$; $n_s = 14$)	Weighted mean 95% CI	67.6 years 95% CI [65.38, 69.75]

n_k = number of knees revised for instability reported for each parameter; n_s = number of articles that reported the parameter; BMI = Body Mass Index; Min = Minimum; Max = Maximum; CI = Confidence Interval.
[a] BMI range not reported for one study included in the calculation of the BMI weighted mean.

current evidence reports knee instability as a cause of early failure and subsequent revision knee surgery. Early revision has shown the potential to instigate a downward spiral for the patient, with high risks of re-revision surgery over the following five years [4], demonstrating the severe clinical implications of an unstable knee.

4.1. Patient characteristics: age, BMI and gender

In regards to gender distribution, a greater number of females were identified as undergoing revision for instability in included studies. This finding is consistent with AOANJRR figures which report greater revision rates for females across all causes [37]. However, it must be emphasised that the data could not be corrected for the gender distribution of the baseline, primary TKA population. This information was omitted from the majority of included articles, and consequently limits plausible inferences regarding gender. Of the two studies which did report the gender distribution of the primary TKA opulation from which the instability subgroup was obtained, the vast majority were female (88.8%). This is comparable to AOANJRR findings, which highlight a consistently higher proportion of females undergoing primary TKA (56.1%) [4].

Average age at revision TKA was low, with patients undergoing the procedure in their mid-to-late sixties. This result is consistent with Australian national data, which suggests revision rates are higher in patients who are less than 70 years of age when the primary knee surgery was performed [4]. Furthermore, a third (34.8%) of all knee arthroplasty revisions reported by the AOANJRR occurred in the 65 to 74 age bracket [37]. Correspondingly, The Swedish Knee Arthroplasty Register also reported the highest incidence of revision for TKA in osteoarthritic patients aged 65 to 74 years [38]. A recent epidemiological study of revision TKA in the United States also identified that patients aged 65 to 74 years underwent the largest number of revisions (30.1%) [39]. Interestingly, Meehan, et al. 2014 [40] reported that patients younger than 50 years had a higher risk for periprosthetic joint infection and aseptic mechanical failure at one-year post-TKA. Finally our data suggests that BMI was not a relevant patient characteristic with regards to revision, however this was reported in a very few number of articles and inferences cannot be concluded.

Table 3
Characteristics of surgical technique and implant.

Primary TKA		N	
Indication for primary TKA	Osteoarthritis	118	
($n_k = 120$; $n_s = 8$)	Rheumatoid arthritis	2	
Surgical technique	Conventional	14	
($n_k = 15$; $n_s = 4$)	Minimal invasive surgery	1	
Implant design	Posterior stabilised	86	
($n_k = 294$; $n_s = 14$)	Cruciate retaining	208	
Revision TKA		**N**	**(%)**
Type of revision	Complete revision (T + F)	106	(77.4)
($n_k = 137$; $n_s = 10$)	Femoral only	6	(4.4)
	Tibial only	4	(3.8)
	PE insert only	18	(13.1)
	Femoral and PE insert	1	(0.7)
	Patella and PE insert	2	(1.5)
Revision prosthesis	Constrained	35	(35.0)
($n_k = 100$; $n_s = 7$)	Semi-constrained	44	(44.0)
	Standard/unconstrained	21	(21.0)

N = number; PE = Polyethylene; n_k = number of knees revised for instability reported for each parameter; n_s = number of articles that reported the parameter.

4.2. Surgical technique and primary implant design

Of the four studies commenting on surgical technique, only one study was performed using a MIS technique, while all other revised knees were performed using conventional instruments. Of the two implant designs, the majority of revised knees had received a CR design; however, this may simply be due to greater use of this implant type. When reviewing the 10 most common knee implants used in Australia in 2014, 76% were CR designs while 24% were PS [4].

An outstanding majority (77.4%) of cases reported were performed with a total revision of all original components. A variety of minor revisions were reported with exchange of, for example, just the polyethylene insert of the tibial component. The use of polyethylene exchange is common as surgeons are concerned about the need for further revisions, especially in younger patients. This practice is supported by AOANJRR results who suggest the risk of re-revision in patients who undergo their first revision in five years is almost 30.0% for major revision surgery in comparison to approximately 20.0% in patients who undergo minor revision such as a poly-insert exchange. As most revisions for knee instability occur in the first five years, a more conservative approach may be more supported given the greater risks of re-revision.

4.3. Diagnostic approach for TKA instability

A combination of clinical assessment and radiological assessments were most commonly used to diagnose instability, highlighting adherence to recommended practice [10,41]. The most important diagnostic factor is the clinical history. Patients with symptomatic instability, particularly in flexion, report a common series of symptoms including a feeling of insecurity in the knee without frank giving way, difficulty with stairs, recurrent knee swelling and anterior knee pain [10].

The primary strength of this review was that a large body of literature was systematically assessed against predefined criteria to critically review and summaries knee instability as a mechanism of failure. A limitation of review methodology was that the initial screening of citations was performed by a single reviewer. Further limitations were a reflection of the limited data available from eligible studies, resulting in an inability to include such studies in review results. Furthermore, demographic data was unable to be corrected for the baseline primary TKA population due to limited data reported in included studies, restricting plausible inferences. In addition, vague definitions and/or inconsistent terminology was used when describing the type and cause of instability across included studies, emphasising the need for uniformity, and detailed reporting in the literature in the future. Appendix B provides a summary of the descriptions used when discussing type of instability across included studies.

4.4. Conclusions

Research on knee instability following primary TKA reported early failure and subsequent revision knee surgery. The need for revision due to instability was frequently reported in a younger patient cohort and most commonly in female TKA patients. Early revision at a younger age highlights the severe implications of an unstable knee.

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Appendix A. Search strategy

Ovid MEDLINE Search Strategy
MeSH Terms
Arthroplasty, Replacement, Knee/
Knee prosthesis/
Causality/ or Precipitating factors/ or Risk factors/
Joint instability/
(Knee joint/ or Knee/) and Arthroplasty/
Free Text Terms
(TKA? or TKR?).tw.
(Knee* adj4 (replacement* or arthroplast* or prosthe*)).tw.
(Stable or stabili* or instabili* or unstable or destabili* or constrain* or balanc* or imbalanc* or unbalanc*).tw.
(Etiology or Adverse effects).fs.
(Causalit* or causati* or cause* or ?etiolog* or risk* or precipitat* or predispos* or multifactor* or multi-factor*).tw/ MeSH/Subheading combination; * Search Term Truncation

Appendix B. Type of instability descriptions provided in included studies

First Author, Year	Number of knees revised for instability	Instability Description
Schwab, J. H., 2005[1]	10	Isolated symptomatic flexion instability in the AP plane
Scott, R. D., 2005[2]	6	late-onset knee instability: ▪ 3 knees: Trauma due to fall; ▪ 2 knees: Status post patellectomy with persistent quadriceps weakness and episodes of giving way; ▪ 1 knee: Muscle weakness and imbalance due to a syringomyelia
Firestone, T. P., 2006[3]	109	*'Patients were found to be at risk for symptomatic instability if they demonstrated one or more of the following findings: laxity in mid-flexion, substantial anteroposterior translation, discomfort with medial-lateral stress, and/or a "ballottable" flexion gap.'* *'Radiographic evidence of instability following primary total knee replacement includes excessive posterior condyle resection, inadequate distal femoral resection, nonweight-bearing component gapping, and bearing surface eccentricity.'*
Girard J., 2009[4]	2	Frontal instability
Raab, G. E., 2009[5]	42	Subtle instability patterns, for example normal-appearing radiographs and multiple subjective symptoms.
Unnanuntana, A., 2010[6]	1	Chronic lateral instability due to lateral collateral ligament deficiency after primary total knee arthroplasty.
Villanueva, M., 2010[7]	6	Residual instability (5 knees: Posterior dislocation; 1 knee: Anterior dislocation).
Arnout, N., 2011[8]	4	Posterior dislocation
Hosaka, K., 2011[9]	2	Instability
Koskinen, E., 2011[10]	10	▪ 8 Knees: Medial collateral instability; ▪ 1 Knee: Lateral collateral instability; ▪ 1 Knee: Instability with subluxation.
Mayle, R. E.,2012[11]	1	Instability
Bieger, R., 2013[12]	13	*'Patients with instability had to report pain and swelling related to activity, the finding of instability upon clinical examination, as well as sterile joint aspiration.' 'In one patient the medial collateral ligament was re-fixated during revision TKA.'*
Kasahara, Y., 2013[13]	13	*'Instability was evaluated using varus/valgus and anterior/posterior drawer stress radiograph.'*
Tay, K. S., 2013[14]	3	Instability
Van Kempen, R. W., 2013[15]	23	*'Instability was defined as a clinical diagnosis with pain and instability experienced by the patient caused by a collateral ligament laxity or PCL insufficiency without any sign of component malpositioning.'*
Abdel, M. P.,2014[16]	60	Symptomatic instability in flexion in the AP plane.
Hamilton, D. F., 2014[17]	25	*'Knee instability was diagnosed clinically by the surgical team on the basis of the patient's symptoms and an assessment of the laxity of the knee in all planes and in both flexion and extension.'*
Kannan, A., 2014[18]	37	Flexion instability *'A clinical diagnosis of flexion instability was made in patients with painful TKA based on the presence of coronal plane instability with or without sagittal plane instability at 90 degrees of flexion, but without instability in extension.'*
Song, I. S., 2014[19]	24	▪ 13 Knees: Coronal instability with posteromedial polyethylene wear and lateral laxity; ▪ 6 Knees: Coronal instability with posteromedial polyethylene wear; ▪ 3 Knees: Sagittal instability (including post breakage); ▪ 1 Knee: Global instability; ▪ 1 Knee: Flexion instability.
Hierl, M. A., 2014[20]	1	Posterior instability
DePuy Synthes, 2014[21]	4	▪ 1 Knee: Excessive constraint, in an unbalanced knee; ▪ 1 Knee: Medial collateral ligament insufficiency; ▪ 1 Knee: The knee presented problems of balance, bone loss and fixation at revision surgery; ▪ 1 Knee: 25 degrees hyperextension and global instability.
Springer, B. D., 2015[22]	1	ligamentous Instability

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