Instrumentation Optimisation for Unicompartmental Knee Replacement

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ABSTRACT

Instrumentation Optimisation for Unicompartmental Knee Replacement

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The cementless medial Oxford Unicompartmental Knee Replacement (OUKR) has improved outcomes and almost halved revision rates compared to the cemented OUKR at 10 years. However, there is limited understanding of long-term complications of the cementless OUKR beyond 10 years, such as aseptic loosening and bearing fracture, and short-term complications, such as tibial component subsidence (TCS) and tibial periprosthetic fracture (TPF). The aims of this thesis were to investigate poorly understood OUKR complications, understand instrumentation limitations that may contribute to the risk of complications, and to optimise the instruments to minimise the risk of complications.

10-year results of a randomised controlled trial with radiostereometric and radiographic analysis found that cementless fixation is likely to be as good, if not better than cemented fixation in the second decade. Two cemented tibial components with substantial early migration had ongoing migration at 10 years. Cementless OUKRs (1/15) had fewer tibial radiolucent lines compared to cemented (6/14) at 10 years.

Bearing fractures, because of excessive polyethylene wear, have been reported with the Phase III OUKR. There is a concern that cementless fixation might be associated with increased wear due to third body debris. The mean linear polyethylene wear of Phase III OUKR (0.06 mm/year) was found to be approximately three times higher than the Phase II wear rate, with no difference in wear rate between cemented and cementless implants. To minimise the risk of bearing fracture in the very long-term, surgeons should position the bearing close to the tibial wall, neutrally align the femoral component, and avoid using the thinnest Size 3 bearings in young patients.

A radiographic study of 94 cementless OUKR patients identified five cases (5%) of TCS. No patient, implant, or surgical factors were found to be associated with TCS, likely due to the small number of TCS cases identified. All TCS patients had an acceptable five-year clinical and radiographic outcome, therefore it is recommended that TCS should be treated conservatively.

The first surgeon survey to identify limitations of the OUKR instrumentation was conducted. The 106 surgeons who responded were satisfied with most of the OUKR instrumentation. Instruments for patient positioning (36%), tibial resection (51%), femoral preparation (41%), and tibial keel slot preparation (29%) were identified to have limitations that required improvement. Most surgeons (63%) believed that computer assisted surgery would improve the OUKR procedure.

The risk of OUKR TPF is higher for cementless OUKRs. Mechanical experiments found that preventing vertical overcut using a prototype resection guide can decrease the risk of TPF. Positioning the component more medially, distally, and valgus was found to increase the risk of TPF in a small tibial model. Preparing a shorter keel slot with a buffer sawblade and rasping the slot ends increased LTF by 11% compared to the standard sawblade without compromising primary fixation. Comparatively, use of a component with a shorter and shallower keel increased LTF by 38%, also without compromising fixation. To minimise the risk of TPF with cementless OUKR it was recommended that the buffer saw and rasp should be adopted clinically until a component with a shorter and shallower keel is available.

This thesis improves the understanding of the risk of aseptic loosening, polyethylene wear, bearing fracture, TCS, TPF, and instrumentation limitations from the surgeon's perspective for the OUKR. It has proposed optimised instruments to minimise the risk of TPF for cementless OUKR and concludes by outlining how these instruments can be introduced clinically to reduce the incidence of TPF.

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LIST OF ABBREVIATIONS

3D	3-dimensional
ACL	Anterior Cruciate Ligament
ADLs	Activities of Daily Living
AJRR	American Joint Replacement Registry
AKSS	American Knee Society Score
AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
Bi-UKR	Bi-unicompartmental Knee Replacement
BMI	Body Mass Index
CAD	Computer Aided Design
CAS	Computer Assisted Surgery
CI	Confidence Interval
CT	Computed-Tomography
Dartec	Used to refer to a servo-hydraulic testing machine (Dartec HC 10, Zwick Ltd, Herefordshire, UK)
ECM	Extracellular Matrix
ICOAP	Intermittent and Constant Osteoarthritis Pain score
LCL	Lateral Collateral Ligament
LTF	Load To Fracture
MCL	Medial Collateral Ligament
MRI	Magnetic Resonance Imaging
MTPM	Maximum Total Point Motion
MHRA	Medicines and Healthcare products Regulatory Agency
NJR	National Joint Registry of England, Wales, Northern Ireland, and Isle of Man
NZJR	New Zealand Joint Registry
OLH	Oxford Leg Holder
OUKR	Oxford Unicompartmental Knee Replacement
OKS	Oxford Knee Score
PSI	Patient Specific Instrumentation
PCF	Pounds per Cubic Foot

PCL	Posterior Cruciate Ligament
QR	Quick Response
r	Pearson's Correlation Coefficient
RCT	Randomised Controlled Trial
RSA	Radiostereometric Analysis
Sawbones	Used to refer to "solid rigid polyurethane foam with a density of 20 pounds per cubic foot".
SD	Standard Deviation
TCS	Tibial Component Subsidence
TKR	Total Knee Replacement
TPF	Tibial Periprosthetic Fracture
UK	United Kingdom
UKR	Unicompartmental Knee Replacement
USA	United States of America

CHAPTER 1 INTRODUCTION AND LITERATURE REVIEW

1.1 OVERVIEW

The global prevalence of knee osteoarthritis increased by 122% from 1990 to 2019 and there are approximately 365 million people globally living with the disease today [1]. Due to the importance of the knee for mobilisation, knee osteoarthritis has an enormous health and financial burden [1, 2]. The prevalence of knee osteoarthritis is expected to increase further with 642 million people predicted to be living with the disease by 2050 [3]. The projected increase is primarily driven by a global increase in the two strongest knee osteoarthritis risk factors, age and obesity [4].

For knee osteoarthritis that fails non-operative management, knee replacement surgery provides an effective treatment to relieve pain and restore function. Given increasing rates of knee osteoarthritis, the need for knee replacement is expected to increase considerably [5-7]. Knee replacements can either be total knee replacements (TKRs), which replace the entire knee joint, or unicompartmental knee replacements (UKRs), which can be used when disease is isolated to a single compartment of the knee. Compared to TKRs, UKRs result in better knee kinematics [8], higher clinical scores [9], lower morbidity [10], shorter hospital stays [11], are more cost-effective [12], and are easier to revise [13]. Up to half of all primary knee replacement patients are eligible for UKR [12]. However, despite the many benefits of UKRs over TKRs, only 10.9% (9.8% unicondylar and 1.1% patellofemoral) of the over 1.5 million primary knee replacements recorded in the National Joint Registry of England, Wales, Northern Ireland and Isle of Man (NJR) are UKRs [14]. The underuse of UKRs is often attributed to the higher revision rates of UKRs in joint registries compared to TKRs [14-18].

The medial Oxford UKR (OUKR) will be the focus of this thesis. The OUKR is reported to be the most commonly used UKR in the NJR [14] and is likely to be the most widely used UKR globally. It has achieved excellent clinical results in the hands of designer and high-volume surgeons [19, 20], but inexperienced surgeons who perform few OUKRs have poorer results [21-23]. The surgical instruments used to implant the OUKR have evolved with the device across almost 50 years of use [24]. Advancements in OUKR instrumentation have improved clinical outcomes and made the procedure more reproducible for surgeons to perform [25-30]. However, like other UKRs, the revision rate of the OUKR continues to be higher than TKRs [14-17]. The OUKR also has some poorly understood complications which may contribute to higher revision rates. This is particularly true for the cementless OUKR, the most recent implant design, which has been reported to have a higher incidence of periprosthetic fracture compared to the cemented OUKR [31]. Tibial component subsidence (TCS), with valgus and posterior tilting of the tibial component, has also been reported with the cementless OUKR [32-36]. This pattern of migration has not been observed with the cemented OUKR and would indicate a loose component that is unlikely to fix if it occurred with a cemented tibial component. A small number of bearing fractures have also been reported with the Phase III OUKR [37-40]. The linear polyethylene wear rate for the Phase III OUKR was significantly higher than the Phase II OUKR at 5 years [41]. For the Phase III cementless OUKR, there is a concern that fragments of the hydroxyapatite-coated porous titanium surface may contribute to third body wear, leading to higher wear rates and possibly bearing fracture. Despite these complications, the cementless OUKR (93%) has better 10-year cumulative survival than the cemented OUKR (90%) [31].

The purpose of this thesis is to investigate poorly understood complications of the OUKR which may contribute to higher rates of revision, understand the limitations of the current OUKR surgical instruments, and to propose how the instrumentation can be optimised to minimise the risk of revision.

This chapter will discuss the pathophysiology of knee osteoarthritis and its management, with a particular focus on knee arthroplasty and the related surgical instrumentation. Then, the OUKR, its outcomes, surgical technique, instrumentation, and complications will be summarised. Finally, the aims, structure, and scope of this thesis will be outlined.

1.2 THE KNEE JOINT

The knee is an intermediate, weight-bearing joint of the lower limb that is crucial for walking and other activities of daily living (ADLs). The distal femur, proximal tibia, and patella articulate to form the knee joint, which can be separated into three compartments (**Figure 1.1**):

> *Medial Compartment* – The medial tibio-femoral joint, where the medial femoral condyle articulates with the medial tibial plateau.
>
> *Lateral Compartment* – The lateral tibio-femoral joint, where the lateral femoral condyle articulates with the lateral tibial plateau.
>
> *Patellofemoral Compartment* – The patellofemoral joint, where the patella articulates with the femoral trochlea.

The articular surfaces of the knee are covered in articular cartilage and surrounded by a capsule lined with a synovial membrane and filled with synovial fluid. Two C-shaped rings of fibrocartilage sit on the surface of the tibial plateaus, named the medial and lateral menisci, respectively. The menisci increase the articular surface area of the tibia, increase joint stability, and dissipate forces transmitted through the joint. The knee permits flexion and extension, but also a small range of internal and external rotation. Given its anatomical structure and function, the knee is classified as a modified synovial hinge joint.

The knee is stabilised by four main ligaments. The anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) restrict anterior and posterior translation of the tibia on a fixed femur, respectively. Meanwhile, the medial collateral ligament (MCL) and lateral collateral ligament (LCL) restrict valgus and varus stress of the leg, respectively. Muscles around the knee also stabilise the joint and facilitate movement. The quadriceps group of muscle on the anterior thigh facilitate knee extension. The hamstrings muscles on the posterior thigh and, to a lesser extent, the gastrocnemius, gracilis, sartorius, popliteus, and plantaris muscles, are responsible for knee flexion. Biceps femoris externally rotates the knee and internal rotation is driven by semimembranosus, semitendinosus, gracilis, sartorius and popliteus. Rotation of the knee cannot occur in full extension as both the MCL and LCL are tight. As the knee flexes, the LCL becomes lax while the MCL remains taut [42]. This, along with other factors such as the lateral pull of the quadriceps during extension, typically results in the tibia internally rotating approximately 20° during flexion and, vice versa, rotating externally during extension in a process known as the "screw-home" mechanism [43].

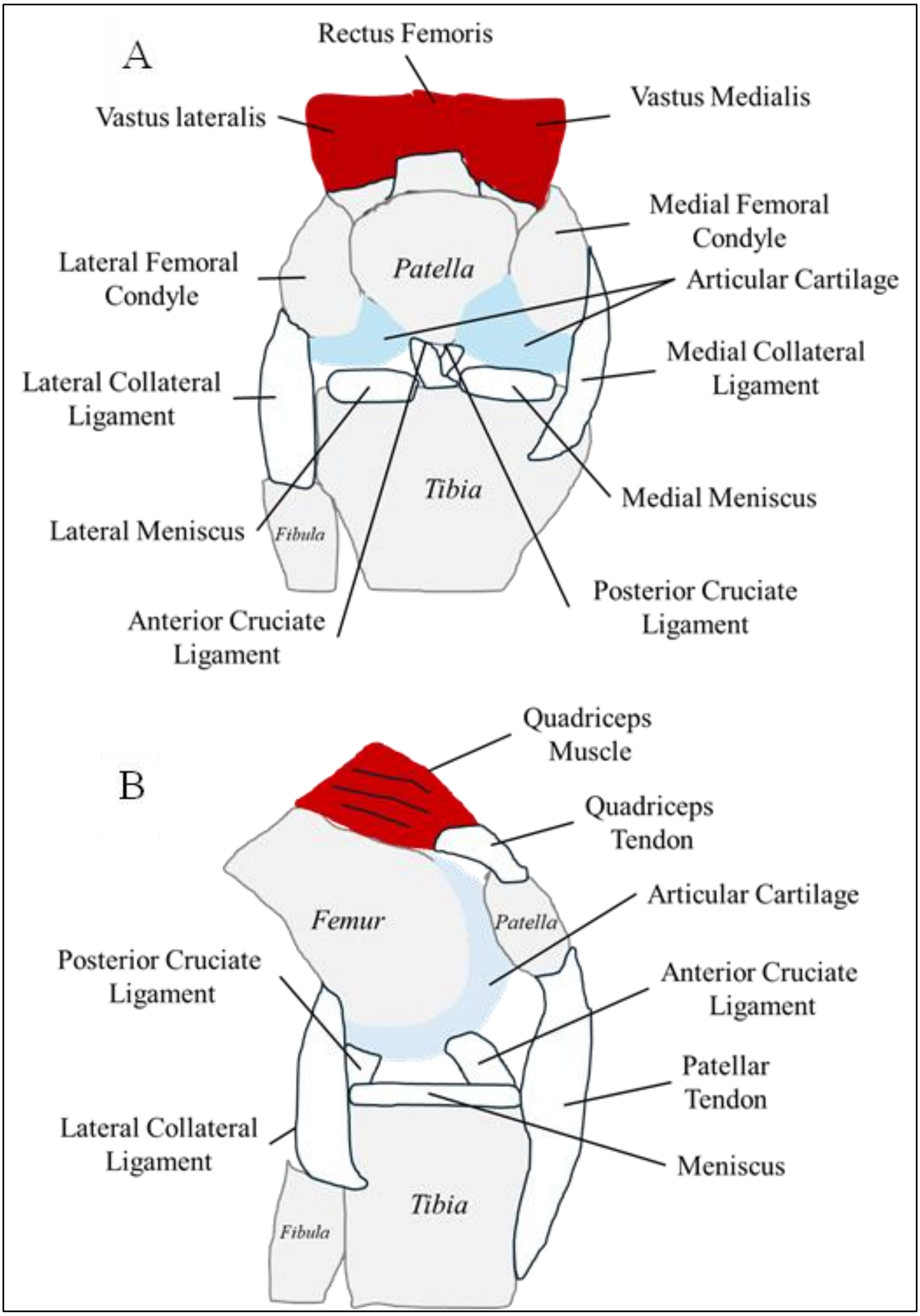


Figure 1.1 A Anterior view of the knee joint showing the major ligaments of the knee including the: Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), and Lateral Collateral Ligament (LCL). **B** A lateral view of the knee joint.

1.3 KNEE OSTEOARTHRITIS

Osteoarthritis is the most common progressive musculoskeletal condition and can occur in any joint of the body, although it is most common in the high-use joints of the knee, hip, and hands due to its partly mechanical aetiology [3]. The knee is the most affected joint, with knee osteoarthritis accounting for more than half of the global osteoarthritis prevalence [3]. As the knee is crucial for ADLs, knee osteoarthritis also accounts for approximately 85% of the Years Lived with Disability (YLDs) attributable to osteoarthritis [44]. Knee osteoarthritis can occur in any or all three compartments of the knee. A systematic review of the distribution of knee osteoarthritis identified that 50% is unicompartmental, 33% bicompartmental, and 17% tricompartmental [45]. This section summarises the pathophysiology, clinical presentation, and treatment of knee osteoarthritis.

1.3.1 Pathophysiology of Knee Osteoarthritis

Osteoarthritis was traditionally thought of as a disease of mechanical degradation of articular cartilage caused by 'wear and tear', but is now recognised as a chronic, progressive, and partly inflammatory disease that effects the whole joint and its surrounding structures [46, 47] (**Figure 1.2**). The pathophysiology of osteoarthritis is an area of ongoing research; however, the current understanding of osteoarthritis pathophysiology is summarised below [48].

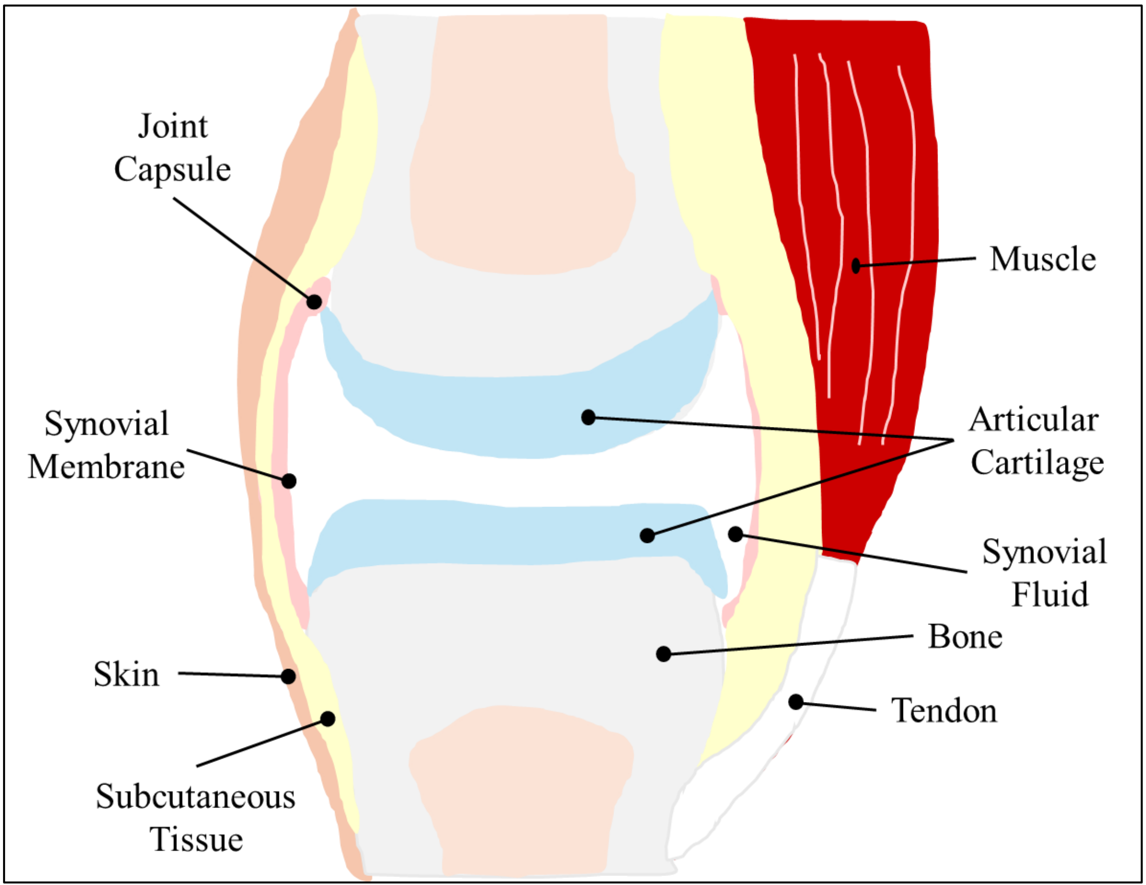


Figure 1.2 A diagram of a generic synovial joint and its surrounding structures.

Articular cartilage is an avascular tissue composed of chondrocytes and extracellular matrix (ECM). ECM consists of water (>70%) and a mix of collagens (predominantly Type II), proteoglycans, glycosaminoglycans, and glycoproteins [49]. Chondrocytes strictly regulate the composition of articular cartilage in response to biomechanical and chemical stimuli [4]. Mechanical loading stimulates articular cartilage metabolism, however, excessive mechanical loading causes chondrocytes to trigger catabolic processes resulting in the depletion of ECM components [50]. This results in irreversible damage to the cartilage, making excessive mechanical loading the most likely trigger of osteoarthritis. In early osteoarthritis, the water content of the ECM increases while degrading enzymes simultaneously breakdown the other components of the ECM and chondrocytes proliferate [49, 51]. The generation of cartilage degradation products results in the release of proinflammatory molecules which stimulates further cartilage degradation as well as proliferation and inflammation of the surrounding synovium [52]. In the early stages of osteoarthritis these cellular processes result in erosions in the superficial layers of the cartilage which progress to full thickness erosions in later stages of the disease that extend to the subchondral bone [49].

Subchondral bone consists of two layers, a plate-like layer cortical bone that lies directly beneath the articular cartilage and a deeper layer of trabecular bone. The composition of subchondral bone is regulated by cells that generate new bone, osteoblasts, and cells that resorb old bone, osteoclasts. Like chondrocytes, osteoblasts are activated in response to excessive mechanical loading resulting in thickening of the subchondral cortical bone in early osteoarthritis [53]. In the later stages of osteoarthritis the balance between osteoblast and osteoclast activity is distorted in subchondral bone leading to changes such as subchondral cyst and osteophyte formation [54].

The synovium is comprised of the synovial membrane, which lines the joint, and the synovial fluid, which supplies nutrients to the avascular articular cartilage and stores cartilage degradation products [55, 56]. Synovitis is present from the earliest stages of osteoarthritis as it is likely initiated by proinflammatory molecules from cartilage degradation [49]. Synovitis also results in the release of further inflammatory mediators, proteolytic enzymes, and infiltration of lymphocytes [57]. This cycle of inflammation results in thickening of the synovial membrane, further degradation of cartilage, and inflammation of other joint structures [49].

Muscles surrounding the knee joint have been found to be inflamed in osteoarthritis and produce myokines which have been shown to interact with cartilage and bone, indicating muscles have a role in osteoarthritis pathogenesis [58]. Meniscal injuries are a strong risk factor for the development of knee osteoarthritis and in patients with radiographically confirmed osteoarthritis meniscal damage is almost always present [59, 60]. Ligament and tendon injuries have also been found predispose a patient to develop osteoarthritis, further highlighting that osteoarthritis is a whole joint disease [61].

In summary, osteoarthritis is a partly inflammatory whole joint disease that has a primarily biomechanical aetiology. Anatomical and functional joint factors contribute to disease development, but systemic risk factors such as age, obesity, gender, and genetics also contribute its pathogenesis [49]. The risk factors of knee osteoarthritis are summarised in **Table 1.1**.

Table 1.1 Summary of Biomechanical and Systemic Risk Factors for Knee Osteoarthritis

Risk Factor	**Involvement in Knee Osteoarthritis Pathophysiology**
Biomechanical Risk Factors	
Excessive Mechanical Loading	The knee can experience excessive mechanical loading because of certain activities such as squatting, kneeling, or heavy lifting. There are low levels of evidence that suggest occupations that have high physical demands such as farming and construction are associated with an increased risk of developing osteoarthritis [62]. Similarly, high level sporting activity is a poorly defined risk factor for osteoarthritis [63].
Knee Malalignment	Knee malalignment can result in excessive loading of the knee compartments. Varus knee alignment is associated with an increased risk of osteoarthritis in the medial compartment of the knee while valgus alignment is associated with an increase in lateral compartment osteoarthritis [64].
Previous Knee Injury	Previous ligament or meniscal injuries are associated with an increased risk of developing osteoarthritis [49, 65]. These injuries can alter knee kinematics and loading.
Muscle Weakness	Weakness of knee extensors is a weak risk factor for knee osteoarthritis [66]. As the knee extensors act as stabilisers for the knee, weakness is likely to result in excessive mechanical loading of the knee joint.
Systemic Risk Factors	
Age	The prevalence of osteoarthritis increases with age. This is likely due to an increased duration of exposure to other risk factors or may relate to a decreased ability for cartilage regeneration [4].
Female Sex	Females are more likely to develop knee osteoarthritis. A systematic review found the odds of females developing osteoarthritis is 1.69 times greater than males [67]. Differences in knee anatomy and hormones may play a role, but it is not currently clear to what extent [68].
Genetics	Several genetic loci and a family history of osteoarthritis are associated with an increased risk of developing osteoarthritis. Elucidating the exact genetic pathways is a topic of ongoing research [69].
Overweight / Obesity	Being overweight or obese increases mechanical loading of the joint through excess body mass. Excess adipose tissue is associated with a low-grade, chronic inflammation which may also contribute to the pathogenesis of osteoarthritis [70].
Inactivity	Inactivity contributes to the risk of an individual being overweight or obese [71].

1.3.2 Clinical Presentation of Knee Osteoarthritis

Patients with knee osteoarthritis usually present with pain and functional loss which is affecting their ADLs. The hallmark symptoms of knee osteoarthritis identifiable from patient history are; (1) Knee pain that has come on gradually which gets worse with activity and better with rest, (2) Stiffness lasting less than 30 minutes in the morning, and (3) Restriction or loss of joint function, often described as difficulty walking, transferring (between sitting and standing), or ascending/descending stairs [72]. Pain is usually intermittent to begin with but becomes constant when the osteoarthritis has progressed to end-stage, bone-on-bone disease. Other symptoms can include joint line tenderness, instability, or weakness. Severity of knee osteoarthritis, and subsequent response to treatment, can be assessed using clinical scores. The Oxford Knee Score (OKS, **Appendix A5.1**) and American Knee Society Score (AKSS, **Appendix A5.2**) are two of the most widely used scores [73].

On examination, crepitus, restricted movement, and bony enlargement of the knee are all key signs of knee osteoarthritis. The knee may have an effusion, which is likely to be small in the case of osteoarthritis. Larger effusions are possible, but more often seen in inflammatory arthropathies. Malalignment of the knee can also occur with cartilage loss with a varus deformity indicative of medial compartment osteoarthritis and a valgus deformity indicative of lateral compartment disease.

Clinical diagnosis is the standard for knee osteoarthritis with diagnostic criteria, such as those from the American College of Rheumatology or the European League Against Rheumatism, providing clear diagnostic guidelines [72, 74]. However, plain radiographs are often also used to diagnose knee osteoarthritis with common features including osteophytes, loss of joint space, subchondral sclerosis, and subchondral cysts [75, 76].

Anteroposterior and lateral views are commonly obtained which together accurately identify 87% of radiographic knee osteoarthritis. Radiographic osteoarthritis is accurately identified over 98% of the time if a skyline view to assess the patellofemoral joint is also obtained [77]. Other imaging modalities such as ultrasound, computed tomography (CT), and magnetic resonance imaging (MRI) can also be used to investigate knee osteoarthritis. They have the advantage of being able to visualise structures of the joint other than bone and possibly to detect knee osteoarthritis before there are clinical or Xray signs [78]. Radiography remains the first-line imaging option with MRI as the second-line option due to its greater sensitivity, however, use of MRI is limited primarily by its high cost and limited availability [79].

1.3.3 Non-surgical Treatment of Knee Osteoarthritis

The aim of knee osteoarthritis treatment is to relieve symptoms by alleviating pain and restoring function. Conservative, non-surgical treatment is the mainstay of knee osteoarthritis management which can be categorised as non-pharmacological or pharmacological. Guidelines such as those published by the Osteoarthritis Research Society International (OARSI) and American Academy of Orthopaedic Surgeons (AAOS) provide guidance to clinicians for non-surgical treatment options [80, 81].

1.3.3.1 *Non-Pharmacological Treatment of Knee Osteoarthritis*

The foundations of non-pharmacological osteoarthritis are patient education, exercise, and, for patients who are overweight, weight loss. Education is important for patients to understand their condition, to set expectations for management, and to engage patients in self-management of their knee osteoarthritis [82]. Patient education is strongly recommended as it has been shown to reduce pain associated with knee osteoarthritis [81]. Both land and water-based exercise which is supervised or unsupervised improves pain and function for knee osteoarthritis, with no clear evidence to suggest one type of exercise is better than the other [80, 81]. Sustained weight loss can reduce pain and, to a lesser extent, improve function for knee osteoarthritis patients that are overweight. A combination of both diet and exercise is recommended for weight loss, which has obvious health benefits for overweight patients beyond the condition of their knee [80].

Biomechanical interventions such as knee braces and lateral wedge foot orthoses have been shown to improve both pain and function in knee osteoarthritis patients [83]. Using a walking stick is also likely to reduce pain and may improve function for knee osteoarthritis patients, but the evidence is limited [84].

1.3.3.2 *Pharmacological Treatment*

Despite research efforts, there are currently no disease-modifying drugs that have been shown to effectively treat osteoarthritis [85]. Therefore, pharmacological treatment of knee osteoarthritis focuses on the relief of pain. Topical or oral Nonsteroidal Anti-inflammatory Drugs are strongly recommended for as first-line treatment of knee osteoarthritis, as they achieve good pain relief for patients [80, 81]. Paracetamol is also recommended for relief of knee osteoarthritis pain, however there is mounting evidence that paracetamol has poor efficacy, and the risk of adverse events may outweigh its benefits [86, 87]. Therefore, paracetamol should be prescribed with caution. Opioids are not recommended for treatment of knee osteoarthritis, owing to their considerable side effects which outweigh any pain reduction benefit [80, 81]. Topical capsaicin has also been shown to relieve knee osteoarthritis pain compared to a placebo, but it should be noted approximately one-third of patients experience local adverse events [88, 89]. Intraarticular corticosteroid injections can effectively relieve knee osteoarthritis pain in the short-term, but the other non-pharmacological and pharmacological treatments mentioned above are likely to be more effective for long-term pain relief [90]. Platelet-rich plasma injections can reduce pain and improve function in knee osteoarthritis patients [91]. However, the AAOS guidelines suggest there is limited evidence for the efficacy of platelet-rich plasma injections for knee osteoarthritis [80]. Evidence for the efficacy of hyaluronic acid injections is weak, although they may be able to provide some relief to patients with mild to moderate knee osteoarthritis that has failed other non-surgical treatments [92]. Hyaluronic acid is currently not recommended for treatment of knee osteoarthritis by the AAOS [80].

1.3.4 Surgical Treatment of Knee Osteoarthritis

Surgical treatment of knee osteoarthritis is usually withheld until non-surgical treatment has failed. Knee replacement is a widely accepted, safe, and cost-effective method for treatment of end-stage knee osteoarthritis which will be discussed in detail in **Section 1.4** [93, 94]. Other surgical options for treatment of knee osteoarthritis include arthroscopy, cartilage repair, and osteotomy. There is a large quantity of high-quality data to suggest knee arthroscopy has no clinically important benefits for patients with knee osteoarthritis and it is strongly discouraged [95]. Cartilage repair techniques have shown some promise for the treatment of focal chondral defects that have failed non-surgical treatment, particularly in younger patients for whom knee replacement surgery is rarely recommended [96-98]. There are many options for cartilage repair surgery, discussion of which is beyond the scope of this thesis. Despite the promise of cartilage repair surgery for the treatment of focal chondral defects, no cartilage repair technique has been able to reproduce normal articular cartilage [96]. There is currently a lack of prospective, long-term data for cartilage repair surgery in the literature and further study is needed to confirm whether it can effectively treat focal chondral defects and prevent the need for knee replacement surgery [97, 98].

Osteotomy is another treatment option for unicompartmental knee osteoarthritis which involves cutting either the proximal tibia or distal femur to change the alignment of the knee to offload the affected compartment of the knee. Medial compartment osteoarthritis can be treated with a valgus-producing osteotomy while lateral compartment osteoarthritis can be treated with a varus-producing osteotomy [99]. There are many types of osteotomies, although valgus-producing high tibial osteotomies are by far the most common followed by varus-producing distal femoral osteotomies [100]. Valgus-producing osteotomies account for the majority of procedures, reflecting the much higher prevalence of osteoarthritis isolated to the medial compartment compared to the lateral compartment [45]. Osteotomy lacks the long-term follow-up that UKR has through joint registries and large prospective studies. Despite this, osteotomy provides a joint preserving option for treatment of unicompartmental knee osteoarthritis that can achieve good outcomes, but outcomes are largely dependent on patient selection and surgeon experience [99, 101, 102].

1.4 KNEE REPLACEMENT

The primary aims of knee replacement are to relieve pain and restore function of the knee in patients with end-stage osteoarthritis that cannot be adequately managed with non-surgical treatment or joint preserving surgery. These goals are widely achieved by modern knee replacements. Therefore, current development in knee replacement design and technique has two primary objectives; (1) To maximise longevity of the replacement, and (2) To recreate normal knee kinematics and function [103].

1.4.1 History

The first documented knee replacements were made of ivory and implanted in the mid-to-late 19th century. In the 1880s, Themistocles Glück had several TKR procedures that were initially successful, but ultimately failed due to chronic infection having been implanted in tuberculous knees [104]. There were more attempts to create a successful knee replacement throughout the first half of the 20th century without any further success. In the 1950s, Walldius developed a hinged implant with large intramedullary stems to replace the femoral and tibial articular surfaces [105]. Similar implants based on the hinged prosthesis were developed by other surgeons which provided satisfactory outcomes for patients for longer periods of time than any previous design. However, the hinged implants only allowed flexion and extension and therefore failed to replicate the complex movements of the knee and had a high failure rate due to early loosening [106, 107].

The 1970s were the beginning of modern knee replacement with the concept of metal-on-polyethylene knee replacements adopted from the successful Charnley metal-on-polyethylene hip replacements. These newer implant designs no longer had a mechanical link between the femur and tibia which reduced constraint of the prosthesis to restore function of the knee. Polymethyl methacrylate also began being used as bone cement which improved fixation of implants. Bicompartmental implants which retained the tibial eminence and cruciate ligaments were designed firstly by Gunston (Polycentric Knee) [108]. This design was closely followed by cruciate-sacrificing design from Freeman & Swanson in London (Freeman-Swanson Bicompartmental Knee Prosthesis) and Insall, Ranawat & Walker at the Hospital for Special Surgery (Duocondylar Knee) [109, 110]. Removal of the tibial eminence and cruciate ligaments meant a larger, single tibial implant could be used and these implants could be aligned mechanically. However, lack of any structure to replace the cruciate ligaments led to instability which was a major cause of failure for these implants. In 1973, Freeman & Swanson introduced the Imperial College London Hospital prosthesis, the first tricompartmental knee replacement with a patellar button added to resurface the patella [111]. Insall et al. followed in 1974 with a similar cruciate sacrificing, tricompartmental design of their own called the Total Condylar prosthesis [112]. This design was the foundation for modern TKR. In 1975, Ritter requested a Total Condylar prosthesis with a posterior slot in the tibial component so that the PCL could be retained for what would be the first cruciate retaining TKR [113]. In 1978, the Insall-Burstein prosthesis was introduced as the first posterior stabilised TKR with a central cam added to the femur which engaged with a post on the tibial component at 70^{o} of flexion for stability [114]. Modern TKR is explored further in **Section 1.4.3**.

The concept of UKR was first proposed by McKeever and MacIntosh in the 1950s [115]. The results of early UKRs were mixed but their designs set the foundation for more successful modern UKRs, discussed in **Section 1.4.4**, which also emerged in the 1970s [116, 117].

1.4.2 Indications for Knee Replacement

Osteoarthritis is the indication for over 97% of the primary knee replacements recorded in the NJR [14]. Other indications for knee replacement include rheumatoid arthritis, other types of inflammatory arthritis, avascular necrosis, trauma, and reconstruction of the knee following the resection of bone tumours [14, 17].

1.4.3 Total Knee Replacement (TKR)

TKR is the mainstay of surgical treatment for knee osteoarthritis accounting for approximately 90% of all primary knee replacement procedures [14]. The most frequently used TKRs, as reported in major English language joint registries, are summarised in **Table 1.2**.

In TKR, the distal femur and proximal tibia are replaced with metal alloy components with or without the resurfacing of the posterior surface of the patella with polyethylene. Whether patellar resurfacing is beneficial remains controversial [118, 119]. To facilitate component positioning, either the ACL or both cruciate ligaments are sacrificed during the implantation of most TKRs. In posterior stabilised TKR both the ACL and PCL are sacrificed with a cam on the femoral component engaging a post on the tibial polyethylene to constrain the implant during flexion. Cruciate retaining TKR designs are less constrained and retain the PCL to provide stability during flexion. There are also bicruciate retaining TKR designs which have had problems historically, but newer bicruciate retaining designs have shown to be non-inferior to other TKR designs and may have substantial benefits for high demand patients [120, 121].

Most TKRs will have a fixed polyethylene bearing on the superior surface of the tibial component. Some designs have a mobile bearing which theoretically decreases polyethylene wear but has the additional risk of bearing dislocation. The bearing allows the femoral component to roll on its surface to facilitate function of the knee.

In most cases the metal components are fixed to the bone with polymethyl methacrylate (bone cement), however the use of cementless implants is increasing [14-17]. Cementless components rely on a roughened, porous undersurface which achieves primary fixation through a press-fit and encourages bony ingrowth to achieve secondary fixation through osseointegration in the long-term [122]. The proposed benefits of cementless fixation are that they allow more bone stock to be retained, eliminate the risk of cementing errors and debris, and provide a biological form of fixation. Cementless fixation may be better than cemented in the in the long-term as with cemented components bone can resorb or cement can degrade and lead to implant loosening. The main disadvantage of cementless fixation is that there is limited evidence on the long-term outcomes of cementless TKRs. Use of bone cement can also lead to the rare complication of pulmonary cement embolism [123]. There was concern about the use of cementless TKR after early results suggested higher rates of aseptic loosening compared to cemented TKRs [124]. More recent results are promising suggesting that the survival of cementless TKRs are as good, if not better, than cemented TKR [122, 125]. As complications of cementless TKRs, such as aseptic loosening, are most often an issue of the tibial component, many surgeons have started to implant hybrid TKRs with a cementless femoral component and cemented tibial component. Hybrid TKR appears to achieve results comparable to cemented TKRs and are increasing in use [126, 127]. However, cemented TKRs remain the standard due to their large body of supportive evidence and as shown in **Table 1.2**, cemented cruciate retaining TKRs are by far the most widely used implant type.

TKRs are a good treatment for end-stage knee osteoarthritis with good long-term survival and clinical outcomes [128, 129]. Historical reports suggest more than 20% of patients are dissatisfied with their outcome after TKR [130]. Although contemporary dissatisfaction rates are closer to 10%, maximising knee function and ensuring patients can fulfil their ADLs to the fullest extent remains a challenge for TKR [131].

Table 1.2 Summary of the most frequently used Total Knee Replacements in major English language joint registries for 2022 [14-17]. Implant name and manufacturer are shown, along with whether the implant is cemented or cementless.

Ranking	**National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man** ** Implant type (i.e. cruciate retaining or posterior stabilised) not specified*	**Australian Orthopaedic Association National Joint Replacement Registry**	**New Zealand Joint Registry**	**American Joint Replacement Registry**
#1	Triathlon *(Stryker, Cemented))*	Triathlon Cruciate Retaining *(Stryker, Cemented)*	Triathlon Cruciate Retaining *(Stryker, Cemented)*	Triathlon Cruciate Retaining *(Stryker, Cemented)*
#2	PFC Sigma Bicondylar *(DuPuy Synthes, Cemented)*	Persona Cruciate Retaining *(Zimmer Biomet, Cemented)*	Attune Cruciate Retaining *(DuPuy Synthes, Cemented)*	Persona Cruciate Retaining *(Zimmer Biomet, Cemented)*
#3	Nexgen *(Zimmer Biomet, Cemented)*	Attune Cruciate Retaining *(DuPuy Synthes, Cemented)*	Persona Cruciate Retaining *(Zimmer Biomet, Cemented)*	Persona Posterior Stabilised *(Zimmer Biomet, Cemented)*
#4	Attune *(DuPuy Synthes, Cemented)*	GMK Primary *(Medacta, Cemented)*	Triathlon Cruciate Retaining *(Stryker,* ***Cementless****)*	Triathlon Posterior Stabilised *(Stryker, Cemented)*
#5	Vanguard *(Zimmer Biomet, Cemented)*	Attune Posterior Stabilised *(DuPuy Synthes, Cemented)*	Attune Cruciate Retaining *(DuPuy Synthes,* ***Cementless****)*	Attune Posterior Stabilised *(DuPuy Synthes, Cemented)*

1.4.4 Unicompartmental Knee Replacement (UKR)

UKR is a treatment option for patients with end-stage knee osteoarthritis that is isolated to a single compartment of the knee. UKRs can be subclassified as unicondylar, where the medial or lateral compartment is replaced, and patellofemoral, where the patellofemoral joint is replaced. UKR usage varies widely between hospitals and countries, however, patellofemoral replacements and lateral UKRs generally account for approximately 1% of all primary knee replacements each [14]. Therefore, this section will focus on medial UKR which is more commonly used, owing to the higher frequency of osteoarthritis isolated to the medial compartment of the knee [14].

The first modern UKR designs were the St Georg Sled and Marmor Modular Knee which were introduced in 1969 and 1972, respectively [24]. The two designs both had polycentric metal femoral condyles and a flat polyethylene tibial component which were fixed with bone cement [24, 116]. These early designs were troubled by loosening secondary to distortion of the polyethylene tibial components [116]. This led to metal-backed tibial implants being used, but due to the very small contact area of a spherical femoral component on a flat tibial component, problems of polyethylene bearing wear and deformation persisted [24, 100, 132]. To overcome this limitation, John Goodfellow and John O'Connor proposed the use of congruous mobile bearings for UKR and developed a design which became the OUKR, which is discussed extensively in **Section 1.6** [24].

Today with improvements in surgical technique, polyethylene manufacturing, and a better understanding of indications for UKR, very good results can be achieved using either fixed or mobile bearing UKRs [133]. However, debate continues as to whether UKR or TKR is the optimal treatment of end-stage osteoarthritis isolated to a single compartment of the knee [134-136]. Compared to TKR, UKR is more cost-effective [12], has fewer perioperative complications [137], faster recovery [11], and results in better functional outcomes for patients [8, 9]. However, UKRs continue to have higher revision rates than TKRs reported in joint registries [14-17]. Reasons for these higher revision rates for UKRs include a lower threshold for revision compared to TKR [138, 139], UKR being a more technically demanding procedure [13], and UKR being underused [12]. Some surgeons view UKR as a penultimate treatment for knee osteoarthritis, especially in younger patients, which they will eventually revise to a TKR. A benefit of UKRs is that they are generally easier to revise as the retained bone stock allows revision with primary TKR components [140]. However, sometimes revisions can be complicated and require revision TKR components with stems and wedges [141, 142]. Therefore, UKRs should not be readily revised or considered a 'stepping-stone' to TKR. UKR has more precise implant positioning requirements compared to TKR, which is further complicated when minimally-invasive surgery and/or mobile bearing implants are used [143]. The thought that a UKR is more difficult to perform and more likely to be revised prevents many surgeons performing UKR, with less than 10% of orthopaedic surgeons globally using UKRs [117]. This further contributes to higher revision rates, which are closely linked to a surgeons UKR volume [21, 22, 144]. Studies have shown that to achieve acceptable results, surgeons should perform UKRs for at least 20% of their knee replacements, with optimal usage being 40% to 60% [21, 22]. This proportion is unattainable if classical Kozin and Scott indications for UKR are applied [145]. These criteria, published in 1989, dictate that UKR patients should be over 60 years old, should not be physically active, and weigh under 82 kilograms, among other criteria. These indications are outdated with more recent studies with modern UKR implants showing that patients younger than 60 years old achieved good results and that clinical outcome is independent of body mass index (BMI) [146-149]. Studies have indicated that by applying broader indications, up to 50% of patients with end-stage knee osteoarthritis may be eligible for UKR [12]. In Denmark, UKR usage has increased from 2% to over 20% in the last 20 years showing that it is possible to increase UKR volume to acceptable levels [150, 151]. Time will tell whether increased usage will bring UKR long-term revision rates closer to TKR.

The most frequently used UKRs as reported in major English language joint registries are summarised in **Table 1.3**. Cementless fixation has proven more popular with UKR compared to TKR (**Table 1.2**), largely due to the success of the cementless OUKR which is currently the most frequently used UKR in the NJR and New Zealand Joint Registry

(NZJR), and second most frequently used in the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). The cementless OUKR is not currently approved by the Federal Drug Agency in the United States of America (USA), and therefore does not appear in the American Joint Replacement Registry (AJRR).

Table 1.3 Summary of the most frequently used Unicompartmental Knee Replacements in major English language joint registries for 2022 [14-17]. Implant name and manufacturer are shown, along with whether the implant is cemented or cementless.

Ranking	National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man	Australian Orthopaedic Association National Joint Replacement Registry	New Zealand Joint Registry	American Joint Replacement Registry
#1	Oxford Unicompartmental Knee Replacement, *(Zimmer Biomet, **Cementless**)*	Restoris MCK *(Stryker, Cemented)*	Oxford Unicompartmental Knee Replacement, *(Zimmer Biomet, **Cementless**)*	Restoris MCK *(Stryker, Cemented)*
#2	Physica ZUK *(Lima, Cemented)*	Oxford Unicompartmental Knee Replacement, *(Zimmer Biomet, **Cementless**)*	Persona Partial Knee *(Zimmer Biomet, Cemented)*	Persona Partial Knee *(Zimmer Biomet, Cemented)*
#3	Persona Partial Knee *(Zimmer Biomet, Cemented)*	Persona Partial Knee *(Zimmer Biomet, Cemented)*	Restoris MCK *(Stryker, Cemented)*	Oxford Unicompartmental Knee Replacement, *(Zimmer Biomet, Cemented)*
#4	Sigma High Performance Partial Knee *(DuPuy Synthes, Cemented)*	Journey II UK *(Smith & Nephew, Cemented)*	Physica ZUK *(Lima, Cemented)*	Triathlon PKR *(Stryker, Cemented)*
#5	Restoris MCK *(Stryker, Cemented)*	Sigma High Performance Partial Knee *(DuPuy Synthes, Cemented)*	Journey II UK *(Smith & Nephew, Cemented)*	Sigma High Performance Partial Knee *(DuPuy Synthes, Cemented)*

1.4.5 Knee Replacement Instrumentation and Technique

The traditional surgical approach for knee replacement is a medial parapatellar incision that is about 20-to-30 centimetres long with eversion of the patella. Other common approaches include the lateral parapatellar, midvastus, and subvastus approaches [152, 153]. Minimally invasive approaches with a much smaller incision were pioneered with

UKRs in the 1990s but are now also being used with TKR [154]. Use of a minimally invasive approach has the benefits of a smaller scar, less blood loss, and faster postoperative recovery, but the limited exposure offered by a small incision may increase the risk of surgical errors and lead to poor outcomes [155, 156]. A minimally invasive approach also usually requires special miniaturised instrumentation.

Following arthrotomy, resection of the distal femur and proximal tibial for knee replacement is set using resection guides which control resection depth and angle to align the components. There are several theories for how to best align components for both TKR and UKR which vary between implants and are a topic of extensive debate. Resection guides can be either extramedullary and attached to a patient's limb or intramedullary where a rod is inserted in the intramedullary canal of the femur or tibia to guide the resection.

After bony resection, trial implants and balancing blocks or gauges are used to ensure the correct polyethylene bearing size is selected so that the soft tissues and gaps in flexion and extension are balanced. Following this step, the final components are implanted.

Due to the difficulty of accurately performing resections, appropriately balancing the knee, and a desire to personalise the surgical technique to the anatomy of each individual patient, technology to aid the surgeon is an ongoing area of development [157]. The main two types of technology being developed are patient specific instrumentation (PSI) and computer assisted surgery (CAS).

PSI involves generating personalised cutting guides for each patient based on 3-dimensional (3D) pre-operative imaging, such as CT or MRI. With the guidance of imaging, the surgeon can make a pre-operative plan for factors such as component size, position, rotation, and gap balancing. Personalised cutting guides can then be produced which are compatible with the standard instrumentation for the procedure. The theoretical benefits of PSI include better functional outcomes, reduced blood loss, and reduced operating time. However, none of these benefits have been shown consistently in the literature [157, 158].

CAS can be separated into two main arms: robotics and navigation. The first TKR surgery using robotics was completed in 1988 and since many robotic surgery platforms for knee replacement have been developed [159]. These systems generate 3D reconstructions of the knee joint using either an imageless system which creates a reconstruction from registration of landmarks intraoperatively or an image-based system that creates a reconstruction from pre-operative imaging. The surgeon can create a surgical plan using these reconstructions and then complete the surgery using a robotic arm to execute this plan. Robotic systems often also have constraints built in to prevent the surgeon from making cuts that are outside the surgical plan. The first navigated TKR was performed in 1997 using an imageless system and, like robotics, the use of navigation in knee replacement has expanded rapidly and navigation systems can be image-based or imageless [160]. Navigation systems will guide a surgeon to make resections so that the components will be aligned according to a pre-operative plan, usually through information displayed on a screen. A recent development in navigation systems is the use of accelerometer guided instruments which can help to align cutting guides and position instruments without the need for a large computer system and screen [157].

The use of CAS, both robotics and navigation, have been widely shown to improve implant alignment compared to standard instrumentation [161, 162]. However, the major criticism of CAS is that given its high cost, improvement in functional outcomes and implant survival have rarely been shown with any demonstrated improvements being modest [161, 163, 164]. Despite this, use of CAS in knee replacement has increased rapidly. The AOANJRR reported that 41% of UKRs and 30% of TKRs were robotically assisted in 2022 [15]. An additional 24% of TKRs were implanted using navigation and 11% with PSI [15]. Robotically assisted UKRs in the AOANJRR were associated with a lower revision rate compared to UKRs implanted without assistance with seven years follow-up [15]. An AOANJRR study also demonstrated that use of navigation for TKR can reduce revision rates in patients under 65 years old [165]. Use of CAS for knee replacement is also increasing in the USA where 17.5% of TKRs implanted in 2022 used CAS (13.4% robotically assisted and 4.1% guided by navigation) [16].

1.5 THE OXFORD UNICOMPARTMENTAL KNEE REPLACEMENT (OUKR)

1.5.1 History, Design, and Clinical Outcomes

Early fixed-bearing UKR designs were plagued by high wear rates [24, 116, 166, 167]. To avoid this complication, the use of a mobile-bearing design was proposed by Oxford-based surgeon John Goodfellow and engineer John O'Connor [24]. The design consisted of a spherical femoral component and flat tibial component that were separated by an unconstrained mobile bearing which remains fully congruent throughout the knee's full range of motion (**Figure 1.5A**). The bearing, which was flat inferiorly and concave superiorly, was held in place only by the compression of the metal articular surfaces generated by the soft tissues of the knee. The design was patented in 1974 and became known as the Oxford Knee. Since the Oxford Knee was first implanted in a patient in 1976, it has gone on to become the most widely used UKR in the world [14-17]. The implant and its associated instrumentation have undergone changes during this time but the fundamental design of the implant has remained constant.

1.5.1.1 *Phase I*

When the first Oxford Knee was implanted in a patient in 1976, it was used as a bicompartmental implant to replace both the medial and lateral compartments of the knee [168]. The spherical femoral component was available in one size (47.6 mm diameter). The undersurface of the femoral component had three inclined facets and one peg for fixation (see **Figure 1.5A**). The tibial components were flat with a wall that would run along the medial tibial spine when implanted and there was an 11 millimetre deep keel on the undersurface for fixation [168]. The Phase I tibial components came in five sizes which were universal and used for the right or left knee and lateral or medial compartment. There were nine bearing thicknesses, ranging from 3.5 mm to 11.5 mm thick, increasing in thickness by 1 mm increments [168].

The Phase I Oxford Knee had no set indications in the beginning and was used in patients with osteoarthritis and rheumatoid arthritis. The designers report of the first 125 bi-UKRs using the Oxford Knee, with two to six years follow-up, found that 90% of patients had relief of pain and improved walking distance in 75% [168]. It was also noted that ACL-deficient patients had worse outcomes with a 10.5% failure rate compared to patients with a functional ACL who had no implant failures. Goodfellow and O'Connor also recognised that approximately half of the knees they were treating had osteoarthritis isolated to a single compartment of the knee, which led to using the Oxford Knee as a UKR, and the birth of the OUKR [169-171]. With a mean follow-up of three years, the first 103 Phase I OUKRs relieved pain in 96% of patients and improved walking distance in 83% [170]. Like with the bicompartmental Oxford Knee, Phase I OUKRs implanted in ACL-deficient patients had a three times higher risk of failure (16% versus 5%) [170]. A further study of 301 knees (205 bicompartmental, 65 medial, 31 lateral) found that the survival rate in knees with a functional ACL was 95% compared to 81% in patients with an absent or damaged ACL [171]. These findings led to recommendation that the OUKR only be used in knees with functional cruciate ligaments [171].

It was acknowledged as early as Ahlback's 1968 study that unicompartmental knee osteoarthritis occurs more commonly in the medial compartment [75]. However, during the early use of the OUKR a pattern of knee osteoarthritis which has become known as anteromedial osteoarthritis was described by White, Ludkowski, and Goodfellow [172]. In anteromedial osteoarthritis there is anterior erosion of the bone and cartilage of the medial tibial plateau while the posterior surface of the plateau remains intact (Figure **1.3**). In patients with anteromedial osteoarthritis, the ACL is functional, and the knee will have a correctable varus deformity. The varus deformity is present in extension but diminishes in flexion as the femoral condyle rolls back onto the intact posterior tibial plateau. The features of anteromedial osteoarthritis were seen in every knee in a series of 46 knees that were treated with medial OUKR. Thus, anteromedial osteoarthritis became the primary indication for the OUKR [24].

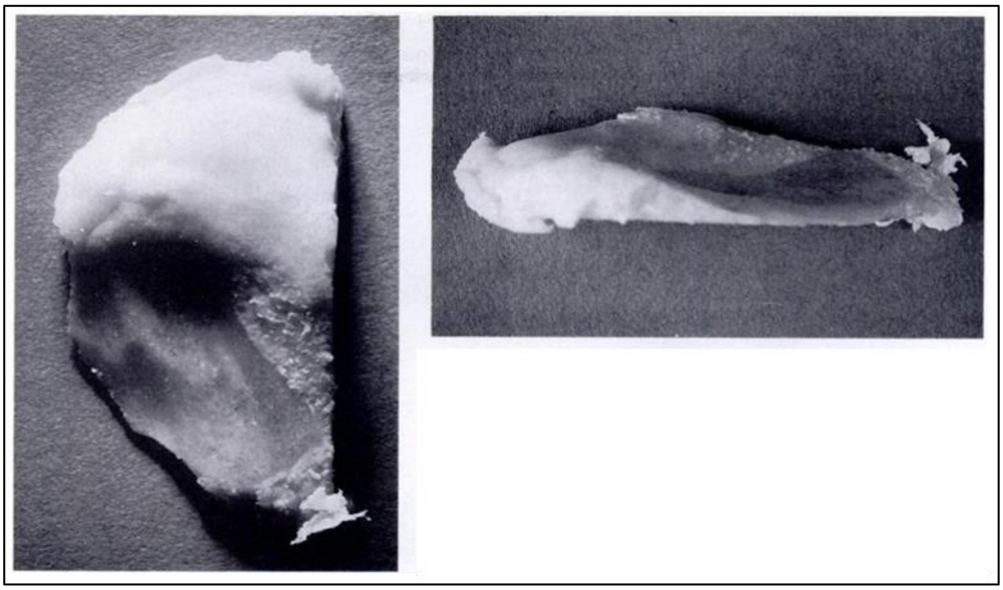


Figure 1.3 An example of anteromedial osteoarthritis from the series studied by White, Ludkowski, and Goodfellow. A medial tibial plateau (which was excised in preparation for a medial Oxford Unicompartmental Knee replacement), with a characteristic anterior erosion is shown. Figure modified from [172].

1.5.1.2 *Phase II*

The Phase II implant was introduced in 1987 specifically for use as a UKR, predominantly for replacement of the medial compartment [24]. Bearing dislocation, along with tibial component aseptic loosening, were the major reasons for revision of Phase I implants [168-171]. To counteract anterior bearing dislocation, the posterior margin of the mobile bearing was increased [173]. Surgeons also reported difficulty positioning the components to balance the flexion and extension gaps when using the Phase I implant, so changes were made to the surgical technique to improve gap balancing (discussed further in **Section 1.6.2**). To accommodate the new technique, the femoral component was modified to have a concave inferior facet and flat posterior facet **(Figure 1.5B)** [24].

These changes reduced the rate of bearing dislocation and improved restoration of knee kinematics [24]. A 10-year cumulative survival of 98% was published in the designer surgeons' 10-year combined results of the Phase I and Phase II OUKR [174]. Similar results were achieved by an independent surgeon, Ulf Svard, who published a series with a 10-year survival of 95% [175].

1.5.1.3 *Phase III*

The Phase III OUKR (**Figure 1.5C**) was designed for replacement of the medial compartment of the knee only. The single femoral component size was replaced with five sizes ranging from extra-small (44 mm diameter) to extra-large (56 mm diameter). The universal tibial component was replaced with anatomically shaped components, specific for left and right knees, that maximise coverage of the proximal tibia. Anatomically-shaped bearings were also introduced in five sizes to match the femoral component sizes and offered in seven thicknesses from 3.5 mm to 9.5 mm [176].

Both Phase I and Phase II OUKRs were implanted through an open approach, however, to improve patient recovery, the Phase III OUKR was designed to be implanted using a minimally invasive approach [169]. This involved miniaturisation of the instrumentation (see **Section 1.6.3**).

Using a minimally invasive approach did improve patient recovery times compared to using an open approach for OUKR [177]. For the Phase III OUKR the designer surgeons have reported a 94% and 91% cumulative survival rate at 10 and 15 years, respectively. [19]. A systematic review found the cumulative survival to be 93% and 89% at 10 and 15 years, respectively, indicating good results can be achieved by both designer and non-designer surgeons [178]. However, the NJR reports a cumulative revision rate of 11% at 10-years for the Phase III OUKR [14]. It is thought that the poorer performance of the implant in registry data is due to higher revision rates from low-volume surgeons and hospitals, who have been reported to achieve worse results with UKR [21, 23, 144, 179].

1.5.1.4 *Cementless OUKR*

Despite the Phase III cemented OUKR achieving very good results, it was still reported that it had higher revision rates than TKRs in joint registries. In NJR data aseptic loosening and pain were common reasons for revision of the Phase III cemented OUKR. However, aseptic loosening and pain were responsible for a much lower proportion of revisions in the designer surgeons' series (see **Table 1.5**). It was thought that this discrepancy in revision indications may be due to the more challenging nature of the minimally invasive technique used with the Phase III OUKR leading to surgical errors. Possible surgical errors include an insufficient cement mantle, bearing impingement on excess cement, loose cement fragments in the joint space, or physiological radiolucencies below the cemented tibial component, which can be misinterpreted as loosening resulting in unnecessary revision [32]. In part to address these issues cementless OUKR components were introduced in 2004 [180]. The cementless components differ from the cemented as they have a hydroxyapatite-coated porous titanium undersurface, and the cementless femoral component had a second, smaller peg anterior to the larger, central peg found on the cemented femoral component (**Figure 1.5D**). This second peg was also added to the cemented design soon after and has been shown to improve fixation and survival [181, 182]. Rather than relying on bone cement for fixation, the cementless components rely on an interference press-fit for primary fixation where the keel slot and femoral drill holes are narrower than the keel and pegs of the tibial and femoral components, respectively (**Figure 1.4**). Bony ingrowth into the porous titanium and hydroxyapatite coating of the components facilitates secondary fixation.

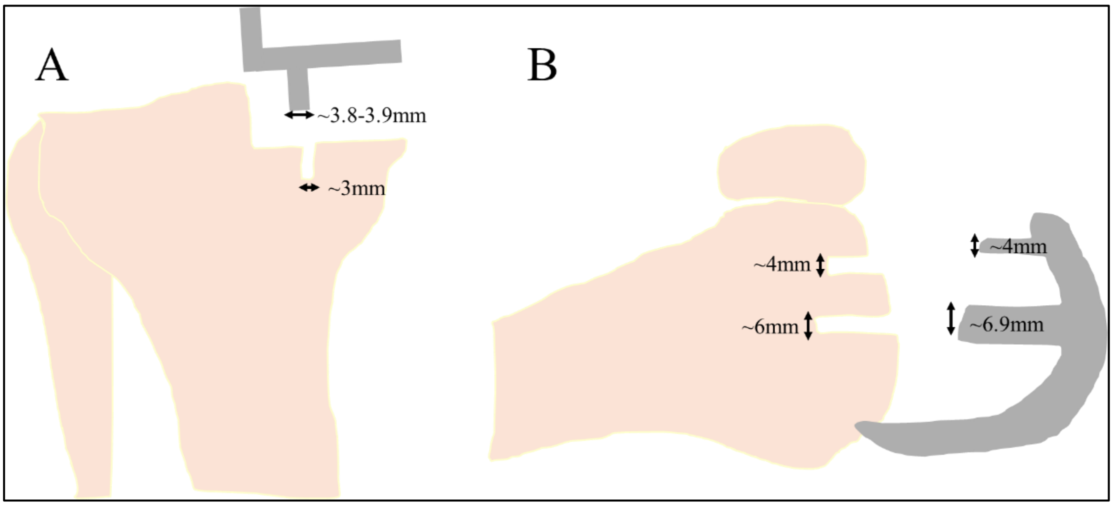


Figure 1.4 A diagram of the interference press-fit the cementless tibial and femoral components rely upon for primary fixation. **A** The cementless tibial keel is approximately 0.8-0.9 mm wider than the tibial keel slot, creating an interference press fit. **B** The larger peg is approximately 0.9 mm wider than the main fixation hole made with a 6 mm drill, creating an interference press fit. There is also interference between the flat posterior flange of the femoral component and the resected posterior tibial condyle. The second smaller femoral peg is the same diameter (4 mm) as the smaller hole made with a 4 mm drill.

The designer surgeons reported a 10-year survival of 98% using the endpoint of revision and 97% for any reoperation with the cementless OUKR [20]. Like the Phase III cemented OUKR, the designer surgeons' results tended to be better than those reported in registries. A matched NJR study also found the 10-year survival of the cementless OUKR (93%) to be superior to the cemented (90%) [181]. In the NJR, the 10-year cumulative revision rate for the cementless OUKR is approximately half that of the cemented OUKR (5.9% versus 11.5%) [14]. However, this may be due to a greater proportion of experienced surgeons using the cementless version, especially when it was first introduced.

1.5.1.5 *Lateral Compartment*

Phase I and Phase II implants were used to replace the lateral compartment of the knee, either as a unicompartmental or bicompartmental replacement [24, 173]. The major issue with use of a mobile bearing implant in the lateral compartment is that there is a higher risk of bearing dislocation largely due to the laxity of the LCL in flexion [24]. In part to address this risk, a lateral compartment-specific implant was introduced in 2004, the Oxford Domed Lateral (ODL) [183]. The ODL had a domed tibial component combined with a biconcave mobile bearing. Due to ongoing issues with dislocation a fixed bearing tibial component, the Fixed Lateral Oxford (FLO), was introduced in 2015 [184]. The ODL and FLO tibial components can be used interchangeably, so if the surgeon is concerned about wear (i.e. in a young, active patient) they can use the ODL. If they are concerned about the risk of bearing dislocation, they can use the FLO.

This thesis will focus on the medial OUKR, and therefore these components will not be discussed further.

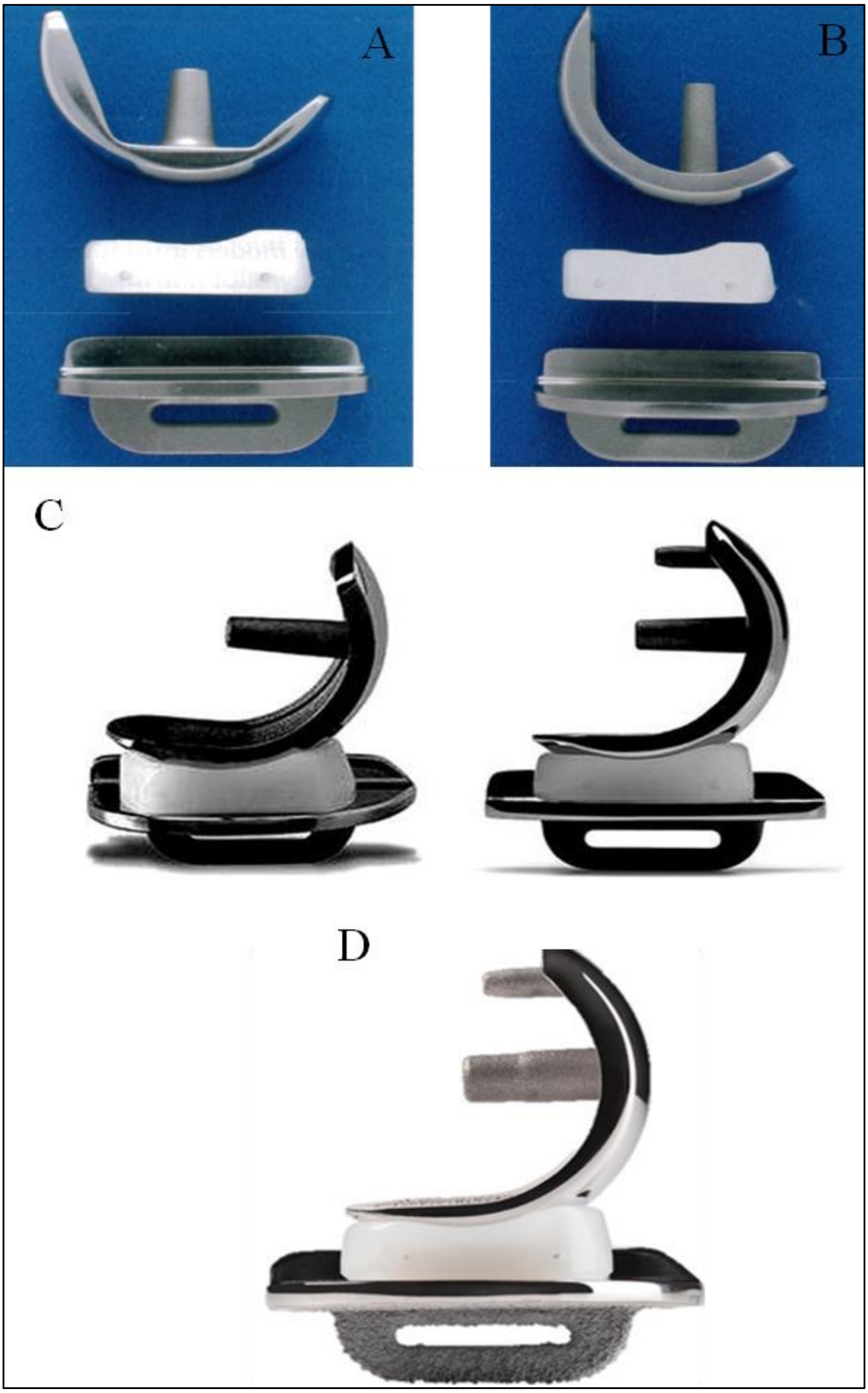


Figure 1.5 A Phase I Oxford Unicompartmental Knee Replacement (OUKR). Image taken from [24]. **B** Phase II OUKR. Image taken from [24]. **C** Phase III Cemented OUKR: Single peg (left) and twin peg (right). Images taken from [181]. **D** Phase III Cementless OUKR with a hydroxyapatite-coated porous titanium under-surface. Image taken from [185].

1.5.2 Indications

According to the designer surgeons, the current primary indication for OUKR (Phase III cemented and cementless) is anteromedial osteoarthritis that is bone-on-bone in the medial compartment of the knee. The knee should also have an intact MCL and cruciate ligaments, a correctable varus deformity, asymptomatic or absent patellofemoral disease and full cartilage thickness in the lateral compartment.

Secondary indications include avascular necrosis and osteonecrosis isolated to the medial compartment of the knee.

Contraindications for the OUKR include [24]:

- Any form of inflammatory arthritis.
- Absence of a functional ACL, PCL or MCL. ACL integrity should be checked intraoperatively.
- Inability to demonstrate bone-on-bone contact in the medial compartment.
- An intra-articular varus deformity that is not fully correctable.
- Flexion deformity greater than 15° (suggestive of ACL deficiency).
- Flexion range <100° under anaesthesia.
- Erosion of central cartilage in the lateral compartment of the knee.
- Bone loss with grooving in the lateral patellofemoral joint.
- Previous tibial osteotomy.

Unlike the Kozinn and Scott indications for UKR, the indications for the OUKR are based on the pathology and anatomy of the knee. In the designer surgeons' first 1000 Phase III OUKRs, patients that were younger than 60 years old, heavier than 82 kilograms, high activity levels, chondrocalcinosis, or exposed bone in the patellofemoral joint achieved results as good or better than patients without these historical contraindications [186]. These findings indicate that the Kozinn and Scott indications do not apply to the OUKR.

1.6 OUKR SURGICAL TECHNIQUE AND INSTRUMENTATION

Innovative surgical techniques and instrumentation have been key to improving the OUKR. It continues to be an area of advancement with several prototype instruments currently undergoing testing and awaiting clinical trial. This section provides an overview of the techniques used for the OUKR, from its introduction to the present, and provides an overview of future optimisation aims.

1.6.1 Phase I

Initially an open anteromedial approach with lateral dislocation of the patella was used to facilitate the replacement of both the medial and lateral compartments of the knee [168]. A triangular prism sawing block (**Figure 1.6**) was used to prepare the femoral condyles simultaneously. Three saw cuts were made to remove 2-to-3 mm slivers of bone matching the three angled facets of the Phase I femoral component.

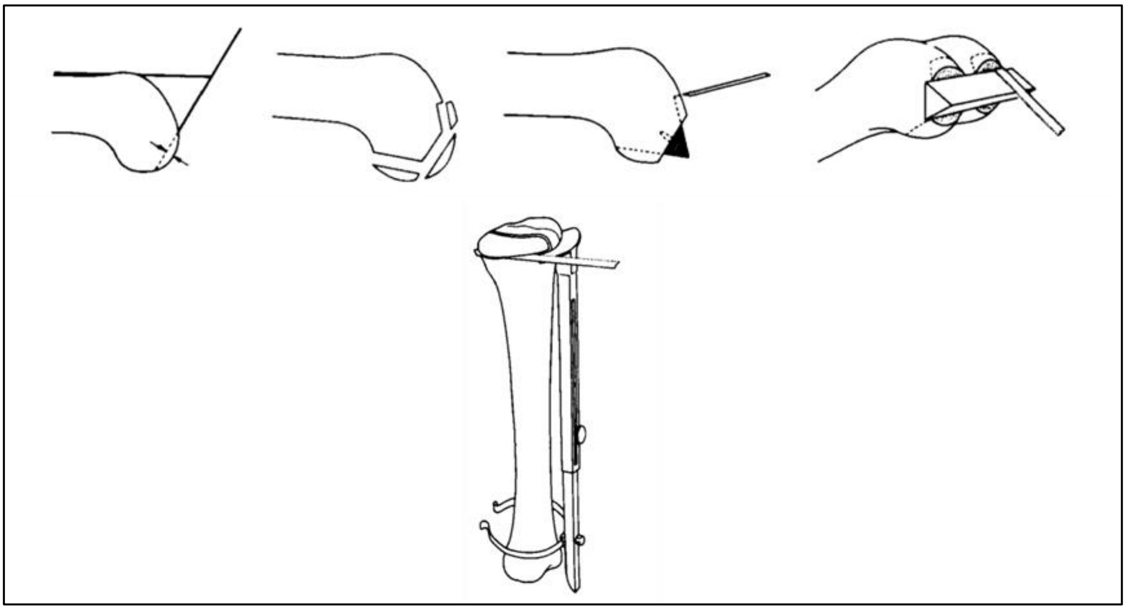


Figure 1.6 The triangular prism saw block used to prepare the femoral condyles and tibial saw guide used to prepare the tibial plateaus for bicompartmental replacement with the Phase I Oxford Knee. Figure taken from [168].

The tibia was prepared using the tibial saw-guide (**Figure 1.6**) to remove small slivers of bone from the medial and lateral tibial plateaus while retaining the intercondylar eminence, including the attachments of the anterior and posterior cruciate ligaments [168]. The tibial saw guide was angled seven degrees inferiorly and posteriorly, an angle which has been retained for the tibial cut to the present day, as this allows for the metal tibial components to be inserted so that the gap between them and the femoral components remains constant throughout the range of flexion [168].

Once the femur and tibia were prepared, trial components were presented to the cut surfaces and gap gauges (**Figure 1.7**) were trialled to determine the thickest possible bearing a compartment could tolerate. The knee would be moved through the whole range of flexion with gap gauges in place to test the stability of the knee. The preparation was finalised by drilling a hole in each femoral condyle for the peg of the femoral components and making a slot in each tibial plateau using a reciprocating saw to receive the keel of the tibial components. The metal components were then fixed with polymethyl methacrylate cement and bearings of correct size were inserted to complete the procedure [168].

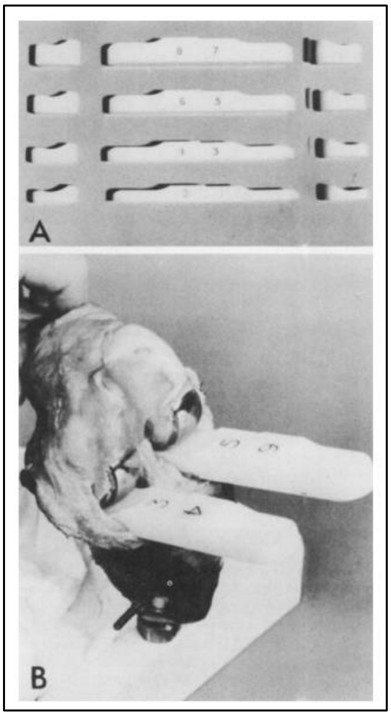


Figure 1.7 A An image showing the different sizes of gap gauges and the bearings of corresponding thickness used with the Phase I Oxford Knee. **B** Gap gauges in situ, highlighting the medial and lateral gaps can be of different sizes and bearings of differing thicknesses can be used to account for this. Figure taken from [168].

1.6.2 Phase II

It was reported that surgeons struggled to accurately position the femoral component in relation to the ligaments of the knee and therefore match the flexion and extension gaps when implanting the Phase I Oxford Knee [24, 175]. To improve the surgeon's ability to accurately place the femoral component, for the Phase II OUKR the femoral condyle was prepared by making a single vertical saw-cut along the posterior surface of the condyle and the inferior surface was milled using a spherically concave bone mill that rotated around a spigot (**Figure 1.8**) [24, 174]. This allowed for the femoral condyle to be appropriately shaped for the Phase II femoral component and bone to be accurately removed in increments so that flexion and extension gaps could be easily balanced intraoperatively [24].

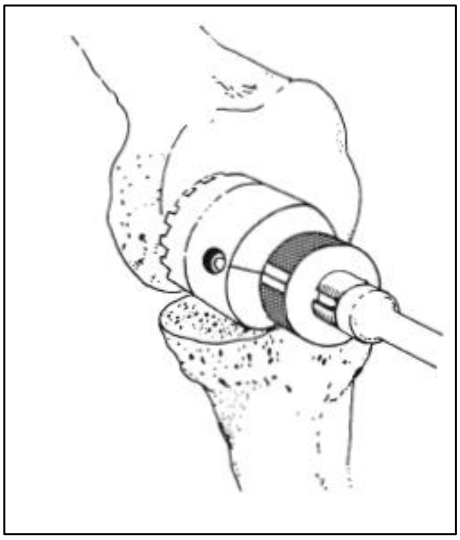


Figure 1.8 Preparation of the medial femoral condyle using the spherically concave bone mill. Figure taken from [24]

1.6.3 Phase III and Microplasty

Miniaturisation of instrumentation for the Phase III Oxford Knee allowed for the operation to be completed using a minimally invasive technique through a small medial parapatellar arthrotomy (**Figure 1.9**) [24, 187]. Standardised instrumentation designed specifically for replacement of the medial compartment also meant the Phase III procedure was more reproducible than previous phases [24].

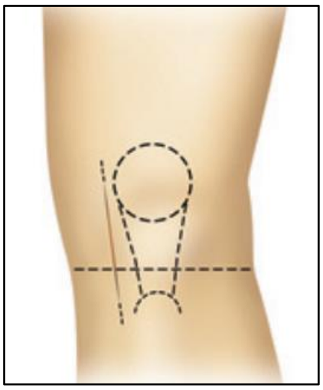


Figure 1.9 The appropriate incision for a minimally invasive medial parapatellar approach used in Phase III Oxford Unicompartmental Knee Replacement. The incision begins 3 cm proximal to the joint line and finishes medial of the tibial tuberosity. The red line marks the incision, horizontal dashed line marks the joint line, dashed circle marks the patella, dashed semi-circle marks the tibial tuberosity, and the dashed oblique lines outline the patellar tendon. Figure taken from [176].

The instrumentation and technique for the tibial resection remained largely the same as in previous phases. A major change was the instrumentation used for drilling the femoral condyle [176]. First, an intramedullary rod was inserted at the point 1 cm anterior to the anteromedial corner of the intercondylar notch. With a tibial template and a gap gauge 1 mm smaller than the flexion gap in situ, the femoral drill guide was positioned as shown in **Figure 1.10**. There were six requirements to ensure this was done appropriately (**Table 1.4**).

Table 1.4 Positioning Requirements for the Original Phase III Femoral Drill Guide and the Microplasty Femoral Drill Guide

Original Phase III (1999)	Microplasty (2012)
1. The gap gauge, which the drill guide sits on, should be against the vertical tibial wall. 2. The 6 mm drill hole of the gauge should lie in the middle third of the femoral condyle, but not necessarily on the centre line. 3. The handle of the femoral drill guide should be aligned with the long axis of the tibia. 4. The anterior face of the femoral drill guide should abut the femoral condyle. 5. The degree of flexion of the knee needs to be manipulated so that the top of the femoral drill guide lies parallel to the intramedullary rod. 6. The lateral surface of the seven-degree fin on the side of the drill guide should be made parallel to the intramedullary rod by internally and externally rotating the tibia.	1. The drill guide must lie in the centre of the femoral condyle. This is confirmed most often by the surgeon marking the centre of the condyle with diathermy or a marker pen prior to positioning the drill. The centreline can then be viewed through the 6-millimetre hole of the drill guide to appropriately position it. 2. The femoral drill guide must abut the bone of the medial femoral condyle.

It was demonstrated that performing the operation through a small incision was associated with a learning curve for surgeons and possibly an increase in surgical errors for inexperienced surgeons [188, 189]. In 2012, instrumentation was modified further with the introduction of “Microplasty” instrumentation to make the procedure more reliable [24]. These instruments were optimised to be compatible with both the cemented and cementless two-peg femoral components [24]. Tibial resection accuracy was improved by the use of the femoral sizing spoon and G-clamp in combination with the tibial saw guide (**Figure 1.11**) [190]. A new femoral drill guide that connects to the intramedullary rod was also introduced to improve the ease and accuracy of drilling the femoral condyle (**Figure 1.11**). Compared to the six positioning requirements of the original Phase III drill guide, the position of the new femoral drill guide is simplified as it comes with only two requirements (**Table 1.4**).

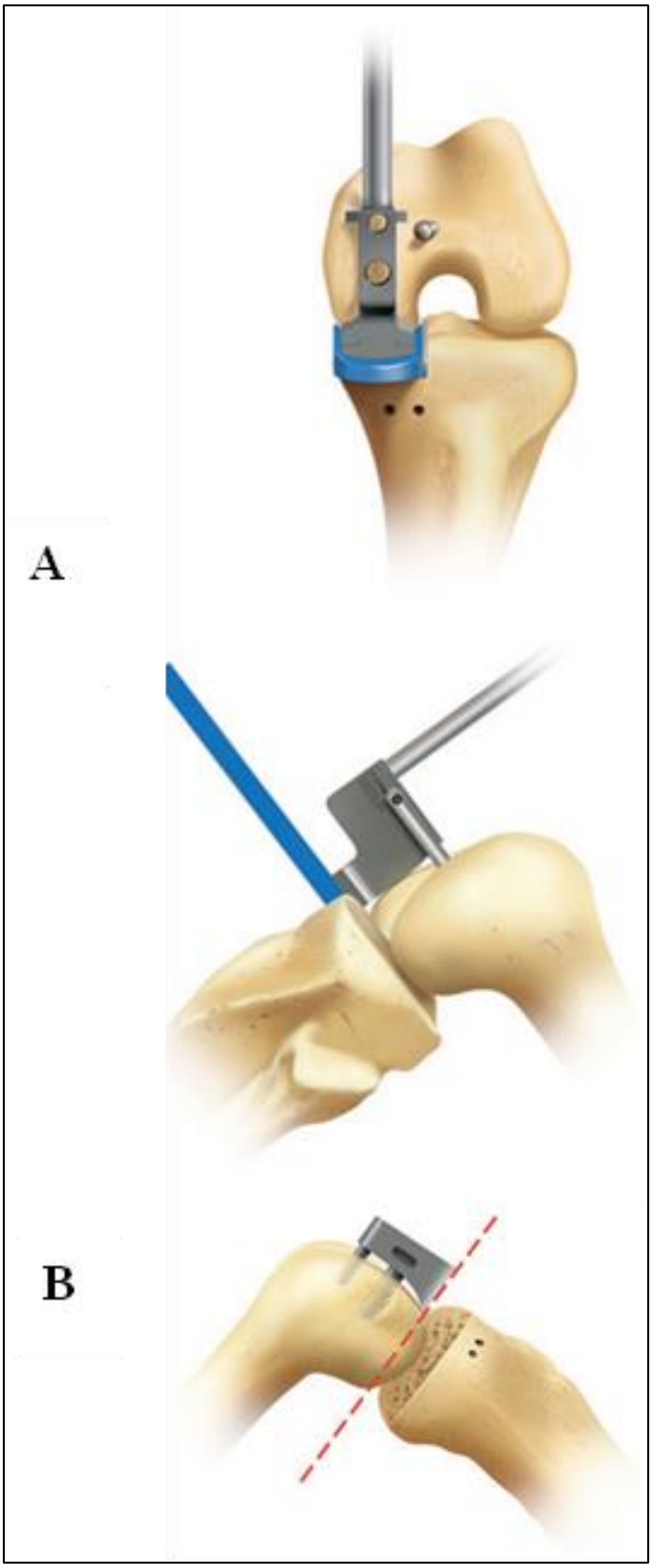


Figure 1.10 A An anterior and lateral view of the position of the Phase III Oxford Unicompartmental Knee Replacement femoral drill guide. **B** The femoral saw block in-situ. The red line indicates the plane of the femoral saw cut to removal the posterior surface of the medial femoral condyle. Figure taken from [176].

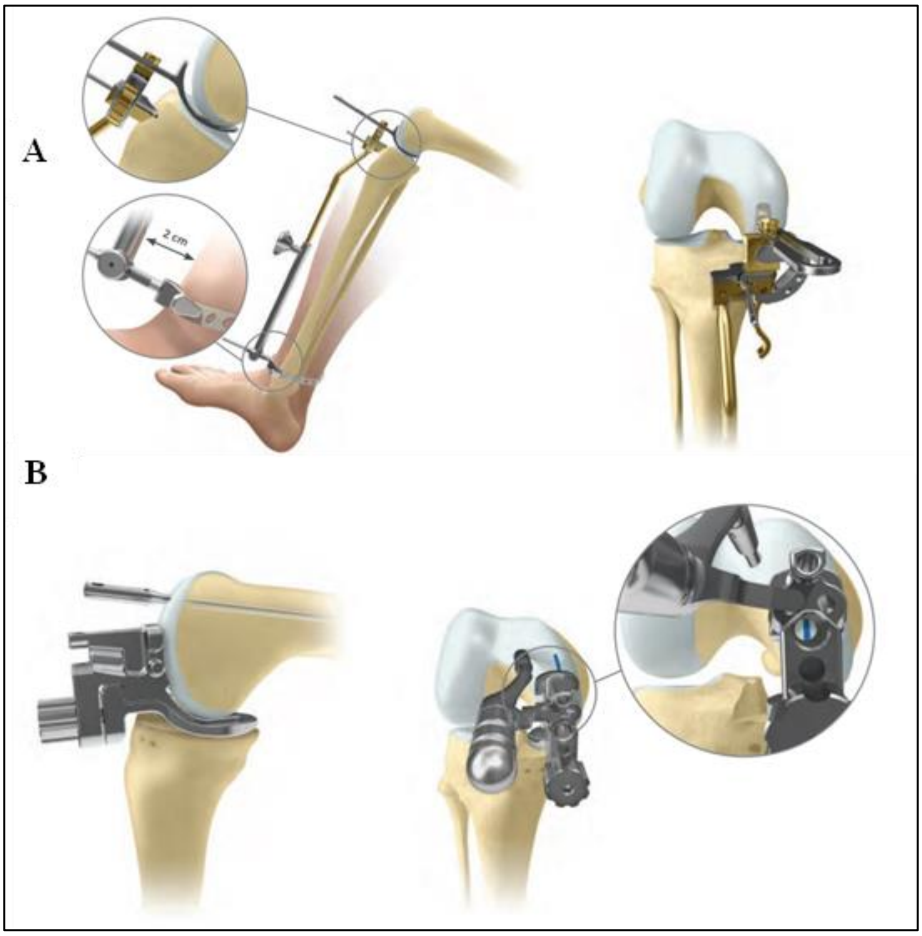


Figure 1.11 A The Microplasty tibial saw guide with femoral sizing spoon and G-clamp. **B** The Microplasty femoral drill guide attached to the femoral intramedullary rod. Figure taken from [190].

A bone collar remover (**Figure 1.12A**) was also introduced to remove the circular collar of bone underneath the flange of the spigot used for the femoral milling is 1 mm or more high [190]. A new anti-impingement guide with anterior mill was introduced to measurably remove bone from the anterior femoral condyle and prevent impingement of the bearing when the knee is in full extension. A new keel-cut saw (**Figure 1.12B**) is now used in place of a reciprocating saw blade to make the cut in the tibia for the keel of the tibial component. Use of this saw assists in the prevention of unnecessarily deep tibial cuts being made, as well as reducing the risk of cuts damaging the anterior and/or posterior cortex of the tibia [190].

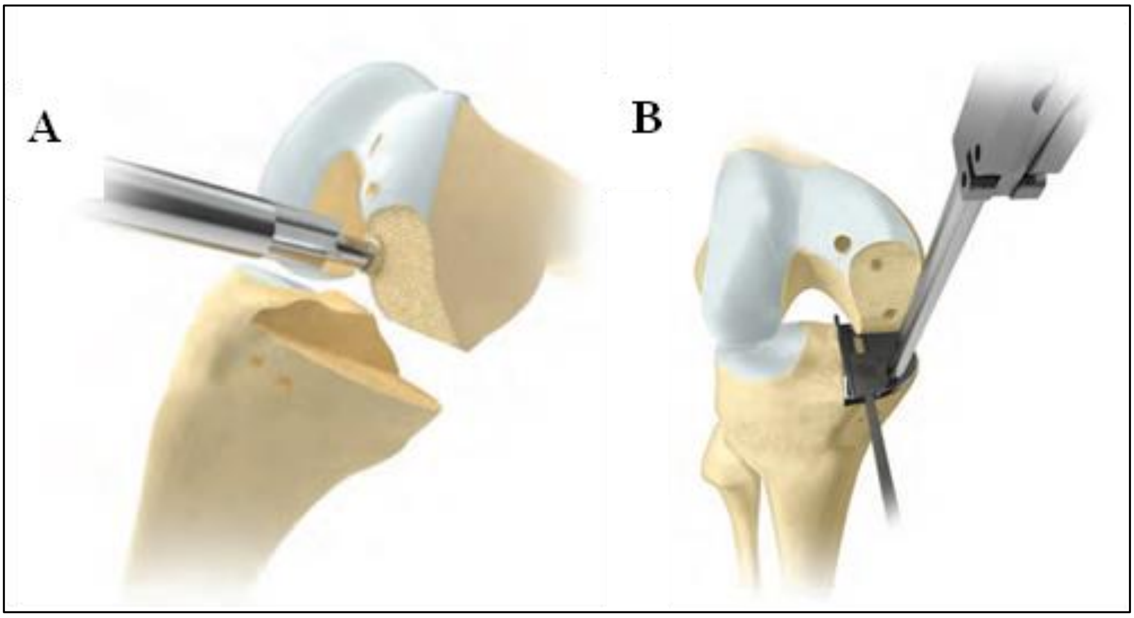


Figure 1.12 A The bone collar remover used to remove excess bone that may accumulate under the flange of the spigot used in the milling of the femoral condyle **B** The Microplasty keel-cut saw used for preparation of the tibial keel slot. Figure taken from [190].

1.6.4 PSI and CAS

In 2012 a patient specific instrumentation system known as Signature was introduced for the OUKR [24]. Based on pre-operative MRIs, the provisional position of the implants can be selected and adjusted by the surgeon [191]. From this data, patient specific cutting guides are produced and used intraoperatively to position the femoral and tibial components. Balancing of the flexion and extension gaps is still done with the conventional instruments. A prospective randomised controlled trial (RCT) by the designer surgeons comparing Signature to Microplasty instrumentation found that Signature instrumentation led to unnecessarily deep tibial resections and the use of larger than optimum (Size 5 or larger) bearings [192]. This resulted in the recommendation that Signature should only be used by experienced OUKR surgeons. In an independent surgeon's cohort, it was found that the Signature system is reliable and achieves the preoperative plan, except for tibial rotation [193]. A further radiographic comparison between OUKRs implanted with Signature and conventional instrumentation revealed there was no difference in implant position between the two surgical techniques [194].

CAS is not presently used routinely with the OUKR. Some studies have reported using navigation systems with the OUKR which have improved implant alignment compared to conventional instrumentation, but significantly increased operating time [195, 196]. Like most CAS systems, no published data has shown that CAS improves long-term outcomes for the OUKR.

1.6.5 Known Instrumentation Limitations and Future Optimisation Aims

Although the Microplasty instruments currently recommended for use with the OUKR achieve very good results, they are not without limitations. There is uncertainty about the optimal patient positioning (supine or hanging leg) [197-199], order of bone preparation (tibia or femur first) [200, 201], use of an intramedullary rod for femoral component positioning [202], and the risk of tibial periprosthetic fracture (TPF) due to vertical overcut or keel slot preparation [203-205]. CAS is now commonly used for knee replacement and there is also speculation whether the OUKR could benefit from CAS [13, 195, 196].

Other considerations for future optimisation of instrumentation include that new instruments have an associated learning curve for surgeons [188, 189]. There is also the known issue of low-volume surgeons having poorer results than experienced surgeons with the current instrumentation [206]. Introducing newer, more complicated instruments may widen the gap in proficiency between inexperienced and experienced surgeons with the OUKR.

The strength of targeting instrumentation optimisation to minimise the risk of complications and improve clinical outcomes is that the regulatory requirements for surgical instruments are less rigorous than the requirements for approval of a new design of the OUKR. In the United Kingdom (UK) the Medicines and Healthcare products Regulatory Agency (MHRA) regulates medical devices. Sterile and/or reusable surgical instruments are given the lowest risk designation Class I whereas total or partial joint replacements, such as the OUKR, are given the highest risk designation of Class III [207, 208]. Consequently, the complexity and time required to get approval for optimised instruments is much less compared to a new implant design. Thus, instrumentation modification is a more immediate way to benefit patients receiving an OUKR and the surgeons who implant them.

1.7 COMPLICATIONS OF THE OUKR

A summary of the common complications that can lead to OUKR revision, reoperation, or unsatisfactory outcomes is presented below. The incidence of complications leading to revision at 10-years in the NJR and the first 1000 designer surgeon cases for the Phase III cemented and cementless OUKR in **Table 1.5.** For each complication an assessment will be made as to whether the complication is well understood and if not whether study as part of this thesis would be feasible and helpful. In addition, issues that could be addressed by improved instrumentation are highlighted.

Table 1.5 The revision incidence (%) due to certain complications at 10-years for the Phase III Cemented and Cementless Oxford Unicompartmental Knee Replacements (OUKRs) in both the designer surgeons' cohorts and a matched study of 10-year data from the National Joint Registry of England, Wales, Northern Ireland, and Isle of Man [20, 31, 142].

Complication	**Cemented Phase III OUKR** **Designer Surgeons' First 1000 Cases**	**Cemented Phase III OUKR** **NJR**	**Cementless OUKR** **Designer Surgeons' First 1000 Cases**	**Cementless OUKR** **NJR**
Lateral Compartment Disease Progression	0.9	1.0	0.4	0.7
Aseptic Loosening	0.1	1.0	0.1	0.4
Bearing Dislocation	0.6	0.4	0.7	0.3
Pain	0.6	0.7	0.5	0.5
Infection	0.5	0.2	0.3	0.2
Periprosthetic Fracture	0	0.1	0	0.3
Bearing Wear	0	0.1	0	0.1
Bearing Fracture	0	0	0	0

1.7.1 Progression of Osteoarthritis in the Lateral Compartment

Progression of osteoarthritis in the lateral compartment is the most common reason for revision of the OUKR in the long-term, accounting for approximately a quarter of OUKR revisions (**Table 1.5**) [209]. Lateral disease progression was the reason for revision of 2.5% of Phase III OUKRs at 15 years in the designer surgeons' series of their first 1,000 and 1.4% at 10 years in systematic review including over 8,000 Phase III OUKRs [19, 178]. In the designer surgeons' unpublished 20-year results of the Phase III cemented OUKR and 15-year results of the cementless OUKRs the revision rates for lateral disease progression were 5% and 1.8%, respectively [210]. A case-control study was unable to identify a link between any component position and lateral disease progression, but there is an increased chance of a patient being revised for lateral osteoarthritis if there is lateral joint space narrowing on their preoperative radiographs [211].

This thesis will not study lateral disease progression as it is unlikely instrument optimisation will reduce the risk of lateral disease progression. However, when considering instrumentation, damage to the MCL and subsequent overstuffing of the medial compartment with a large size bearing should be avoided as it is likely to overload the lateral compartment of the knee and increase the risk of lateral osteoarthritis occurring. It is also suspected that if the bearing is jammed against the tibial wall, this may cause subluxation with an increased risk of lateral osteoarthritis.

Revision to TKR is the usual treatment for lateral disease progression. However, the conversion of an OUKR to a bi-UKR with addition of a lateral UKR, such as the ODL or FLO, has also been shown to be a reliable treatment for lateral disease progression [212, 213]. Conversion to bi-UKR may be advantageous over revision to TKR due to faster recovery, fewer complications, and better function, although a study comparing the two revision methods with a matched cohort of patients is required to make a definitive conclusion [141, 214].

1.7.2 Aseptic Loosening

Aseptic loosening is one of the major causes of revision for the OUKR. 1.3% of cemented Phase III OUKRs in the NJR have been revised due to aseptic loosening [178]. However, in NJR data cementless OUKR (0.4%) are revised for aseptic loosening at less than half the rate of cemented OUKR (1%) at 10 years [181]. Early loosening is likely the result of poor initial fixation because of inadequate cementing with the cemented OUKR [24]. Late loosening may be a result of micromotion preventing osseointegration of the accumulated effects of loading from bearing impingement or implant malalignment [24, 209]. Loosening with the cementless OUKR is rare, so it is poorly understood. The only case of cementless OUKR loosening in the designer surgeons' series was a case of femoral loosening where the main hole for the main fixation peg had been damaged intraoperatively, reducing the interference press-fit [20]. Early aseptic loosening with OUKR may be treated by recementing loose cemented components or replacement of cementless components with cemented ones [20, 24]. In late aseptic loosening the underlying bone is likely to have been damaged and revision to TKR is required [24].

The best method to predict the risk of revision due to aseptic loosening in the long-term is radiostereometric analysis (RSA). A randomised RSA study comparing cemented and cementless fixation of the OUKR was started over 10 years ago [215-217]. Results of this study showed that cementless fixation was as good, if not better, than cemented at five years [216]. However, it is unknown whether cementless fixation of OUKR will be good after 10 years and whether it will be as good as cemented in the very long-term. This needs to be understood before initiating a line of further research into instrumentation related to cementless components. Therefore, a 10-year analysis of this study will be undertaken to assess long-term OUKR fixation in **Chapter 2** of this thesis.

1.7.3 Tibial Component Subsidence

Although late aseptic loosening has rarely been seen with the cementless OUKR, there have been a small number of reports of tibial loosening of cementless OUKR presenting in the few months after operation [33-35, 180, 218, 219]. The phenomenon, described as early tibial component subsidence (TCS) typically occurs when a patient presents with new or persistent pain, and radiographs reveal that the tibial component has subsided into valgus and tilted posteriorly [24]. This subsidence is in the order of several millimetres and differs from the inferior subsidence of tenths of a millimetre seen in RSA studies within the first six months for almost all cementless tibial components, which is an order of magnitude less and probably represents bedding in [215, 216]. The symptoms from TCS usually improve and the component tends to achieve secondary fixation.

Given the small number of studies reporting on TCS, the incidence and aetiology of TCS is poorly understood. Therefore, this thesis will investigate TCS in a cohort of cementless OUKR patients in **Chapter 4**.

1.7.4 Bearing Dislocation

Bearing dislocation is a complication unique to mobile bearing UKRs, such as the OUKR. Bearing dislocation rates for the OUKR are usually reported to be less than 1%, however rates can be as high as 5% [178, 209, 220]. Bearing dislocation is most often caused by failure to remove posterior osteophytes on the femoral condyle which results in anterior dislocation of the bearing. Inequality of the flexion and extension gaps, protrusion of cement above the tibial component, and positioning the femoral component too far from the tibial component wall so that the bearing is free to spin can also result in bearing dislocation [24]. Included in the Microplasty instrumentation is an osteophyte chisel and guide designed to remove posterior osteophytes and an anti-impingement mill to remove bone anteriorly [190]. These instruments appear to have reduced the rate of bearing dislocations [221].

As bearing dislocation and its risk factors are well understood, this thesis will not include a study of dislocation.

1.7.5 Pain

Pain after OUKR is often multi-factorial, but in many cases it is unexplained. Factors such as impingement, soft tissue irritation, and cementing errors may all contribute to ongoing pain [24]. Patients with early post-operative pain should be treated conservatively as the pain often settles and revision for unexplained pain is not advised as it rarely resolves the symptoms [222].

Causes of pain will not be directly investigated in this thesis, but pain in the context of TCS will be studied in **Chapter 4**.

1.7.6 Infection

Infection is a major risk in knee replacement, however the risk of revision for periprosthetic joint infection is significantly lower for UKR compared to TKR [64, 223]. For the OUKR the rate of revision for infection is low, normally less than 0.5% (**Table 1.5**). Periprosthetic joint infection with the OUKR is treated either with a one or 2-stage revision to TKR, with a two stage revision preferred by the designer surgeons [24].

Instrumentation changes are unlikely to reduce the rate of infection and will not be explored in this thesis.

1.7.7 Polyethylene Wear and Bearing Fracture

Polyethylene wear by itself is rarely a reason for OUKR revision [224]. There have been no reports of excessive wear causing osteolysis leading to component loosening, which is a common reason for revision for TKR [224]. However, several case reports have reported on bearing fracture caused by extreme linear wear in the long-term for the Phase III OUKR [37-39, 225]. Three bearing fractures were also reported in the unpublished 20-year results of the cemented Phase III OUKR [210]. A fractured bearing can usually be treated with a bearing exchange.

The five-year results of an in-vivo study of wear using RSA for Phase III cemented and cementless found that the linear wear rate was significantly higher than the wear rate of the Phase II OUKR, for reasons that were not clear [41]. This analysis will be extended as part of a study of wear and risk of bearing fracture in **Chapter 3.**

1.7.8 Periprosthetic Fracture

In Western populations, OUKR TPF is a serious but rare complication [24, 226]. Femoral periprosthetic fracture has rarely been reported with the OUKR [227]. The risk of fracture leading to revision with the OUKR has increased with the introduction of the cementless OUKR (0.26% incidence) which has a fracture rate almost three times that of cemented version (0.09%) [31]. However, the true incidence of fracture may be underreported as registries and most studies do not report the fracture unless it results in revision. In Asian populations, such as in Japan, the incidence of TPF has been reported to be as high as 8% [228]. Treatment of the fracture depends on when it occurs. If the fracture occurs intraoperatively, it should be reduced and internally fixed. If the fracture occurs within the first three months either conservative treatment (if the fracture is not displaced or minimally displaced) or open reduction with internal fixation (for a displaced fracture) is recommended [24, 226]. If the fracture continues to cause pain or has failed to unite beyond three months revision to TKR is recommended [24, 226].

Risk factors for TPF are well documented (see **Section 6.1**), therefore instrumentation optimisation aimed at minimising surgical risk factors that arise from the tibial resection (**Chapter 6**) and tibial keel slot preparation (**Chapter 7**) will be investigated, developed, and tested in this thesis.

1.7.9 Malpositioning of Components

The introduction of Microplasty instrumentation has greatly improved the reliability of component positioning [27]. While component malpositioning is rarely a reason for revision itself, it will not be a focus of this thesis, but it will be considered as it may contribute to all the complications discussed above [178, 209].

1.8 THESIS AIMS

The OUKR is a very good treatment for end-stage anteromedial osteoarthritis. Introduction of the cementless OUKR has further improved outcomes and almost halved the revision rate compared to the Phase III cemented OUKR [14, 31]. However, there is currently limited evidence for long-term complications of the cementless OUKR, such as aseptic loosening and bearing fracture, which may occur more frequently with cementless OUKRs due to third body wear caused by debris from the hydroxyapatite-coated porous titanium. Use of the cementless OUKR has also introduced new complications such as TCS and has increased the risk of TPF.

As explored in **Section 1.6**, iterative modifications to the surgical technique and instrumentation have resulted in improved results for the OUKR. However, there were no major changes in the surgical technique or instrumentation when the cementless OUKR was introduced. Thus, instrumentation optimised for the cementless OUKR may reduce the risk of complications and improve clinical outcomes further.

Consequently, this thesis aims to:

1. Conduct clinical studies to investigate poorly understood complications of the OUKR and how they may be minimised with optimised instrumentation, with a focus on the cementless OUKR.

2. Investigate how the OUKR instrumentation can be optimised from the perspective of the surgeon and to minimise the risk of complications, with a focus on TPF with the cementless OUKR.

1.9 THESIS STRUCTURE AND SCOPE

Introduction and Background

Chapter 1 provides an overview of knee osteoarthritis management, with a focus on knee arthroplasty and the OUKR. The instrumentation used to implant the OUKR and complications of the OUKR are reviewed in detail.

Study of Poorly Understood Complications of the OUKR

The first three experimental chapters used clinical studies to investigate poorly understood complications of the OUKR, with a focus on the cementless OUKR. The aim of **Chapter 2** was to assess the long-term fixation of the cementless OUKR using RSA analysis of 10-year data from an RCT comparing Phase III cemented and cementless OUKR. Radiographic and clinical outcomes were also assessed. Following on from the previous chapter, the aim of **Chapter 3** was to use RSA of the same RCT cohort to investigate long-term linear bearing wear of the Phase III OUKR. The effect of patient, implant, and surgical factors on wear rate were also studied. **Chapter 4** studied the incidence of TCS and its association with pain in a cohort of cementless OUKR patients with comprehensive 5-year follow-up. Factors associated with TCS were also investigated.

Investigation of how OUKR Instrumentation can be Optimised

The remaining experimental chapters of this thesis investigated how limitations of the OUKR instrumentation from the surgeons' perspective and how instrumentation limitations can be optimised to minimise the risk of complications, with a focus on TPF with the cementless OUKR. The aim of **Chapter 5** was to identify limitations with the OUKR instrumentation from the surgeons' perspective. The results of a mixed-methods online survey which had responses from 106 OUKR users are reported in this chapter. In

Chapter 6 the results of mechanical studies which assessed the effect of various tibial resection factors on the risk of TPF with the cementless OUKR are reported. Continuing from the previous chapter, **Chapter 7** presents the results of mechanical studies that were used to investigate how the tibial keel slot preparation can be optimised to minimise the risk of TPF.

<u>Discussion and Conclusions</u>

Chapter 8 summarises the key findings of this thesis and proposes the future work to advance the current studies and to implement the proposed instrumentation modifications clinically.

CHAPTER 2 – LONG-TERM FIXATION OF THE CEMENTED AND CEMENTLESS OUKR

*This chapter is currently under review for publication with Acta Orthopaedica as Arthur LW, Campi S, Jackson WFM, Dodd CAF, Price AJ, Mellon SJ, Murray DW, Kendrick BJL. Cementless Fixation Has Long-Term Advantages Over Cemented Oxford Unicompartmental Knee Replacement: 10-Year Results of a Randomized Controlled Trial Using Radiostereometric Analysis

2.1 CHAPTER MOTIVATION

2.1.1 Background

RSA is the gold standard method for measuring orthopaedic implant migration and has been used to predict the risk of aseptic loosening and implant failure [229-231]. The first RSA system was described by Goran Selvik in 1974 which led to systems being developed for orthopaedic applications [232, 233]. Selvik's system measured cranial growth using metal bone markers, a calibration system, a roentgen calibration frame containing further metallic markers, and a comprehensive computational system based on the kinematics of rigid bodies [233]. Since its introduction RSA has been used to evaluate bone growth [234], fracture healing [235], and joint stability [236]. However, its most successful orthopaedic application has been to measure the migration and bearing wear of orthopaedic implants [230].

Implant migration can be measured using marker-based or model-based RSA. Marker-based RSA has been used historically and relies on markers attached to or inserted within an implant, which increases the cost of RSA studies due to the need for custom implant modifications. Alternatively, model-based RSA eliminates the need for implant markers and instead uses computer software which matches the contours of the implant on stereoradiographs to a 3D computer aided design (CAD) model to determine the position of the implant in 3D space. Model-based RSA is now widely used and has been shown to achieve comparable results to marker-based RSA [237, 238]. Computer advancements have removed bias in the analysis and greatly improved the speed with which RSA can be performed [230].

Due to the high accuracy of modern RSA it is regarded by experts as a valuable tool for the early study of new implants or fixation methods [230]. This is because migration measured using RSA in randomised studies with small case numbers (i.e. less than 50 patients per group) and only 2-years follow-up can be used to predict the long-term survival of an implant. Evidence for the relationship between ongoing early migration and long-term failure is limited to a small number of studies from the 1990s which focused on migration of TKR tibial components [239-241]. The most common measure of ongoing migration is Maximum Total Point Motion (MTPM), which is defined as the length of the translation vector of the marker in a rigid body that has the greatest migration [242]. Most RSA studies of knee replacements use an MTPM threshold of greater than 0.2 mm between 12 and 24 months, first published by Ryd et al. [239], but other thresholds for TKRs have been proposed more recently based on data from systematic reviews with meta-analyses [237, 243]. UKRs have been shown to have similar migration patterns to TKRs with RSA, however UKRs migrate slightly more in the first two years and MTPM thresholds that correlate with long-term implant failure are yet to be defined [244].

Most RSA studies have focused on analysis of early migration, thus there is a lack of long-term RSA data which may be valuable for the understanding of long-term fixation, the process of loosening, and the migration profile of different implants. RSA was initially used by a small number of research groups but is now used widely by many orthopaedic research groups across the world. To ensure comparable methods are used and results are published using a standardised format, expert guidelines, and an International Standard

(ISO 16087) relating to the use of RSA for orthopaedic implant migration have been developed [229, 242].

As discussed in **Section 1.7.2**, aseptic loosening is one of the most common reasons for revision of the OUKR. For the OUKR, the only definitive radiographic evidence of aseptic loosening is the displacement of a metal component such as tilting of a tibial component or rotation of a femoral component [24]. However, thin, non-progressive radiolucent lines are common at the bone-cement interface of the cemented OUKR [245]. These physiological radiolucencies are thought to be misinterpreted by some surgeons to be evidence of aseptic loosening and consequently it is thought that many cemented OUKRs may have been revised inappropriately [24]. Therefore, along with the elimination of cementing errors and providing better fixation, the cementless OUKR was also introduced to reduce the incidence of radiolucencies in the hope it would minimise the number of unnecessary revisions. As the incidence of radiolucent lines and revision rate for aseptic loosening are both significantly lower in cementless, it would appear the cementless OUKR has achieved its short-term objectives, but there is little evidence for the fixation quality of cementless OUKRs at 10 years and beyond [31, 245].

Due largely to concerns about cementless fixation arising from higher rates of aseptic loosening observed with cementless TKR [246], the early assessment of cementless OUKR included an RCT comparing it to cemented OUKR using RSA [215]. This RCT and the associated model-based RSA system were developed as part of the DPhil thesis of Benjamin Kendrick [217]. The 2-year results of this study identified that cementless tibial components had significantly more inferior subsidence than cemented tibial components [215]. However, there was no significant difference in migration in any direction between femoral or tibial cemented and cementless components, from one to two years or two to five years [216], so it was concluded that cementless fixation was as good as cemented

[215, 216]. However, it is unclear how cementless fixation of the OUKR will compare with cemented in the long-term as late aseptic loosening has rarely been observed with the cementless OUKR [24]. RSA is the best tool for predicting long-term fixation as continuous migration measured by RSA is likely to lead to radiographic evidence of loosening and give rise to symptoms in the patient [237].

In the previously reported results of the OUKR RSA study the mean migration and rotation about three orthogonal axes of cemented and cementless components were compared. This approach can underestimate migration and fail to identify individual implants at risk of loosening as components migrate in different directions. For example, some migrate anteriorly and some posteriorly, resulting in a mean migration of approximately zero. An alternative is to use MTPM, which was not reported for earlier timepoints of this RSA study as it compounds errors and therefore can overestimate migration. To avoid this problem, MTPM thresholds above which a component is considered to have an increased risk of aseptic loosening can be set. Various MTPM thresholds at various time points have been reported, but there is no consensus for what threshold is best for the OUKR [247, 248], and TKR thresholds are probably not applicable to UKRs due to differences in migration patterns [244].

2.1.2 Aims

The primary aim of this study was to continue the RSA analysis out to 10 years and identify components continuing to migrate using MTPM. The hypothesis was that after the early phase there would be no difference in migration between cemented and cementless OUKR components. If true, this would suggest that the fixation beyond 10 years for cemented and cementless OUKRs will be equally good.

The secondary aims were to complete a radiological assessment of the 10-year radiographs to compare the incidence of radiolucent lines beneath the cemented and cementless OUKR components. The 10-year clinical outcome of the cemented and cementless OUKRs will also be assessed using the OKS.

2.2 METHODS

2.2.1 Patients and Study Design

A consecutive series of OUKR patients were invited to participate in the study. A power calculation that suggested 16 patients were required in each of the cemented and cementless groups to detect a clinically significant difference in migration of 0.2 mm [279]. Therefore, allowing for loss to follow-up, 47 patients were recruited (**Figure 2.1**). Exclusion criteria were age greater than 80 years, American Society of Anaesthesiologists score greater than 3, and previous surgery on the same knee. Consenting participants received an OUKR between November 2008 and March 2010 at the Nuffield Orthopaedic Centre. Block randomisation allocated patients to cemented (24) or cementless (23) implants following arthrotomy confirming suitability for OUKR [24]. The recommended surgical technique for the Phase III cemented and cementless OUKRs with a minimally invasive approach was used [176]. After tibial and femoral preparation, tantalum marker balls (0.8 mm diameter) were inserted using a pre-loaded injector (RS-M08, Tilly Medical Products, Lund, Sweden). Seven markers were inserted in the femur and six in the tibia (**Figure 2.2A**). Phase III OUKR (Biomet) components were used in all patients. The cemented femoral components had one peg and the cementless had two. Cemented components were fixed using CMW1 gentamicin-impregnated cement (DePuy International Limited, Leeds, UK). Cementless components were examined to ensure a good layer of porous titanium and hydroxyapatite was present.

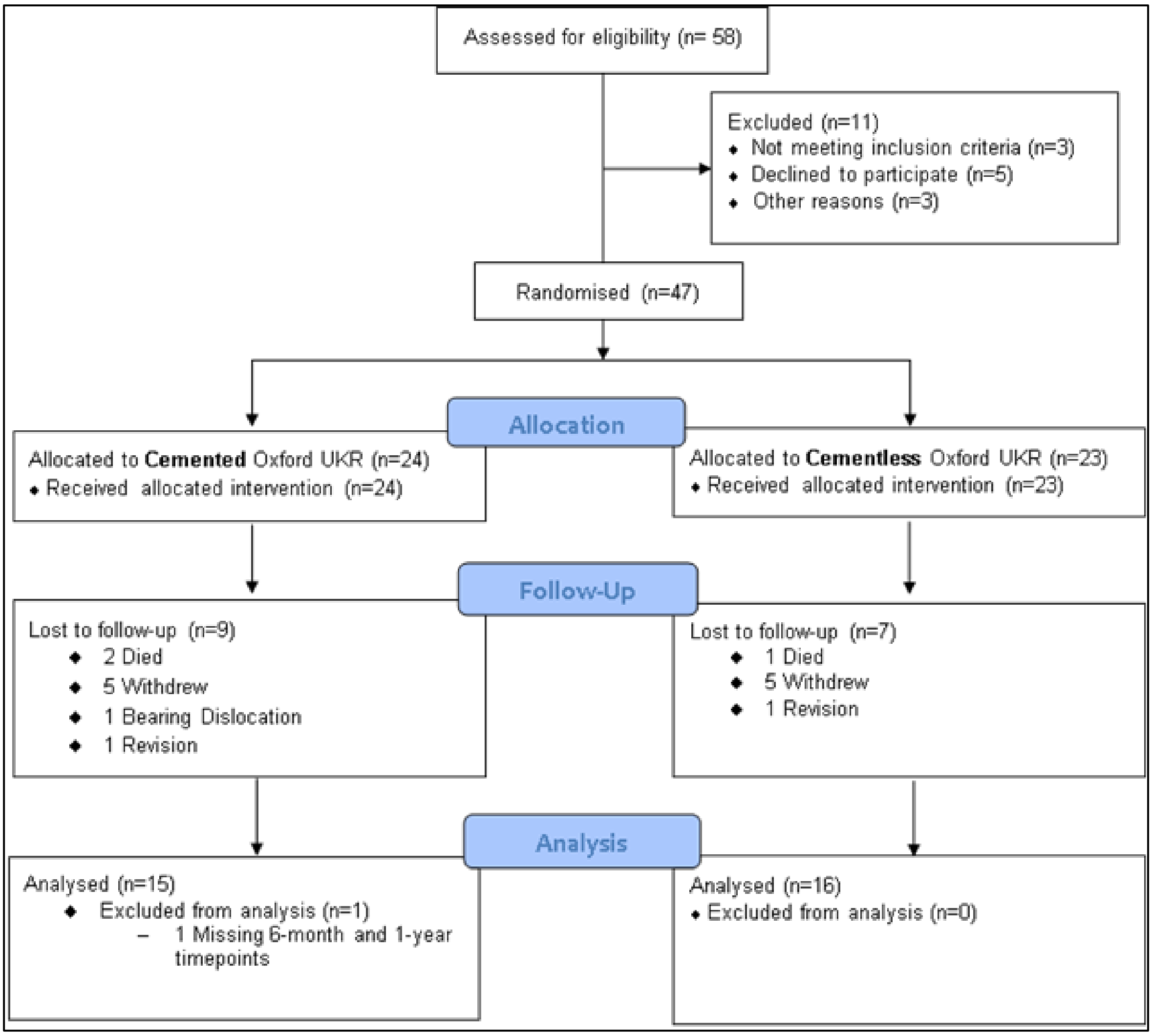


Figure 2.1 Consort diagram for the randomised controlled trial comparing cemented and cementless fixation for the Oxford Unicompartmental Knee Replacement.

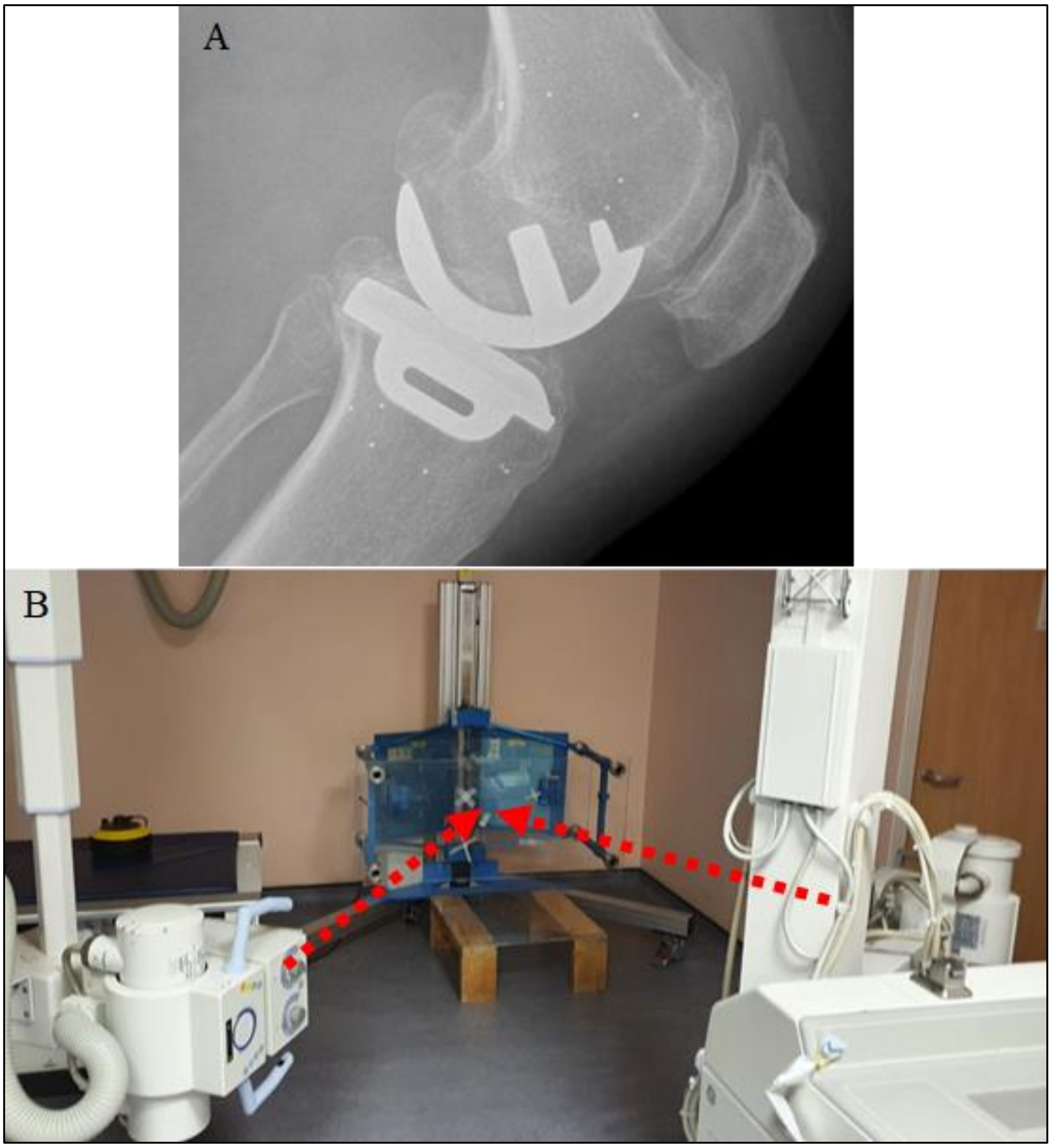


Figure 2.2 **A** Plain lateral radiograph of showing the seven femoral and six tibial tantalum marker malls, positioned proximal to the femoral component in the femur and distal to the tibial component in the tibia. **B** The set-up for capturing stereoradiographs for this study. Two X-ray tubes are positioned 1.5 metres from the calibration frame (blue) angled at 60 degrees to perpendicular. Both tubes were aligned to target the knee of the patient standing in the calibration frame, with the red arrows indicating the theoretical path of the X-rays to the target.

Patients had weight-bearing stereoradiographs post-operatively and at three, six, 12, 24, 60, and 120 months using the set-up shown in **Figure 2.2B**. The stereoradiographs were taken with the patient standing in the calibration frame with full knee extension. The stereoradiographs were analysed using model-based RSA (version 4.11, Medis Specials, Leiden, The Netherlands.) with CAD models supplied by the manufacturer (Biomet, Bridgend, UK). The RSA system accuracy and precision was previously validated for the OUKR by performing RSA of a phantom and double exposure experiments [217]. The RSA system used was accurate to 0.1 mm for the OUKR [217]. The technique used for RSA measurements was compared to results of the 5-year analysis completed by another user to ensure the technique was consistent. The differences were less than the precision of the RSA system, suggesting the technique used was consistent (**see Appendix A2.1**). RSA results were reported according to standard guidelines [242]. At each review, radiographs were obtained with the X-ray beam aligned to the tibial tray and Oxford Knee Scores (OKS) were recorded [249].

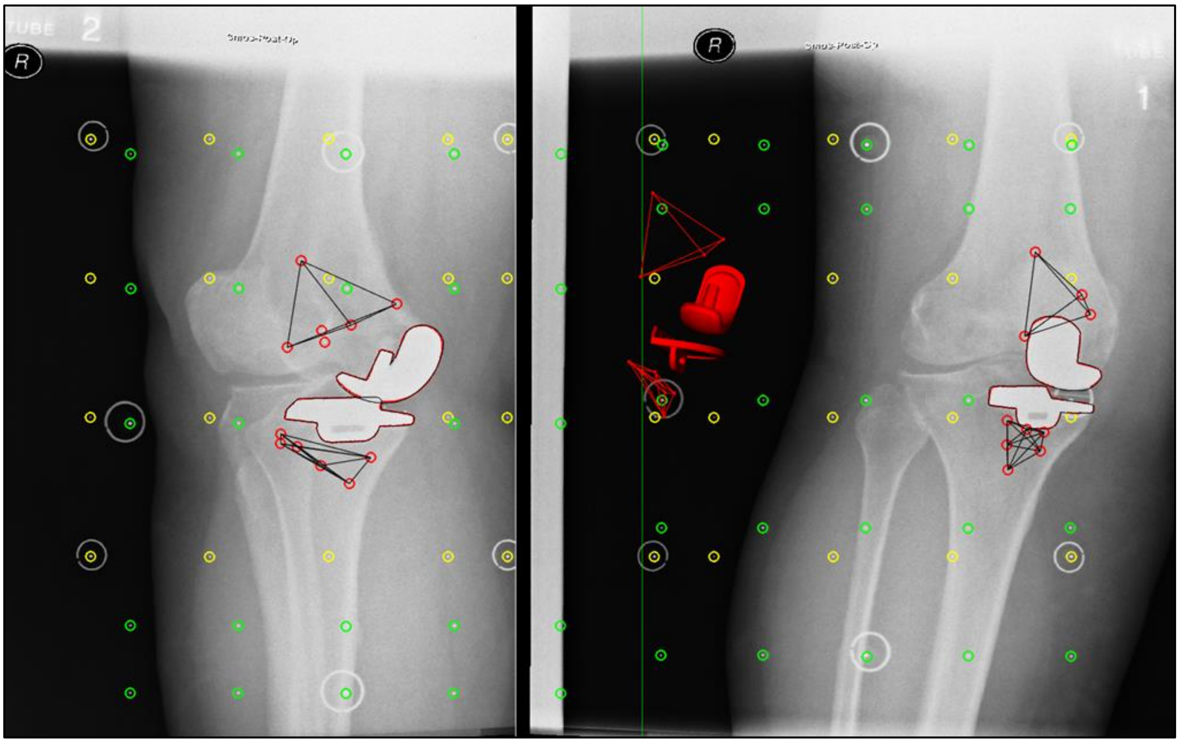


Figure 2.3 An example of the model-based radiostereometric analysis software. Fiducial markers are outlined in yellow, control markers in green and tantalum marker balls in red. The femoral and tibial components are outlined in red.

2.2.2 Data Analysis

RSA calculations were performed as per expert recommendations [229]. Translations were measured in millimetres and rotations in degrees. The clinical conversions of these measurements are shown in **Table 2.1**. Left-sided measurements were converted to right-sided for analysis of direction and magnitude. Condition numbers were calculated for each set of stereoradiographs, with lower numbers indicating better marker ball spacing. Components with condition numbers over 120 were excluded [242]. An established method was used to identify radiolucent lines beneath the femoral and tibial components on lateral and anteroposterior radiographs, respectively [245].

Table 2.1 Conversions of 3-axis migration and rotation for femoral and tibial components to clinical descriptions.

	Femur		**Tibia**	
	+ve	**-ve**	**+ve**	**-ve**
X	Medial	Lateral	Medial	Lateral
Y	Superior	Inferior	Superior	Inferior
Z	Anterior	Posterior	Anterior	Posterior
Rx	Increased flexion	Decreased flexion	Reduced slope	Increased slope
Ry	Internal rotation	External Rotation	Internal rotation	External Rotation
Rz	Valgus	Varus	Valgus	Varus

Migration and rotation rates were determined using linear regression, measured as millimetres per year (mm/year) and degrees per year (°/year), respectively. MTPM was calculated to measure overall migration. Early migration was considered to occur between the post-operative and six-month timepoints. Ongoing migration was considered to occur between the six-month and 10-year timepoints. MTPM thresholds were set based on data distributions. Components were classified as substantial early migrators if their MTPM between postoperative and six months was >1 mm and substantial ongoing migrators if their change in MTPM between six months and 10 years was >1 mm. To determine if components had late-stage migration, a threshold of five to 10-year MTPM>0.3 mm was applied. These methods were developed with input from RSA expert Bart Kaptein (Leiden University).

2.2.3 Statistical Analysis

R [250] was used for statistical analysis. The Wilcoxon signed test was used to assess migration compared to zero, Mann-Whitney U-test for differences in migration between fixation methods, Fisher's Exact Test to compare the proportion of radiolucent lines, and t-test for comparison of clinical outcomes and cohort characteristics. All values are reported as means unless indicated otherwise. Statistical significance was set at $p<0.05$.

2.2.4 Ethical Approval and Clinical Trial Registration

This study was approved by the Oxfordshire Regional Ethics Committee B (CO2.101) (**Appendix A3.1**). The trial was retrospectively registered with ClinicalTrials.gov (ClinicalTrials.gov ID: NCT05935878) (**Appendix 4**).

2.3 RESULTS

30 knees had RSA stereoradiographs at 10 years, which included 14 cemented and 16 cementless OUKRs (**Figure 2.1**). There were no OUKR revisions for aseptic loosening at 10 years. The mean condition number ranged between 42-64 (Standard Deviation (SD) 17-23) and 39-56 (SD 12-18) for the femoral and tibial bone markers, respectively. One set of femoral bone markers was >120, and therefore was excluded. Poor quality stereoradiographs with bone marker obstruction prevented migration for four femoral and one tibial component from being calculated. In all, 25 femoral components (12 cemented and 13 cementless) and 29 tibial components (13 cemented and 16 cementless) were included in the linear regression analysis. The cemented and cementless groups had comparable age, sex, BMI, laterality, and preoperative OKS (**Table 2.2**). The migration results are summarised in **Table 2.3**.

Table 2.2 Characteristics of patients in the cemented and cementless groups at 10 years.

	Cemented Group	Cementless Group	p- value
Cases	14	16	-
Age	64 (8, 49-79)	67 (8, 59-79)	0.31
Sex (Male:Female)	5:9	10:6	0.27
Body Mass Index	29 (8, 19-47)	31(6, 24-42)	0.48
Laterality (Right:Left)	8:6	8:8	0.73
Pre-operative Oxford Knee Score	22 (5, 13-34)	25 (7, 12-36)	0.15
10-Year Oxford Knee Score	39 (10, 18-47)	42 (7, 25-48)	0.54

- Brackets indicate (Standard Deviation, Range)

2.3.1 Femoral Migration

During the first six months MTPM measurements showed that both cemented (1.3 mm/year, p<0.001) and cementless femoral components (1.7 mm/year, p<0.001) migrated significantly, but there was no significant difference between fixation methods. However, the cemented femoral components had no significant translations or rotations in any direction, whereas the cementless femoral components migrated anteriorly (0.5 mm/year, p<0.01), laterally (0.4 mm/year, p=0.02), and rotated internally (0.9°/year, p<0.01). Both translation along the X-axis (p=0.01) and rotation around the Y-axis (p=0.03) were significantly greater for cementless femoral components compared to the cemented. Between six months and 10 years there were no significant translations, rotations, or changes in MTPM of cemented or cementless components, or differences between fixation methods.

Table 2.3 Mean femoral and tibial component migration for translations (mm/year) along each axis (X, Y, Z), rotation (degrees/year) around each axis (Rx, Ry, Rz), and Maximum Total Point Motion (MTPM; mm/year). Migration rates for cemented and cementless components during primary and long-term fixation periods are shown.

FEMORAL						
	Early Fixation (Post-Operative to Six Months)			**Long-term Fixation (Six Months to 10 Years)**		
	Cemented N= 12	Cementless N= 13	Cemented vs. Cementless p-value	Cemented N = 12	Cementless N = 13	Cemented vs. Cementless p-value
X	0.173	-0.408	**0.01**	0.012	0.008	0.65
	(0.41, 0.13)	(0.62, **0.02**)		(0.03, 0.20)	(0.06, 0.38)	
Y	-0.218	-0.294	0.81	-0.002	-0.003	0.94
	(0.54, 0.18)	(0.59, 0.15)		(0.02, 0.52)	(0.02, 0.46)	
Z	0.273	0.523	0.44	-0.008	-0.009	0.73
	(0.53, 0.06)	(0.70, <**0.01**)		(0.02, 0.13)	(0.03, 0.34)	
Rx	0.617	-0.004	0.30	-0.011	-0.009	0.57
	(1.43, 0.20)	(0.92, 1)		(0.07, 0.85)	(0.06, 0.27)	
Ry	-0.026	0.921	**0.03**	0.037	-0.003	0.25
	(0.93, 0.73)	(1.00, <**0.01**)		(0.08, 0.15)	(0.08, 0.89)	
Rz	0.471	-0.365	0.25	-0.015	0.051	0.15
	(1.22, 0.38)	(1.97, 0.54)		(0.10, 0.79)	(0.12, 0.13)	
MTPM	1.319	1.702	0.27	0.013	0.012	0.89
	(0.56, <**0.001**)	(0.72, <**0.001**)		(0.03, 0.34)	(0.04, 0.41)	

TIBIAL						
	Early Fixation (Post-Operative to Six Months)			**Long-term Fixation (Six Months to 10 Years)**		
	Cemented N = 13	Cementless N = 16	Cemented vs. Cementless p-value	Cemented N = 13	Cementless N = 16	Cemented vs. Cementless p-value
X	-0.086	0.011	0.75	-0.005	0.001	0.25
	(0.34, 0.24)	(0.47, 0.38)		(0.02, 0.50)	(0.03, 0.67)	
Y	-0.192	-0.508	**0.02**	-0.006	-0.002	0.85
	(0.41, 0.27)	(0.29, <**0.01**)		(0.03, 0.64)	(0.01, 0.47)	
Z	-0.063	-0.129	0.13	0.001	0.004	0.68
	(0.55, 0.79)	(0.21, **0.03**)		(0.03, 0.95)	(0.02, 0.50)	
Rx	-0.668	-1.212	0.23	-0.048	0.014	0.60
	(1.57, 0.27)	(1.68, **0.01**)		(0.22, 0.79)	(0.03, 0.12)	
Ry	0.084	0.137	0.68	0.018	0.011	0.62
	(0.63, 0.54)	(1.14, 0.98)		(0.04, 0.09)	(0.03, 0.27)	
Rz	0.503	0.775	0.33	-0.084	-0.076	0.78
	(2.30, 1)	(1.52, **0.04**)		(0.09, <**0.01**)	(0.05, <**0.01**)	
MTPM	1.397	1.601	0.45	0.039	0.002	0.08
	(1.09, <**0.001**)	(0.93, <**0.001**)		(0.11, **0.04**)	(0.02, 0.74)	

- Brackets indicate (Standard deviation, p-value for mean migration compared to zero migration (Wilcoxon Signed Test))
- Significant values shown in **bold.**
- Migration of cemented versus cementless components are compared using a Mann-Whitney U Test

2.3.2 Tibial Migration

During the first six months, MTPM values for the cemented (1.4 mm/year, p<0.001) and cementless (1.6 mm/year, p<0.001) tibial components suggested that both undergo significant migration, but there was no significant difference between fixation methods (p=0.5). Cementless components subsided inferiorly (0.5 mm/year, p<0.01), which was significantly greater (p=0.02) than the subsidence of cemented components (0.2 mm/year) (**Figure 2.4**). The cementless components also had significant posterior translation (0.1 mm/year, p=0.03), and underwent valgus rotation (0.8°/year, p=0.04). In contrast, there was no significant migration of the cemented tibial components.

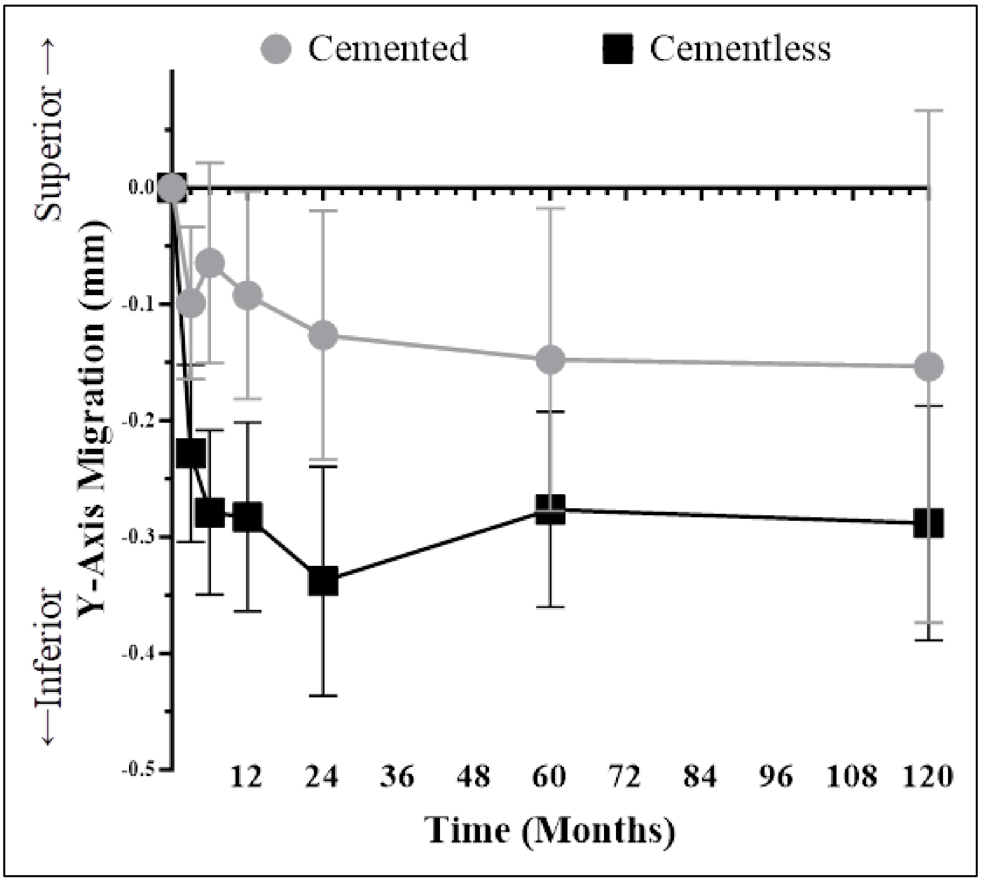


Figure 2.4 Mean subsidence (±95% Confidence Intervals, (CI)) along the Y-axis (Y, inferior/superior) of cemented (grey) and cementless (black) tibial components.

Between six months and 10 years there were no significant differences in migration in any direction between cemented and cementless tibial components (**Table 2.3**). However, there was significant MTPM of cemented tibial components (0.04 mm/year, p=0.04), but not of cementless tibial components (0.002 mm/year, p=0.74). Both cemented (0.08°/year, p<0.01) and cementless (0.08°/year, p<0.01) tibial components undergo varus rotation after six months (**Figure 2.5**).

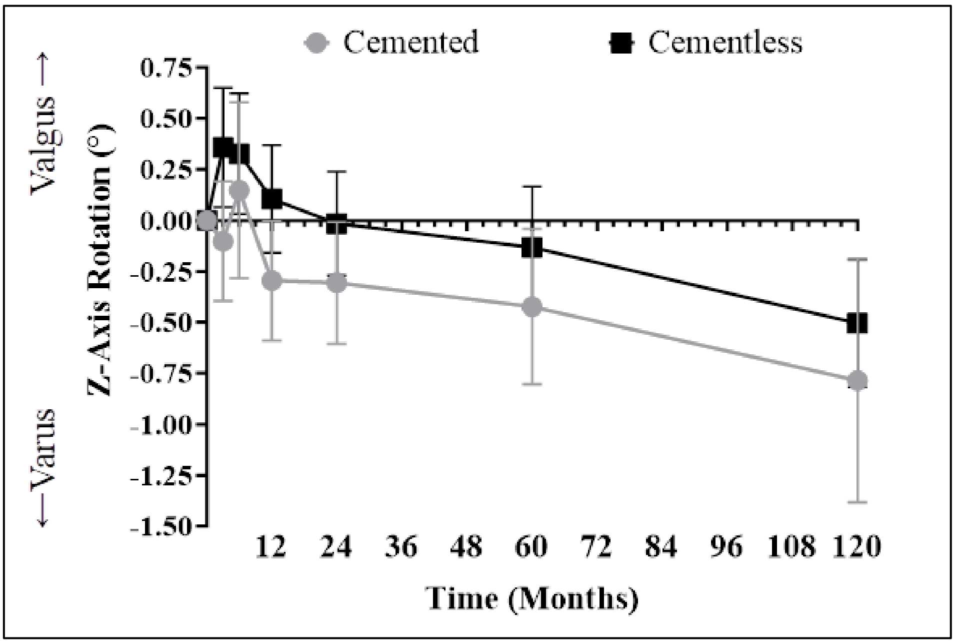


Figure 2.5 Mean (± 95% Confidence Intervals) rotation around the Z-axis (Rz, varus/valgus) of cemented (grey) and cementless (black) tibial components.

There were two cemented and six cementless tibias classified as substantial early migrators based on six-month MTPM>1 mm (**Figure 2.6 A&B**). The two early cemented substantial migrators (MTPM 1.8 mm and 1.8mm) had the highest MTPM during the early period. They were the only two cases with >1 mm MTPM between six months and 10 years (MTPM 3.6 mm and 1.3 mm) and had the highest MTPM between five years and 10 years (MTPM 2.2 mm and 0.4 mm). During the 5-year to 10-year period the cemented tibial components (0.32 mm) had significantly greater (p=0.04) mean MTPM than the cementless (0.08 mm). Furthermore, the four components with the highest MTPM during this period were cemented (**Figure 2.6 C&D**).

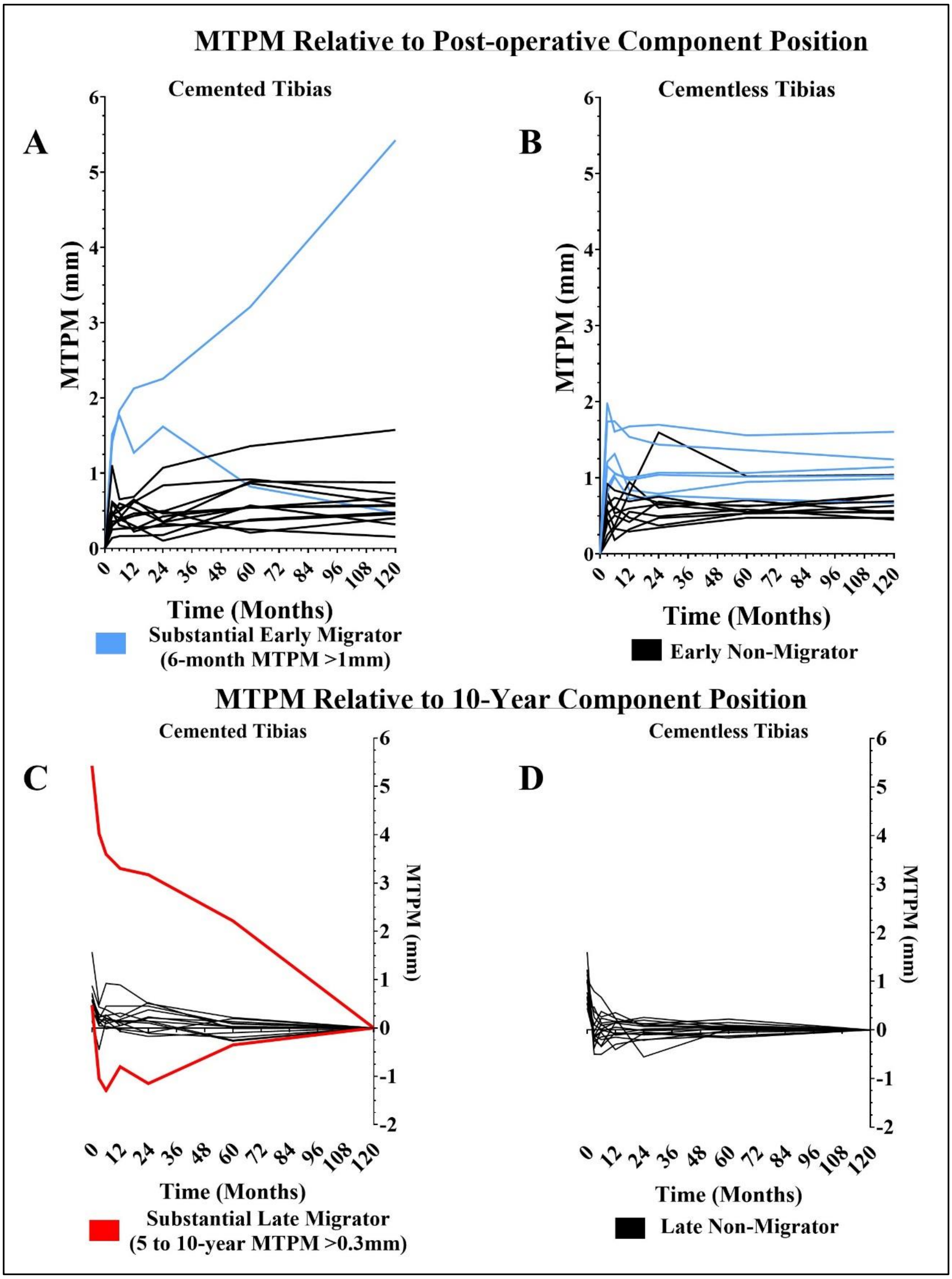


Figure 2.6 Individual component Maximum Total Point Motion (MTPM) for cemented (left) and cementless (right) tibial components. Top row displays MTPM relative to the post-operative component position and the bottom row displays MTPM relative to the 10 Year component position. Non-early migrator (6-month MTPM <1 mm) components are shown in black while early migrator (6-month MTPM >1 mm) components are shown in blue. The two cemented early migrators (red, five to 10-year MTPM >0.3 mm) also migrate substantially in the long-term whereas all other cemented and cementless components, including cementless, early migrators appear solidly fixed beyond six months (black).

The cemented tibial component with the greatest MTPM (0-10yr 5.43 mm, 5–10-year MTPM of 2.22 mm) at 10 years had an atypical partial radiolucency below the tibial component (Figure **2**.**7**), and an OKS of 45. The other cemented tibial component with ongoing migration (10-year MTPM=0.47 mm, five to 10-year MTPM=0.35 mm) did not have a radiolucency (Figure **2**.**7**) but did have an OKS of 26.

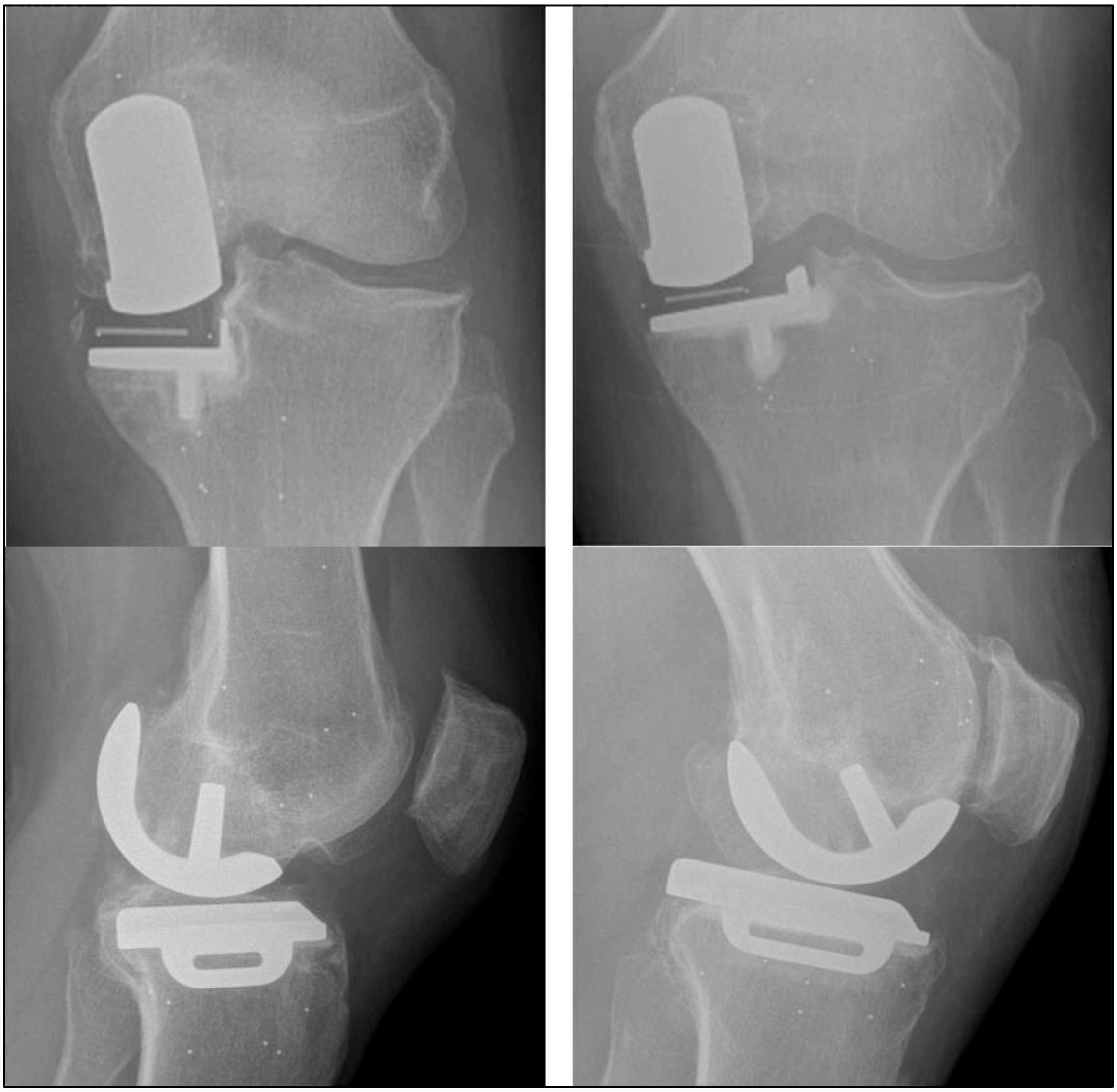


Figure 2.7 10-year anteroposterior (top) and lateral (bottom) radiographs of cemented Oxford Unicompartmental Knee Replacements with substantial five to 10-year tibial migration. **Left:** Radiographs of the patient with five to 10-year MTPM 2.22 mm. **Right:** 10-year radiograph of the other case with substantial late migration with five to 10-year MTPM 0.34 mm.

2.3.3 Radiological Assessment

Plain radiographs were available for all 14 cemented OUKRs and 15 of 16 cementless OUKRs at 10 years. Significantly more (p=0.03) cemented OUKRs (6/14) had radiolucent lines (**Figure 2.8**) below the tibial component compared to cementless OUKRs (1/15). All radiolucent lines were partial, with none encompassing the entire tibial component under-surface. The presence of radiolucent lines beneath the tibial component was not correlated with 10-year OKS (p=0.45) or tibial MTPM (p=0.31).

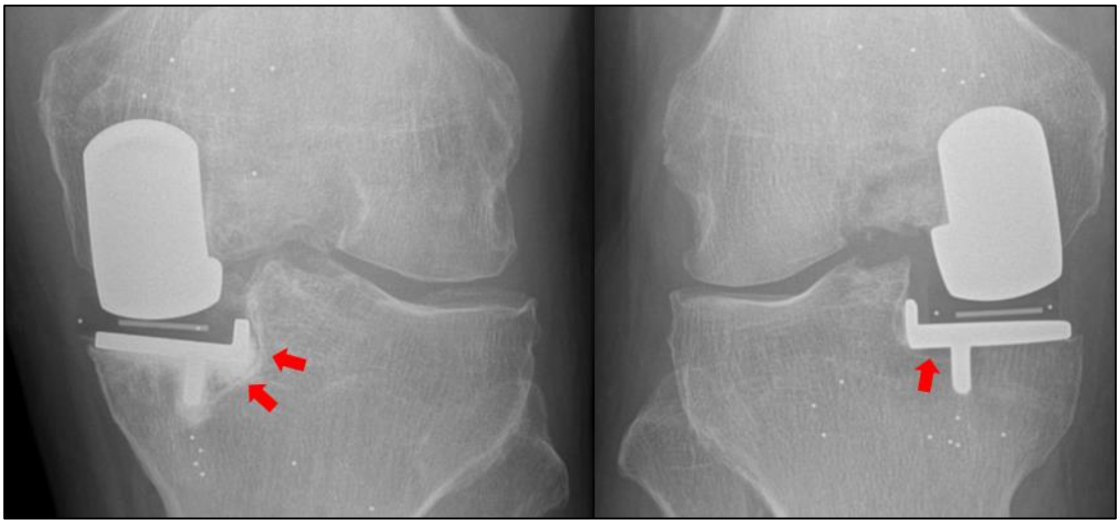


Figure 2.8 Examples of radiolucent lines (indicated by red arrows) below cemented (left) and cementless (right) Oxford Unicompartmental Knee Replacement tibial components.

2.3.4 Clinical Outcome

The mean 10-year OKS was 39 (SD 10) for patients in the cemented group and 42 (SD 7) for patients in the cementless group, a non-significant (p=0.5) difference.

2.4 DISCUSSION

There was no significant difference in migration, whether translation, rotation, or MTPM, between cemented and cementless fixation for either femoral or tibial components during the six-month to 10-year period. Therefore, the hypothesis that, after the early phase, there is no significant difference in migration between the two fixation methods at 10 years is accepted and it can be concluded that cementless fixation of the OUKR should be at least as good as cemented at 10 years and beyond. Further analysis suggested that cementless tibial fixation will perform better than cemented in the long-term, whereas cemented and cementless femoral fixation should be equally good.

For femoral components, during the first six months there was significantly more migration of the cementless than the cemented components. This is expected as osseointegration of cementless components is occurring in this phase. The main direction of early migration cementless femoral components was anterior (0.53 mm/year at six months); the direction of the greatest force. However, between six months and 10 years there was no significant migration of either cemented or cementless femoral components (**Table 2.3**). This indicates, that if appropriately implanted, both cemented and cementless achieve secure long-term fixation. With cemented femoral OUKR components it is important to put cement in the main fixation hole. With cementless OUKRs care must be taken to avoid damaging this hole, as damage has been shown to result in femoral loosening [20, 24].

At six months cemented tibial components had no significant migration in any direction. In contrast, cementless tibial components migrated significantly, particularly inferiorly (0.51 mm/year at six months) and this subsidence was significantly more than that of cemented components (**Figure 2.4**). Subsidence of cementless components is likely due to the component 'bedding-in' with weight-bearing before osseointegration occurs. However, between six months and 10 years there was no significant migration of cemented or cementless tibial components in any direction or significant differences in migration between fixation methods.

Analysis of tibial MTPM indicates fixation is more complex. During the first six months both cemented (1.4 mm/year $p < 0.001$) and cementless (1.6 mm/year, $p < 0.001$) had significant MTPM, but they were not significantly different. However, between six months and 10 years cemented, but not cementless, had significant MTPM. Between five and 10 years cemented had significantly greater MTPM than cementless. Furthermore, there are two cemented cases that had substantial early migration and continued to migrate in the late phase. **Figure 2.6** demonstrates the different migration patterns of cemented and cementless OUKRs. The cemented tend to have less early migration than the cementless but there are substantial early migrators in the cemented group. Later the cemented, excluding these two substantial migrators and all cementless, have low levels of migration within the RSA system precision [217]. The MTPM data therefore suggests that in the second decade the cemented will have a higher incidence of aseptic loosening than cementless. This conclusion is supported by NJR studies that have found the revision rate for aseptic loosening for cementless OUKRs to be half that of cemented at 10 years [31, 178].

The two cemented tibial components that had substantial early migration and continued migrating in the late phase are interesting. The component with the most migration (10-year MTPM of 5.4 mm), subsided (1.5 mm) and tilted posteriorly (9.45°). At 10 years the OKS (45) was excellent and the radiograph (**Figure 2.7**), showed only a partial radiolucent line. Based on the 10-year clinical and radiographic data, this would have been classified as a good result and not loose. However, given its ongoing migration it may become symptomatic in the long-term and require revision for aseptic loosening. The second case had slower ongoing migration (5 to 10-year MTPM=0.34 mm) and no tibial radiolucency but did have a poor OKS (26) (**Figure 2.7**). It is unclear why there is pain or ongoing migration given the radiographic appearance, however there is likely to be an increased chance of aseptic loosening for this implant in the future.

Radiological assessment identified that significantly ($p=0.03$) more cemented (43%, N=6) than cementless (7%, N=1) tibial components had radiolucent lines. All radiolucent lines were partial, thin, and well demarcated with a sclerotic margin indicating that they were physiological. The lower incidence of radiolucent lines with the cementless components also suggests that their fixation is better than cemented components [36, 213, 245]. The presence of radiolucent lines did not correlate with differences in migration or clinical outcomes, as found in previous studies [36, 245, 251].

Although the difference in OKS between cementless and cemented OUKRs at 10 years was not significant, the mean OKS of cementless (42) OUKRs is slightly higher than cemented (39), as has been found in several comparative studies [185, 252, 253]. This may be a related to the improved fixation of the cementless components.

A surprising finding was that between six months and 10 years both cemented and cementless tibial components progressively rotated into varus (**Figure 2.5**). Varus rotation of tibial components was also detected in the 5-year results of this study but was thought to be a result of measurement error [216]. As the rotation rate was the same (0.08 degrees per year) and statistically significant ($p<0.01$) for both cemented and cementless tibial components it is likely to be a real phenomenon. Further study is required to understand why the rotation is occurring.

2.4.1 Limitations

A major limitation of the study was that loss to follow-up meant there were less than 16 knees in each group required by the power calculation for the study [215]. This is due to the initial study being planned for two years of follow-up and therefore not accounting for the loss to follow-up that has occurred over 10 years. Differences were observed between cemented and cementless fixation for the OUKR, however these differences may have been underestimated due to the study being underpowered. As the study was powered to detect differences in migration using RSA, the patient numbers were too small to detect differences in clinical outcome from the outset. However, the trend of cementless OUKR having a higher OKS in this study is consistent with larger, sufficiently powered studies which attribute the better functional outcomes largely to improved pain relief compared to cemented OUKR [185].

A further limitation was the use of MTPM, and particularly MTPM thresholds. MTPM was reported as an overall indicator of migration, however MTPM compounds measurement errors so tends to overestimate migration. The mean precision of tibial MTPM for the OUKR with the RSA system used was determined to be 0.2 mm (SD=0.09 mm) by double-exposure experiments [217]. A threshold of MTPM>1 mm was selected for identification of early migrators based on the distribution of the data, rather than a priori, to minimise the influence of MTPM measurement error. These thresholds were illustrative of how early tibial migration was associated with late tibial migration for cemented OUKRs, but not for cementless OUKRs. However, an ideal threshold would be based on whether and implant is likely to fail due to aseptic loosening. As there were no cases of aseptic loosening in this study, setting a threshold on this basis was not possible. Based on previous RSA studies of TKR tibial components, it is expected that the two cemented components that are continuously migrating at 10 years will eventually develop radiographic evidence of loosening and become symptomatic [237, 239, 240]. Further follow-up will be able to confirm this which would provide stronger evidence to suggest that cementless OUKR achieve better fixation than cemented OUKR. However, with 10 years of follow-up, this RSA study remains the best available predictor of Phase III OUKR fixation in the second decade.

2.5 CHAPTER SUMMARY

The 10-year results of this randomised study suggest that cementless OUKR femoral fixation is as good as cemented and cementless tibial fixation is likely to be better than cemented in the long-term. Although cementless tibial components tend to migrate more than cemented components before achieving early fixation, they are solidly fixed thereafter. In comparison, two cemented tibial components that migrated early continue to migrate at 10 years and therefore have an increased chance of loosening. Cementless fixation is also associated with fewer tibial radiolucent lines than cemented fixation at 10 years, which is a further indicator that cementless fixation is as good, if not better, than cemented fixation for the OUKR in the long-term. Fewer tibial radiolucencies with the cementless OUKR is also likely to minimise unnecessary revisions caused by surgeons misinterpreting radiolucent lines as an indicator of aseptic loosening.

CHAPTER 3 – 10-YEAR POLYETHYLENE BEARING WEAR OF THE PHASE III OUKR

*This chapter has been published [254] as Arthur LW, Ghosh P, Mohammad HR, Campi S, Kendrick BJL, Murray DW, Mellon SJ. Polyethylene bearing wear is comparable for cemented and cementless Oxford unicompartmental knee replacements: Ten-year results of a randomized controlled trial. Knee Surgery Sports Traumatology Arthroscopy 2024;32(2):405-17. https://doi.org/10.1002/ksa.12042. (**Appendix 1**)

3.1 CHAPTER MOTIVATION

3.1.1 Background

Polyethylene wear leading to osteolysis-induced aseptic loosening is one of the commonest causes of knee replacement failure [255]. Excessive polyethylene wear has historically been a problem for fixed bearing UKRs, as discussed in **Section 1.5.1**. This was due to fixed bearing designs having flat, non-conforming tibial components which resulted in high contact stresses and high wear leading to failure of the implant [24, 166, 167]. In contrast, the mobile bearing design of the OUKR minimises contact stress between the metal components and polyethylene bearing which theoretically minimises wear [24]. Subsequently, polyethylene wear has been a rare cause of revision for the OUKR [209].

Wear of polyethylene in knee replacements can be studied as linear penetration or volumetric wear and can be measured in vitro or in vivo. Historically, retrieval studies have been used to measure polyethylene wear rate of knee replacements in vivo [256, 257]. These studies are limited as the polyethylene bearing has been extracted from an implant that was not functioning adequately and required re-operation or revision. Therefore, wear measured in retrieval studies may not be comparable to the wear of the average, well-functioning implant. Wear machines have also been used to measure in vitro wear of TKRs and UKRs [258, 259]. The strength of using a wear machine is it eliminates many confounding variables that may influence wear rate, but the major weakness is that the loading, kinematics, and wear patterns of the implant may not be replicated as they would be in vivo. More recently RSA has become a gold-standard for measurement of in vivo polyethylene wear thanks to its precision and accuracy [41, 253, 260-264]. For knee replacements, the thickness of polyethylene can be accurately calculated from weight-bearing stereoradiographs by determining the distance between the proximal and distal metal components. This works well for fully congruent bearings like the mobile bearing of the OUKR but may not work as well for non-congruent devices as the femoral component may not sit in the deepest erosion in the polyethylene. By taking bearing thickness measurements at multiple timepoints, the rate of linear penetration can be calculated. Volumetric wear can also be estimated using RSA, but results have poor accuracy [265].

With the OUKR it is optimal to minimise the depth of the tibial resection to preserve bone stock in case revision is required. Larger bearings, Size 5 or greater, are also associated with worse outcomes for the OUKR [19]. Consequently, thin bearings (commonly 3.5 mm or 4.5 mm thick, or Size 3 and 4 bearings, respectively) are routinely used with the OUKR. Despite the use of thin bearings, wear is a rare cause of failure [209]. However, excessive linear wear can result in bearing fracture, a complication which has been reported with the Phase III OUKR [37-40]. The main disadvantage of a mobile bearing is dislocation, but this also is rare [266]. Bearing dislocation could theoretically occur if a bearing wears too thin although dislocations are more often attributed to surgical errors (see **Section 1.7.4**). In a 24 year study of 1000 cemented Phase III OUKRs, with mean follow-up of 18 years there were four bearing fractures (0.4%) occurring at a mean time of 16 years [267]. In a 19-year study of the designer surgeons' first 1000 cementless OUKRs, with a mean follow-up of 10 years there were two bearing fractures (0.2%) at 13 and 14 years, respectively [268]. OUKR bearing fracture can easily be treated by inserting a new bearing if the patient detects the event and presents promptly. However, in some cases the femoral and/or tibial components are damaged requiring revision to TKR [40, 269]. In at least one case, OUKR bearing fracture led to severe metallosis which required revision using revision TKR components [268].

In a retrieval analysis of OUKR bearings it was found that evidence of impingement was associated with a marked increase in bearing wear, when combining wear on both superior and inferior surfaces [257, 264]. It is believed that the increased wear on the articular surfaces was caused by detached bone or cement fragments acting as third bodies. There is also a concern that fragments of the hydroxyapatite-coated porous titanium surface of cementless OUKRs may dislodge into the joint space and cause third body wear (**Figure 3.1**) [253]. Cementless total hip arthroplasties, which have fully congruent articulations like that of the OUKR, have been found to have increased wear with hydroxyapatite particles found embedded in the polyethylene [270-273].

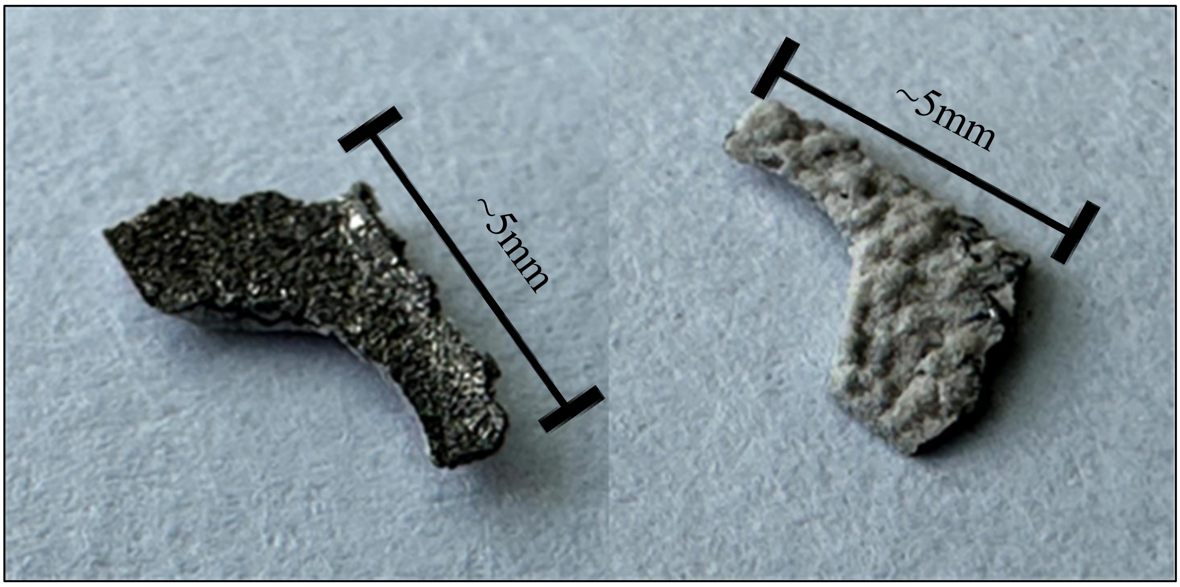


Figure 3.1 Example of a fragment of the hydroxyapatite-coated porous titanium from the undersurface of the cementless Oxford Unicompartmental Knee Replacement tibial component. This fragment was found in the joint intraoperatively and thought to have been dislodged when introducing the tibial component.

RSA studies have found the mean linear wear of Phase I OUKR bearings was 0.07 mm/year [274] while Phase II bearing wear was found to be lower at 0.02 mm/year [262, 274]. This difference was likely due to impingement which was not obvious for Phase I during the operation, whereas with Phase II it was obvious and it was appreciated that impingement had to be avoided [225]. The cohort of patients from the RCT comparing Phase III cemented and cementless OUKR, featured in **Chapter 2**, were also studied in a short-term analysis of wear at five years. This study found that with both cemented and cementless components the wear rate was 0.07 mm/year, which was significantly higher than Phase II [275]. It was possible that this increase might have been due to changes in the polyethylene used to manufacture the bearings, but a further RSA study showed no difference in wear rate between polyethylene types [276]. It has also been suggested that the increased wear of Phase III relative to Phase II is associated with the use of a minimally invasive approach which results in patients having higher activity levels and may also increase the risk of surgical errors leading to bearing overhang or impingement which may increase wear [275, 276].

3.1.2 Aims

The primary aim of this study was to compare the long-term linear wear rate between cemented and cementless Phase III OUKRs at 10 years given the concerns that:

1. Theoretically, cementless fixation of OUKRs may increase wear.
2. Linear wear of the Phase III OUKR was significantly higher than Phase II at five years.
3. There has been an increase in reporting of the long-term complication of bearing fracture with the Phase III OUKR.

The secondary aims were to identify implant, surgical, and patient factors that are associated with linear wear rate in the long-term.

It was hypothesised that there would be no difference in linear wear rate between cemented and cementless Phase III OUKRs at 10 years.

3.2 METHODS

3.2.1 Study Design and Analysis

The cohort of patients analysed in this study come from the RCT comparing Phase III cemented and cementless OUKRs featured in **Chapter 2.** The study design is summarised in **Section 2.2.1**.

Weight-bearing stereoradiographs of the knees taken post-operatively and at three, six, 12, 24, 60, and 120 months were analysed using model-based RSA software (version 4.11, Medis Specials, Leiden, The Netherlands). The technique used to measure bearing thickness with RSA differed slightly from the technique used in **Chapter 2** to measure implant migration. Only the contours of the inferior surface of the femoral components were marked to ensure that the fitting of the CAD model focused on this region. This provided the best-fit for the CAD model of the femoral component to ensure the distance between the inferior surface of the femoral component and superior surface of the tibial component could be measured accurately. The RSA determined the position of the OUKR femoral and tibial components in three-dimensional space. The coordinates of the implant positions were exported, and this data was used to calculate the closest linear distance between the femoral and tibial components with a custom MATLAB program (The Math Works Inc., Natick, Massachusetts. **Figure 3.2**). This distance was taken as the bearing thickness for each knee at each timepoint. Linear penetration at each timepoint was calculated by subtracting the bearing thickness from the initial thickness measured from post-operative stereoradiographs (**Table 3.1**).

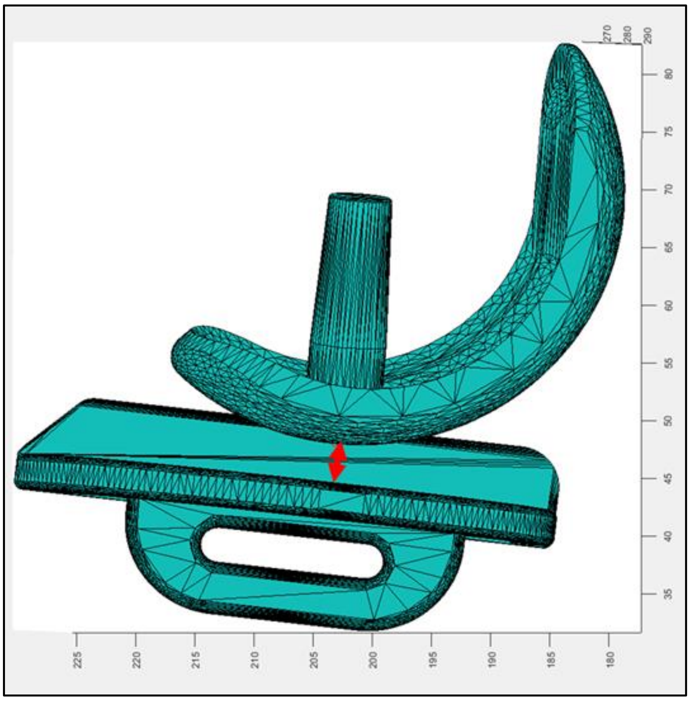


Figure 3.2 Example of the Oxford Unicompartmental Knee Replacement component models exported to a custom MATLAB program. Red arrows indicate the closest linear distance between the femoral and tibial component which was taken as the bearing thickness.

Table 3.1 Mean bearing penetration at each follow-up timepoint, calculated using the initial bearing thickness as the reference.

Months	3	6	12	24	60	120
Number of Knees	37	38	38	39	38	30
Mean Penetration (mm)	0.10	0.12	0.12	0.22	0.39	0.66
Standard Deviation	0.13	0.11	0.12	0.13	0.16	0.31
95% Confidence Interval	0.04	0.04	0.04	0.04	0.05	0.11

The technique used for measuring bearing thickness was compared to 5-year analysis completed by another user to ensure the technique was consistent. The differences were less than the accuracy of the RSA system, suggesting the technique used was consistent (see **Appendix A2.2**).

Polyethylene penetration in the early post-operative period is a combination of creep and wear [275, 277-279]. When the penetration rate becomes constant it is assumed that it is due to wear only, which for the Phase III OUKR was found to be after six months post-operatively [275]. Therefore, the wear rate in this study was calculated using linear regression of bearing thickness between six months and 10 years. Knees were included in the analysis if they had data to at least five years and bearing thickness measurements for a minimum of four time points between six months and 10 years, resulting in 39 knees being included in the analysis. Bearing overhang of the tibial component and bearing to femoral component contact area were calculated using the methods described by Ghosh et al with custom MATLAB programs [275]. Both medial bearing overhang (the linear distance between the medial edge of the bearing and medial edge of the tibial component) and area overhang (the area of the bearing overhanging the tibial component) were calculated. Femoral contact area was defined as the percentage of the superior surface of the bearing that is in contact with the femoral component. Distance between the bearing and vertical wall of the tibial component was also calculated, based on the assumption that the bearing was articulating congruently with the surfaces of the femoral and tibial component. A negative distance between the bearing and tibial wall indicated that the bearing was impinging on the wall and was therefore no longer fully congruent (see **Figure 3.5**). All calculations were made with the assumption that the bearing was parallel to the wall.

3.2.2 Statistical Analysis

Differences in wear rate between fixation method (cemented or cementless), overhanging versus non-overhanging bearings, and BMI greater or less than 30. GraphPad Prism (version 10.2.0 for Windows, GraphPad Software, Boston, Massachusetts USA) was used for statistical analysis. Unpaired T-tests (Shapiro-Wilk $p>0.05$) were used for parametric data and the Mann-Whitney U-tests for non-parametric data (Shapiro-Wilk $p<0.05$). Pearson correlation was used to test the association of age, BMI, 10-year OKS, distance of the bearing from the tibial wall, bearing overhang of the tibial component, and femoral contact percentage. The magnitude of Pearson's correlation coefficient (r) was used to categorise associations as negligible (<0.1), weak (0.1-0.39), moderate (0.40-0.69), strong (0.70-0.89), or very strong (0.90-1.00) [280]. The associations of component size (femoral and tibial) and bearing size with bearing wear were analysed using one way ANOVA. A change in wear rate of 0.025 mm/year (0.5 mm at 20 years) was considered clinically significant [276]. A p-value <0.05 was considered statistically significant.

3.3 RESULTS

The rate of penetration for the 39 Phase III OUKRs in this study was constant after six months and the mean linear wear rate was calculated to be 0.06 mm/year (SD 0.03) (**Figure 3.3A**). The mean bearing penetration attributable to creep, determined from where the wear regression line crossed the vertical axis, was 0.08 mm (SD 0.02). Most (97%) of this creep occurred in the first three months.

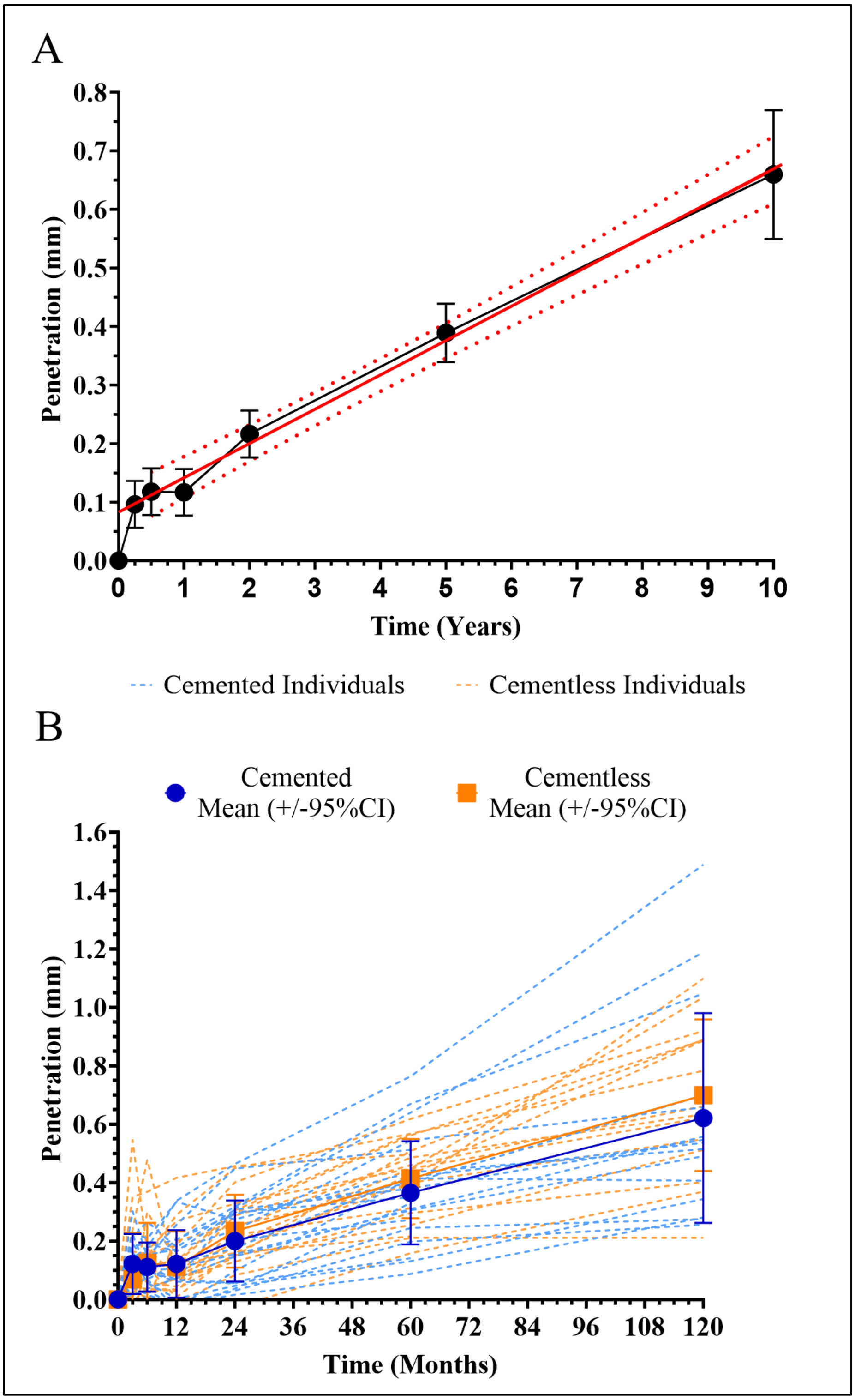


Figure 3.3 A Overall penetration of the Phase III Oxford Unicompartmental Knee Replacement bearing (Mean ± 95% Confidence Intervals, Black). Linear wear rate was calculated by linear regression of penetration between six months and 10 years (Red line, 95% confidence intervals as red dashed lines). Creep was calculated from where the regression line intersects the vertical axis (0.084 mm). **B** Mean penetration (±95% Confidence Intervals) of bearings from cemented (dark blue) and cementless (dark orange) knees. Penetration of individual bearings is shown for cemented (light blue) and cementless (light orange)

3.3.1 Implant Factors

There was no significant difference (p=0.2) in linear wear rate between cemented (0.05 mm, SD 0.03) and cementless (0.06, SD 0.03) implants (**Figure 3.3B**). The size of the implanted tibial (p=0.9) or femoral (p=0.8) components did not have a significant association with linear wear rate, nor did the thickness of the mobile bearing used (p=0.4).

3.3.2 Surgical Factors

Bearings had area and medial overhang (Figure **3.4**) of the tibial component in 27 and 25 knees, respectively. For overhanging bearings, the mean area overhang was 44.7 mm^2 and mean medial overhang was 1.84 mm (**Table 2.2**). When considering only overhanging bearings, there was no significant correlation between linear wear rate and area (p=0.4) or medial (p=0.4) overhang. There was also no significant difference in wear rate between overhanging and non-overhanging bearings for either area (p=0.2) or medial overhang (p=0.06) (**Table 3.3**). One bearing was found to have slight impingement (0.1 mm) on the medial wall of the tibial component but did not have significantly greater linear wear (0.04 mm/year).

The distance between the bearing and the vertical wall of the tibial component (**Figure 3.5**) was weakly correlated (r = 0.338, p=0.04) with linear wear rate. This translated to wear increasing by 0.025 mm/year for every 6.25 mm further away from the wall the bearing is placed (**Figure 3.6A**). The percentage of the upper surface of the bearing in contact with the femoral component (**Figure 3.7**) had a weak negative correlation (r = -0.329, p=0.04) with linear wear, with a 25% increase in contact area decreasing wear by 0.025 mm/year (**Figure 3.6B**).

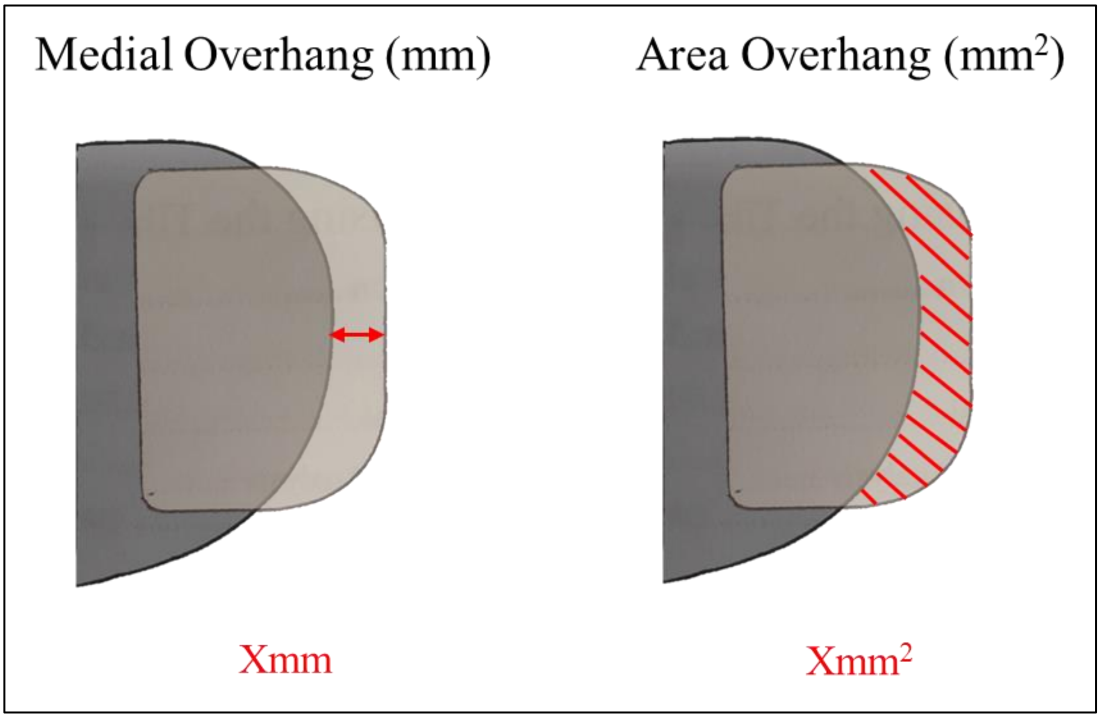


Figure 3.4 An example of a bearing overhanging a tibial component. The medial overhang (mm) is measured as the distance between the medial edge of the bearing and medial edge of the tibial component (shown on the left, indicated by red arrows). The area overhang (mm^2) is the area of the bearing overhanging the component (shown on the right, indicated by red shading**)**

Table 3.2 Correlation of Linear Wear Rate with Implant and Patient Factors

Factor	Mean (SD)	Gradient vs. wear/year (mm)	Association - Pearson's Correlation, r (95% Confidence Interval)	P-value
Age at Operation (Years)	65.9 (8.15)	0.001	0.253 (-0.07 to 0.53)	0.121
Body Mass Index (kg/m^2)	30.1 (6.69)	-0.002	-0.434 (-0.67 to -0.11)	**0.009****
10-Year Oxford Knee Score (0 = worst, 48 = best)	39.8 (8.86)	0.001	0.260 (-0.07 to 0.54)	0.120
Medial Overhang – ALL (mm)	0.486 (2.25)	0.004	0.305 (-0.01 to 0.57)	0.059
Medial Overhang – Overhanging Bearings Only (mm)	1.84 (1.46)	0.004	0.170 (-0.24 to 0.53)	0.416
Area Overhang – ALL (mm^2)	31.0 (39.2)	0.0002	0.262 (-0.06 to 0.53)	0.107
Area Overhang – Overhanging Bearings Only (mm^2)	44.7 (40.0)	0.0001	0.158 (-0.24 to 0.51)	0.433
Femoral Contact Area (%)	84.5 (7.34)	-0.001	-0.329 (-0.58 to -0.01)	**0.041***
Bearing to Tibial Wall Distance (mm)	3.94 (2.17)	0.004	0.338 (0.03 to 0.59)	**0.035***

Significant values are shown in **bold**. Level of statistical significance: * $p<0.05$, ** $p<0.01$

Table 3.3 Comparisons of Linear Wear Between Categories of Implant and Patient Factors

Factor	Group	Mean Wear Rate mm/year (SD)	P-value (Unpaired T-test, Mann-Whitney U-test, or ANOVA)
Overall Wear	All Knees (n=39)	0.058 (0.029)	Not Applicable
Fixation Method	Cemented (n=20)	0.054 (0.032)	0.175
	Cementless (n=19)	0.063 (0.025)	
Medial Overhang	Overhangers (n=25)	0.064 (0.031)	0.176
	Non-Overhangers (n=14)	0.049 (0.023)	
Area Overhang	Area Overhang (n=27)	0.064 (0.031)	0.055
	No Area Overhang (n=12)	0.047 (0.020)	
Tibial Component Size	A (n=5)	0.063 (0.026)	0.933
	B (n=8)	0.054 (0.024)	
	C (n=14)	0.055 (0.035)	
	D (n=2)	0.073 (0.033)	
	E (n=7)	0.058 (0.026)	
	F (n=3)	0.069 (0.038)	
Femoral Component Size	Small (n=16)	0.057 (0.029)	0.762
	Medium (n=12)	0.056 (0.022)	
	Large (n=11)	0.064 (0.036)	
Bearing Thickness (Size)	Size 3 (n=7)	0.052 (0.021)	0.352
	Size 4 (n=22)	0.058 (0.028)	
	Size 5 (n=8)	0.070 (0.035)	
	Size 6 (n=2)	0.032 (0.019)	
Body Mass Index	BMI <30kg/m^2 (n=23)	0.070 (0.029)	**0.007****
	BMI ≥30kg/m^2 (n=13)	0.044 (0.021)	

Significant values are shown in **bold**. Level of statistical significance: * p<0.05, **p<0.01

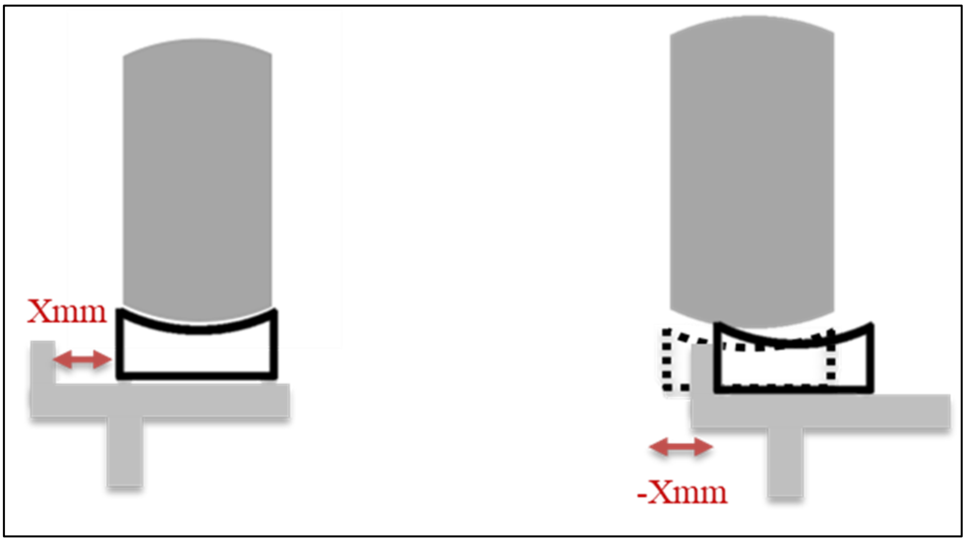


Figure 3.5 Left: An illustration of a bearing positioned X mm from the vertical wall of the tibial component. Right: When there is marked impingement of the bearing on the lateral wall of the tibial component, the bearing becomes incongruent. In this study, if the distance between the centre of the bearing and the wall was less than half the bearing width, it was deemed to impinge. The measurement of where the lateral edge of the bearing is relative to the tibial component wall would then be negative, shown as -X mm, for where the bearing would be positioned if the wall did not exist (dashed outline)

3.3.3 Patient Factors

There was no significant correlation between the patient's age at the time of operation (p=0.12) or 10-year OKS (p=0.12) and linear wear rate. BMI had a moderate negative correlation (r = -0.431) with wear rate, with a 12.5-point increase in BMI decreasing wear by 0.025 mm/year. Patients with a BMI greater than 30 (0.04 mm/year) had significantly less (p=0.004) wear than those with a BMI less than 30 (0.07 mm/year) (**Figure 3.6C**).

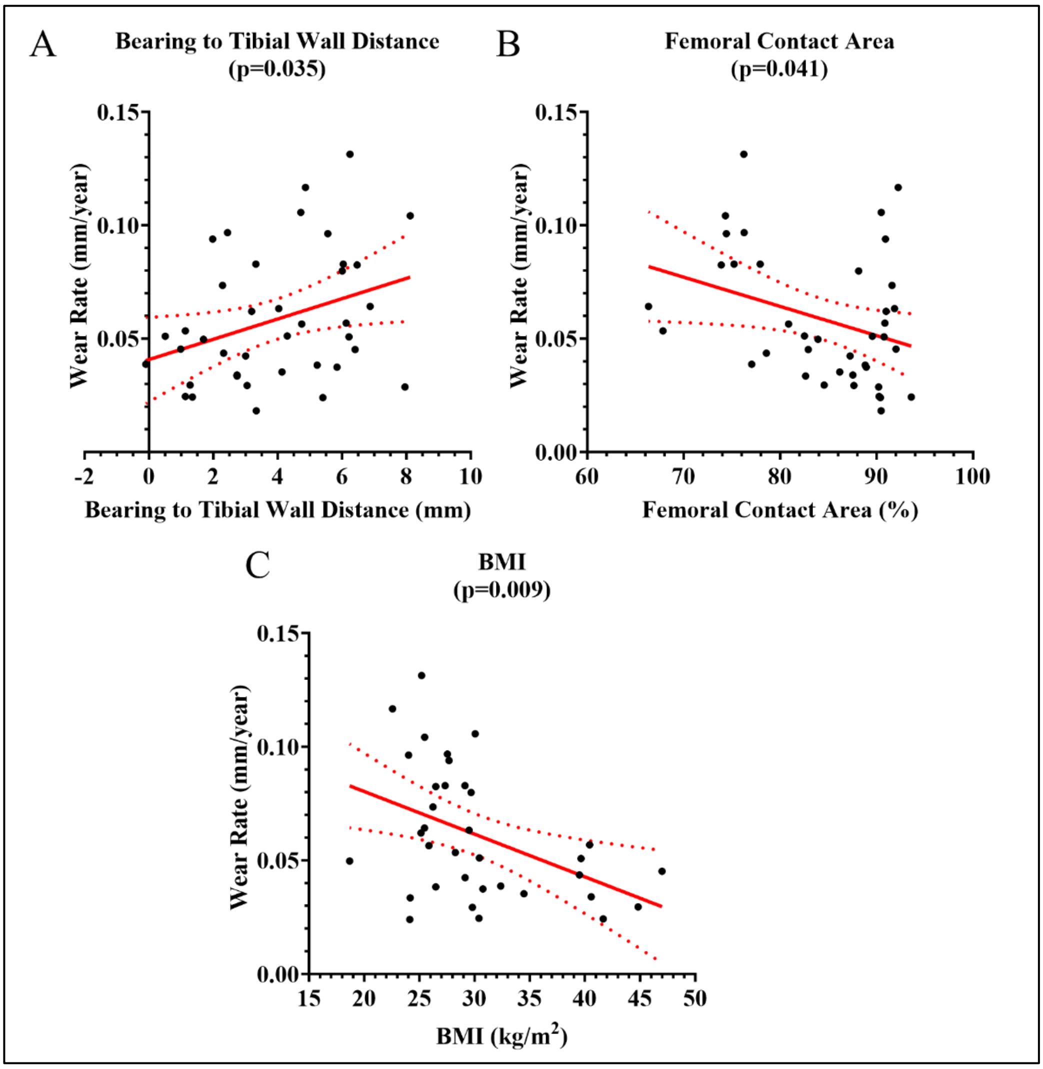


Figure 3.6 Surgical and patient factors that have a significant correlation with linear wear rate. Linear regression ± 95% confidence intervals shown in red. P-values for Pearson correlation are shown. **A** Distance of the bearing from the vertical wall of the tibial component. **B** Femoral Component Contact Area. **C** Body Mass Index (BMI).

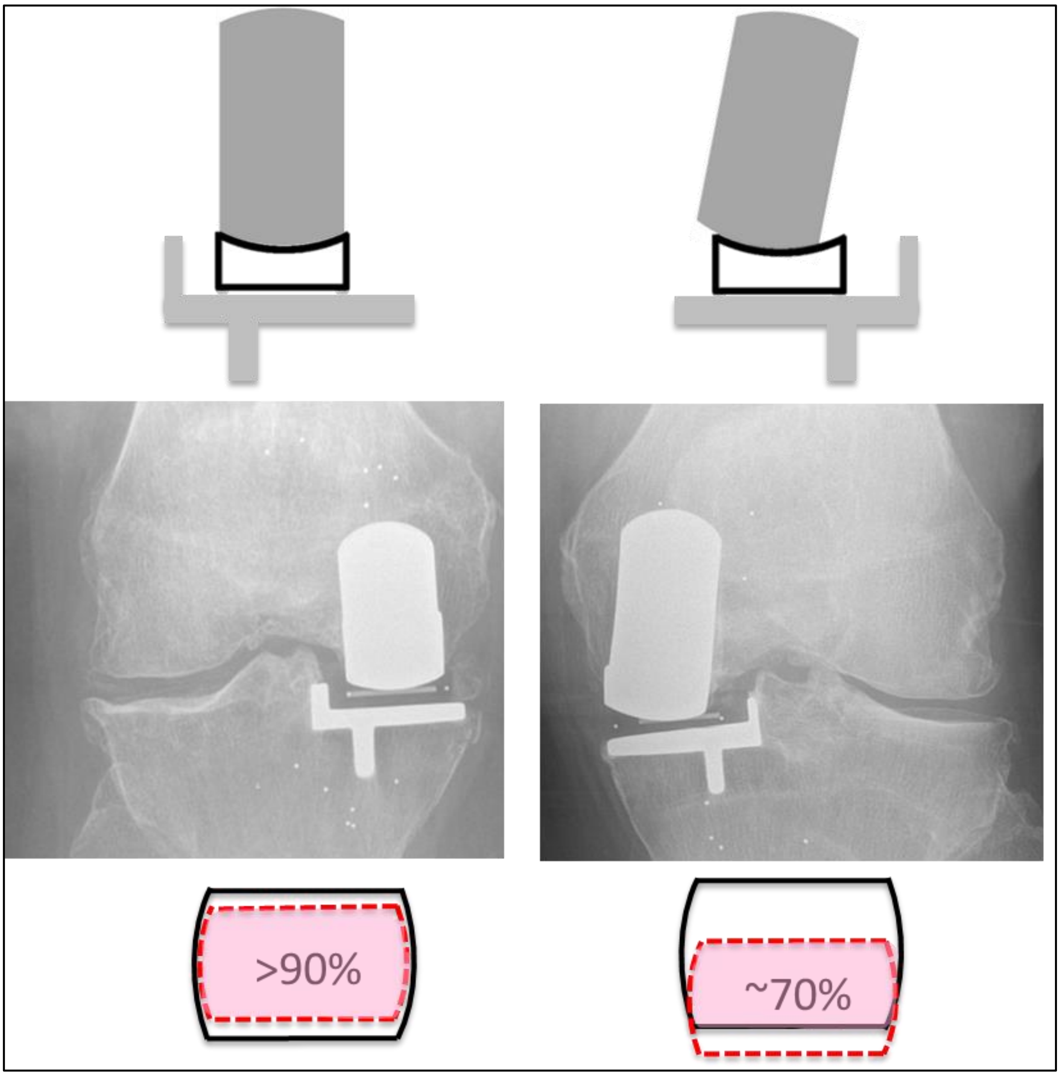


Figure 3.7 Left: Shows a diagram and radiograph of a femoral component aligned neutrally, perpendicular the tibial component tray, which tended to have greater than 90% femoral component contact percentage. The schematic shows a superior view of the mobile bearing, with the femoral contact area outlined and shaded in red. **Right:** A diagram and radiograph showing a femoral component with varus alignment. Femoral components aligned with significant varus/valgus tended to have approximately 70% femoral component contact percentage.

3.4 DISCUSSION

The most important finding of this study is that there is no significant difference in the long-term bearing wear rate of cemented and cementless OUKR. Overall, the mean linear wear rate was 0.06 mm/year. There was substantial variability (SD 0.03) in the wear rate and as a result there is a chance that a very small percentage of the thinnest bearings might fracture due to wear in the long-term. However, the rate would be similar with cemented or cementless fixation. The study also identified various surgical factors that influenced the wear rate, such as the position of the bearing and the orientation of the femoral component. If these factors could be addressed wear could be minimised and bearing fractures prevented.

The finding that there is no significant difference in the long-term polyethylene wear between cemented and cementless OUKR is important as fragments of the hydroxyapatite-coated porous titanium surface could potentially be released into the joint and increase the wear rate by acting as third bodies. As well as contributing to bearing fracture a higher wear rate might contribute to osteolysis and aseptic loosening [281]. NJR studies have shown that at 10 years the revision rate for the cementless OUKR is about 25% less than for the cemented [266]. This difference was primarily because the revision rate for aseptic loosening of cementless components was less than half that for cemented components [266]. As wear is not related to fixation method, in the very long term the revision rate of cementless is likely to be less than cemented. There are other advantages of the cementless OUKR, for example it has better functional outcomes with less pain, and fewer radiolucencies [185]. The main disadvantage of cementless OUKRs is that there is a higher TPF rate [266, 282]. Further surgical strategies to minimise the risk of TPF with cementless OUKR are studied in **Chapters 6 and 7**.

The combined linear wear rate on upper and lower surfaces of the bearing is, on average, 0.06 mm/year and is constant, at least out to 10 years, and is independent of bearing thickness. This results in wear of about 0.6 mm at 10 years and 1.2 mm at 20 years. Approximately 0.08 mm of creep occurs in the early post-operative period, with almost all creep occurring before three months. This wear rate is consistent with previously published short term linear wear rates for the Phase III OUKR [253, 275]. It is substantially lower than linear rates published for fixed-bearing knee replacements of 0.15 mm/year and 0.49 mm/year from two retrieval studies [166, 167]. It is however larger than the wear of the Phase II OUKR (0.02 mm/year) [264, 274]. It is unclear why the Phase III wear rate is higher than Phase II. It has been suggested that, compared to the open approach used for the Phase II, the minimally invasive approach used for Phase III results in higher levels of function which may account for the higher wear rate [275]. However, in the current study the wear rate was not related to the OKS. Another possible explanation is that minimally invasive surgery may result in more surgical errors, particularly with implant positioning, impingement, or cementing, that would account for higher wear rates [176]. Minor changes to the shape of the bearing and tibial component were made between Phase II and III which may have unintentionally contributed to increased wear. The resin used and manufacturing process for bearings also changed between Phase II and Phase III, however, a previous study found that these changes had no effect on wear rate [276]. Highly crosslinked polyethylene has been shown to decrease wear for total hip and knee replacements [283, 284]. To compensate for the higher wear seen with the Phase III OUKR, manufacturing bearings from highly crosslinked polyethylene could be considered.

The surgical factor most strongly related to wear was the distance between the bearing and the wall of the tibial component. The analysis suggested that for every 6.25 mm further away from the wall the bearing is placed, linear wear increased by 0.025 mm/year (**Table**

3.2, Figure 3.6). There were five bearings (13%) positioned 6.25 mm or more from the tibial wall in this study which could potentially have been positioned a clinically significant distance closer to the tibial wall. Bearings further away from the wall may rotate as they move resulting in increased wear due to cross-shear [285]. Furthermore, bearings further from the wall will overhang the tibial plateau more, particularly if they rotate. Overhanging bearings may impinge on the soft tissues and structures surrounding the knee. Impingement may subsequently increase contact stress and thus wear. There was a trend (p=0.06) towards increased wear with increased bearing overhang, even though the overhang was calculated based on the assumption the bearing did not rotate. Therefore, it to minimise linear wear the femoral component should be positioned so that the bearing is close to the wall. Further studies are required to determine exactly how close to optimal wall-to-bearing distance, which may be a good candidate for a wear simulator study where other variables can be controlled. The main concern being that bearings positioned too close to the tibial wall will impinge on it, risking higher wear rates or dislocation of the bearing [286]. There was one bearing impinging against the wall in this study, but the impingement was only 0.1 mm, which did not result in a significantly higher rate of wear (0.04 mm/year). A further advantage of having the bearing close to the wall is it will decrease the risk of the bearing spinning and dislocating [287]. An intraoperative study of 32 knees showed that in flexion and extension the mean change in bearing-to-wall distance for the OUKR was approximately 1 mm and less than 2 mm in 27 of the knees [288]. Therefore, it is suggested that surgeons aim to position the bearing approximately 2 mm from the tibial wall to minimise the risk of linear wear and impingement.

Femoral component contact percentage with the bearing had a significant negative correlation with wear rate, with a 25% increase decreasing wear by 0.025 mm/year. The highest femoral contact area in this study was 94%. There were two knees in this study (femoral contact areas of 66% and 68%, respectively) that could have theoretically improved their femoral contact percentage by 25% or more. Femoral component contact percentage is maximised when the femoral component is neutrally aligned relative to the tibial component, whereas valgus or varus implantation decreases the contact percentage (**Figure 3.7**).

Patient BMI was found to be negatively correlated with wear rate, with a 12.5-point increase in BMI resulting in a 0.025 mm/year decrease in linear wear rate (**Table 3.2**). When separated into obese (BMI≥30) and non-obese (BMI<30), OUKRs in obese patients had a significantly lower ($p<0.01$) rate of linear wear. This phenomenon may be explained by the fact that patients with a lower BMI are possibly more physically active and therefore may have high wear rates [289].

Excessive linear wear may result in bearing fracture, which although a rare complication, has been increasingly reported for Phase III OUKRs [37-40, 267, 269]. This may be a result of an increased wear rate but is also likely a consequence of the operation being done in younger patients with increasing life expectancy, with most reported bearing fractures occurring in the second or third post-operative decade. Thinner bearings, particularly those worn to less than 2 mm thick, are at higher risk of fracture [37, 269, 276]. In this study two bearings (5%), both size 3, were projected to be less than 2 mm thick by 20 years. Although initial bearing thickness is not related to the linear wear rate, OUKRs with bearings of Size 5 or larger are known to have significantly decreased implant survival [19, 290]. Therefore, it is suggested that Size 4 bearings are used in young, active patients to minimise their risk of bearing fracture in the long term without impairing implant survival. In very small patients the tibial resection should be as small as possible to minimise the risk of TPF or damage to the medial collateral ligament, so in these patients it may be sensible to aim for a Size 3 bearing.

The Microplasty instrumentation [190], which was introduced after the OUKRs in this study were implanted and is now routinely used, was designed to make the operation simpler and more reproducible. Several studies have shown that Microplasty improves component positioning [25, 221, 291, 292] and decreases the rate of bearing dislocation [28]. It includes instrumentation to accurately determine the height of the tibial cut, which facilitates selecting a Size 3 or Size 4 bearing as suggested for very small patients and young, active patients, respectively. It also has instrumentation to prevent impingement of bone on the bearing both anteriorly and posteriorly which is a potent cause of wear [257]. The femoral drill guide is linked to an intramedullary rod, which ensures that the femoral component is neutrally orientated. The instrumentation is also designed to position the femoral component so that the bearing is about 2 mm from the wall. The IM rod should be inserted about 1cm in front of the notch and medial to the medial border to the notch. If it is inserted too far laterally it can cause the patella and thus the tibia to sublux laterally, which results in the femoral component being positioned too far laterally [286, 293]. This can cause the bearing to jam against the wall, which may cause early valgus TCS [218]. It is important that the position of the bearing should be checked before the keel slot is formed and if the bearing is jammed against the wall the tibial component should be moved laterally. With the correct use of the Microplasty instruments the bearing wear and the risk of bearing fracture should decrease.

3.4.1 Limitations

This study was limited by not being able to analyse the stereoradiographs of all patients at 10 years, either due to loss to follow-up or stereoradiographs that were unable to be analysed. The loss of nine knees (six cemented, three cementless) between five and 10 years reduced the accuracy of the wear rate calculation for these knees. However, as wear rate is linear beyond six months this is unlikely to have an appreciable effect on the results.

The sample size of 39 is another limitation. The study was originally designed to measure migration. However, a retrospective power calculation based on wear (SD 0.029 mm/year) indicated that there was adequate power (80%) in the current study to detect a clinically important difference of 0.025 mm/year (0.5 mm at 20 years). The difference in wear between cemented and cementless (0.007 mm/year, p=0.2) is therefore neither clinically or statistically significant.

Another limitation is that confounding variables that have not been studied may influence the wear rate, therefore a causal link between the factors studied and linear wear rate cannot be concluded. Wear simulator studies may help to confirm that the bearing to tibial wall distance and femoral component contact area are associated with wear rate, independent of other variables.

Two assumptions were made when calculating bearing overhang and distance from the vertical tibial wall. It was assumed that the bearing was parallel to wall and that bearing position in extension, where standing radiographs are taken, is similar throughout the knee's range of motion. If there is appreciable space between the bearing and tibial wall the bearing is likely to rotate so the analysis probably underestimates overhang. Had it been possible to measure bearing rotation and include this in the calculation, there might have been a significant relationship between overhang and wear. The bearing is typically closest to wall in mid flexion and moves approximately 1 mm laterally in extension and full flexion [288]. Therefore, distance between the wall and bearing in this study is likely an indicator of the maximum distance.

3.5 CHAPTER SUMMARY

At 10 years, there is no significant difference in the wear rate between the cemented and cementless Phase III OUKR, so the failure rate due to wear should be similar for both devices. Although the mean linear wear rate is low (0.06 mm/year), it remains higher than the Phase II OUKR and there is considerable variability (SD 0.03) in the wear rate so there is a small risk of bearings fracturing in the long term. The wear rate can be minimised by careful surgery aiming to position the bearing approximately 2 mm from the tibial wall, neutral alignment of the femoral component, avoiding bearing impingent, and using Size 4 bearings in very young active patients. The current Microplasty instrumentation should help surgeons achieve this.

Although bearing fracture has been a rare complication to date, it is being reported more frequently with the Phase III OUKR at 10 years and beyond and can lead to revision of the implant. Thus, surgeons should take the steps suggested above to minimise the wear rate, and therefore the risk of bearing fracture. Further study is needed to confirm whether the introduction of Microplasty instrumentation has reduced long-term linear wear for the OUKR compared to OUKRs implanted with the original Phase III instrumentation.

CHAPTER 4 – TIBIAL COMPONENT SUBSIDENCE OF THE CEMENTLESS OUKR

4.1 CHAPTER MOTIVATION

4.1.1 Background

The findings of **Chapter 2** indicate that fixation of the cementless OUKR is as good, if not better than the cemented OUKR despite cementless OUKRs having greater early migration. There are also few reports of late aseptic loosening of cementless OUKRs in the literature, however, there have been several reports of early TCS with the cementless OUKR. [32-35, 180, 219]. TCS is summarised in **Section 1.7.3** and reports of TCS published in the literature are summarised in **Table 4.1.**

Although tibial subsidence has been reported for fixed bearing UKRs, it has not previously been described for the cemented OUKR [294]. TCS differs from the small (<1 mm) inferior migration observed for almost all cementless OUKR tibial implants during the first six months post-operatively, which was demonstrated in the RSA study in **Chapter 2** (**Figure 2.4**) [215, 216]. These components are not fully seated at surgery and "bed-in" with weight-bearing (**Figure 4.1**). The cases of TCS reported for the cementless OUKR describe the lateral and/or posterior tibial component tilting by several degrees [32-35, 180, 219] (**Figure 4.2**). For most cementless OUKR patients, TCS appears to cease within the first post-operative year [32, 33]. TCS is often accompanied by pain, but in most cases the pain resolves between three months and 1-year postoperatively with patients having good long-term clinical outcomes. However, in some cases cementless OUKRs with TCS have been revised either due to ongoing pain, bearing dislocation, or TCS continuing at one year or more [32, 33, 219].

Table 4.1 Summary of reports in the literature of early Tibial Component Subsidence (TCS) with the cementless Oxford Unicompartmental Knee Replacement (OUKR)

Publication	Study Description	Incidence of TCS	Number of TCS Cases Revised	Proposed risk factors and/or aetiology of TCS
Liddle et al., 2013 [180]	Multicentre study of 1000 cementless OUKRs. 1-year radiographs were reviewed.	3/1000 (0.03%)	0	None
Liddle et al., 2014 [32]	6 case reports from three different centres of patients with tibial components that subsided into a valgus position in the early post-operative period.	6/- (NA)	2 (33%)	• Impingement of the mobile bearing against the lateral wall of the tibial tray during flexion in the early post-operative period. • Damage to the lateral part of the horizontally-cut surface of the medial tibial plateau (i.e. due to an excessively deep vertical cut).
Kamenaga et al., 2019 [33]	Retrospective cohort study of 120 patients who received a cementless OUKR. Radiographs were reviewed post-operatively and at three, six, and 12 months to identify knees with >2° of valgus subsidence.	6/120 (5%)	0	• Tibial component positioned too medially or in excessive external rotation → leading to impingement of the bearing on the tibial wall and/or decreased bony coverage. • Excessively deep vertical cut. • Damage to the posterior cortex when making the keel slot.
Hefny, et al., 2020 [34]	A retrospective review of a single surgeon series of cementless OUKRs with at least five years follow-up. Subsidence measured on **both** anteroposterior and lateral post-operative and 1-year radiographs.	4/158 (2.5%)	1 (25%)	• Elderly patients with poor tibial metaphyseal bone quality due to periarticular osteoporosis, associated with reduced loading in the arthritic knee, may be at higher risk for TCS.
Hefny, et al., 2020 [35]	Prospective study of a consecutive series of OUKRs. Subsidence measured on **both** anteroposterior and lateral post-operative and 1-year radiographs.	1/61 (1.6%)	0	• Same as Hefny, et al., 2020 [34] above.
Panzram, et al., 2020 [219]	A retrospective cohort study of a consecutive series of 228 cementless OUKs with minimum two years follow-up. Subsidence measured on **both** anteroposterior and lateral radiographs.	2/164 (1.2%)	1 (50%)	None

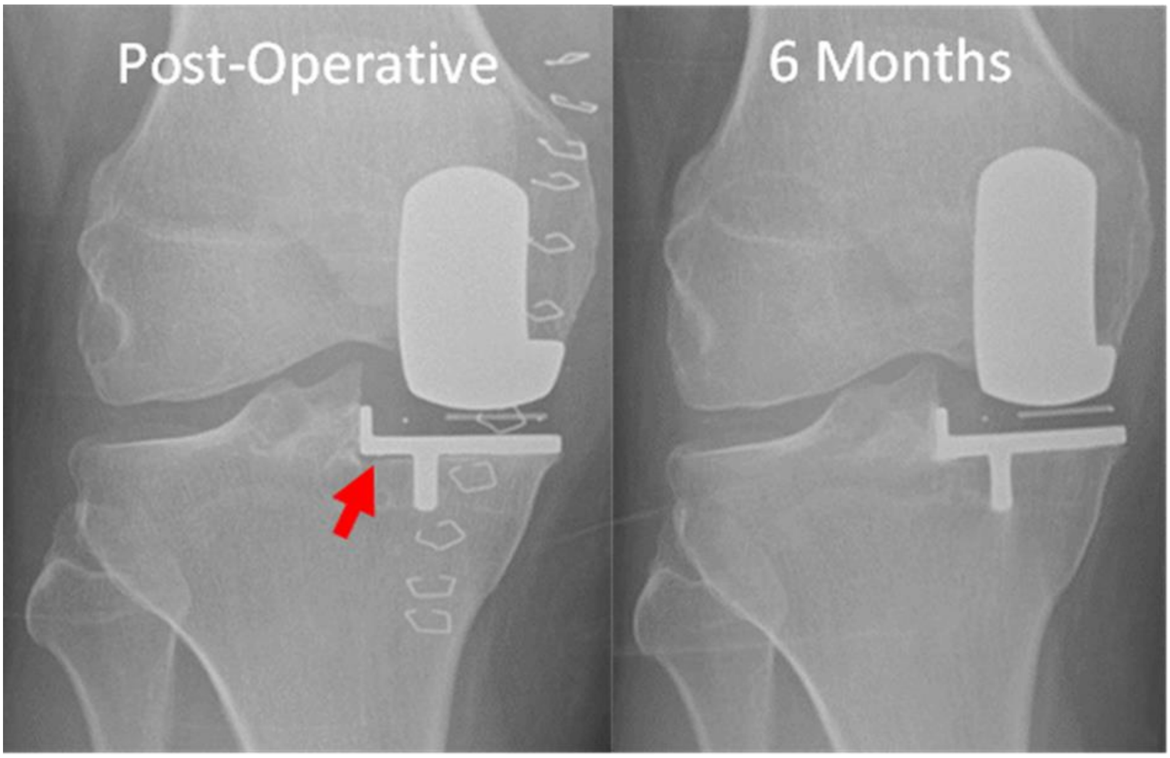


Figure 4.1 Example of tibial component 'bedding in' with the cementless Oxford Unicompartmental Knee Replacement. This phenomenon occurs with almost all cementless tibial components if they are not fully seated intraoperatively, as shown by the radiolucent line beneath the component (red arrow) post-operatively. By six months the component has fully seated and the radiolucent line is no longer present.

The cause of TCS in cementless OUKRs is not fully understood. It has been suggested that impingement of the bearing against the lateral wall of the tibial component combined with lateral implantation of the femoral component could cause tilting of the mobile bearing with excessive loading of the lateral tibial component and unloading of the medial tibial component [32]. Damage to the posterior tibial cortex, such as a deep vertical cut during tibial resection, can result in weakened bone beneath the posterior tibial component resulting in TCS [32]. Implantation of the tibial component in a more medial position and with excessive external rotational has also been associated with TCS [33]. Tibial component underhang has also been cited as a theoretical cause of TCS [295], as has periarticular osteoporosis, associated with reduced loading in the arthritic knee, in elderly patients [34].

A major challenge of TCS is to understand whether it is linked to worse long-term clinical outcomes and whether it is an indication for revision. The majority (18/22) of TCS cases in the literature have not been revised and gone on to have satisfactory clinical and radiographic outcomes at their last follow-up. Given the positive long-term outcome for most cases, the generally accepted treatment for TCS patients of making them non- or partial-weightbearing until the pain improves seems sensible [32-34]. However, some surgeons see the migration of the tibial component in TCS patients as an indication for revision of the prosthesis. The four TCS cases in the literature that have been revised are summarised in **Table 4.2**.

Table 4.2 Summary of TCS cases in the literature that have been revised.

Case	Publication	Description
1	Liddle et al., 2014 [32]	Was found to have a loose tibial component with bony ingrowth restricted to the keel region. Revision to a cemented TKR relieved the patient's pain.
2	Liddle et al., 2014 [32]	The tibial component was well fixed at the time of revision surgery but there was an un-displaced fracture of the posterior tibial cortex. The knee was revised to a TKR. The patient had an unremarkable recovery.
3	Hefny, et al., 2020 [34]	Had progressive subsidence between one and two years of 4 mm and 7° of valgus rotation which was deemed to cause progression of osteoarthritis in the lateral compartment. The knee was revised to a long-stem TKR.
4	Panzram, et al., 2020 [219]	Had a bearing dislocation within the first post-operative year which was revised by exchanging the bearing.

It is not possible to conclude whether the four revised TCS cases would also have had a satisfactory outcome. However, given the satisfactory outcome of the other 18 TCS cases it is reasonable to expect that Cases 1 and 2 may have had a satisfactory outcome if treated conservatively, while 3 and 4 had the additional complications of lateral osteoarthritis progression and bearing dislocation which would have required revision independent of TCS.

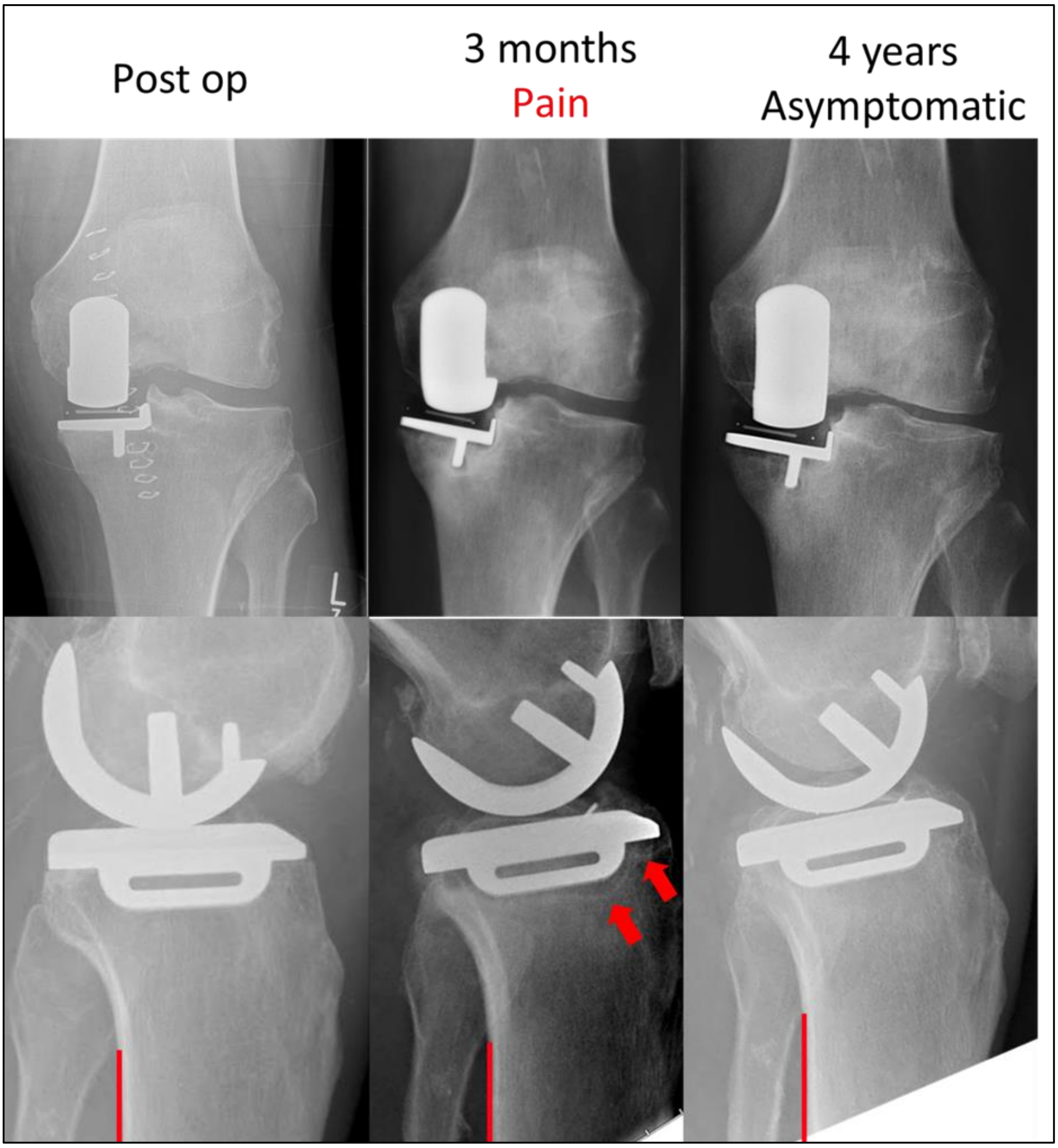


Figure 4.2 Example of Tibial Component Subsidence (TCS) with valgus rotation (see anteroposterior radiographs, top row) and posterior tilting (see lateral radiographs, bottom row) of the component that has occurred within 3 months of the operation. An anterior radiolucency accompanying the posterior tilting can be seen on the lateral radiograph, indicated by red arrows. TCS has been observed in a small number of patients with the cementless Oxford Unicompartmental Knee Replacement (OUKR) and has been reported to often be accompanied by pain in the early post-operative period.

4.1.2 Aims

The reported incidence of TCS ranges from 0.03% and 5% [32-36], there is little understanding of the risk factors for TCS, and there is no published data on the clinical outcome of patients with TCS at five years or more. Given the limited understanding of TCS, this study aimed to:

1. Determine the radiographic incidence of TCS in the largest cementless OUKR cohort to date.

2. Investigate which patient, surgical, and implant factors, if any, are associated with TCS.

3. Study the relationship between TCS and 5-year clinical outcome, particularly pain.

4.2 METHODS

TCS was studied retrospectively in patients from a longitudinal cohort study of patients at a single centre who received a medial OUKR between 2006 and 2012 from four experienced surgeons. This study included 278 cementless OUKRs and collected comprehensive post-operative clinical outcomes for patients at five years, which have been reported previously [185].

TCS has been reported to occur almost entirely in the early post-operative period and rarely continues beyond three months [32-34]. Most patients in the study cohort had radiographs immediately post-operatively, and at one, two, and five years. Given TCS is thought to occur in the first post-operative year a knee was included if it had anteroposterior and lateral radiographs from immediately post-operatively and at least one time point between one and five years.

123 knees had the required radiographs. The field of view and the alignment of these radiographs were assessed by two authors with 94 knees found to have sets of radiographs of sufficient quality for analysis of TCS. TCS was assessed based on migration between the post-operative and five -year radiograph, with a 1 or 2-year radiograph used if the five -year radiograph was of insufficient quality for analysis. Knees identified to have TCS had their radiographs analysed at all available timepoints to assess the progression of TCS over time.

4.2.1 Analysis of Subsidence and Component Position

Measurement of anterior/posterior and varus/valgus tilt of cementless OUKR tibial components from radiographs was essential to identify knees with TCS. The position of the components and mobile bearing was also of interest to determine whether implant positioning is related to TCS. To measure these factors a custom MATLAB program written for the purpose of TCS analysis was used. On the anteroposterior radiographs, the tibial component axis was a bisector of the tibial component baseplate, generated by identifying the top and bottom of the tibial baseplate laterally and medially (**Figure 4.3A**). The mechanical axis of the tibia was determined by marking the centre of the diaphysis proximally and distally. Angle change between tibial component axis and the anatomical axis of the tibia was used to measure tibial component varus/valgus rotation (**Figure 4.3B**). Other measures recorded from anteroposterior radiographs included depth of tibial resection (mm), medial overhang/underhang of the tibial component (mm), medial-lateral bearing location (0-1 scale: 0 = against lateral wall of tibial component, 1 = completely displaced from the tibial baseplate medially), and femoral component varus/valgus angle relative to the tibial axis (degrees). On lateral radiographs, the tibial component axis was marked as the superior surface of the tibial component wall. Tilting of the tibial component was assessed by measuring change in the tibial component axis and the axis of the posterior cortical surface of the tibia. As determined by comparison with radiostereometric analysis results, the accuracy of radiographic measurements for tibial component varus/valgus rotation and anterior/posterior tilt were 1.7° and 1.6°, respectively (see **Appendix A2.3**). TCS was defined as a tibial component having >2º of valgus and/or posterior rotation, as per the Kamenaga et al. definition of TCS [33]. The value of 2° was also greater than the accuracy of the system. Validation of the analysis method, inter- and intra-observer agreement, and calculation of the accuracy of the system is discussed in **Appendix A2.3**.

4.2.2 Clinical Scores

The OKS, Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP), and AKSS were used to evaluate clinical outcome at five years (see **Appendix 5**). The OKS is a 12-question patient reported outcome measure (PROM) of knee replacement outcome and has two components; pain (Questions 1,4,5,8,9) and function (Questions 2,3,6,7,10,11,12) [249]. It is scored on a scale of 0 (worst) to 48 (best) and can be separated into 'Excellent' (42–48), 'Good' (34–41), 'Fair' (27–33), and 'Poor' (0–26) categories based on the Kalairajah classification [296, 297]. The AKSS is a clinical score (0-200) completed by an observer to assess the outcome of knee replacement and has a functional (0-100) and objective (0-100) component, where a higher score is better [73]. The objective component has a subset of questions addressing pain that is scored 0-50 which was used in this study. The ICOAP is an interviewer administered score that differentiates between constant and intermittent pain related to osteoarthritis and is responsive to improvements in joint paint related to hip or knee replacement [298, 299].

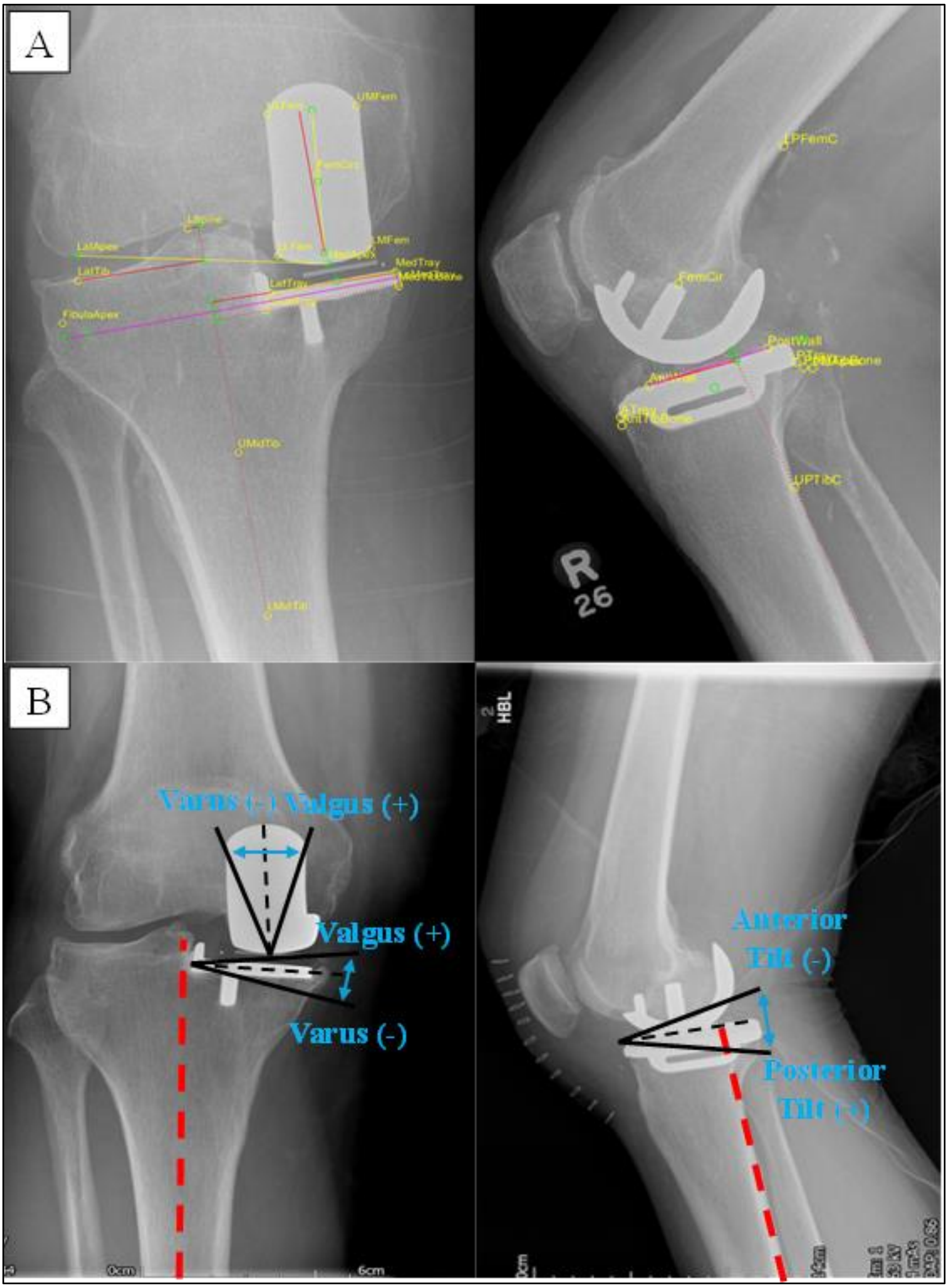


Figure 4.3 A The custom MATLAB program used to assess anteroposterior and lateral radiographs of Oxford Unicompartmental Knee Replacements. Shown are the user identified landmarks (yellow markers), tibial component axis (solid purple line), and tibial anatomical axis (anteroposterior – red dotted line) or posterior tibial cortical axis (lateral – red dotted line). **B** Simplified diagram indicating how the axis of the tibial and femoral components were marked (black dashed line) and which directions were designated as varus/valgus (anteroposterior) or anterior/posterior tilt (lateral). The red dashed lines indicate the tibial anatomical axis (anteroposterior) and posterior tibial cortical axis (lateral).

4.2.3 Statistical Analysis

Data analysis was completed using GraphPad Prism (version 10.2.0 for Windows, GraphPad Software, Boston, Massachusetts USA). Descriptive statistics were generated for component positions, patient demographic information, clinical scores, and component sizes. These measures and outcomes were compared between knees with and without subsided tibial components. Normality of data was assessed using the Shapiro-Wilk test. Continuous values were tested using an unpaired T-test if they were normally distributed (Shapiro-Wilk $p<0.05$) or a Mann-Whitney U-test if they were not (Shapiro-Wilk $p>0.05$). Fisher's Exact test was used to analyse the relationship between TCS and implant or bearing size.

4.2.4 Ethical Approval

This study received Institutional Review Board approval (REC 11/SC/0480).

4.3 RESULTS

Radiographic analysis identified five cementless tibial components (5%) that had TCS greater than two degrees (**Figure 4.4** to **Figure 4.8**). These included four that had both posterior and valgus subsidence (Subsiders 1-4) and one subsiding only posteriorly (Subsider 5) (**Table 4.3**). The subsiders are summarised below with their migration and OKS across five -years shown in **Figure 4.9**. For all subsiders most of the bone implant interface showed direct apposition of bone to the porous implant under surface, except for Subsiders 1 (**Figure 4.4**) and 5 (**Figure 4.8**) which had anterior radiolucencies. None of the five subsiders reported any abnormal pain associated with their OKS in the first post-operative year and at 1-year three of the subsiders had an excellent OKS while the other two had good scores.

Subsider 1

A 71-year-old male with a five-year BMI of 34. The operation was completed using Signature patient-specific instrumentation. Intraoperatively, the first tibial resection was deemed not deep enough, and a second cut was made. The radiograph showed a retained posterior osteophyte that might impinge on the bearing in high flexion. The patient was also diagnosed with prostatic adenocarcinoma approximately four years after the operation. At five-years his OKS was poor (26/48) and the knee was moderately painful as indicated by an AKSS Pain score of 20/50 and ICOAP of 21/100.

Subsider 2

A 65-year-old male. The radiographs showed a medial vertical cut, resulting in the tibial component being too far medial and overhanging. However, the bearing was not impinging on the wall. The patient developed cognitive impairment sometime after the 2-year assessment, which prevented five-year clinical scores from being obtained. At 2-year follow-up the patient had excellent clinical scores with an OKS of 48/48, AKSS Pain of 50/50 and ICOAP of 0/100. The five-year radiographs were poorly aligned and excluded from analysis. However, TCS could be observed on the two-year radiograph.

Subsider 3

A 74-year-old female with a five-year BMI of 39. At five-years she had a fair OKS (31), an AKSS pain score of 45/50 and mild pain indicated by a scaled ICOAP score of 16/100. She had a contralateral neck of femur fracture approximately one year post-operatively, which has caused ongoing pain and loss of function, and a myocardial infarction at approximately four years after their operation. Her OKS became significantly worse between two and five-years follow-up (**Figure 4.9B**)

Subsider 4

A 69-year-old male with a five-year BMI of 29. On the post-operative radiograph, a slightly deep tibial resection (10.8 mm deep versus a cohort mean depth of 4.2 mm, **Figure 4.10A**). There was also a significant vertical overcut visible on the post-operative radiograph. The knee has excellent clinical scores at five-years with an OKS of 48/48, AKSS Pain of 50/50, and scaled ICOAP of 0/100.

Subsider 5

A 57-year-old female with a five-year BMI of 24 had posterior tibial component subsidence of 3.8° with no valgus subsidence, instead having 1.6° varus rotation. The radiographs show a vertical cut lateral to the medial tibial spine, which perhaps resulted in a slightly larger tibial component. This knee had excellent outcomes at five-years with an OKS of 45/48, AKSS Pain of 50/50, and scaled ICOAP of 0/100.

Table 4.3 Summary of Cementless Oxford Unicompartmental Knee Replacements with Tibial Component Subsidence.

	Tibial Varus / Valgus Angle Change (°)	**Tibial Anterior / Posterior Tilt Change (°)**	**Valgus and/or Posterior Subsidence?**	**Age at Operation**	**BMI (kg/m^2)**	**5-Year OKS** [0 (worst) – 48 (best)]	**5-Year AKSS Pain** [0 (worst) – 50 (best)]	**5-Year ICOAP** [0 (best) – 100 (worst)]
Subsider 1	2.7 valgus	6.0 posterior	Both	71	34	26	20	21
Subsider 2	2.8 valgus	1.6 posterior	Both	65	-	48*	NA	0*
Subsider 3	2.4 valgus	2.7 posterior	Both	74	39	31	45	16
Subsider 4	4.9 valgus	1.0 posterior	Both	70	29	48	50	0
Subsider 5	1.6 varus	3.8 posterior	Posterior Only	57	24	45	50	0

*2-year scores as five-year scores unavailable

Figure 4.4 Post-operative and five-year radiographs for Subsider 1. Red arrow indicates an anterior radiolucency beneath the tibial component on the five-year lateral radiograph.

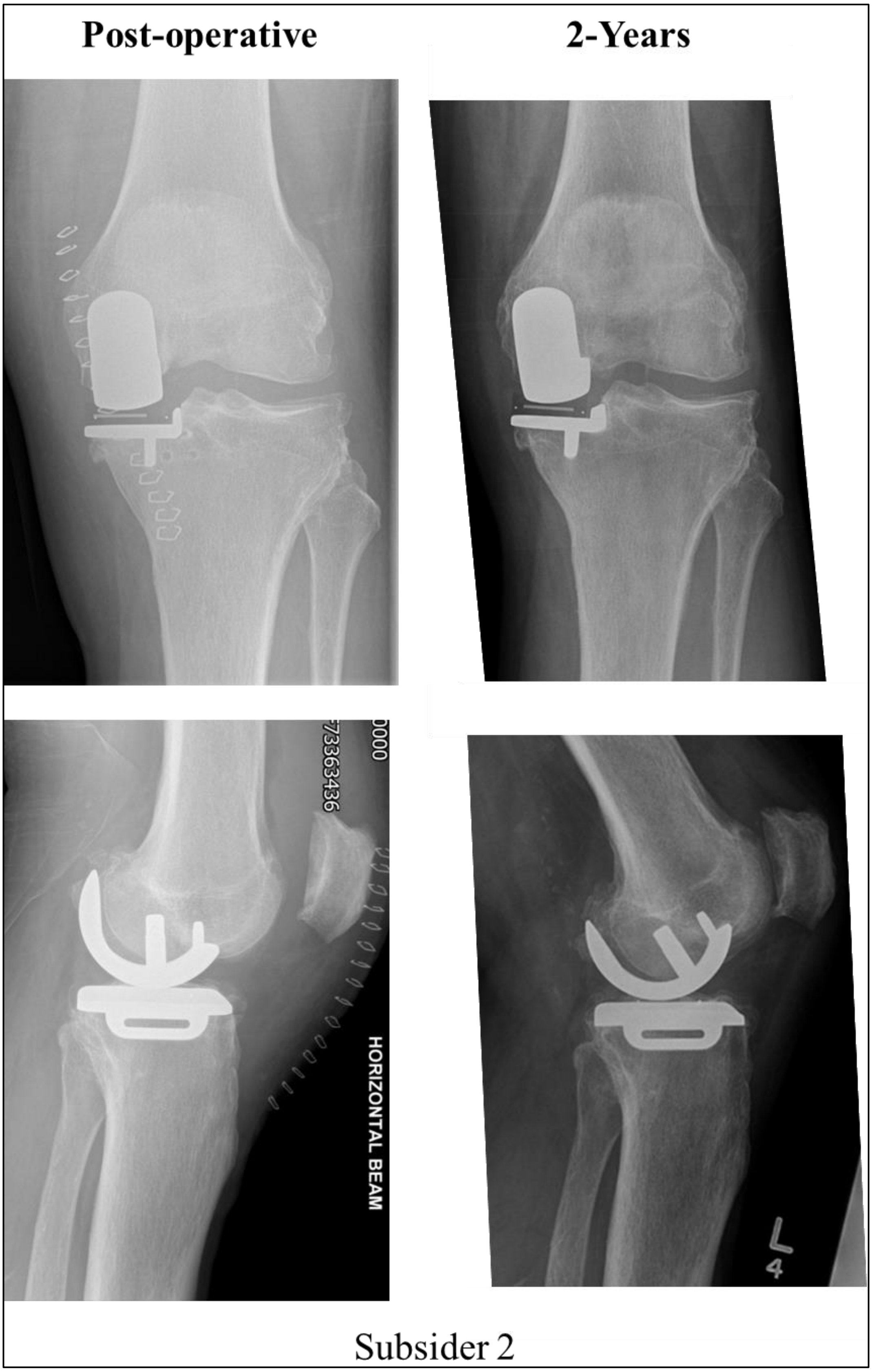


Figure 4.5 Post-operative and five-year radiographs for Subsider 2.

Figure 4.6 Post-operative and five-year radiographs for Subsider 3.

Figure 4.7 Post-operative and five-year radiographs for Subsider 4.

Figure 4.8 Post-operative and five-year radiographs for Subsider 5. Red arrow indicates an anterior radiolucency beneath the tibial component on the five-year lateral radiograph.

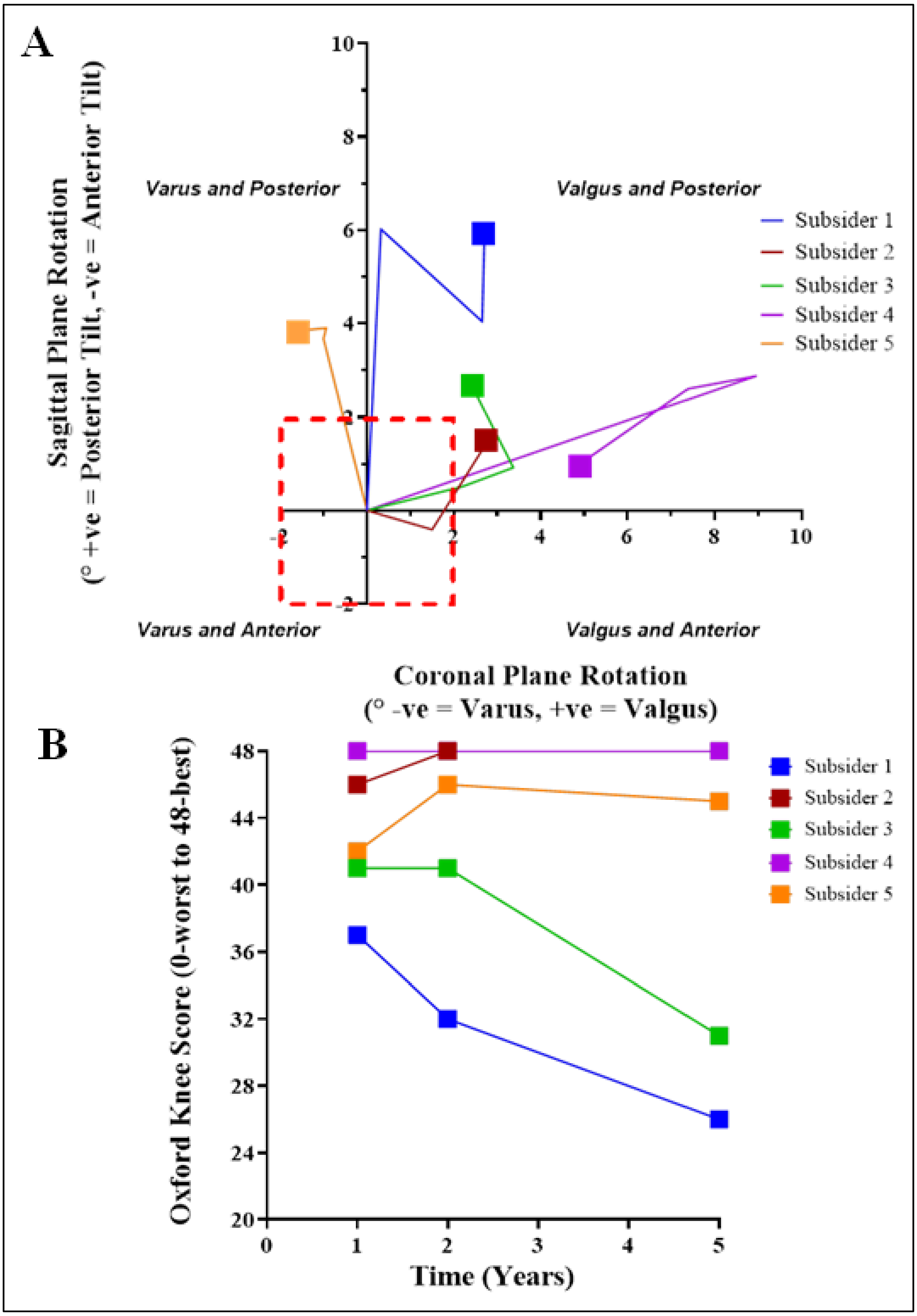


Figure 4.9 A A visualisation of the migration of the five subsiders. Coronal plane rotation (° +ve = Valgus, -ve = Varus) is shown on the horizontal axis and sagittal plane rotation (° +ve = Posterior Tilt, -ve = Anterior Tilt). Component position shown at 1-year, 2-year, and five-year timepoints along the line for each subsider, relative to the post-operative position (at the origin) The square marker identifies the component position at five years. The red dashed box indicates the subsidence cut-off of >2° valgus rotation and/or posterior tilt. **B** Post-operative Oxford Knee Scores of the five subsiders over time from one to five years.

4.3.1 Cohort Demographics

The mean valgus rotation for subsiders was 3.2° (SD 1.5), which was significantly greater ($p=0.03$) than the mean of 0.0° (SD 2.5) for non-subsiders. Subsiders had a mean of 3.0° (SD 2.0) of posterior tilt which was significantly greater ($p<0.01$) than 0.1° (SD 2.0) for non-subsiders (**Table 4.4**). There was no significant difference in age, sex, BMI, activity level (TAS), femoral/tibial component size, or bearing size, between subsiders and non-subsiders. Subsiders in this study had only larger tibial component sizes implanted (Four Size D, one Size E), but this was not significantly different to the component sizes of non-subsiders even though this group had many smaller tibial components (10 Size B and 31 Size C).

Table 4.4 Demographics of the knees in the cohort that subsided (Subsiders) and did not subside (Non-Subsiders). Presented as mean (SD) for continuous variables and number for component/bearing sizes.

Measure	**Subsiders (n=5)**	**Non-Subsiders (n=89)**	**p-value**
Tibial Varus/Valgus Angle Change (°, +ve = valgus, -ve = varus ***Valgus Subsiders Only (n=4)***	3.2 (1.5)	0.00 (2.5)	**0.03****
Tibial Anterior/Posterior Tilt Change (°, +ve = posterior, -ve = anterior) (n=5)	3.0 (2.0)	0.1 (2.0)	**<0.01****
Age (Years)	67.5 (6.5)	66.4 (8.4)	0.77
Sex (Female/Male)	2 / 3	38 / 51	~1
Body Mass Index	31.6 (5.6)	30.8 (5.07)	0.81
Femoral Component Size			
Smaller Sizes (Small, Medium)	2 (0 S, 2 M)	59 (31 S, 28 M)	0.34
Larger Sizes (Large, Extra Large)	3 (3 L, 0 XL)	30 (30 L, 0 XL)	
Tibial Component Size **Component size not recorded for one non--subsider*			0.06
Smaller Sizes (A, B, C)	0	41 (10 B, 31 C)	
Larger Sizes (D, E, F)	5 (4 D, 1 E)	47 (18 D, 18 E, 11F)	
Bearing Size			~1
3	2	37	
≥4	3 (3 Size 4)	52 (39 Size 4, 10 Size 5, 3 Size 6)	

4.3.2 Component Position

Post-operative tibial component medial overhang/underhang, the orientation in the coronal plane, depth of tibial resection, and medial-lateral bearing position were not significantly different between subsiders and non-subsiders (**Table 4.5**). Relative to the tibial anatomical axis, the femoral component angle of valgus subsiders was significantly more (p=0.02) valgus (4.8° valgus) than non-subsiders (0.2° valgus).

Table 4.5 Component positions of the knees in the cohort that subsided (Subsiders) and did not subside (Non-Subsiders) immediately post-operatively. Presented as mean (SD) [Range].

Measure	Subsiders (n=5)	Non-Subsiders (n=89)	p-value
Tibial Component Medial Overhang (+ve) / Underhang (-ve) (mm)	-0.2 (2.1) [-2.8 to 2.2]	-1.3 (1.9) [-8.2 to 3.1]	0.29
Femoral Component Angle Valgus (+ve) / Varus (-ve) (°)	2.9 (4.5) [-4.6 to 6.8]	0.3 (5.2) [-21 to 1]	0.16
Femoral Component Angle – ***Valgus Subsiders Only*** Femoral Component Angle Valgus (+ve) / Varus (-ve) (°)	4.8 (2.0) [2.1 to 6.8]	0.2 (5.2) [-21 to 11]	**0.02***
Tibial Component Angle Valgus (+ve) / Varus (-ve) (°)	-6.0 (2.2) [-8.2 to -2.6]	-4.9 (2.4) [-12.9 to 2.2]	0.29
Depth of Horizontal Tibial Resection (mm)	5.7 (3.0) [3.3 to 10.8]	4.2 (2.4) [0.0 to 9.8]	0.22
Bearing Position (0 = against tibial wall, 1 = off the tibial tray laterally)	0.5 (0.1) [0.3 to 0.6]	0.5 (0.1) [0.4 to 0.7]	0.97

4.3.3 Clinical Scores

The mean OKS, AKSS, and ICOAP scores and their subscales were generally worse for knees with TCS, however none of the clinical scores measured were significantly worse for subsiders (**Table 4.6**).

Table 4.6 Five-year Clinical Scores of the knees in the cohort that subsided (Subsiders) and did not subside (Non-Subsiders) immediately post-operatively. Presented as Mean (SD) [Range].

Clinical Score	Subsiders (n=4)	Non-Subsiders (n=89)	p-value
Oxford Knee Score (OKS) [0 (worst) – 48 (best)]	39 (6.2) [26 to 48]	44 (5.8) [15 to 48]	0.40
OKS (Pain) [0 (worst) – 100 (best)]	79 (14) [54 to 100]	92 (12) [32 to 100]	0.21
OKS (Function) [0 (worst) – 100 (best)]	76 (15) [55 to 100]	89 (16) [20 to 100]	0.27
OKS Categorised			0.08
Poor/Fair (OKS <34)	2	10	
Good/Excellent (OKS≥34)	2	79	
Tegner Activity Score [0 (worst) – 10 (best)]	2.5 (0.5) [2 to 3]	3.1 (1.4) [1 to 8]	0.31
American Knee Society Score (AKSS) [0 (worst) – 200 (best)]	151 (24.0) [109 to 188]	171 (22.0) [91 to 200]	0.25
AKSS (Pain) [0 (worst) – 50 (best)]	41.3 (2.7) [20 to 50]	45.9 (8.6) [0 to 50]	0.69
AKSS (Functional) [0 (worst) – 100 (best)]	72.3 (17.1) [29 to 100]	84.4 (18.6) [0 to 100]	0.62
AKSS (Objective) [0 (worst) – 100 (best)]	70.5 (7.7) [49 to 88]	82.9 (12.8) [31 to 100]	0.08
Intermittent and Constant Osteoarthritis Pain (ICOAP) [0 (best) – 100 (worst)]	7.3 (9.7) [0 to 21]	3.9 (6.8) [0 to 34]	0.60
ICOAP (Intermittent) [0 (best) – 100 (worst)]	5.8 (14) [0 to 29]	6.1 (11) [0 to 54]	0.81
ICOAP (Constant) [0 (best) – 100 (worst)]	9.0 (6.1) [0 to 45]	1.3 (3.9) [0 to 20]	0.67

4.4 DISCUSSION

This is the first radiographic study of valgus and posterior TCS in a large cohort of cementless OUKRs with detailed five-year clinical follow-up. 5% of cases (5 out of 94) had TCS with >2º valgus and/or posterior tilting, which occurred mostly in the first post-operative year. All the TCS cases had radiographic evidence of secure fixation of the tibial component at five years, with direct apposition of bone to the porous coated parts of the implant. There was no significant difference in five-year clinical outcome between subsiders and non-subsiders (**Table 4.6**). This suggests that TCS is a phenomenon that should be treated conservatively.

As TCS occurred in only 5% of patients the number of subsiders may be too small for some important differences to be statistically significant. Although three of the subsiders had excellent outcomes at last review (OKS 48, 48, 45; AKSS Pain all 50, ICOAP all 0), two had fair/poor outcome scores at five years (OKS 26, 31; AKSS Pain 20, 45; ICOAP 21, 16), which were worse than the mean scores for non-subsiders (OKS 44, AKSS Pain 46, ICOAP 3.9) (**Table 4.6**). These two patients (Subsiders 1 and 3) were the oldest subsiders at time of operation (71 and 74) and had the greatest BMIs (34, 39), however, more importantly, they both had significant comorbidities which probably contributed to their poor clinical scores. It should also be noted that these two subsiders both had a good OKS (37 and 41, respectively) at 1-year post-operatively and did not report any abnormal pain during their first post-operative year. The decline in their OKS occurred after the first year when most of their subsidence occurred (**Figure 4.9**), suggesting their pain at five-years is unlikely to be linked to their TCS.

Bedding-in is seen with most cementless OUKRs early post-operatively where the tibial component moves <1 mm inferiorly to seat on the cut tibial surface after being left slightly proud intraoperatively (**Figure 4.1**). Unlike bedding-in, cementless OUKR tibial components that subside tilt and end up in a position below the original cut tibial surface. This can be accompanied by pain in the early post-operative period [32]. In this study, although the components tilted in different directions, on average they tilted three degrees posteriorly and three degrees into valgus. This is associated with the postero-lateral part of the implant subsiding several millimetres and possibly the antero-medial part lifting slightly. The most probable cause of TCS is the trabecular bone being crushed below the implant [300]. For the tibial component to be displaced below the cut level of the tibia there must be some damage to the underlying bone. The timeline of component migration and pain occurring within the first few months post-operatively before ceasing is also consistent with crushing of bone occurring (either intraoperatively during impaction of the implant or in the early post-operative period with weight bearing) and then healing [301]. The process seems to be self-limiting, perhaps in part because the density of the trabecular bone increases as it is crushed and subsequently the pain settles. Early on radiolucencies may appear under the component, but these tend to disappear in the longer term, except in the case of large posterior tilting of the component which can result in an anterior radiolucency (**Figure 4.4 & Figure 4.8**). By five years, the radiographic appearance in this study suggested that all components were securely fixed.

The only patient, surgical, or implant factor that was significantly different between subsiders and non-subsiders was the varus/valgus alignment of the femoral component relative to the tibial anatomical axis, but only for the Subsiders 1-4 which had valgus rotation of the tibial component (**Table 4.5**). The femoral components do not appear to be majorly misaligned on the post-operative radiographs of the subsiders, but the significantly greater valgus alignment compared to the tibial anatomical axis of the subsiders may indicate that the tibial component is externally rotated. Anteroposterior OUKR radiographs are aligned to the tibial component. Therefore, if the tibial component is externally rotated the femoral component may appear to have a valgus alignment, which is particularly obvious for Subsider 1 (**Figure 4.4**) and Subsider 2 (**Figure 4.5**). It is difficult to confirm the internal/external rotation of the tibial component from a plain anteroposterior radiograph. However, Kamenaga et al. demonstrated that valgus subsidence was associated with more externally rotated tibial components which would then be consistent with this study [33]. Kamenaga proposed that the bearing would impinge on the tibial wall in deep flexion if the tibial component was externally rotated, increasing loading of the lateral aspect of the component, and causing it to subside into valgus.

Although a benefit of UKR is that revision is often more straightforward than revision of TKR, it can be complex and require revision TKR components (**Table 4.2**, Case 3) [34, 140, 141, 302]. UKR patients revised for unexplained pain, which may be the case for some TCS patients, have also been found to have worse clinical outcomes after revision compared to patients with UKRs revised for aseptic loosening [303]. Therefore, surgeons should treat TCS conservatively in the first instance and be cautious of revising a patient with TCS. Given the finding of this study and others, the generally accepted treatment for TCS patients of making them non- or partial-weightbearing until the pain improves and the crushed bone heals seems sensible [34, 218].

Other than femoral component alignment, there were no statistically significant differences in any radiographic measurements related to implant position. This is probably because the cause of subsidence is multifactorial and in different cases the main cause may have been different. Another reason is that the number of subsiders is low. During the operation the medial tibial condyle is weakened as the subchondral bone plate is removed [304]. It is for this reason that complications such as TCS, fracture, and pain tend to be related to the tibia. Any surgical errors that weaken the bone further may predispose to subsidence [33, 180, 218]. Errors that are particularly likely to cause subsidence include the bearing hitting the wall in flexion, and therefore loading the component posterior laterally [33, 218]. Factors that may contribute to this are an externally rotated tibial component, which was not able to be assessed from the plain radiographs in this study, or the femoral component being too far lateral relative to the tibial component, which was not significantly different between subsiders and non-subsiders in this study. The OUKR bearing moves closer to the wall in mid-flexion [288]. Therefore, surgeons should check before positioning the tibial component that the bearing is not hitting the wall in flexion. Secondly, an incomplete horizontal cut may result in a small bone fragment remaining posteriorly after the tibial surface is removed. If this fragment is knocked off posteriorly (i.e. with a chisel) it may damage the posterior cortex. Neither of these errors can be seen on standard radiographs. Other important errors are a vertical tibial overcut, seen in Subsider 4 and possibly 3 (**Figure 4.10 A & B**), unnecessary nail holes (Subsider 2 has two nail holes, **Figure 4.10C**), a tibial cut that is substantially medial to the tibial spine resulting in a poorly supported component (Subsiders 1&2, **Figure 4.4 & Figure 4.5**), a tibial cut that is too far lateral (Subsider five, **Figure 4.8**) resulting in either a poorly supported component medially or too large a component.

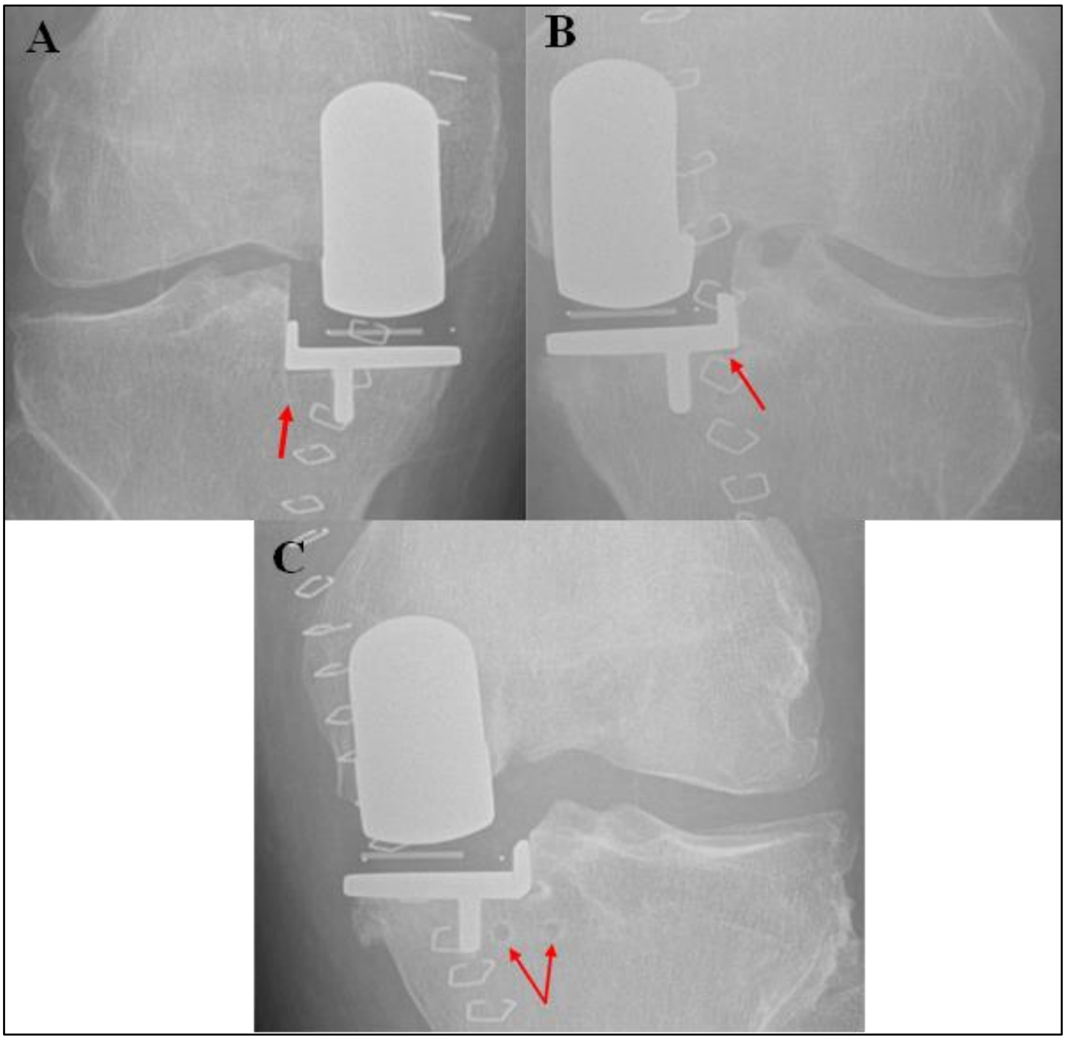


Figure 4.10 Examples of surgical errors that may contribute to crushing of bone below the lateral side of the tibial component, resulting in tibial component subsidence. **A** Excessive vertical overcut (Subsider 4). **B** Small vertical overcut (Subsider 3). **C** Two holes are visible beneath the tibial component due to two bone nails being used to attach the tibial resection guide. (Subsider 2).

Previously only 22 cases of TCS have been reported in the literature, with only Kamenaga et al. thoroughly analysing component positioning and clinical outcome [33]. The incidence of TCS reported in this study is similar to the incidences published in previous reports which range from 0.03% to 5% [32-35, 180, 219]. These previous studies have suggested that similar surgical mistakes to those identified in this study are the most likely cause of TCS [33, 180, 218]. Hefny et al. suggested that subsiders tend to be the elderly and consequently they now use cemented components in older patients [34]. However, other studies, including this study, have not found age to be associated with subsidence [32, 33].

4.4.1 Limitations

The main limitation of this study is the small number of OUKRs included, and consequently the small number of TCS cases. This study aimed to be the largest radiographic study of TCS, and it would have been if all 278 cementless OUKRs in the cohort had the radiographs at the required timepoints of sufficient quality. However, of the 278 cementless OUKRs only 123 (44%) had the required radiographs, with only 94 (34%) having radiographs of sufficient quality for analysis. The radiographic analysis method used was validated and had sufficient accuracy to detect angle changes of several degrees, however, it lacks the accuracy of RSA, which is the gold-standard for measuring implant migration (see **Chapter 2**) [215, 216]. However, because TCS is associated with several degrees of migration, a highly precise and accurate technique like RSA would be superfluous. It has been suggested that external rotation of the tibial component may contribute to TCS from a study based on computed-tomography images [33]. Internal/external rotation of the tibial component was not able to be evaluated in this study as only plain radiographs were available. Furthermore, radiographs and clinical scores were only recorded at one year onwards, meaning there was limited insight into TCS and pain that may have occurred in the first post-operative year. The other limitation is that patients in this cohort were operated on by experienced surgeons. The incidence of TCS may therefore be underestimated given it seems surgical errors are at least partially responsible for TCS, and it is known that less experienced surgeons are known to have higher rates of complications [21-23, 178, 305].

4.5 CHAPTER SUMMARY

This study identified five TCS cases from a cohort of 94 cementless OUKRs (5% incidence) that had valgus and/or posterior subsidence of >2º. Two (2%) subsiders had moderate pain at five-years, although pain was likely related to other comorbidities and not TCS. As all patients with TCS in this study had an acceptable five-year clinical and radiographic outcome, it is recommended that patients with TCS are treated conservatively. A larger study with more cases of TCS is needed to correlate patient, surgical, and implant factors with TCS.

The results for TCS patients of this study are consistent with most previous reports of TCS in the literature in that most TCS patients have good short-to-medium term outcomes without any post-operative intervention. Therefore, it is recommended that surgeons treat TCS patients conservatively as it seems revision surgery would be the worst outcome for a TCS patient.

CHAPTER 5 – A SURVEY OF SURGEONS TO IDENTIFY INSTRUMENTATION IMPROVEMENTS FOR THE OUKR PROCEDURE

*This chapter is currently under review for publication with The Journal of Arthroplasty as Arthur LW, Min X, Marks B, Mellon SJ, Murray DW. A Surgeon Survey to Identify Instrumentation Improvements for Unicompartmental Knee Arthroplasty

5.1 CHAPTER MOTIVATION

5.1.1 Background

Iterative improvements to the OUKR instrumentation have improved the outcomes of the procedure, as detailed in **Section 1.6**. These advancements have primarily been driven by changes in implant design, identification of clinical issues, or the change from open to minimally invasive surgery. For example, after surgeons had difficulty balancing the flexion and extension gaps with Phase I OUKRs, a spherical femoral mill was introduced with Phase II OUKRs to allow incremental milling of the femoral condyle to balance the gaps intraoperatively [306]. Instruments were miniaturised for Phase III OUKRs so that a minimally invasive approach could be used to improve patient recover. However, these instruments were associated with a learning curve that resulted in poor component alignment and tibial resection errors [176]. Less experienced low-volume surgeons also had worse outcomes than surgeons who used OUKR for 40-60% of their knee arthroplasty caseload with the most common surgical errors being excessively deep tibial resections or femoral component misalignment [13, 21, 222]. Microplasty instruments were introduced to reduce these surgical errors and to make the overall procedure easier, more reliable and improve implant positioning [190]. Microplasty instruments have been found to improve patient satisfaction, component positioning, and trainee surgeon performance while reducing revision rate, operating time, and bearing dislocations [26-28, 30, 307-309].

The current Microplasty instruments used for the OUKR have some known limitations which are detailed in **Section 1.6.5**. Therefore, there is a need to optimise the instrumentation further to minimise these limitations and improve OUKR outcomes.

5.1.2 Aims

If the OUKR instrumentation is to be modified, designers need to consider the orthopaedic surgeons who will be the end-users. The importance of integrating end-user feedback into the design process for surgical instruments has been shown previously and online surveys are an effective way to obtain end-user feedback [310-317]. For the current Microplasty instrumentation and previous iterations of the OUKR instrumentation, a broad survey of OUKR users has not been conducted. Instead, previous developments have been centred around input from a few expert designer surgeons.

Therefore, the aim of this chapter was to conduct a survey of OUKR surgeons to:

1. Identify instrumentation that requires improvement, either through optimisation or the introduction of new instruments, including CAS.
2. Investigate the relationship between surgical experience and identified need for improved instruments, given low-volume surgeons are known to have poorer results with the OUKR.

5.2 METHODS

5.2.1 Survey Design

An anonymous online mixed-methods survey was developed using Microsoft Forms (Microsoft Corporation, Redmond, Washington, USA) to collect feedback on the instruments used for the OUKR procedure (see **Appendix 6**). The inclusion criteria was any surgeon who had completed at least one OUKR. Surgeon demographic information including years of OUKR experience, annual OUKR caseload, and the OUKR proportion of their entire knee replacement caseload was collected. Respondents were asked to identify which instruments had limitations, with instruments separated into operative steps, as per the manufacturer's operative technique using Microplasty instrumentation (**Table 5.1**) [190]. Respondents could also provide free text responses to communicate necessary instrumentation changes. Respondents were also asked whether CAS would benefit the OUKR, and if so, which surgical steps would benefit and what type of technology should be used.

Table 5.1 Description of the steps of the medial Oxford Unicompartmental Knee Replacement Procedure as defined for the survey.

Step	Description
1	**Patient Positioning, Incision and Osteophyte Removal** • Positioning of patient on the operating table, including use of the Oxford Leg Holder. • Initial incision, with removal of medial meniscus and retropatellar fat pad. • Removal of osteophytes
2	**Tibial Preparation and Resection** • Use of the extramedullary tibial resection guide and associated instruments (femoral sizing spoons, tibial shims, G-clamp) to make the tibial resection (vertical and horizontal cut)
3	**Femoral Preparation and Posterior Resection** • Use of the femoral drill guide, including implanting the femoral intramedullary rod and using the intramedullary link to position the drill guide. • Resection of the posterior femur using the femoral resection guide.
4	**Femoral Milling and Gap Balancing** • Initial femoral milling with the spherical mill and 0 spigot. • Subsequent millings to achieve gap balancing judged using the feeler gauges and smaller spigots.
5	**Impingement Prevention** • Removal of bone from the anterior femoral condyle using the anterior mill and the posterior femoral condyle using the osteophyte chisel and anti-impingement guide.
6	**Final Tibial Preparation and Keel Cut** • Preparation of the tibial keel slot using the keel slot ("toothbrush") saw through the tibial keel slot template. • Plus or minus use of the tibial pick/gouge.
7	**Implantation/Removal of Trial Components and Bearing** • Final trial reduction with the trial femoral/tibial components and trial bearing.
8	**Insertion of Final Components** • Implantation of the femoral and tibial components, including cementing if using cemented components. • Insertion of the bearing.

5.2.2 Survey Validation

The survey was developed with guidance from a designer OUKR surgeon (Professor David W. Murray) and input from a quantitative research expert (Dr. Coral Milburn-Curtis). A pilot survey was distributed to eight experienced OUKR surgeons (7 consultants and one trainee). Pilot respondents provided additional feedback on the survey structure and questions to the authors. Feedback from the validation process was applied before the survey was widely distributed.

5.2.3 Survey Distribution

The survey was distributed to orthopaedic networks in the UK and internationally through social media (Twitter and LinkedIn) and orthopaedic conferences attended by the authors. The survey was also translated into Chinese (Mandarin) by Xiaoyi Min so that Chinese-speaking surgeons could respond. Authors who had recently published papers related to OUKR instrumentation were contacted by direct email. Responses were collected between 1st August 2022 and 28th June 2023.

5.2.4 Statistical Analysis

Descriptive and inferential statistical analysis was conducted using GraphPad Prism (version 10.2.0 for Windows, GraphPad Software, Boston, Massachusetts USA). Differences in surgeon experience between consultants and non-consultants were assessed using T-tests. Differences in the number of consultants and non-consultants who identified limitations with instruments were analysed using Fischer's Exact Test. Correlations between surgeons identifying limitations with instruments for a certain step and their OUKR experience, annual OUKR caseload, and OUKR as a proportion of their entire knee replacement caseload were calculated using logistic regression (likelihood ratio). Statistical significance was set at $p<0.05$.

Thematic analysis was used to qualitatively analyse text responses. Text responses were firstly associated with a specific procedural step and instrument before being coded to a specific theme.

5.2.5 Ethical Approval

Level 1 Approval for this study was granted by the University of Oxford Central University Research Ethics Committee (Approval Reference: R81755/RE001) (see **Appendix A3.2**).

5.3 RESULTS

106 survey responses were received from 90 consultant orthopaedic surgeons and 16 non-consultant OUKR users including orthopaedic trainees (8), fellows (4), and other medical professionals (4). Compared to non-consultants, consultant orthopaedic surgeons had significantly ($p<0.001$) more experience using the OUKR, performed a significantly higher number of OUKRs per year, and OUKRs made up a significantly higher proportion of their knee replacement caseload (**Table 5.2**). Surgeons who have more years of OUKR experience ($p<0.05$), performed more OUKRs per year ($p<0.01$), and performed a higher proportion of their knee replacements as OUKRs ($p<0.001$) were more likely to suggest that Step 3, femoral preparation, needs improvement (**Table 5.3**). No other steps had this correlation with all three measures of experience. At least one in four respondents had issues with the Oxford Leg Holder (36%) and instrumentation used for steps two (51%), three (41%) and six (29%) of the OUKR procedure (**Figure 5.1**). No other steps had more than 20% of surgeons identify them as having limitations.

Table 5.2 Summary of Oxford Unicompartmental Knee Replacement (OUKR) Experience and Use Among Survey Respondents

Demographic	**Consultants (n=90)** Mean (95% Confidence Intervals)	**Non-Consultants (n=16)** Mean (95% Confidence Intervals)	**T-test (p-value)**
Years of Experience	10 (8.4 – 11.6)	2.6 (1.4 – 3.8)	***<0.001***
Number of Procedures per Year	41 (35 - 47)	15 (9 - 21)	***<0.001***
OUKR Use as a Proportion of Knee Arthroplasty Caseload (%)	48 (39 - 57)	17 (9 - 25)	***<0.001***

Surgeons who had said the Oxford Leg Holder (OLH) had limitations fit into two themes; those who use no longer use the OLH and those who believe it needs modifications (**Figure 5.2A**). Those who use an alternate set-up preferred to use a TKR set-up with the patient supine or an automatic leg holder, claiming that conversion to TKR is difficult if using the OLH. Surgeons suggesting OLH modification focused on an improved locking mechanism to prevent the holder from moving during surgery, making TKR conversion easier, and installing a feature to catch dropped instruments.

More than half of the respondents indicated that the instruments for tibial resection had limitations. The extramedullary cutting guide was identified as having limitations most frequently (Figure **5.2B**). Surgeons were concerned that no guidance for the medio-lateral position or rotation of the vertical cut is provided and that they must rely on “feel” and “experience” to avoid overcutting posteriorly. Some surgeons found the selection of the femoral spoon size to be “arbitrary” and that their use to set resection depth, along with the G-clamp, often leads to over-resection. Surgeons also identified that shims used for the extramedullary cutting guide loosen during resection and require a better locking mechanism. It was also suggested that the MCL retractor could be widened to better protect the ligament.

Table 5.3 Associations between whether a respondent identified instrument limitations with a step of the medial Oxford Unicompartmental Knee Replacement (OUKR) procedure and their position (consultant or non-consultant), years of OUKR experience, number of OUKR procedures per year or OUKRs as a proportion of total. Logistic Regression (Likelihood Ratio) was used to analyse all categories except Consultant versus Non-Consultant, for which Fischer's Exact Test was used. Significant values indicated in bold.

Step of the Procedure	**Consultant versus Non-Consultant** P-value	**Years of OUKR Experience** Odds Ratio [95% Confidence Interval] (P-Value)	**Number of OUKR Procedures Performed per Year** Odds Ratio [95% Confidence Interval] (P-Value)	**OUKRs as a Proportion of Knee Arthroplasty Caseload** Odds Ratio [95% Confidence Interval] (P-Value)
Use of Oxford Leg Holder	0.78	1.04 [0.98 to 1.10] (0.20)	1.00 [0.98 to 1.01] (0.69)	1.00 [0.99 to 1.01] (0.40)
<u>Step One</u> Patient Positioning, Incision and Osteophyte Removal	0.52	0.99 [0.92 to 1.05] (0.67)	1.00 [0.98 to 1.01] (0.75)	1.00 [0.99 to 1.02] (0.42)
<u>Step Two</u> Tibial Preparation and Resection	0.11	1.05 [0.99 to 1.11] (0.09)	1.01 [0.99 to 1.02] (0.25)	1.00 [0.99 to 1.01] (0.50)
<u>Step Three</u> Femoral Preparation and Posterior Resection	0.58	1.06 [1.00 to 1.12] **(0.04)**	1.03 [1.01 to 1.05] **(<0.001)**	1.02 [1.01 to 1.03] **(<0.001)**
<u>Step Four</u> Femoral Milling and Gap Balancing	0.73	1.03 [0.97 to 1.10] (0.32)	1.02 [1.01 to 1.04] **(<0.01)**	1.01 [0.99 to 1.02] (0.37)
<u>Step Five</u> Impingement Prevention	0.21	1.10 [1.02 to 1.19] **(0.01)**	1.02 [1.00 to 1.04] (0.05)	1.01 [0.99 to 1.02] (0.40)
<u>Step Six</u> Final Tibial Preparation and Keel Cut	0.39	1.03 [0.98 to 1.09] (0.23)	1.01 [1.00 to 1.03] (0.13)	1.00 [0.99 to 1.01] (0.48)
<u>Step Seven</u> Implantation/Removal of Trial Components and Bearing	0.62	1.03 [0.94 to 1.12] (0.52)	1.01 [0.99 to 1.03] (0.40)	1.00 [0.99 to 1.02] (0.58)
<u>Step Eight</u> Insertion of Final Components	0.67	1.10 [1.02 to 1.29] **(0.02)**	1.01 [0.99 to 1.04] (0.18)	1.01 [1.00 to 1.02] (0.08)
Would the OUKR benefit from Computer-Assisted Surgery (CAS)?	0.78	0.96 [0.91 to 1.01] (0.11)	1.01 [0.99 to 1.02] (0.42)	1.01 [1.00 to 1.02] (0.08)

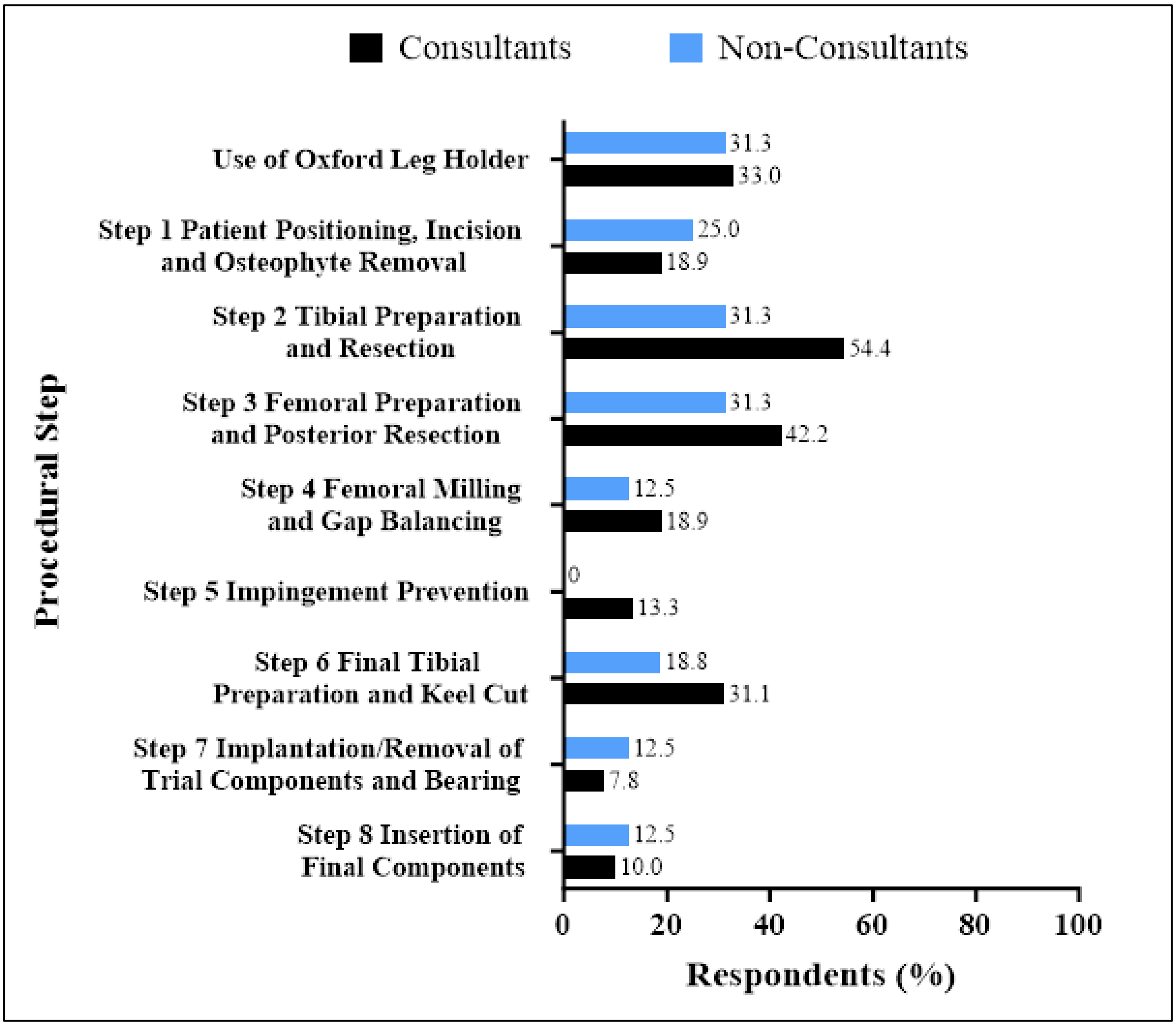


Figure 5.1 Proportion of consultants (black) and non-consultants (blue) who identified limitations of instruments associated with the different steps of the Oxford Unicompartmental Knee Replacement procedure.

For the femoral preparation (Figure **5.2C**), surgeons found it difficult to set the femoral drill guide's medio-lateral position and had experienced the guide rotating while in use, resulting in misaligned femoral components. Some surgeons find the intramedullary rod difficult to position, with others suggesting that invasion of the femoral canal is unnecessary and can cause harm by hitting the sides of the canal or exiting the femur. The slap hammer was reported to often fail to grasp instruments for removal. Use of the 5 mm awl to open the femoral canal was deemed redundant by some surgeons who suggest either a 5 mm drill should be used in place of a 4 mm drill followed by 5 mm awl, or the diameter of the intramedullary rod should be made 4 mm to obviate the need for an awl.

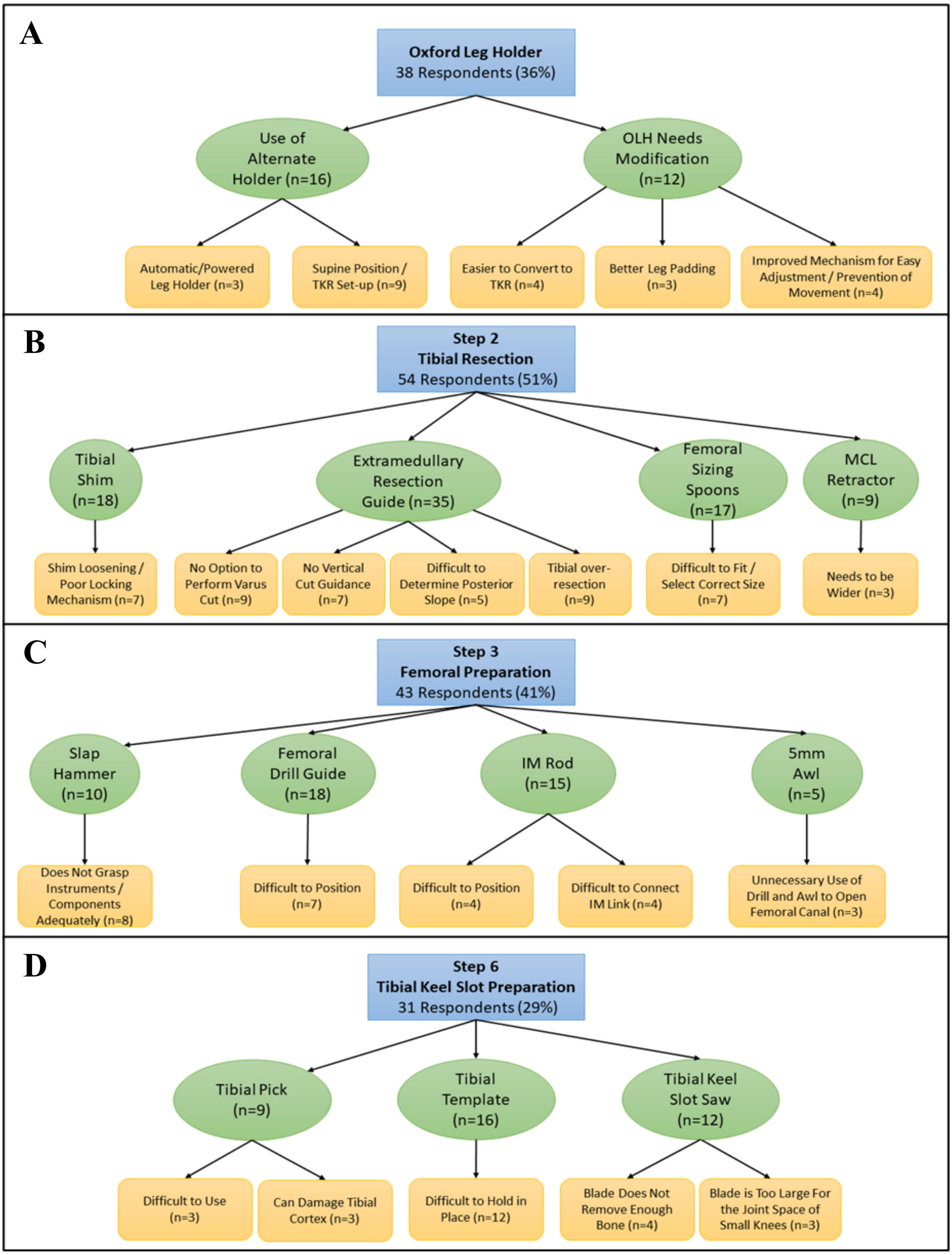


Figure 5.2 Summary of thematic analysis of the four surgical steps identified as having limitations by more than 25% of respondents. Themes of limitations (yellow) were defined for each instrument (green) within a step of the procedure (blue). The number of respondents (n) that fit within each theme is indicated.

The primary issue identified with tibial keel slot preparation was that the tibial template can move during use due to inadequate fixation with the tibial template nail (**Figure 5.2D**). It was suggested that a nail with two prongs and a proper handle for the surgeon to hold may solve this problem. Some surgeons found the tibial keel cut saw was too large to fit into the joint space of small patients and that it often did not remove enough bone. Some surgeons stated that they would use the tibial pick to remove retained bone from the slot but were concerned that this could damage the tibial cortex and suggested that extreme caution is required when using the pick.

The majority of respondents (63%, **Figure 5.3**) believe CAS would improve the OUKR procedure. Tibial resection and femoral component positioning were the two steps that most surgeons wanted assistance with. Robotics and navigation, both image-based and model based, were the preferred CAS modalities for assistance.

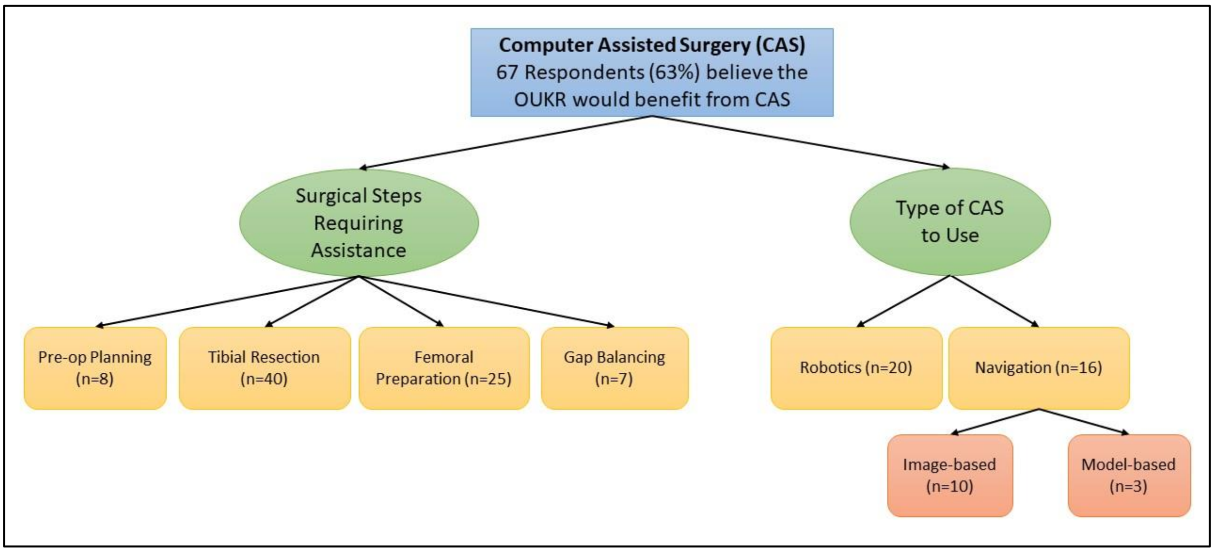


Figure 5.3 Thematic analysis results for the surgical steps of the procedure that respondents believed would benefit from Computer Assisted Surgery (CAS) and the types of CAS respondents believe would be most suitable. The number of respondents (n) that were categorised within each theme is indicated.

5.4 DISCUSSION

This survey identifies that surgeons consider the current Microplasty instrumentation for the OUKR to be adequate for most operative steps, however the majority believe that CAS would improve the procedure. The OLH and instruments for tibial, femoral, and keel slot preparation were identified by more than one in four surgeons as having limitations. Therefore, future development and optimisation of the OUKR instrumentation should focus on these steps with any changes made with considerations that any new instruments will have learning curves and increasing the number of instruments can increase costs, confusion, and workload in the operating theatre [189, 311].

OUKR designer surgeons recommend the procedure is performed using the OLH, as this allows surgeons to look directly into the incision and the knee to be freely extended and flexed [24]. However, some surgeons in this study preferred to have patients in a supine position or use an automatic leg holder, as is routine for most knee arthroplasty. There is a paucity of evidence for use of the supine position with the OUKR. One cadaveric study found no difference in component alignment when the OLH or supine position is used and a clinical study found no difference in gap balancing or clinical outcome when either position is used [197, 199]. However, a cadaveric study found greater variation in the internal/external rotation of the OUKR tibial component when implanted in a supine position compared to those implanted using the OLH [198]. Excessive external rotation of the tibial component can cause the mobile bearing to collide with the tibial wall, possibly resulting in poorer clinical outcomes, excessive wear, bearing dislocation, or TCS [318]. The current operative technique instructs surgeons to make the vertical cut by aiming the saw at the ipsilateral anterior superior iliac spine [190]. Respondents in this study indicated that they had difficulty with the vertical cut direction, (**Figure 5.2B**) suggesting that the vertical cut could be improved if it was constrained by the resection guide. If proper

OUKR indications are followed, the need for surgeons to convert to a TKR intraoperatively will be rare [24, 319]. Therefore, rather than using a supine position and undermining the philosophy of the OUKR, use of the OLH is recommended. Modifications to ensure the OLH does not move intraoperatively, add extra padding, and make TKR conversion easier should be made to appease surgeons who may otherwise opt for a supine position and thus compromise the outcome of the procedure.

TPF is a concern with OUKR, particularly for the cementless version [203, 204]. Surgical errors such as a deep resection, vertical overcut, or damage to the posterior tibial cortex during keel slot preparation can increase the risk of fracture [24, 203, 226]. Surgeons in this study found that using the Microplasty instrumentation to select the resection height resulted in over-resection, with difficulty selecting the correct femoral sizing spoon the primary issue. To avoid vertical overcut, surgeons are now encouraged to make the horizontal tibial resection first and make the vertical cut onto the horizontal saw blade or 'Boomerang' shim to eliminate the risk of overcut. Making a varus tibial resection using an adjustable ankle yoke for the extramedullary resection guide has been shown to reduce the risk of TPF [320, 321]. The concern with an adjustable yoke is that a surgeon could implant the OUKR in extreme varus or valgus, which may result in poor outcomes. To compromise, surgeons could be offered the current neutral (0°) ankle yoke, and an ankle yoke with 3° of varus, to allow a varus resection that is still within the $\pm 5°$ limit of varus/valgus rotation that is known to not impact outcomes [295].

The interference press-fit of the cementless tibial keel and a slot cut in the proximal tibia is crucial for primary fixation. but also contributes to TPF risk. Most TPFs are observed to pass through the keel slot [226, 322]. Poor fixation of the tibial keel slot template contributing to damage of the tibial cortex during slot preparation was a concern of surgeons (**Figure 5.2C**). As suggested by respondents, amending the template to use two nails for fixation and have a nail with an ergonomic handle that can be easily grasped by the surgeon would be an improvement. Mohammed et al. found that using a wider saw blade to prepare the keel slot reduced TPF risk and consequently this blade is now used clinically [204]. Using the cemented pick to prepare the slot does not reduce TPF risk and given the concerns about its potential to damage the tibial cortex, pick use is not recommended. Respondents complained that the current keel saw does not remove enough bone from the slot, necessitating use of the pick. A recent study found that using a single blade keel saw resulted in a decreased incidence of TPF for cementless OUKR without compromising fixation [205]. Therefore, development of a saw that minimises TPF risk and removes sufficient bone from the keel slot should be pursued.

The use of intramedullary rods to guide femoral preparation is commonplace for knee arthroplasty but are invasive and increase the risk of blood loss, thromboembolic events, and intraoperative periprosthetic fractures [323-325]. Furthermore, they may not be compatible for femurs with distal deformities or existing metalwork. Some surgeons have difficulty locating the recommended entry point of the intramedullary rod and use the intra link (**Figure 5.2C**). Correctly positioning the femoral drill guide medio-laterally is difficult for some surgeons and use of the intramedullary link could cause the guide to be rotated. Positioning the femoral component too far laterally can cause bearing impingement on the lateral tibial wall leading to increased wear, tibial subsidence, or dislocation [32, 41]. If the femoral component is placed too medially the bearing may impinge on soft tissues, spin, or dislocate. It has been reported that using the intramedullary rod can result in the femoral component being placed too far laterally, which risks the bearing impinging on the lateral tibial wall [21]. There was a correlation between the identification of limitations with femoral preparation and the surgeon's experience suggesting more experienced surgeons may recognise this limitation. It is optimal to have the bearing track as close to the wall as possible without impinging (approximately 2 mm) as this minimises polyethylene wear for the OUKR (see **Chapter 3**) [41, 254]. Given the limitations of the intramedullary rod, alternate instrumentation to align the femoral drill guide should be explored to optimise placement of the femoral component relative to the tibial component and bearing tracking.

Use of CAS in knee arthroplasty has increased in the past decade [326, 327], and 63% of respondents believing that CAS would improve the OUKR procedure indicates that there is user demand for it. The high interest in CAS in this survey is similar to the results of a survey by Marullo et al. which reported 57% of UKR surgeons were interested in robotics [328]. CAS has been shown to improve alignment for the OUKR [195], however the main arguments against introducing CAS for knee arthroplasty are it has not been shown to improve clinical outcome despite improved alignment, increases operating time, and cost [164, 329]. However, the steps of tibial resection and femoral preparation, as identified by respondents, could feasibly benefit from CAS. CAS could guide the vertical resection depth and rotation to eliminate vertical overcut and errors in tibial component rotation. CAS could also guide accurate femoral component placement to ensure optimal bearing tracking without the need for an intramedullary rod. Robotics and navigation were the most popular suggestions for types of assistance, but both involve high costs, extensive set-up, and pre-operative planning or imaging which adds to theatre time. If CAS was to be used to guide just two steps of the procedure, a non-image-based form of navigation that is quick to register and provides real-time feedback to the surgeon may be most convenient.

5.4.1 Limitations

The primary limitations of online surveys are that the population they are distributed to cannot be described and biased respondents can select themselves into the sample [330]. This was evident in this study as most respondents that were consultant orthopaedic surgeons with extensive OUKR experience. The opinions and experience of these surgeons are unlikely to reflect those of the average OUKR surgeon. The sample of non-consultant surgeons was also small (n=16) and therefore may not be representative of non-consultant OUKR users.

As the survey was anonymous, the geographic location of the respondents cannot be determined. However, it is known that the English survey received 73 responses and the Chinese version of the survey received 33 responses. Given the methods of distribution, it is suspected that most respondents for the English survey are from the UK or mainland Europe while the respondents of the Chinese survey are mostly from mainland China. Ideally the respondents would have come from a homogenous geographic distribution, but this is another inherent limitation of an anonymous online survey that is freely distributed.

5.5 CHAPTER SUMMARY

Orthopaedic surgeon users of the OUKR are satisfied with most instruments used for the OUKR procedure, but the instruments used for patient positioning, tibial resection, femoral preparation, and tibial keel slot preparation were identified as having limitations that could be optimised. Optimisation of the tibial resection and tibial keel slot preparation, in relation to preventing the risk of TPF, will be the focus of **Chapters 6 and 7**.

Most respondents believed that CAS would improve the OUKR, therefore CAS should be investigated as a solution to the surgical steps that require optimisation in future studies.

CHAPTER 6 – OPTIMISING THE TIBIAL RESECTION FOR THE OUKR

6.1 CHAPTER MOTIVATION

6.1.1 Background

As summarised in **Section 1.7.8**, TPF is a rare, but serious complication of the OUKR in Caucasian populations. However, TPF is more common in some Asian populations, such as Japan, where the incidence can be as high as 8% [228]. TPFs occur in both cemented and cementless OUKR patients, however the incidence of TPF is higher for cementless OUKR in the NJR [31]. Many surgeons avoid using cementless OUKR tibial components they consider to be at risk of TPF, such as those with small size tibias or overhanging medial condyles and instead opt to implant cemented or hybrid (cementless femoral component with a cemented tibial component) OUKRs [228, 331, 332].

The exact mechanism of TPF is not known, but most occur within the first 3 months postoperatively [333]. Some TPFs have been reported to occur intraoperatively but most TPFs occur in the early post-operative period after the patient begins bearing weight, possibly propagating microcracks that were initiated intraoperatively during implant impaction [226, 333-336]. Occasionally TPFs occur because of trauma that would usually be significant enough to fracture a normal limb. TPFs due to trauma will not be considered in this thesis.

The risk factors for OUKR TPF are well-documented and summarised in **Table 6.1.** A systematic review of UKR TPFs by Burger et al. identified two main patterns of TPF observed with the OUKR which are shown in **Figure 6.1** [333]. For this thesis, these TPF patterns have been classified as Type A, which pass through the corner of the tibial resection and extend to the medial tibial cortex, and Type B, which pass through the keel slot cut in the tibia to the tibial cortex. Type A TPFs appear to be closely linked to the tibial resection, which is identical for cemented and cementless OUKR, while Type B TPFs seem to be related to the keel slot preparation, which differs between cemented and cementless implants. Furthermore, the need to optimise the instrumentation for the tibial resection and keel slot preparation was identified by 51% and 29% of surgeons, respectively, in the survey reported in **Chapter 5**. This chapter will focus on how the tibial resection can be optimised to minimise the risk of TPF, while **Chapter 7** will focus on optimisation of the tibial keel slot.

Table 6.1 Risk factors for tibial periprosthetic fracture of medial Oxford Unicompartmental Knee Replacements

Patient Risk Factors	Surgical Risk Factors	Implant
Small tibia size (particularly those requiring size AA or A components) [228]	Extended Vertical Cut [203, 226, 337, 338]	Use of cementless tibial components [203]
Overhanging medial tibial condyle / tibia vara, particularly common in Asian populations [228, 339]	Use of multiple bone nails [340]	Use of small size cementless tibial components (A or AA) [228]
Female sex (likely due to males having larger tibias and rarely requiring AA or A size tibial components) [339]	Excessive impaction / use of a heavy hammer [335, 340]	
Low bone mineral density [300, 335]	Damage to the posterior cortex (when preparing keel slot or making vertical resection) [204, 205, 334]	
High body mass index [335]	Preparing a keel slot with high interference / that is too narrow [228]	
	Implant position i.e. deep, valgus, medial and/or externally rotated tibial resection [337, 341, 342]	
	Positioning the implant such that there is a short distance between the keel and posterior cortex. Occurs when implant is too inferior, medial, or valgus [342, 343]	
	Under-sizing the tibial component [344]	

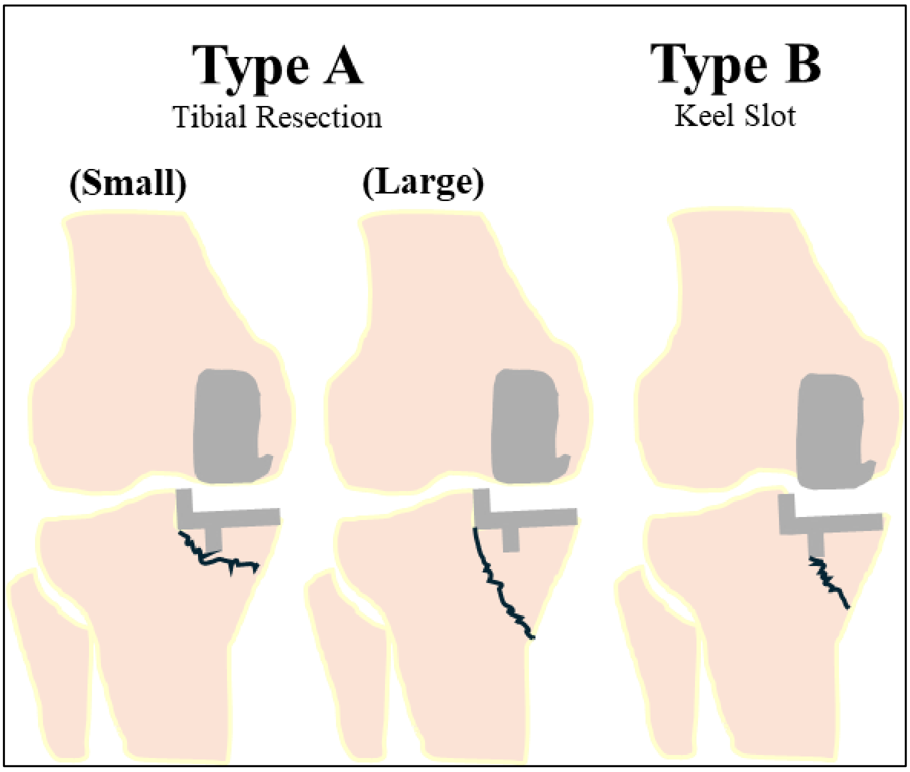


Figure 6.1 Tibial periprosthetic fracture patterns observed with the Oxford Unicompartmental Knee Replacement in the literature [333]. Type A fractures arise from the corner of the tibial resection and extend to the medial tibial cortex. The fracture lines on radiographs can pass more horizontally, resulting in 'small' fracture of the medial tibial condyle, or more vertically, resulting in a 'large' fracture of the medial tibial condyle. Type B fractures pass from the keel slot cut in the tibia to the medial tibial cortex.

Fractures arising from stress risers are a well understood mechanism of failure in engineering and are also known to be associated with fractures in orthopaedics, particularly those of iatrogenic origin (**Figure 6.2**) [345]. Stress risers can be classified as geometric discontinuities, material discontinuities (i.e. changes in composition or density), and discontinuities in applied loads [345]. Examples of stress risers for the OUKR include the corner of the tibial resection (geometric discontinuity), the tibial resection guide nail hole/s in the anterior cortex (geometric discontinuity), the interface between the keel and the surrounding trabecular bone (material discontinuity), and, if present, a vertical overcut (geometric discontinuity).

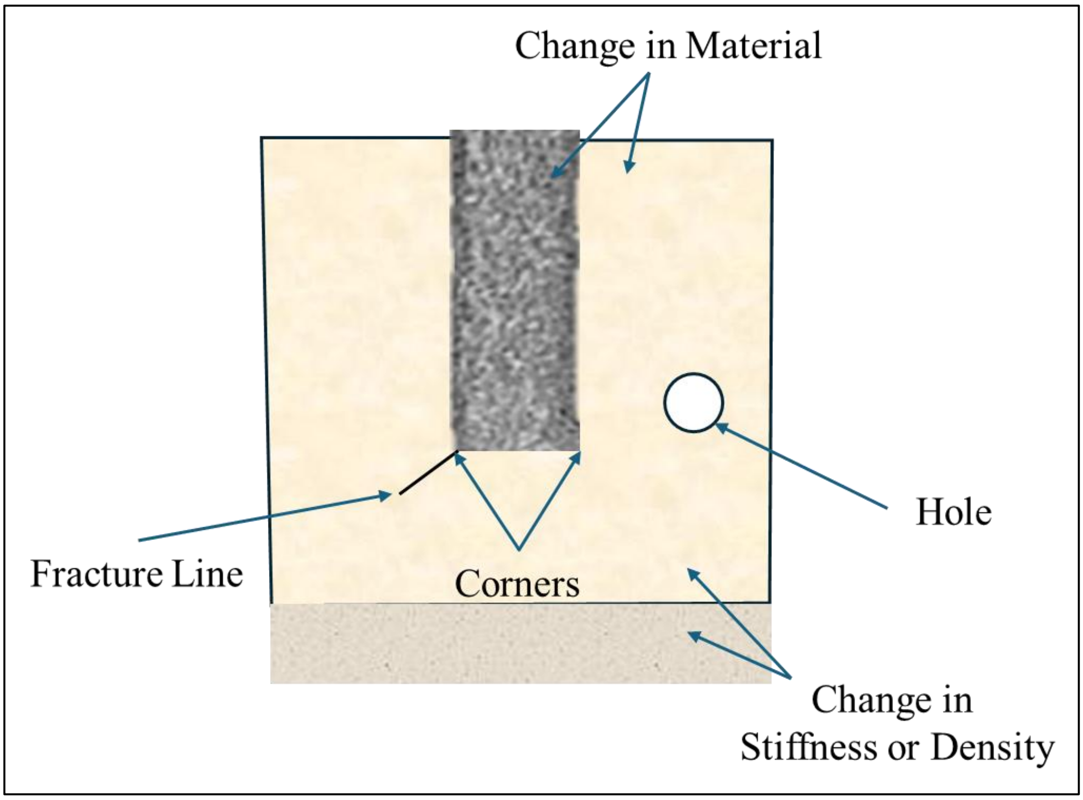


Figure 6.2 A simplified diagram illustrating possible stress risers in the context of orthopaedics. The coronal cross-section of the proximal medial tibia with a cementless Oxford Unicompartmental Knee Replacement tibial component implanted is used as an example.

As shown in **Table 6.1**, patient and implant factors contribute to the risk of TPF for the OUKR, however they are outnumbered by the surgical risk factors. One of the most well-documented surgical errors that contributes to TPF for OUKR is an extended vertical cut [203, 226, 337, 338]. Vertical overcut is a TPF risk factor for most UKRs as almost universally UKRs require an L-shaped resection to be made in the proximal tibia to accommodate the tibial component. An extended vertical overcut is an easy mistake for surgeons to make, as demonstrated by a study of surgeons attending an OUKR training course which found 18% of surgeons made an extended vertical overcut of 4 mm or more despite being directly instructed not to [346]. The design of the OUKR tibial resection guide contributes to the risk of vertical overcut as it consists of a horizontal bar fixed to the proximal tibia which restricts the depth of the vertical resection anteriorly (see **Figure**

1.11A). This bar is also used to set the depth of the horizontal resection and the posterior slope of 7°. The depth of the vertical resection therefore needs to be estimated by the surgeon, accounting for the slope, so that it perfectly meets the horizontal resection for a 90° resection. Given the difficulty of this task, it is a common error for OUKR surgeons. 14 of 94 (15%) of OUKRs in the cohort studied in **Chapter 4** had evidence of a vertical overcut on their post-operative radiograph, indicating even experienced surgeons at the designer centre can make this error. Cadaveric studies have found that the load required to fracture cadaveric tibias decreased by 30% when an extended vertical cut is made [338].

Other than careful technique, vertical overcut can be prevented by performing the horizontal cut first and making the vertical cut onto a shim such as the horizontal sawblade or the 'Boomerang' instrument now included in many OUKR instrument kits (**Figure 6.3**). As a further method to prevent vertical overcut with the OUKR, a prototype cutting guide has been proposed. This is an L-shaped cutting guide which attaches to the current tibial resection guide, constrains both the vertical and horizontal cuts, and has the surgeon cut onto a drill bit to prevent overcut (**Figure 6.4**). Although this method will theoretically prevent overcuts, there are concerns that the drill bit could initiate TPF or act as a vertical overcut to increase the risk of TPF.

The position and number of nails used to fix the resection guide to the proximal tibial has also been implicated in TPF risk for UKRs, including the OUKR [340, 347, 348]. Finite Element Analysis (FEA) studies have also shown that medial positioning of bone nails and use of multiple bone nails increases the risk of TPF for UKRs [349]. Historically, two nails have been used to fix the OUKR resection guide to the proximal tibia for the OUKR and the current surgical technique published by the manufacturer allows one or two nails to be used [190]. However, it is now recommend that one nail is used to fix the resection guide to minimise the risk of TPF [24]. There are no published mechanical studies investigating the influence of nail number and/or position on tibial load to fracture (LTF) for the OUKR.

Figure 6.3 The horizontal sawblade (left) and ‘Boomerang’ shim (right) which can be inserted into the horizontal cut for surgeons to make the vertical cut onto to prevent vertical overcut. *Not to scale.

Figure 6.4 The prototype drill bit resection guide in use on a left cadaveric knee (Left: anterior view, Right: Lateral View).

The position of the tibial component, which is dictated by the tibial resection, has also been associated with OUKR TPF risk [320, 342, 343]. This has been studied most extensively in Japanese patients where retrospective clinical studies have found that tibial components positioned more medially, in a valgus orientation, with a deeper resection, and/or a shorter distance between the keel and the posterior tibial cortex have a higher risk of TPF [320, 342, 343]. FEA studies have also demonstrated that a vertical tibial overcut, deep tibial resection, and valgus inclination of the tibial component increases TPF risk [337, 350]. To date, no mechanical studies have explored the influence of these factors on the risk of TPF with the OUKR.

Surgeons are instructed to make the vertical resection just medial to the medial tibial spine to maximise the tibial component coverage and avoid positioning the tibial component too medially [24]. With Microplasty instrumentation, the tibial resection depth is controlled using the femoral sizing spoon and 3 or 4G-clamp (see **Figure 1.11A**) [190]. If the horizontal cut is made using this method, and the tibia is not recut, the resection should not be too deep. Before the introduction of Microplasty instrumentation, the surgeon was required to estimate the depth of the resection to be 2-3 mm below the deepest part of the tibial erosion [176]. This varies with the depth of erosion between patients and could result in a very deep tibial resection if the depth was overestimated by the surgeon. The tibial resection guide should be positioned parallel to the long-axis of the tibia in both the coronal and sagittal planes, resulting in a horizontal resection (and therefore tibial component orientation) that is orthogonal to the long-axis of the tibia. However, it was noted in Japanese patients that have more overhanging medial tibial condyles, often associated with tibia vara (congenital varus deformity of the proximal tibia), that using the conventional tibial resection method would result in the tibial component being implanted in a valgus orientation relative to the long axis of the tibia [339]. Hiranaka et. al have proposed a novel method using an adjustable ankle yoke to make an intentional varus resection [321]. In Japanese patients, implanting the cementless OUKR tibial component in slight varus has been shown to increase the posterior keel to cortex distance of the tibial component and decrease the risk of TPF [320, 343]. Under-sizing the tibial component has also been suggested as a risk factor for TPF [344]. The effect of component size on TPF risk will also be investigated in this chapter.

6.1.2 Aims

There is a known or proposed contribution of vertical overcut, use of nails to position the tibial resection guide, and implant position and size to the risk of TPF for the OUKR. Except for one cadaveric study which investigated vertical overcut [338], no mechanical studies have investigated how these factors contribute to OUKR TPF risk. Therefore, this chapter aims to use mechanical studies to:

1. Investigate the relationship between vertical overcut and LTF for the OUKR and optimise the current instrumentation to minimise the risk of TPF.

2. Investigate the effect of tibial resection nail number and position on the LTF of the cementless OUKR.

3. Investigate the effect of tibial component position and size on LTF.

6.2 METHODS

6.2.1 Testing Material

Factors effecting orthopaedic fractures are often investigated using either mechanical testing or FEA [351]. The strengths and weaknesses of these two methods are highlighted in **Table 6.2**. It was decided that mechanical tests would be used in this study to investigate factors related to TPF and how these factors could be optimised with instrumentation. This was primarily because although FEA is useful to assess many factors that may affect TPF risk, it does not allow the clinical practicality of prototype instruments to be assessed. FEA models are also normally developed and validated with data from Sawbones studies, or occasionally cadaveric studies, making it logical to start investigating new instrumentation with Sawbones experiments.

Biomechanical studies using cadavers remain the gold-standard for orthopaedic testing, but as outlined in **Table 6.3**, these tests are expensive, require valuable human tissue, and the properties of cadaveric bone can vary widely [351]. While cadaveric experiments may be necessary to provide a "ground truth" before changes to implants or instruments are made clinically, they are not suitable for optimisation experiments. Some types of animal bone (porcine/bovine/ovine) may have similar material properties to human bone, but they all have significant differences in anatomical structure which makes them inappropriate to use for orthopaedic fracture testing [352]. Pigs, cows, and sheep all have proximal tibial anatomy that differs significantly from humans [353]. Notably, all three animals have domed proximal tibial surfaces that are a stark contrast to the flat, concave tibial plateaus of humans.

Table 6.2 Comparison of the strengths and weaknesses of mechanical testing and Finite Element Analysis for orthopaedic fracture testing

Method	Mechanical Testing	Finite Element Analysis
Strengths	• Allows the use of clinical instruments and implants. • Generally does not require expertise to perform tests. • Simple results that are easy to interpret and provide clinical insight. • Allows the practicality of prototype implants or instruments to be evaluated during testing.	• Inexpensive – testing equipment, implants, instruments are not required. • Once an appropriate model is developed, testing of multiple implant designs, clinical factors, scenarios can be tested efficiently. • Easy to repeat and test an array of variables. • Can be used for patient-specific solutions (i.e. predictions and evaluation of clinical cases).
Weaknesses	• Can require expensive equipment (i.e. materials testing machine), implants, testing materials (i.e. cadaveric bone), and implants/instruments. • Models may deviate significantly from the clinical reality (i.e. polyurethane foam, animal bone, and even cadaveric bone differ from the properties of a living human bone). • Tests are often low throughput and time consuming to perform. • Variation between testing material can be high.	• Time consuming to develop models. • Requires expertise to develop models. • Simplification of models means they can deviate from clinical reality. • Abstraction of FEA makes its it prone to errors in interpretation and implementation.

Due to the limitations of using human and animal bone for orthopaedic biomechanical testing (**Table 6.3**), synthetic bone analogues have emerged as a popular alternative [354]. Of the available synthetic bone analogues, polyurethane foam is the most widely used and validated. Solid rigid polyurethane foam (Sawbones, Vashon, USA) with a density of 20 pounds per cubic foot (PCF), hereby referred to as 'Sawbones', was selected for use in this study as it has similar properties (density 0.32g/cm^3, compressive modulus: 210MPa) to human trabecular bone (density: 0.3g/cm^3, compressive modulus range 14–345MPa) [355-357]. Solid rigid polyurethane foam is closed cell in structure, which differs from the open cell structure of human trabecular bone. However, it provides a uniform structure with only ±10% variation in density as per standard ASTM F-1839-08, making it ideal for comparative testing of orthopaedic implants and instrumentation [354]. Compared to human and animal bone, Sawbones are easier to obtain, store, and dispose of (**Table 6.3**).

Table 6.3 Summary of the materials and models considered for fracture testing.

Specimen Type	Human Cadaveric Bone	Porcine/Bovine/Ovine Bone	Polyurethane Foam Machined Tibia	Simple, Rectangular Polyurethane Foam Model
Strengths	- Exact human anatomy and bone properties	- Somewhat similar anatomy and bone properties to humans. - Relatively cheap.	- Geometry can be controlled. - Material characterised for orthopaedic mechanical testing. - Patient anatomy can be recreated from 3D imaging (CT/MRI) - Easy to store	- Geometry can be controlled. - Material characterised for orthopaedic mechanical testing. - Easy to prepare and store. - Cheap
Limitations	- Highly variable properties between individuals (size, shape, density). - Difficult to obtain cadaveric knees with end-stage osteoarthritis - Paired tibia required to compare two experimental conditions. - Expensive and wasteful use of human tissue - Storage, use, and disposal is expensive and tightly regulated by the Human Tissue Authority	- Highly variable properties between individuals (size, shape, density). - Bone often from young animals (more elastic than bone of a typical knee replacement patient, often the epiphyseal plate has not ossified). - Anatomy similar, but not identical to humans. - Requires refrigeration for storage.	- No cortical bone “equivalent” structure - Requires specialist engineering and manufacturing input. - No cortical bone “equivalent” structure	- Lacks anatomical shape. - No cortical bone “equivalent” structure
Cost	~£1250 per lower limb	~£5 per lower limb	£48 per tibial condyle (material = £3, bespoke machining = £45)	£0.5 to £2.50 per test, depending on volume of material used

6.2.2 Tibial Components

Tibial components used for the mechanical experiments in this chapter were 3D-printed in titanium (Cp-Ti Grade 2, AP&C, Saint-Eustache, Canada) with a Direct Metal Laser Melting system (Concept Laser MLAB200, General Electric, Boston, Massachusetts, USA). The components were printed based on CAD models of the clinically used, right-sided, Size A cementless tibial OUKR component prepared by an engineer using Solidworks (SOLIDWORKS, Dassault Systèmes, France) (**Figure 6.5**). In addition to the standard component a tibial component of the same size, but with no keel, was also produced (**Figure 6.5**). These components had a porous undersurface but did not have the hydroxyapatite coating that is present on clinically used implants. This was intentional to maintain consistency across experiments as the hydroxyapatite coating will wear off after repeated use, thus changing the implant properties (i.e. keel width).

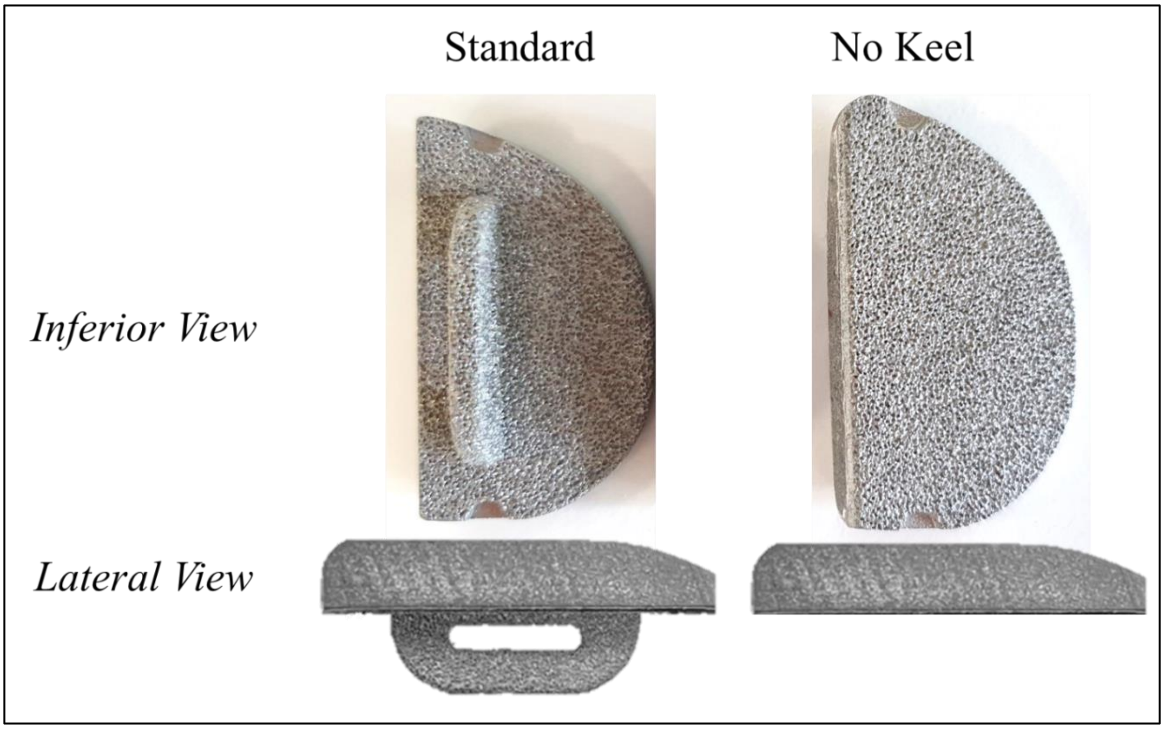


Figure 6.5 The tibial components used for mechanical testing. **Left** 3D-printed titanium right-sided, Size A cementless tibial Oxford Unicompartmental Knee Replacement component. **Right** 3D-printed "no keel" tibial component that is identical to A, except the keel has been removed.

6.2.3 Tibial Resection Method

As these experiments were primarily concerned with the geometry of the tibial resection, a keel slot was not prepared in the specimen and the no keel tibial component (**Figure 6.5B**) was used.

6.2.3.1 *Preliminary Experiments*

To develop the fracture model and investigate certain elements of the tibial resection some preliminary experiments were performed. Initially, experiments were performed in blocks measuring 65 mm × 45 mm × 20 mm (**Figure 6.6A**), with a resection measuring 26 mm wide (the width of the tibial component) and 10 mm deep made in the top right corner of the block using a micro bandsaw (MBS 240/E, Proxxon Micromot System). The different resection preparations tested are outlined in **Table 6.4**.

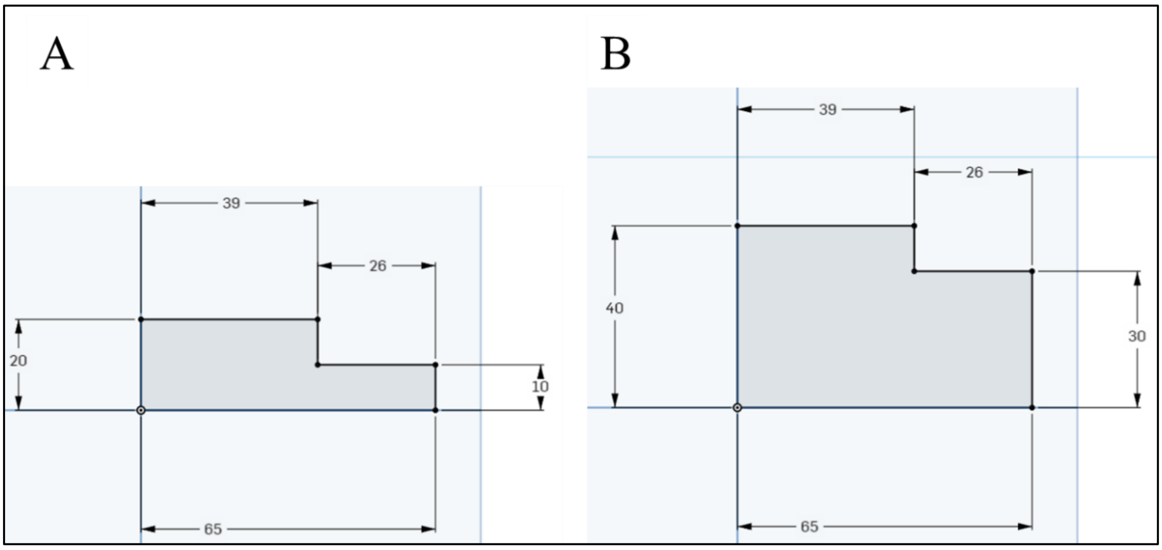


Figure 6.6 Diagrams of the models used for preliminary tibial resection load to fracture experiments. All measurements are in millimetres. **A** 20 mm deep blocks. **B** 40 mm deep blocks.

Early LTF results with blocks 20 mm deep were unable to discern differences between resection preparation methods. This was thought to be due to the low LTF of blocks with only 10 mm of Sawbones beneath the resected surface. Therefore, the block depth was doubled to 40 mm so that there was 30 mm of Sawbones beneath the resected surface, which achieved discernible results.

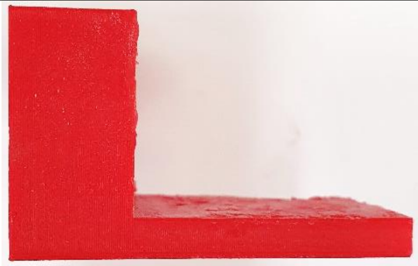
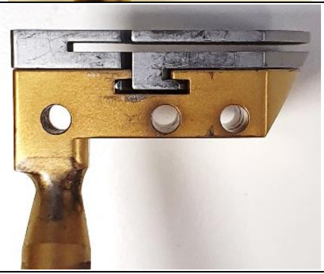
Table 6.4 Description of how the different tibial resections were made using a micro bandsaw for the preliminary experiments.

Preparation	Description
Ideal Orthogonal Resection	The resection was made so that the vertical and horizontal cuts meet perfectly, resulting in a perfect orthogonal resection.
Vertical Overcut	The vertical cut was made beyond the level of the horizontal resection. (3 mm in 20 mm deep blocks / 6 mm in 40 mm deep blocks)
Horizontal Overcut	The horizontal cut was made beyond the level of the vertical resection. (3 mm in 20 mm deep blocks / 6 mm in 40 mm deep blocks)
Drill Incomplete	The drill hole was positioned so the centre of the drill hole was where the vertical and horizontal cuts would have otherwise met. The drill bit was drilled through the specimen until it was several millimetres from the posterior surface.
Drill Complete	The drill hole was positioned so the centre of the drill hole was where the vertical and horizontal cuts would have otherwise met. The drill bit was drilled through the entire specimen.
Drill Fillet	Like drill complete, the drill bit was drilled through the entire specimen. However, the drill bit was positioned so that the circumference of the drill hole was tangent to both the horizontal and vertical resections.

6.2.3.2 *Clinical Simulation Experiments*

Clinical simulation experiments were conducted using the 40 mm deep blocks optimised in the preliminary experiments (**Section 6.2.3.1**). Rather than using the micro bandsaw, the clinically used reciprocating and oscillating sawblades were used to make the resection. Instruments that were compatible with the blocks that simulated the clinical instruments were designed using the online CAD software onshape (PTC, Boston, USA) and 3D printed in PLA using an Ultimaker 2 Extended printer (Ultimaker, Utrecht, Netherlands) (**Table 6.5**). For all resections the horizontal cut was made first. The vertical overcut specimens were prepared as shown in **Figure 6.7** so that the posterior overcut depth was consistent. For the slotted shim specimens, the slotted shim was used for the horizontal cut and replaced with the standard shim for the vertical cut. For the horizontal sawblade shim specimens, the horizontal sawblade was removed from the saw after making the horizontal cut and wedged beneath the location of the impending vertical cut to act as a shim. For the prototype resection guide, a 3 mm drill bit was drilled through the guide hole and all the way through the Sawbones block prior to the horizontal and vertical cuts being made.

Table 6.5 Instruments used in the clinical simulation experiments in the laboratory which were 3D-printed in polylactic acid (PLA) and the clinical instruments they were designed to simulate.

Instrument Name	Clinically Used Instrument	3D-printed PLA instrument for Laboratory Use
Standard Tibial Resection Guide		
Tibial Resection Guide with Slotted Shim		
Prototype 'Drill bit' Resection Guide		

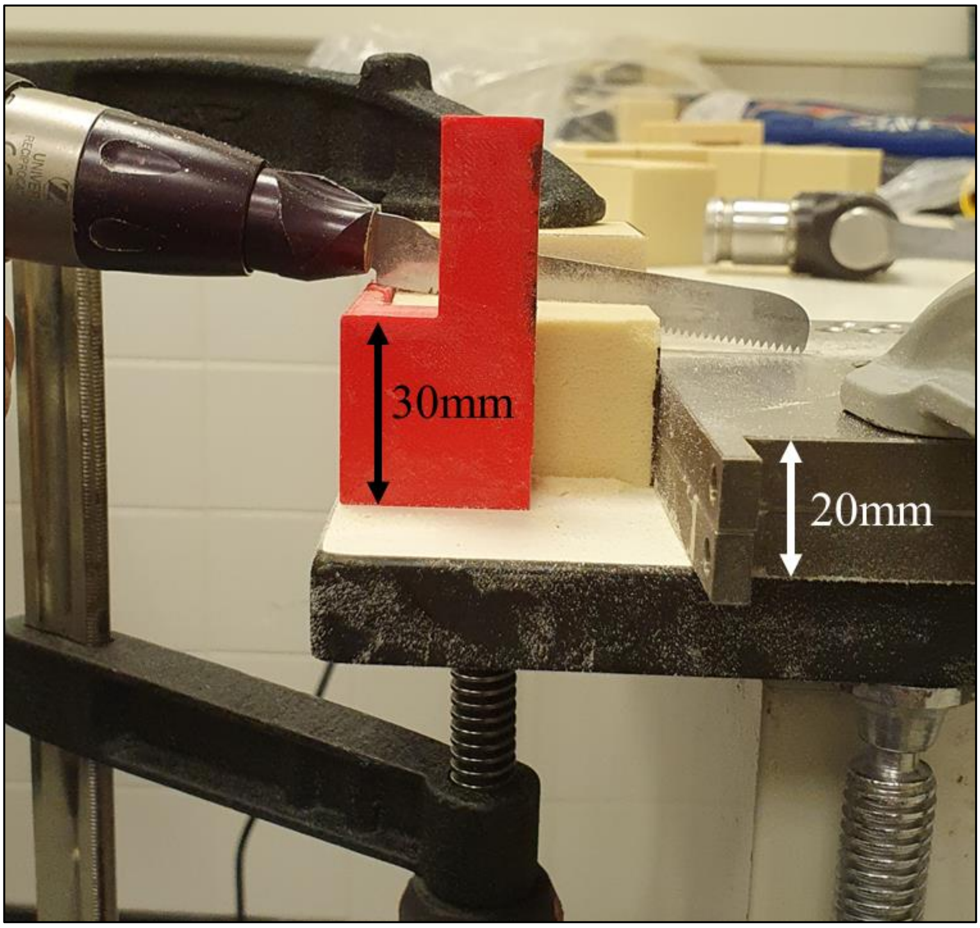


Figure 6.7 Image of how the vertical overcut load to fracture specimens were prepared. The standard tibial resection guide was placed anteriorly at the level of the resection and a 20 mm high stainless steel plate was placed posteriorly. The surgeon then cut and raised their hands until the sawblade met the stainless steel plate to simulate how a vertical overcut occurs clinically.

6.2.3.3 *Load to Fracture Testing Protocol*

Specimens from both the Preliminary Experiments and Clinical Simulation Experiments were loaded to failure using a servo-hydraulic testing machine (Dartec HC 10, Zwick Ltd, Herefordshire, UK), hereby referred to as the 'Dartec', which measures displacement and a 2.5kN S-beam load cell (FSB-01, Force Logic, Berkshire, UK) which measures vertical force. Testing was performed using this equipment as per the protocol outlined in **Table 6.6**.

The fracture specimens were positioned as shown in **Figure 6.8,** fixed in a vice beneath the servo-hydraulic arm of the testing machine with the resected surface overhanging the vice.

The No Keel tibial component was positioned on specimens so that it abutted the corner of the resection. A Size 9 bearing was positioned on the tibial component with the centre of the bearing positioned at the anteroposterior midpoint of the component. Size 9 is the largest available bearing size and was used to avoid the risk of fracturing a thinner bearing through repetitive LTF testing. The bearing was positioned 1.5 mm from the tibial component wall using a wooden spacer, so that it was not jammed against the wall which is discouraged by the designer surgeons [24]. A hemi-spherical stainless-steel loading component, designed to mimic the OUKR femoral component, was fitted to the load cell. The centre of this component was also aligned with the centre of the tibial component and bearing. Once the experiment was set up in this manner, the block was loaded to failure using the protocol outlined in **Table 6.6.** The LTF was defined as the maximum force recorded by the load cell and was used to infer the comparative risk of OUKR TPF for this set of tests and all following LTF tests in this thesis.

Table 6.6 Load to Fracture Protocol for the servo-hydraulic testing machine and 2.5kN S-beam load cell

Test Step	Step Description
1 – Seating the Component	The hydraulic arm lowers at a rate of 0.17 mms^{-1} until the load is 30N. This step ensures the tibial component is fully seated and allows the tester to assess the test set-up a final time before loading to failure.
2 – Load to Failure	After approval by the tester, the hydraulic arm continues to lower at a rate of 0.17 mms^{-1}.
3 – End of Test	Test ends when a load <10% of the maximum load achieved is reached (i.e. the testing material has failed).

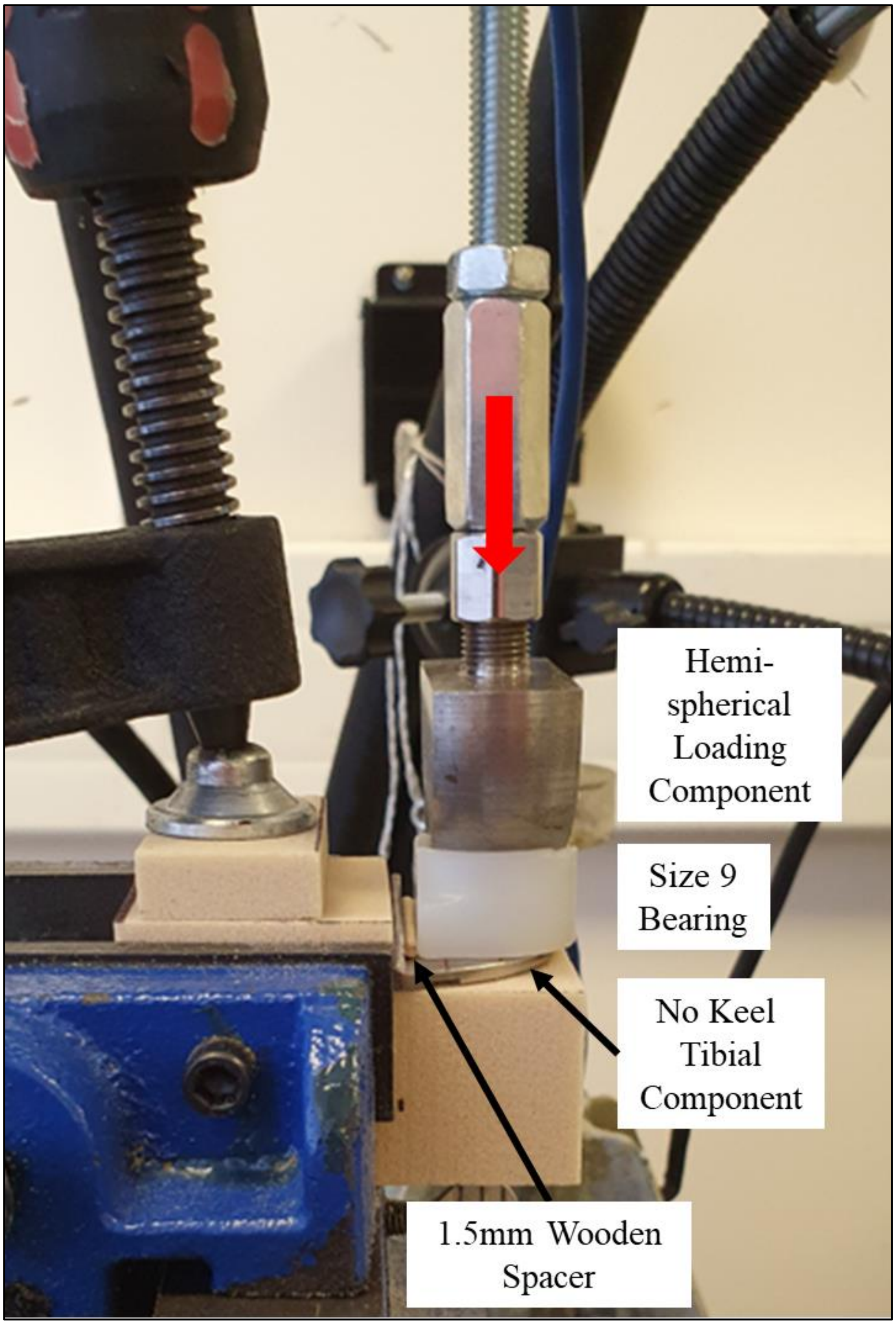


Figure 6.8 Set-up for tibial resection load to fracture experiments. The red arrow indicates the direction of the force applied by the servo hydraulic arm.

6.2.4 Tibial Resection Guide Nail Positioning

Post-operative radiographs of the cohort studied in **Chapter 4** were reviewed to determine where nails for the tibial resection guide were placed by surgeons. Clinically, one or two of the most medial nail holes of the tibial resection guide are used. (**Figure** 6.9**A**). The lateral hole usually sits over the patient's skin and/or patellar tendon and therefore cannot be used. It was found that surgeons used either one or two nails and these would leave holes that were approximately below the vertical resection and/or immediately adjacent or passing through the tibial keel slot (**Figure** 6.9**B**).

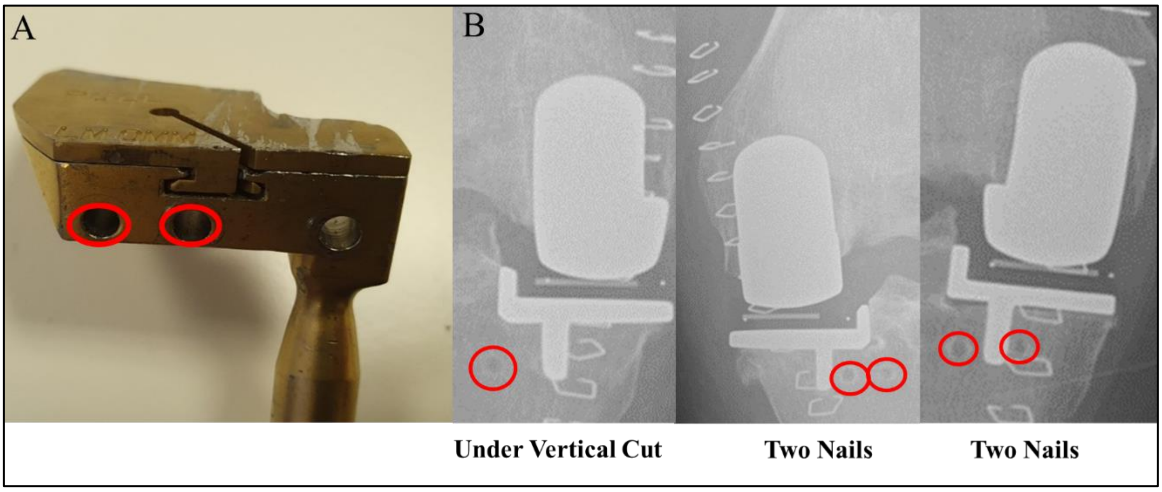


Figure 6.9 A The tibial resection guide with the two medial nail holes that are most used by surgeons (circled in red). **B** Examples of nail holes (circled in red) in the proximal tibia on post-operative radiographs of patients who received an Oxford Unicompartmental Knee Replacement.

A custom LTF experimental set-up using the Dartec was developed. Sawbones blocks were cut into rectangles of 130 mm × 45 mm × 20 mm to be used for the experiments. The block width was based on the length of the Size A tibial component (45 mm) and a depth of 20 mm was chosen as blocks of this width fractured within a loading range (~500N to ~1000N for most slot preparations) readily detectable by the 2.5 kN load cell fitted to the Dartec. The length of 130 mm was a product of the manufacturer producing blocks that were 180 mm × 130 mm × 20 mm, therefore it was possible to cut eight blocks of the required testing size from blocks prepared by the manufacturer. Four slots were made in each testing block ~28 mm apart from one another from right to left, with the first slot made so that the tibial cutting template abutted the right edge of the block (**Figure 6.10**). These slots were made using the Standard Sawblade recommended for the cementless OUKR (see **Table 7.1**) by the manufacturer [190] .

Figure 6.10 Images of how the keel slots were prepared using the Standard Sawblade.

A nail positioning tool that simulated the nail positions of the clinical tibial resection guide and was compatible for use with Sawbones blocks in a laboratory setting, was designed and 3D printed in PLA using the technology outlined in **Section 6.2.3.2**. Attempts were made to use the headed nail provided by the manufacturer to make the holes in the Sawbones, but this would split the blocks. Instead, the holes were drilled using a 3 mm drill bit (the same diameter as the headed nail) to the same depth as the headed nail (~25 mm) using a benchtop pillar drill (RSPro, London, UK). A mark was made on the nail positioning tool which was aligned with the keel slot so that the holes could be consistently made in the same positions relative to the keel slot. The most medial hole in the tool would be just medial to the keel slot and the middle hole was approximately beneath where the vertical tibial resection would be (i.e. approximately below the wall of the tibial component) (**Figure 6.11**).

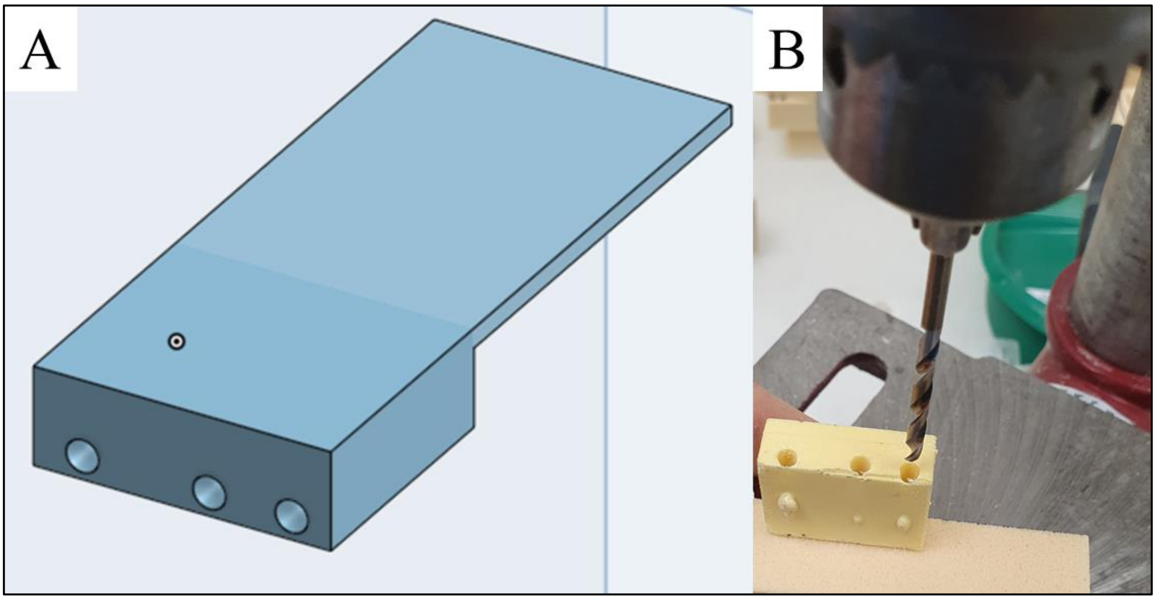


Figure 6.11 The tibial resection guide nail positioning tool. **A** CAD model of the tool. **B** The tool in use in the laboratory.

To complete LTF testing, the Standard tibial component was implanted in a slot by compressing it using a benchtop vice until it was completely seated against the upper surface of the block. A Size 9 bearing was positioned on the tibial component and positioned and loaded as described in the LTF protocol (**Section 6.2.3.3**) and shown in **Figure 6.12.** Once the experiment was set up in this manner, the block was loaded to failure using the protocol outlined in **Table 6.6** with each slot in the Sawbones block fractured one after the other, from right to left.

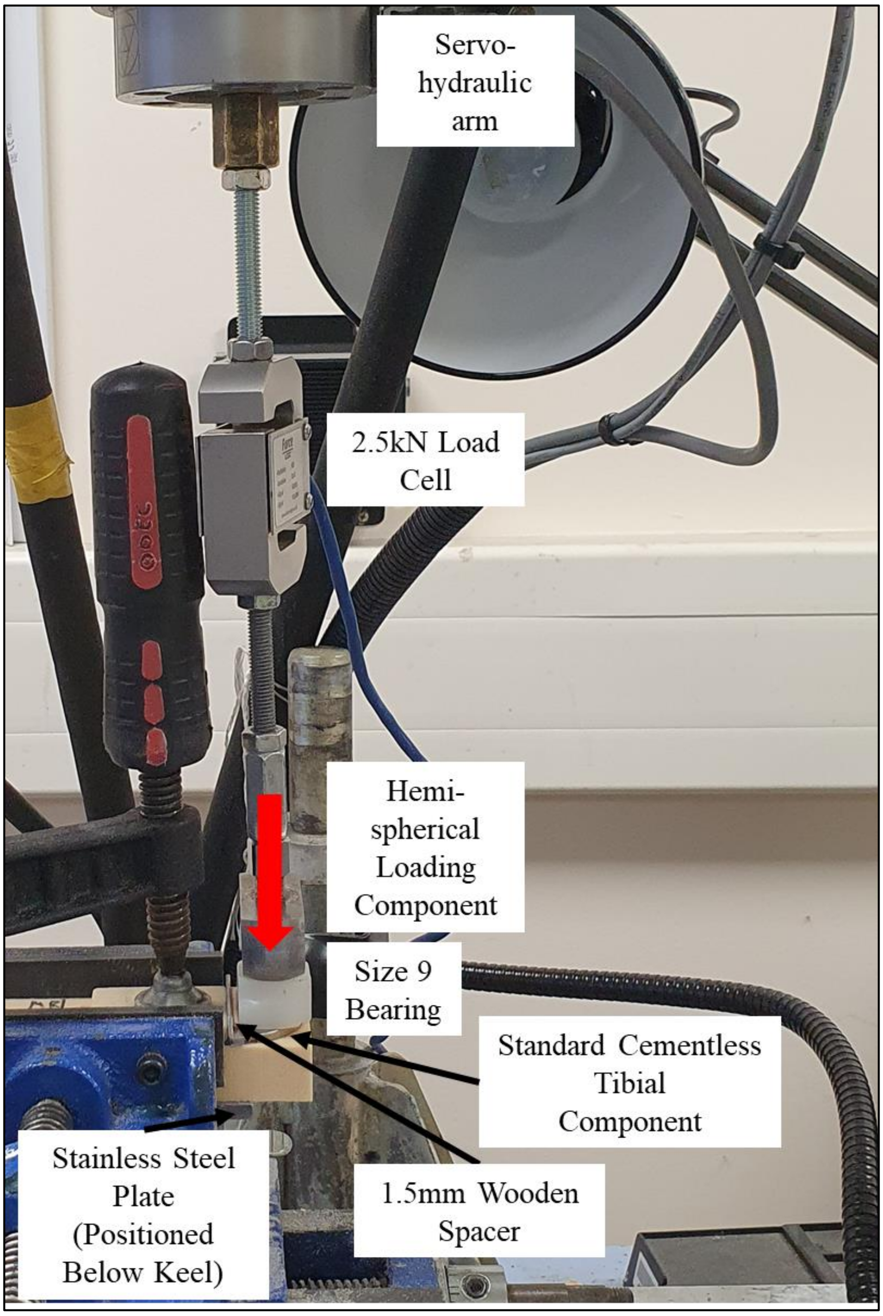


Figure 6.12 Experimental set-up for Load to Fracture Testing. The red arrow indicates the direction of the force applied by the servo hydraulic arm.

6.2.5 Tibial Component Positioning

To study the effect of component position, tibial models were machined from Sawbones based on the CT scans of a Japanese patient that underwent bilateral cementless OUKR obtained from collaborator Takafumi Hiranaka (Takatsuki General Hospital), known as "Case 2" (**Figure 6.13**). This patient had a TPF in their right knee, but not in their left. Size C cementless tibial components were implanted in both knees. Analysis of the post-operative CT scans identified that the tibial component in the right knee, compared to the left knee, was implanted in 19° more external rotation, 2° more valgus, 1 mm more medial, and had a 2 mm deeper resection. More externally rotated, valgus, medial and/or distal tibial resections have previously been identified as risk factors for OUKR TPF [337, 341, 342]. To investigate if these resection parameters, which dictate component position, affect the risk of TPF a series of LTF experiments were proposed using a Sawbones model based on Case 2. The effect of tibial component size on LTF was also studied.

These experiments used Sawbones blocks machined into the shape of the medial condyle of the left proximal tibia of the Case 2. The left knee was chosen as it did not fracture clinically and therefore it was deemed to be representative of adequate (Non-Fracture) tibial component positioning of the OUKR compared to the right knee's inadequate (Fracture) component positioning. Therefore, altering the component position in a controlled fashion relative to the Non-Fracture position as a control would help to identify which positional factors, if any, contribute to a decreased LTF. Details of the specimens prepared, and their modifications from the original component positioning of Case 2, are provided in **Table 6.7**. CAD models of the tibias were prepared by Xiaoyi Min and Chris Hunt. The models were inverted so that right-sided tibial components could be used for testing. The tibial condyle models were machined from Sawbones blocks by Billy Jones (Heritage Engineering Ltd, Bicester, UK) (**Figure 6.14**). Keel slots were machined in the tibial condyles to consistently reproduce the clinical interference.

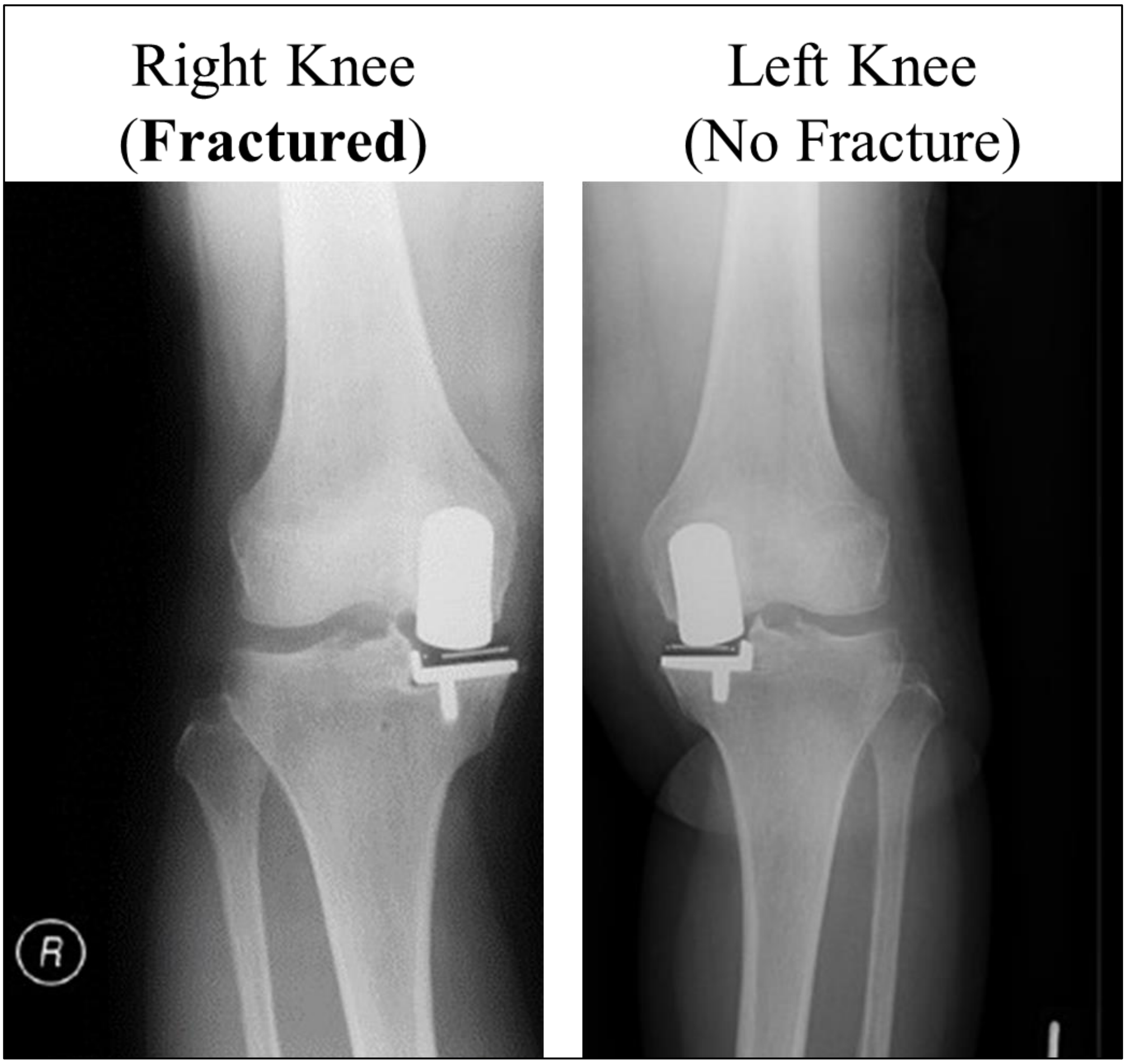


Figure 6.13 Post-operative anteroposterior radiographs of the right and left knees of Case 2. The right knee had a tibial periprosthetic fracture, while the left knee has had no complications to date.

Table 6.7 List of the tibial specimens prepared and their specifications.

Specimen	**Description**	**Tibial Component Size Used**	**Distance from Keel Slot to *Anterior* Cortex (mm)**	**Distance from Keel Slot to *Posterior* Cortex (mm)**	**Factor Being Assessed**
Size C Non-Fracture Position	Standard Left Knee Position	C	3.0	3.5	Nil (Control)
Size B Non-Fracture Position	Standard Left Knee Position	B	5.0	3.9	Smaller Component Size
Size B 3 mm MEDIAL	Standard Left Knee Position Vertical Resection Positioned 3mm More Medial	B	3.4	2.6	Smaller Component Size Medial Resection
Size B 3 mm DISTAL	Left Knee Position with 3 mm Deeper Horizontal Resection	B	4.1	2.7	Smaller Component Size Deeper Resection
Size B 5° VALGUS	Left Knee Position with 5 degrees valgus rotation	B	4.5	3.6	Smaller Component Size Valgus Rotation
Size B 20° EXTERNAL	Left Knee Position with 20 degrees external rotation	B	6.4	3.4	Smaller Component Size External Rotation
Size C Fracture Position	Standard Right (*Fractured*) Knee Position	C	1.4	2.8	Deeper Resection Medial Resection Valgus Rotation External Rotation
Size B Fracture Position	Standard Right (*Fractured*) Knee Position	B	3.3	2.1	Smaller Component Size Deeper Resection Medial Resection Valgus Rotation External Rotation Smaller Component Size

LTF testing was completed by implanting an OUKR Size B or C cementless tibial component in the keel slots machined in the condyles. A Size B component was used for most tests despite a Size C being used clinically as there was concern that implanting the larger component may break the condyle before it could be loaded. The Non-Fracture and Fracture component positions were tested with the Size C component to investigate whether increasing the component size influences LTF as the post-operative radiographs for Case 2 suggest that a Size B component may have been more suitable for the patient.

For LTF testing, the sawbones block was clamped vertically and secured horizontally in a vice with the condyle overhanging (**Figure 6.15**). A size 9 bearing was positioned on the tibial component and loaded to failure using the servo-hydraulic arm of the Dartec as per the protocol outlined in **Table 6.6**.

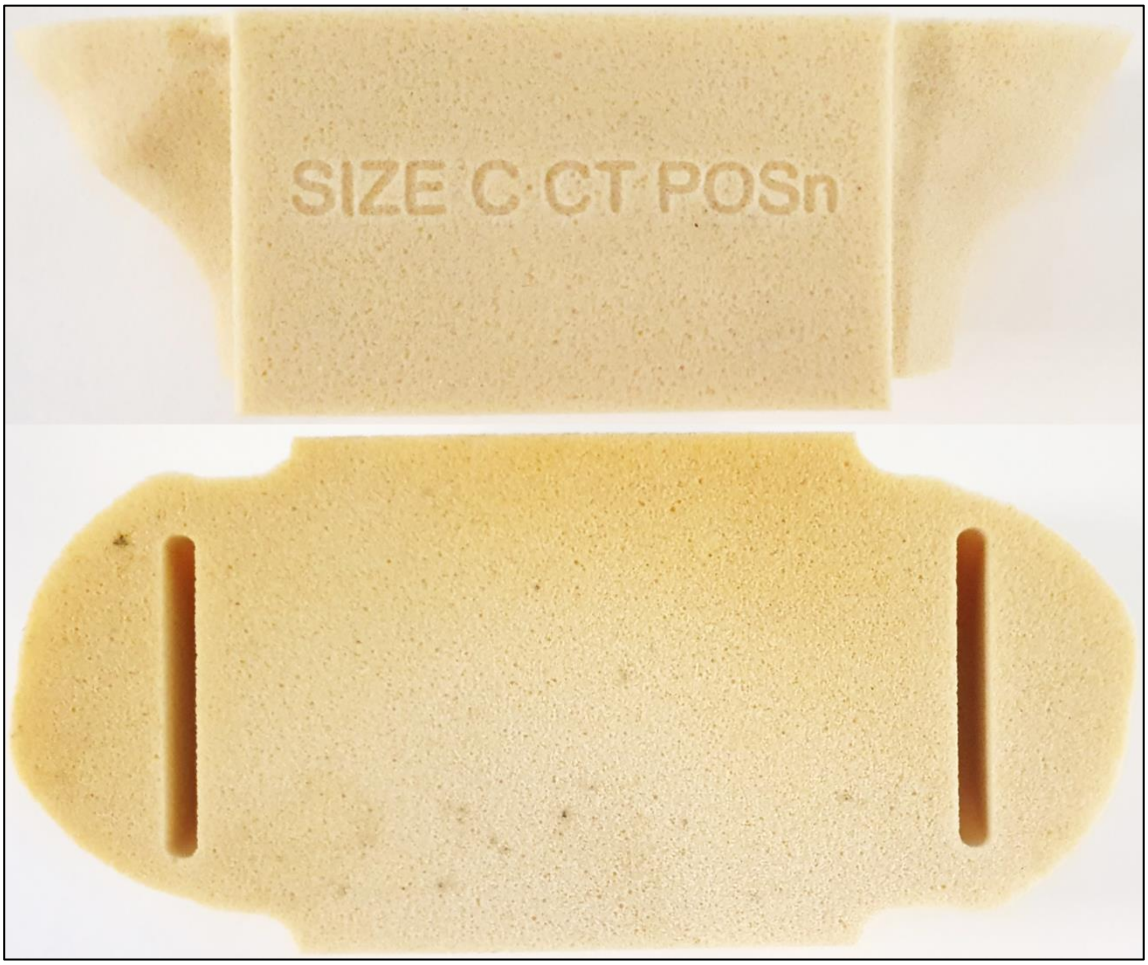


Figure 6.14 A lateral (top) and superior (bottom) view of a tibial condyle model machined from a Sawbones block.

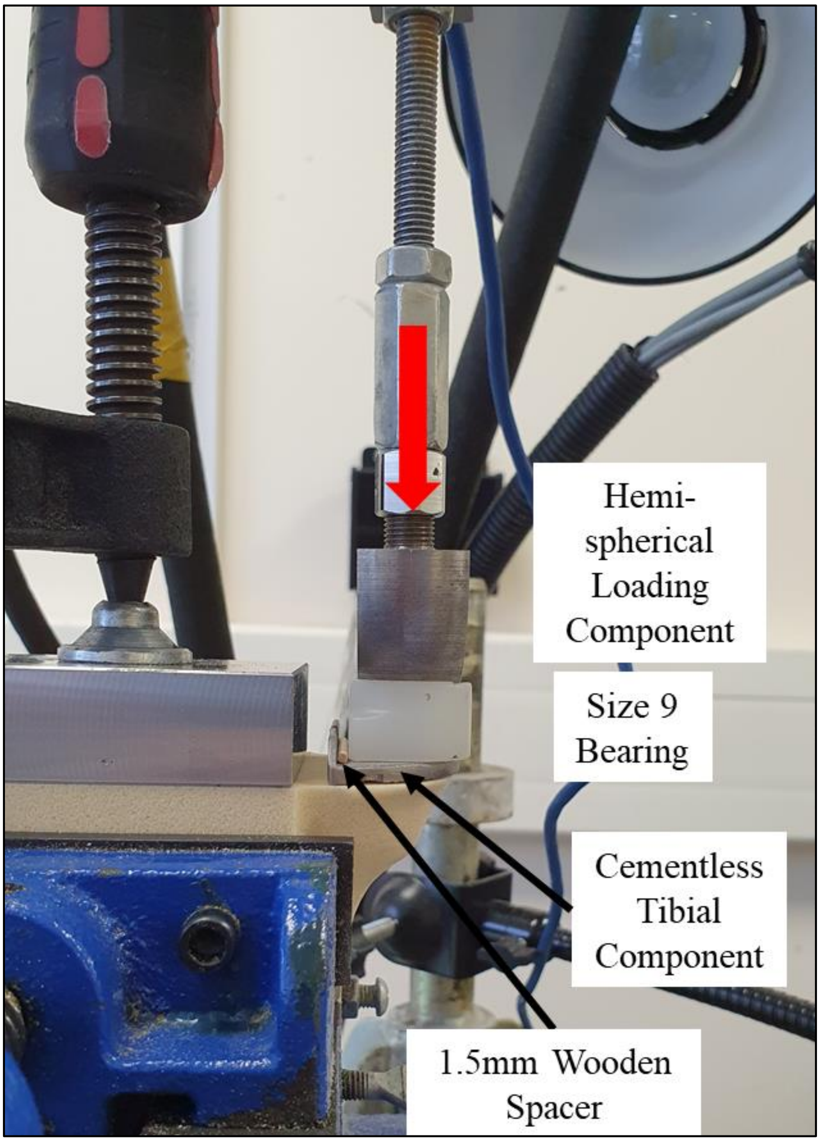


Figure 6.15 Experimental set-up for Load to Fracture Testing with the machined tibial condyles. The red arrow indicates the direction of the force applied by the servo hydraulic arm.

6.2.6 Statistical Analysis

GraphPad Prism (version 10.2.0 for Windows, GraphPad Software, Boston, Massachusetts USA) was used for statistical analysis. When comparing the means of two groups, unpaired T-tests (Shapiro-Wilk $p>0.05$) were used for parametric data and the Mann-Whitney U-tests for non-parametric data (Shapiro-Wilk $p<0.05$). When comparing three or more groups, One-way ANOVA was used with Brown-Forsythe and Welch's ANOVA used when standard deviations or sample sizes were unequal. To compare the means of multiple groups to a control mean, Dunnett's T3 multiple comparisons test was used while Tukey's multiple comparisons test was used to compare the mean of each group with every other mean. Pearson correlation was used to test the association of the shortest distance between the keel slot and the anterior or posterior cortex with LTF. The magnitude of Pearson's correlation coefficient was used to categorise associations as negligible (<0.1), weak (0.1-0.39), moderate (0.40-0.69), strong (0.70-0.89), or very strong (0.90-1.00) [280].

6.3 RESULTS

6.3.1 Tibial Resection Method

6.3.1.1 *Preliminary Experiments*

The preliminary experiments using 20 mm deep blocks did not demonstrate any significant differences between tibial resection preparations. However, the vertical overcut specimens did have a mean LTF (85N) approximately half that of all other preparations which had mean LTFs of 159N to 202N (**Figure 6.16A**). There was no significant difference in the LTF when the drill hole was complete or incomplete. Similarly, when the position of the drill hole was moved so it made a fillet there was no significant increase in LTF.

When 40 mm deep blocks were used, the mean LTF of the vertical overcut specimens was significantly lower than the ideal orthogonal resection, drill complete, and drill incomplete specimens **Figure 6.16B**). Except for the vertical overcut, the mean LTFs of all other resection preparations were not significantly different from the ideal orthogonal resection.

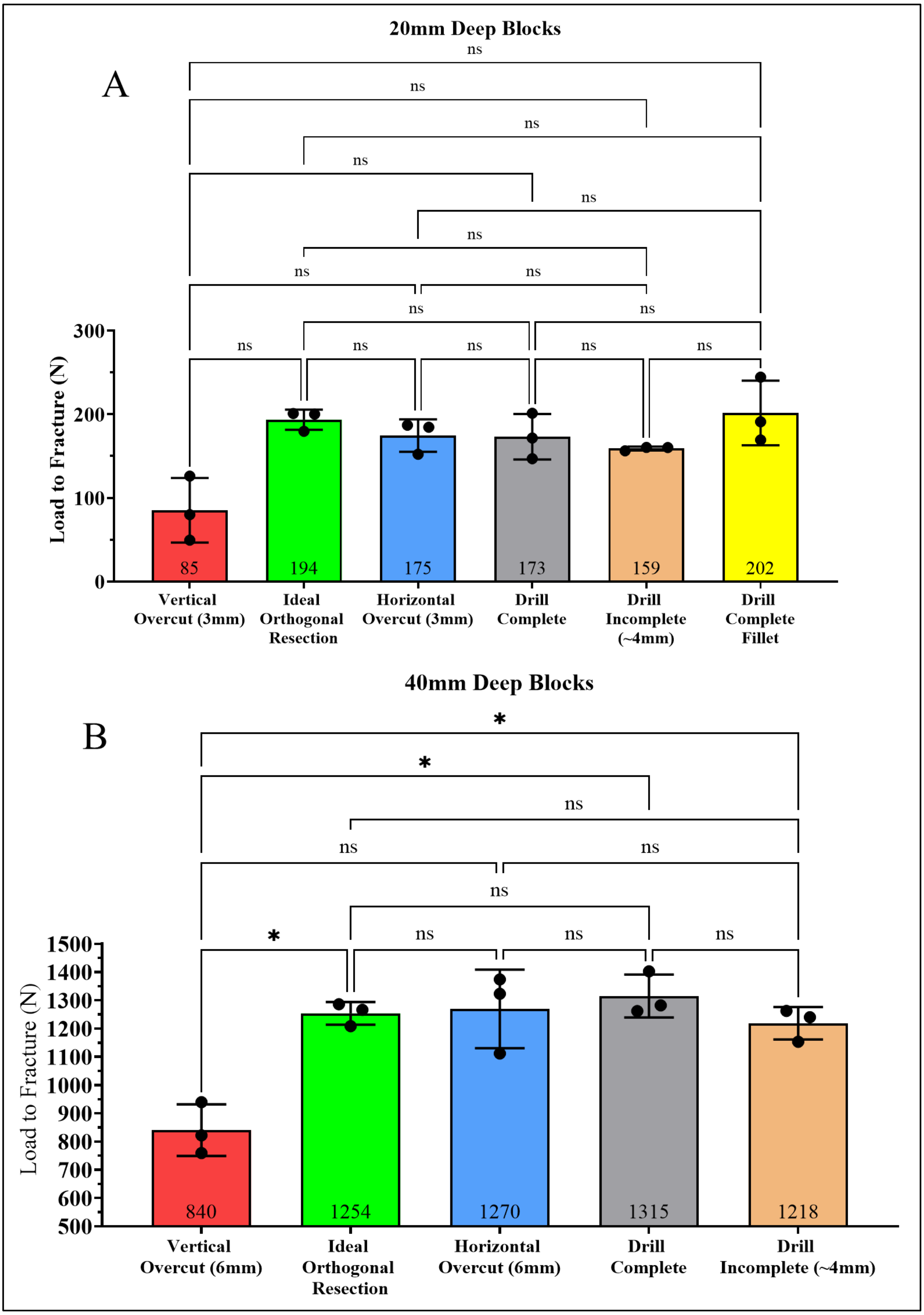


Figure 6.16 Results of preliminary experiments evaluating load to fracture (mean ± 95% confidence intervals, individual results shown) for tibial resection specimens. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates $p>0.05$, $*p<0.05$. **A** Results for 20 mm deep blocks. **B** Results for 40 mm deep blocks.

6.3.1.2 *Clinical Simulation Experiments*

The clinical simulation experiments again demonstrated that the vertical overcut specimens had a significantly lower LTF (1005N, 95% confidence intervals (CI) 929 to 1081) compared to all other resection preparation methods **Figure 6.17**. There was no significant difference in LTF between standard (1196N, 95%CI 1141 to 1252) and slotted shim preparations (1221N, 95%CI 1125 to 1318), which was expected given horizontal overcut (which is prevented by the slotted shim) did not significantly alter LTF in the preliminary experiments. Specimens prepared with the Drill Bit Resection Guide were the only specimens to have a significantly ($p<0.01$) higher LTF (1376N, 95%CI 1293 to 1459) compared to the standard resection method.

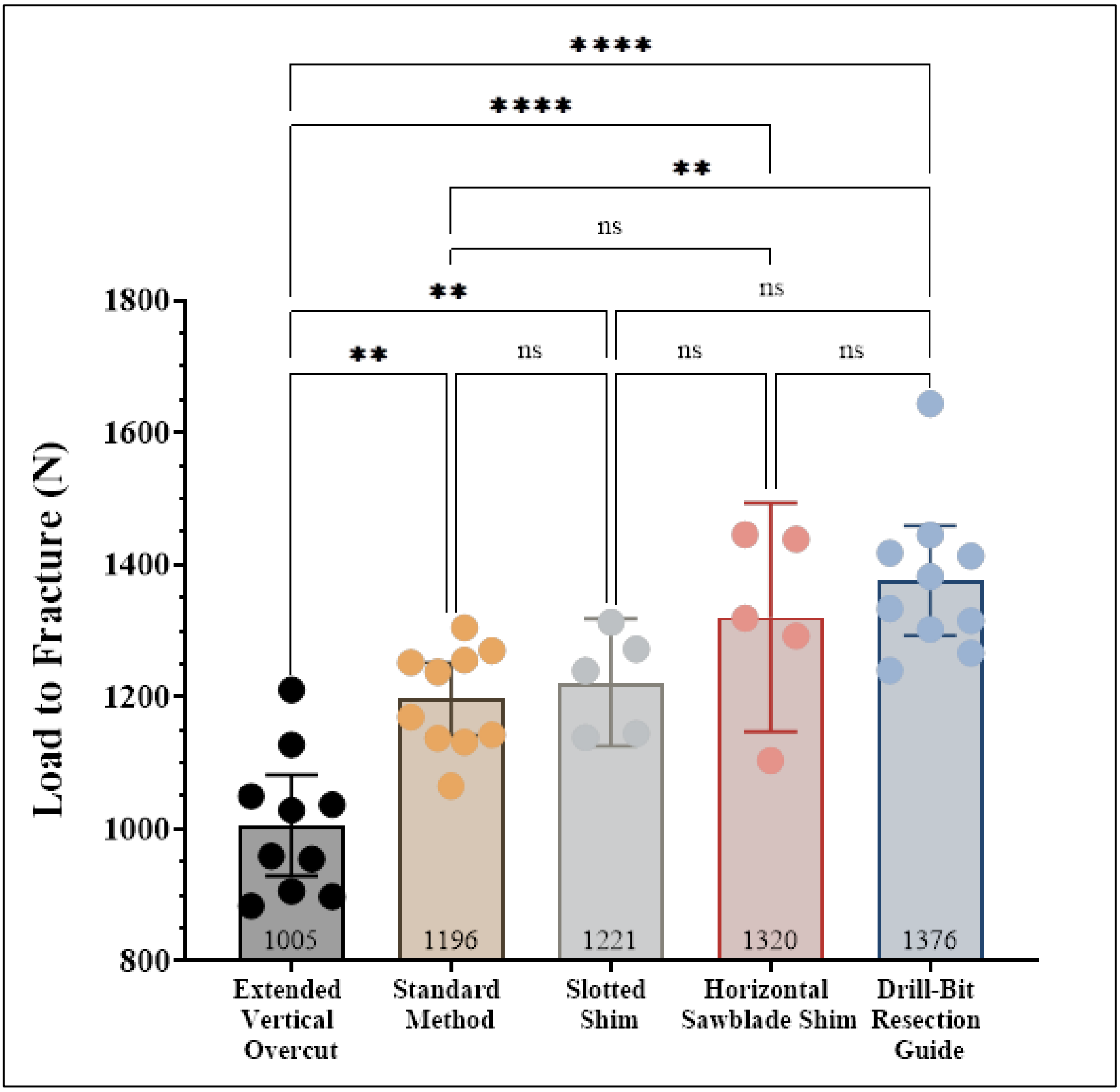


Figure 6.17 Load to fracture (mean ± 95% confidence intervals, individual results shown) testing results for tibial resection specimens from clinical simulation experiments. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates p>0.05, **p<0.01, ****p<0.0001.

6.3.2 Tibial Resection Guide Nail Positioning

Compared to when there were no holes made in the specimens (807N, 95% CI 782 to 832), mean LTF was significantly reduced when a hole was made approximately under the location of the vertical cut (745N 95%CI 708 to 782) and when two holes were made (736N, 95%CI 699 to 774), both near the keel slot and under the vertical cut (**Figure 6.18**). When a single hole was made near the keel slot, there was no significant reduction in LTF.

There was no significant difference in LTF between specimens with holes, regardless of location and whether one or two holes were made.

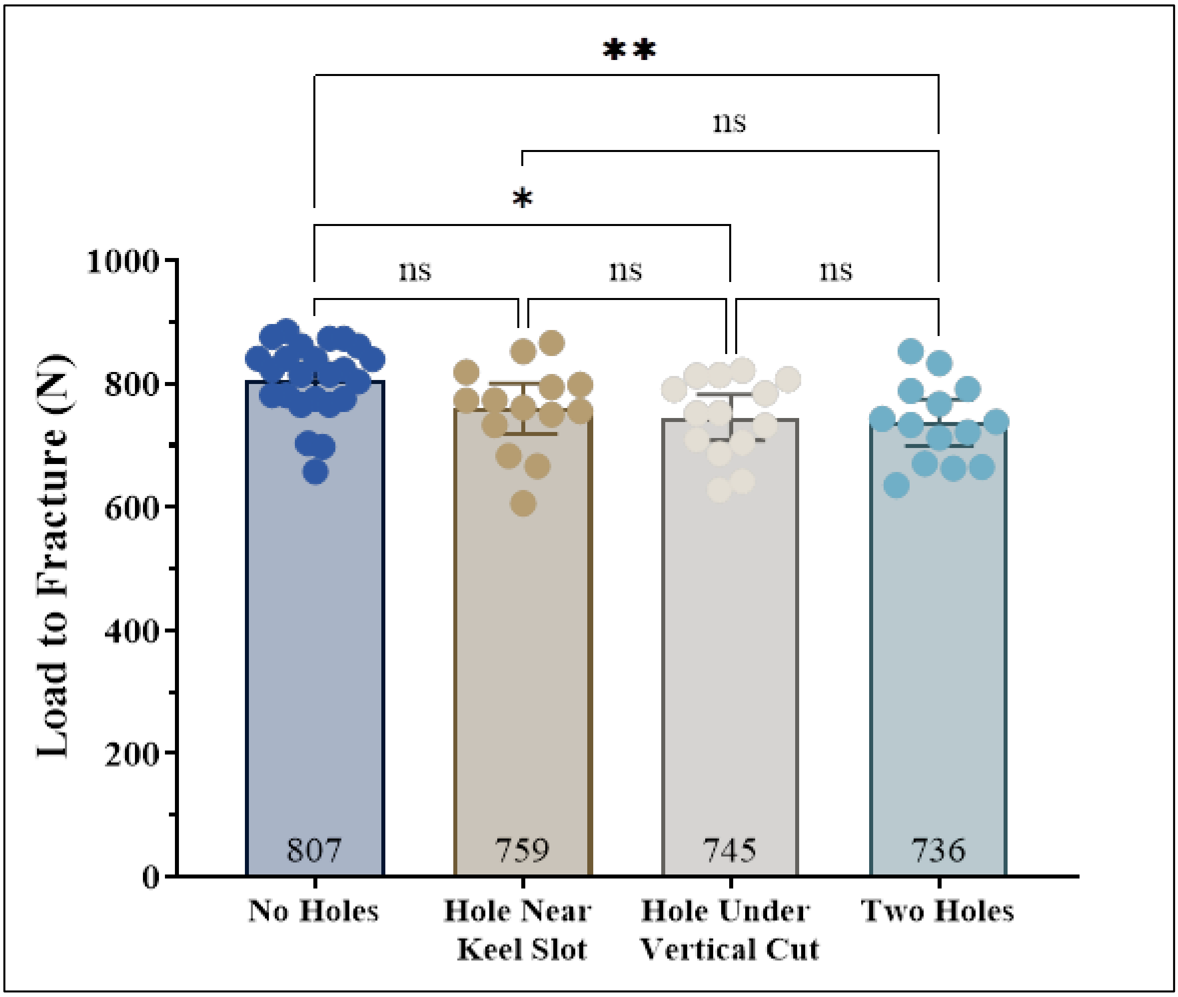


Figure 6.18 The load to fracture (mean ± 95% confidence intervals, individual results shown) of specimens with different numbers of nail holes in varying locations beneath the level of the horizontal resection. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates p>0.05, *p<0.05, **p<0.01.

6.3.3 Tibial Component Positioning

When the tibial condyles machined from Sawbones were loaded to failure the fractures always passed through the tibial keel slot. For the majority of specimens, the fracture line extended through the antero-medial corner of the slot anteriorly and central slot posteriorly (**Figure 6.19A**). The fracture lines all extended inferiorly directly beneath the keel (**Figure 6.19B**).

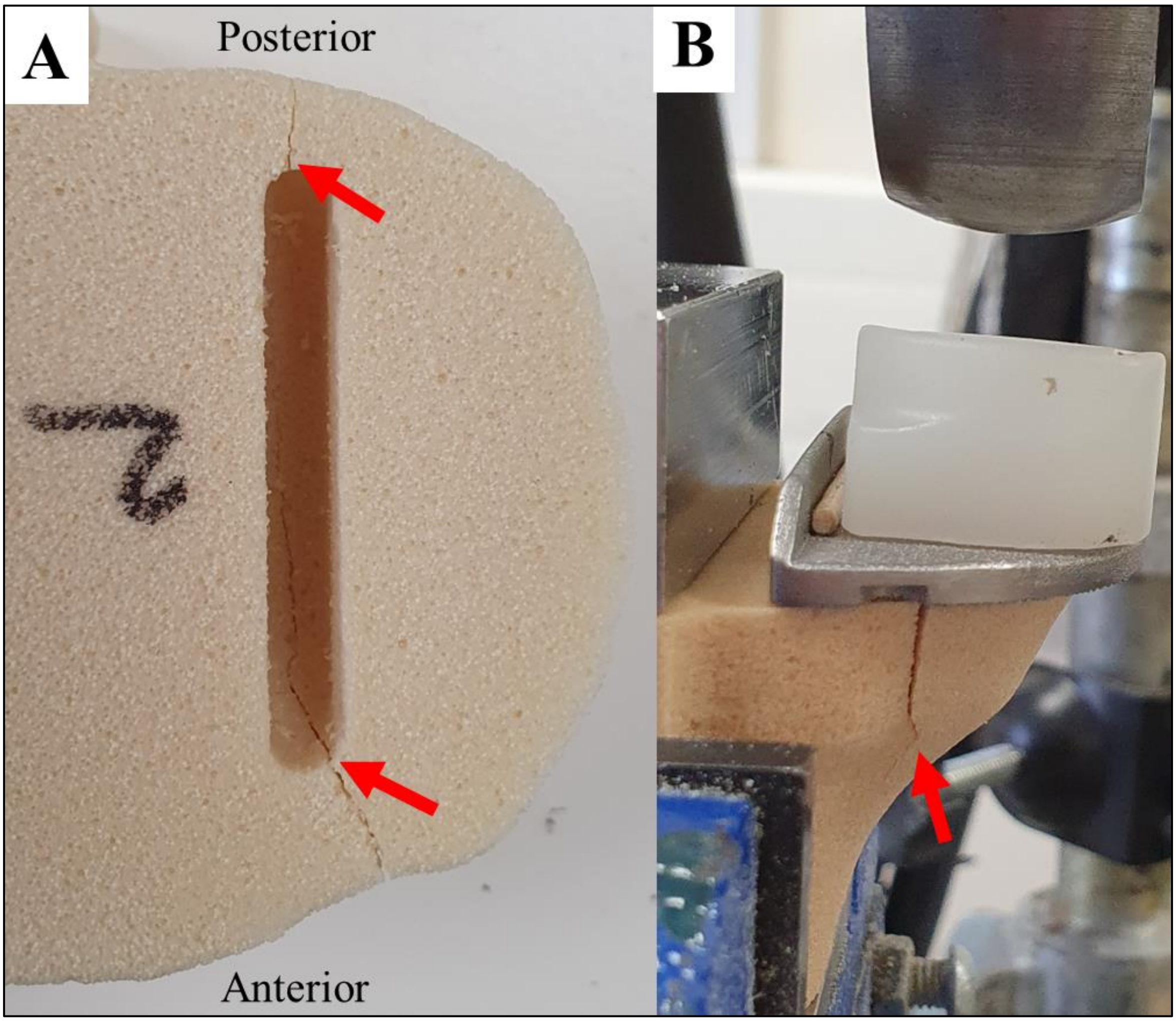


Figure 6.19 A Example of a tibial condyle fracture through the keel slot after the cementless tibial component has been removed. **B** Example of a fracture line passing inferiorly along the line of the keel to the medial cortex of the tibia.

When components were positioned in the Non-Fracture position, there was no significant difference in mean LTF when either a Size B (817N) or C (804N) tibial component was used (**Figure 6.20**). However, when positioned in the sub-optimal Fracture position, use of a Size B component (354N) significantly ($p<0.01$) increased the mean LTF compared to a Size C component (242N).

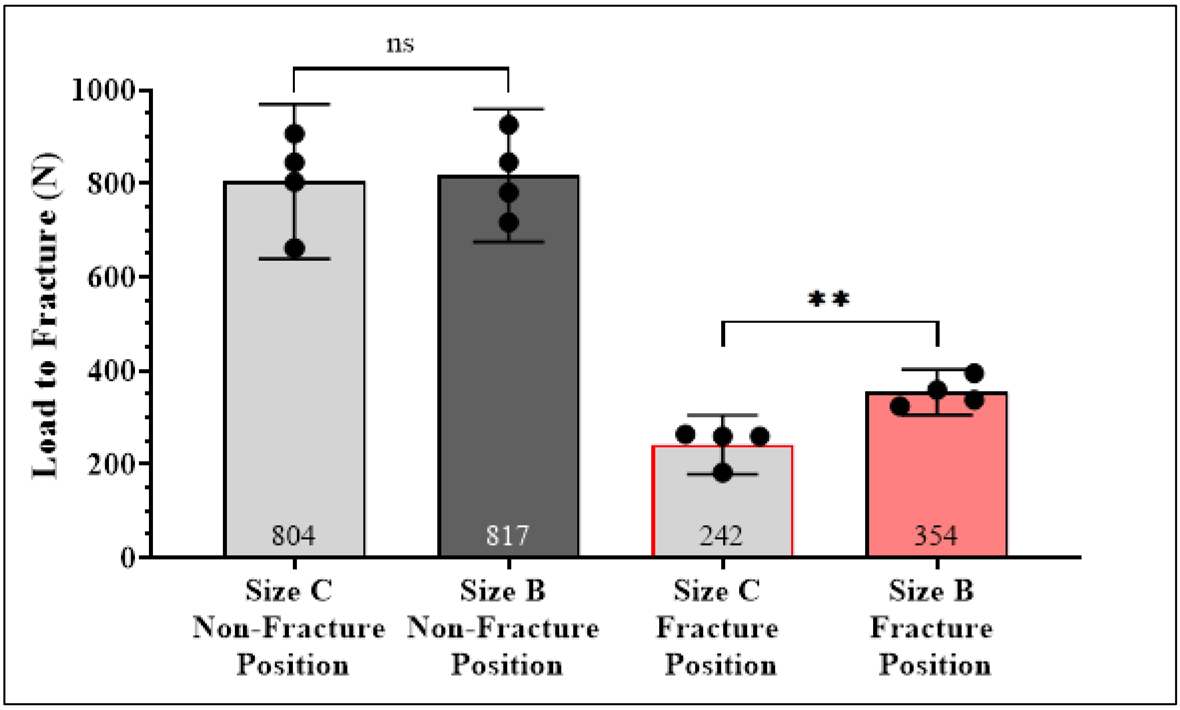


Figure 6.20 Comparison of load to fracture (mean ± 95% confidence intervals, individual results shown) when a Size B or C cementless tibial component is used with the implant positioned in the Non-Fracture or Fracture Position. Annotations indicate p-values for Welch's T-test: ns indicates $p>0.05$, **$p<0.01$.

Compared to the Non-Fracture position (817N), mean LTF was significantly decreased by making the tibial resection 3 mm more medial (458N, p<0.0001), 3 mm more distal (522N, p<0.0001), or 5° more valgus (574N, p<0.001) when using a Size B tibial component (**Figure 6.21**). However, making the tibial resection in 20° more external rotation does not result in any significant change in mean LTF (771N, p>0.05). When these resection factors are combined by making the resection in the Fracture position (2° more valgus, one mm more medial, 2 mm more distal, 19° more externally rotated), the LTF is reduced further (354N, p<0.0001).

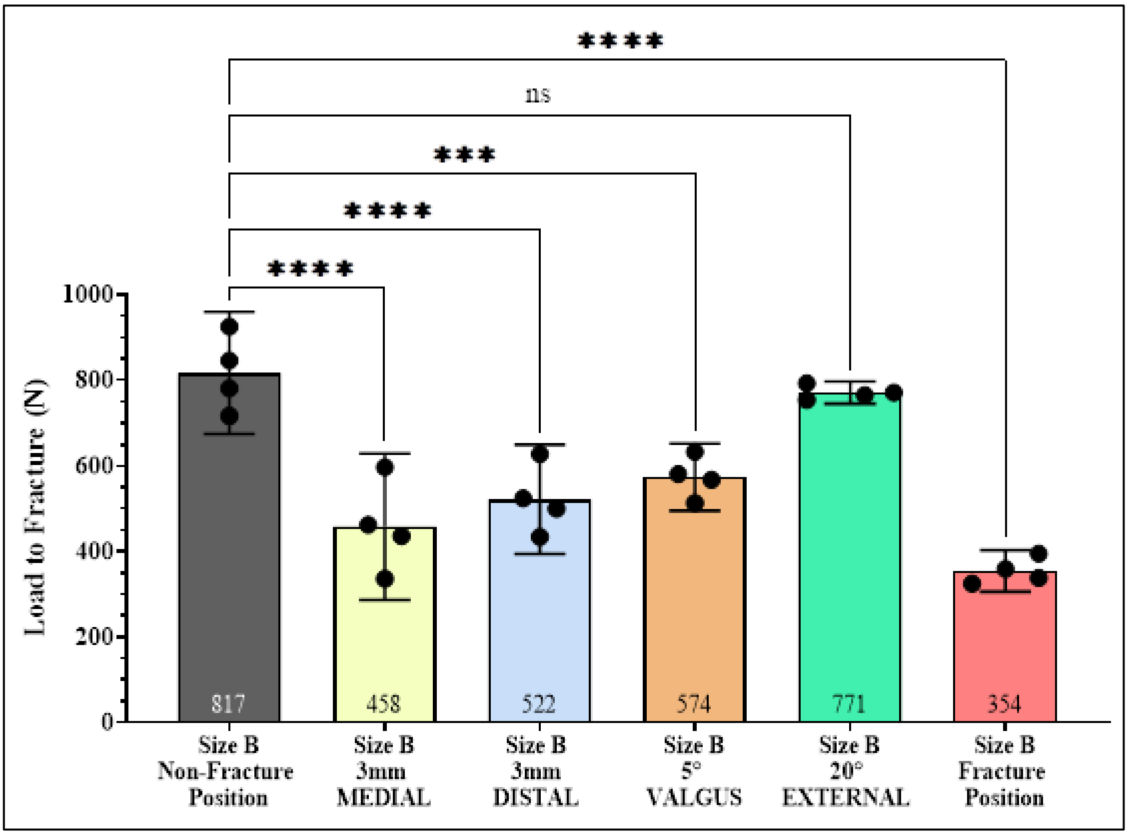


Figure 6.21 Comparison of load to fracture (mean ± 95% confidence intervals, individual results shown) between the Non-Fracture or Fracture positions and more medial, distal, valgus, and externally rotated resections with a Size B cementless tibial component. Annotations indicate p-values for Dunnett's T3 multiple comparisons test with the Size B Non-Fracture position used as the control value: ns indicates p>0.05, ***p<0.001, ****p<0.0001.

There were strong positive correlations between LTF and the distance between the keel slot and the anterior (r=0.70, 95%CI 0.00 to 0.94) or posterior (r=0.80, 95%CI 0.22 to 0.96) edge of the tibial specimens (**Figure 6.22**). However, only the correlation between LTF and distance from the keel slot to posterior cortex was statistically significant ($p<0.05$). The relationship between the shortest distance from the keel slot to the cortex, either anterior or posterior, and LTF was even stronger (r=0.88, 95%CI 0.46 to 0.98, $p<0.01$) than if only the anterior or posterior keel slot to cortex distance was considered.

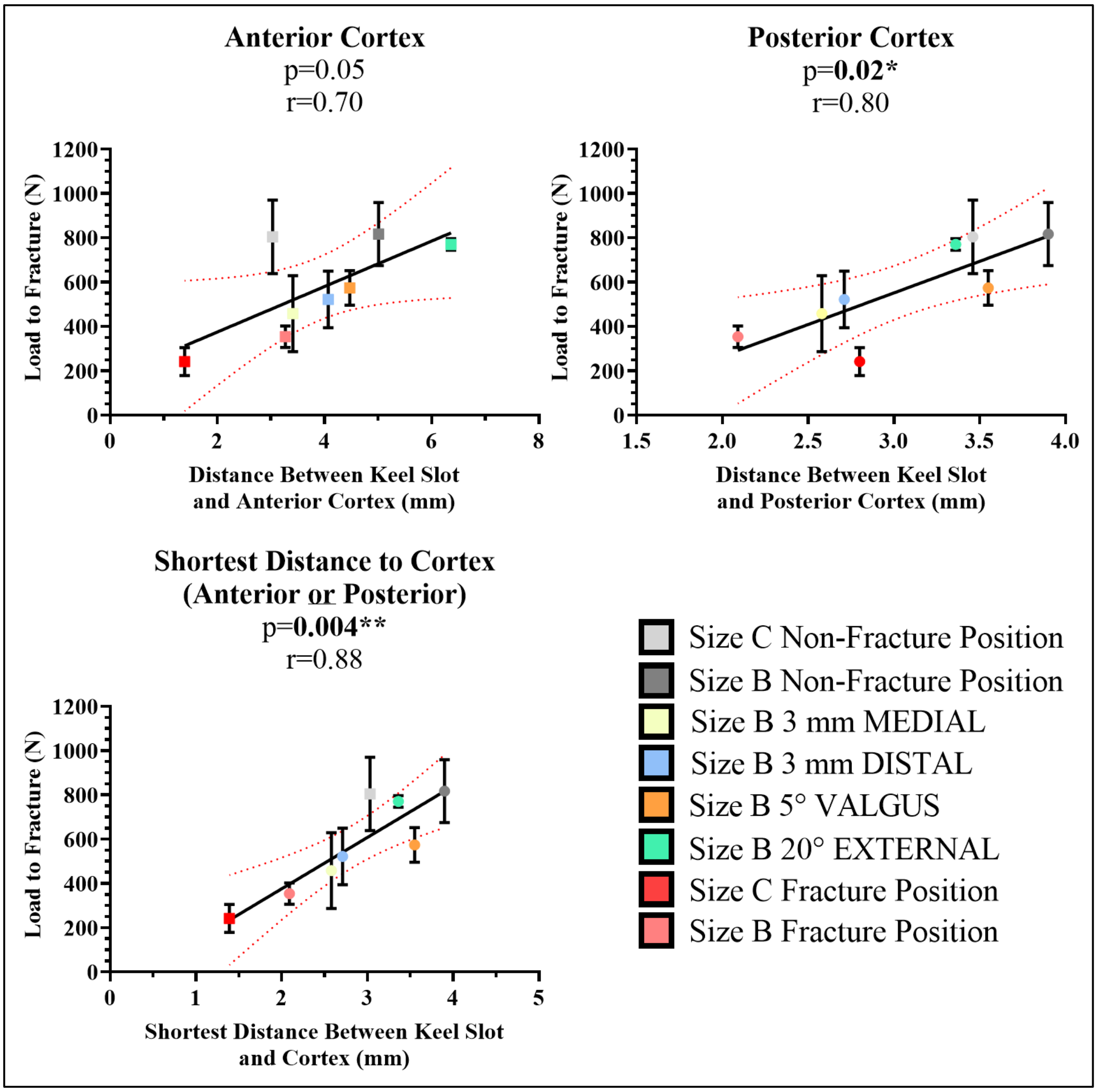


Figure 6.22 Linear regression (black line, red dashed line indicates ± 95% confidence intervals) of the load to fracture (mean ± 95% confidence intervals) versus the shortest distance between the keel slot and the anterior (top left), posterior (top right), or either the anterior or posterior edge (bottom) of the various resection specimen positions tested. The Pearson's correlation coefficient (r) and associated p-value are shown.

6.4 DISCUSSION

The results of this Chapter indicate that vertical overcut is a major risk factor for OUKR TPF that can be prevented by a prototype drill bit resection guide, which also increases the LTF compared to the standard resection method. The position and number of nail holes beneath the level of tibial resection were found to have a minor influence on the LTF. Compared to no holes, both when a hole was made approximately under the location of the vertical cut and when two holes were made (near the keel slot and under the vertical cut) the mean LTF was significantly reduced. Making the tibial resection more valgus (5°), medial (3 mm), or distal (3 mm) significantly increases the risk of OUKR TPF. Excessive external rotation of the tibial component (20°) did not reduce the LTF. When the tibial component is poorly positioned more valgus, medially, and distally, a smaller component size (B versus C) can increase the LTF of the medial tibial condyle. There is also a positive linear correlation between keel slot to posterior cortex distance and LTF.

Compared to the standard resection technique, Sawbones tibial resection specimens with a vertical overcut had a 19% reduction in LTF (1196N versus 1005N). These results support a previous FEA study which also identified that vertical overcut increases the risk of OUKR TPF [337].This mechanical study is the first to assess the effect of vertical overcut on OUKR LTF using a Sawbones model, however the effect of vertical overcut on LTF has been studied previously using cadaveric tibiae by Clarius et al [338]. Clarius found the mean LTF of the standard resection was 50% greater than when a vertical overcut was present (3.9kN versus 2.6kN). There are several potential reasons why the difference in LTF improvement between the Sawbones experiments in this study and the cadaveric study differ. The greatest difference is the testing material, given Clarius used cadaveric tibia while the Sawbones studies used comparatively small Sawbones blocks that lack the anatomical shape of a human tibia and do not have a cortical bone equivalent. The fractures in cadaveric tibias were also atypical as they passed through the shaft of the tibia rather than splitting off the medial tibial condyle, as occurs in clinical fractures [333]. Clarius et al. also used cemented implants while the sawbones study used a cementless no keel tibial component. The difference could be associated with the presence of a keel slot and use of a cemented component with a keel.

Compared to vertical overcut specimens, the mean LTF of Sawbones tibial resection specimens increased by 37% when the prototype resection guide was used. The LTF when the prototype resection guide is used is also 15% greater than when the standard resection method is used. The prototype resection guide prevents vertical and horizontal overcut to make the corner of the tibial resection round, thus eliminating the potential stress risers of vertical overcuts and the square corner of the tibial resection (**Figure 6.23**). Elimination of these stress risers is likely to account for its use increasing LTF compared to both the vertical overcut and standard resection specimens.

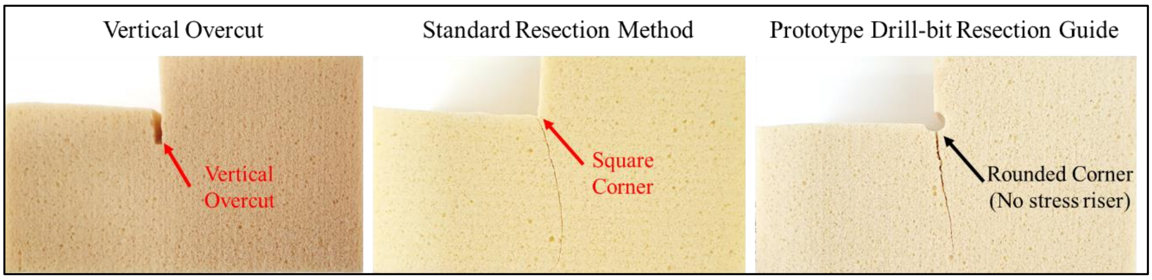


Figure 6.23 Diagram of how the Prototype Drill bit Resection Guide eliminates stress risers for the Oxford Unicompartmental Knee Replacement tibial resection.

The superiority of the prototype resection guide is likely to be due to it preventing any possibility of vertical overcut. Even with careful technique in a laboratory setting, minor vertical overcuts were made when using the standard resection technique. Similarly, when using the horizontal sawblade as a shim, if the horizontal resection was not complete posteriorly, it was still possible to make vertical overcuts posteriorly. Using the horizontal sawblade as a shim also gave the surgeon a false sense of security that they would not be able to overcut, and therefore if the blade was not appropriately positioned posteriorly it was easy to make an overcut. This same phenomenon could also occur if the surgeon used the Boomerang shim.

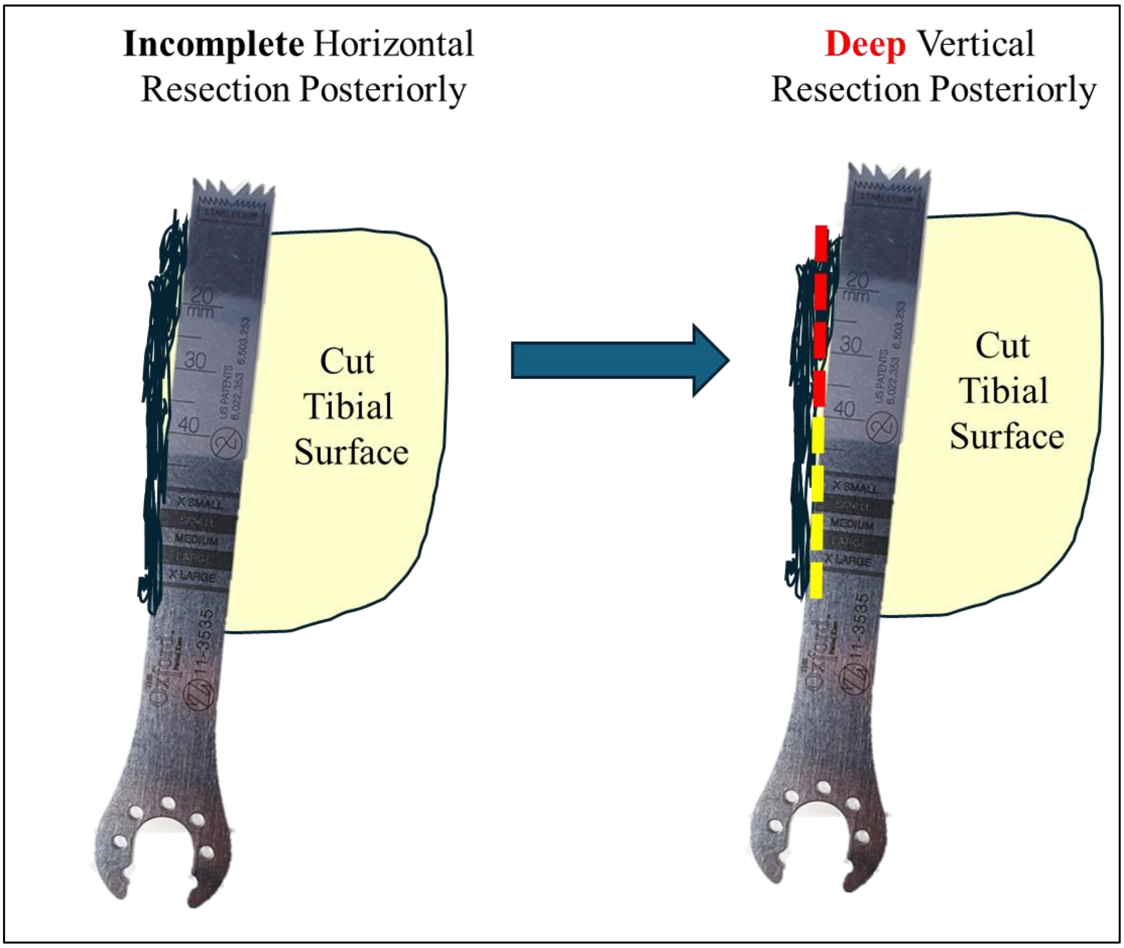


Figure 6.24 Diagram of how it is possible to make a vertical overcut posteriorly when using the horizontal sawblade as a shim. If the horizontal resection is incomplete posteriorly (black shading indicates retained bone), the horizontal sawblade shim will not align with the trajectory of the vertical cut. Therefore, the sawblade will not cut deep anteriorly (yellow dashed line) but may cut deep posteriorly (red dashed line) where the vertical cut can be extended without being impeded by the horizontal sawblade shim.

The current tibial resection guide for the OUKR must be fixed to the proximal tibia with at least one nail. The results indicate that the optimal nail position is a single hole near the keel slot as a hole in this position does not significantly reduce LTF compared to no hole specimens (**Figure 6.18**). However, there was no significant difference in LTF when either one or two holes were made, or when a single hole was made either near the keel slot or beneath the vertical cut. Furthermore, the reductions in LTF when there were two holes or a hole beneath the vertical cut compared to no holes were relatively minor, at 9% and 8%, respectively. In the absence of a tibial resection guide that does not require placement of nails in the proximal tibia, such as a resection guide held by a robotic arm, use of a single nail near the keel slot is optimal to minimise the risk of TPF with the cementless OUKR. To achieve the optimal nail positioning, it is recommended that surgeons use a single nail through the central hole of the resection guide. If the surgeon positions the resection guide with the lateral hole of the resection guide aligned to the medial tibial spine and makes the vertical resection just medial to the spine, the hole from the nail should be very close to, or pass through, the keel slot (**Figure 6.25A**). With the use of the prototype drill bit resection guide, this corresponds with the latch of the guide being placed over the head of the nail (**Figure 6.25B**).

These findings support recommendations made by the designer surgeons that one nail should be used to fix the resection guide [24]. The lack of a significant difference in LTF when there are one or two holes suggests it is unlikely that using two nails will significantly increase the risk of fracture. Although the number and position of tibial nails have been reported as a potential risk factor for TPF [340, 347], there are no published studies assessing its effect on OUKR TPF risk. An FEA study of another UKR model, the Zimmer Unicompartmental High Flex Knee, found that placing nails more centrally in the tibia minimises the risk of TPF [349]. However, the resection guide for this implant always uses two nails in a different configuration to the OUKR and the tibial component also has pegs, rather than a keel, for fixation.

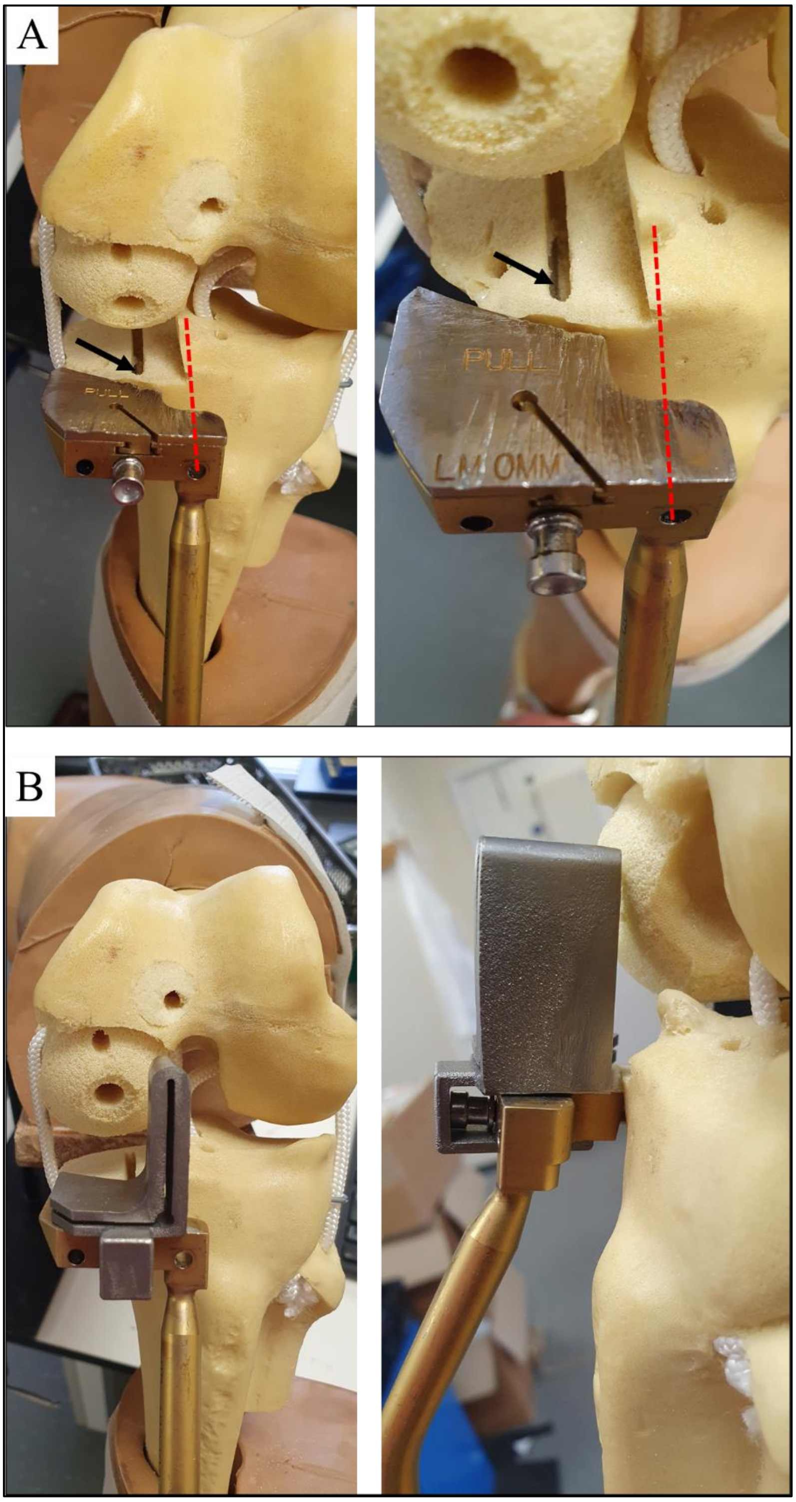


Figure 6.25 A Example of optimal tibial resection guide positioning with a single nail used through the central hole of the resection guide in a prepared Sawbones knee. For illustrative purposes, the red dashed line indicates the lateral hole of the resection guide aligned to the medial tibial spine. The black arrow indicates where the nail passes through the keel slot. **B** The same knee and resection guide positioning with the prototype drill bit resection guide in place. Note that the latch of the prototype guide is positioned over the head of the nail.

The position and orientation of the tibial resection was found to significantly impact the LTF of tibial condyles machined in Sawbones based on the anatomy of Case 2. Independently, positioning the cementless OUKR tibial component 3 mm more medial, 3 mm more distal, and 5° more valgus all decreased the LTF significantly compared to the Non-Fracture position (**Figure 6.21**). Therefore, to minimise the risk of OUKR TPF surgeons should aim to position the tibial component as lateral as possible by making the vertical resection immediately medial to the medial tibial spine [24]. In patients with very small tibias, surgeons should aim to use the thinnest Size 3 bearing to reduce the risk of TPF with the cementless OUKR. This can be achieved by using the Microplasty instrumentation, using the 3G clamp to set the resection depth, and avoiding making a recut [190]. The current Microplasty instrumentation uses an extramedullary guide which facilitates an orthogonal resection made perpendicular to the long axis of the tibia [190]. However, in patients with small tibias, tibia vara, or an overhanging medial tibial condyle, using this technique can result in the tibial component being positioned so that the keel is very close to the tibial cortex, especially posteriorly [228, 321]. Hiranaka et al. have proposed a custom, adjustable ankle yoke which allows the tibial component to be implanted in varus [321]. Varus implantation of the OUKR tibial component has been shown to increase the distance between the tibial keel and posterior cortex and decrease the risk of TPF in Japanese patients [320, 343]. Similarly, for models of Case 2 used in this study the distance between the keel slot and posterior cortex decreased by 0.3 mm (3.9 mm to 3.6 mm) when positioned in 5° more valgus compared to the Non-Fracture position (**Table 6.7**). It has been shown that OUKR outcomes are not compromised if the tibial component is positioned within ±5° varus/valgus [295]. Therefore, positioning the tibial component in up to 5° of varus may have the benefit of reducing TPF risk without compromising outcomes. There is likely to be some error in component placement (i.e. a surgeon aiming for 5° of varus may implant the component at 7° varus), so to be cautious it is recommended that surgeons aim for approximately 3° of varus to avoid potentially compromising outcomes.

Kamenaga et al. identified that the posterior keel to cortex distance for cementless OUKRs was shorter for knees that had a TPF (mean 2.7 mm) than those without (3.6 mm) [342]. This study also found that the distance between the keel slot and posterior edge of the specimen (representative of the cortex) had a strong, positive correlation with LTF (**Figure 6.22**). This result suggests that a greater distance between keel and posterior cortex will decrease the risk of cementless OUKR TPF. Furthermore, all component positional changes that decreased LTF (3 mm medial = 1.3 mm decrease, 3 mm distal = 1.2 mm decrease, Fracture position = 1.8 mm decrease) also decreased the keel to cortex distance compared to the Non-Fracture position. When the component was externally rotated by 20° relative to the Non-Fracture position, there was a relatively small reduction (0.5 mm) in distance between the keel slot and posterior cortex, which may explain why this positional change did not significantly reduce LTF. When the relationship between LTF and the shortest overall distance between the keel slot and cortex (either anterior or posterior) was considered in this study, there was an even stronger positive correlation. This suggests that the distance between the keel and the proximal tibial cortex, whether that be anteriorly or posteriorly, is one of the main factors influencing LTF.

Reducing the tibial component Size from C to B did not significantly alter LTF when positioned in the Non-Fracture position but it did increase the LTF when the component was in the fractured position (**Figure 6.20**). In the Fracture position, the distance from the posterior cortex to keel slot was larger for the Size C component (2.8 mm) compared to the Size B component (2.1 mm). However, the distance from the anterior cortex to the keel slot was very small when the Size C component was used (1.4 mm, compared to 3.3 mm for Size B) which may explain the lower LTF. The decrease in LTF with the Size C component in the fracture position may also be due to the larger component having a greater amount of overhang and therefore having a lower proportion of the component being supported by Sawbones. Tibial component overhang has previously been suggested as a risk factor for cementless OUKR TPF [343]. Overall, these results suggest that if the component is adequately positioned, oversizing the tibial component by one size is unlikely to increase the risk of cementless TPF, but it may increase the risk of TPF if the component is poorly positioned. However, surgeons should aim to avoid tibial component oversizing by selecting the component size that is flush with the tibial cortex posteriorly and does not overhang anteriorly, as recommended by the designer surgeons [24].

6.4.1 Limitations

As a single density trabecular bone analogue, Sawbones has distinct advantages compared to other testing materials, as outlined in **Table 6.3**. However, it also has several limitations when used for LTF testing. Firstly, Sawbones cannot replicate the material properties of the tibial cortex. Composite tibial bone analogues exist. These use short fibre filled epoxy as a cortical bone analogue filled with solid rigid polyurethane foam as the trabecular bone analogue [358]. However, the cortex on these composite tibial bone analogues is too thick and unrealistic. They are also two orders of magnitude more expensive than the Sawbones used in this Chapter. Studies using composite bone analogues for fracture studies have been published [359] but the experiments in **Chapters 6 and 7** of this thesis are the first to use a simplified Sawbones fracture model. As such, the LTF model and protocol used is not validated. However, the method used did allow differences in LTF between slot preparations to be evaluated and give clinical insight into TPF risk.

The fractures in Sawbones occurred instantaneously in this study. Clinical reports suggest TPFs with the OUKR either occur intraoperatively during impaction of the tibial component or in the early post-operative period after weight-bearing, which is possibly due to a microfracture that occurred intraoperatively propagating after repetitive loading [226, 333-336]. Therefore, loading specimens at 0.17 mms^{-1} until failure, as was done in this Chapter, is not representative of the clinical TPF mechanism. As the exact mechanism of OUKR TPF is not known and probably varies between cases, it is impossible to replicate the loading pattern that causes clinical TPFs. All experiments in this Chapter were comparative studies between different tibial preparation conditions. In these studies specimens were loaded to failure with the servo-hydraulic arm compressing the tibial component at a constant displacement, which allowed the test conditions to be controlled and facilitated a controlled comparison between conditions. Therefore, it is likely LTF correlates with TPF risk, but further studies are required to understand how instrumentation changes translate to clinical TPF risk.

The Sawbones specimens, except for the machined Sawbones tibias, are limited as they are simplified specimens that do not reflect the complex anatomy of the proximal tibia. Despite their simplicity, they were able to be reproduced consistently to enable controlled comparisons between different conditions. The machined Sawbones tibias are also limited as they only represent the anatomy of one patient and therefore the results may not be generalisable to all OUKR patients. However, the results of the machined Sawbones tibias are likely to be representative of Asian patients with small tibias who have the highest known risk of TPF with the OUKR [228].

For the tibial resection experiments, the effect of the interaction between the cementless OUKR keel and keel slot was not factored into the study. The no keel tibial component was used to control this variable to focus on the tibial resection preparation method.

Consequently, the potential effect of the interference press-fit of the keel on LTF in combination with resection method could not be assessed. As both cemented and cementless OUKR require the same tibial resection, the results of this study are applicable to both implant types. However, the studies of tibial nail and tibial component position used a cementless OUKR component, and therefore are not applicable to cemented OUKR.

There are many combinations of possible nail positions relative to the tibial component. This study only tested four possible combinations: no nails (as a baseline) and the two most common nail locations based on review of OUKR post-operative radiographs with either a hole at each or both locations. It was impractical to test every possible combination of positions in mechanical experiments, but these experiments did give insight into the effect of common nail positions on LTF. Testing a larger range of nail positions is a task that could be performed using FEA.

6.5 CHAPTER SUMMARY

Vertical overcut is a major risk factor for OUKR TPF which can be minimised by use of the proposed prototype drill bit guide, which also minimises the risk of fracture compared to the standard resection method. Nail hole number and position is a minor risk factor for OUKR TPF. As recommended by the designer surgeons, one nail should be used to fix the tibial resection guide to minimise the risk of TPF and this nail should be positioned near the keel slot. This can be achieved with the current resection guide by aligning the lateral hole of the resection guide with the medial tibial spine and fixing the guide with a nail through the central hole. In patients with small tibias, positioning the cementless OUKR tibial component more medially, distally, or valgus increases the risk of TPF. It appears the driving factor behind TPF risk in these studies is the distance between the keel slot and tibial cortex, which supports previous clinical findings. Therefore, to minimise the risk of cementless OUKR TPF surgeons should aim to make the vertical cut immediately medial to the medial tibial spine, make a conservative tibial resection using the 3G clamp, and consider implanting the component in slight (<5°) varus.

CHAPTER 7 – OPTIMISING THE TIBIAL KEEL SLOT FOR THE CEMENTLESS OUKR

7.1 CHAPTER MOTIVATION

7.1.1 Background

Independent of the tibial resection factors associated with an increased risk of TPF explored in **Chapter 6**, the cementless OUKR has a higher risk of TPF compared to the cemented OUKR [31, 203]. This was demonstrated by a cadaveric study in which tibias (with a vertical overcut) were loaded with a cementless OUKR tibial component and fractured at less than half the load of tibias loaded with a cemented component [203]. A higher risk of TPF for cementless OUKR is thought to be largely due to the interference press-fit of the tibial keel into a slot cut in the proximal tibia (see **Figure 1.4).** This interference press-fit is essential for primary fixation of the cementless OUKR tibial components, although likely also contributes to TPF risk. Furthermore, most cementless OUKR TPFs reported in the literature pass through the keel slot [226, 333-336].

When the wider keel (typically 3.7-3.8 mm wide, variable due to the thickness of the hydroxyapatite-coated porous titanium) is implanted in a narrower slot (~3.0 mm wide when prepared using the saw recommended by the manufacturer) it creates a tensile force on the surrounding tibial bone. It has been postulated that during impaction of the tibial keel that the resulting stresses in the surrounding bone are large enough to cause microfractures [204, 360]. With excessive impaction, or in a patient with risk factors for TPF (as described in **Table 6.1**), these microfractures may propagate to the cortex resulting in a complete TPF intraoperatively. Alternatively, these microfractures may not propagate intraoperatively but instead propagate in the weeks and months after the operation once the patient begins weight-bearing and using the limb more vigorously. This hypothesis would account for the observation that TPFs usually occur intraoperatively or in the early post-operative period [226, 333-336].

7.1.2 Aims

If OUKR TPFs involving the keel slot do occur as described above, it is likely the TPFs initiate at stress risers. The hypothesis of this chapter is that eliminating stress risers in the tibial keel slot may reduce the risk of OUKR TPFs. The major stress risers in the keel slot are the interference between the tibial keel and the slot (a material discontinuity) and the corners/ridges of the slot created by the keel slot saw (geometric discontinuities) (**Figure 7.1**) [345]. The interference between the cementless tibial keel and the slot has already been studied extensively. Campi et al. established that the optimal interference between the tibial keel and keel slot is 0.7 mm, which at the time was lower than the 0.9 mm to 1.3 mm interference used clinically [322]. This interference maximises pull out force (a surrogate measure for the strength of primary fixation) without greatly increasing push in force (a surrogate measure for the force required to implant the component, and therefore risk of TPF). Further experiments by Mohammad et al. demonstrated that widening the keel slot sawblade by 0.2 mm decreased push in force without decreasing pull out force, hence lowering the risk of TPF without compromising primary fixation [204]. This wider sawblade is now the Standard Sawblade recommended for use by the OUKR manufacturer (**Table 7.1**).

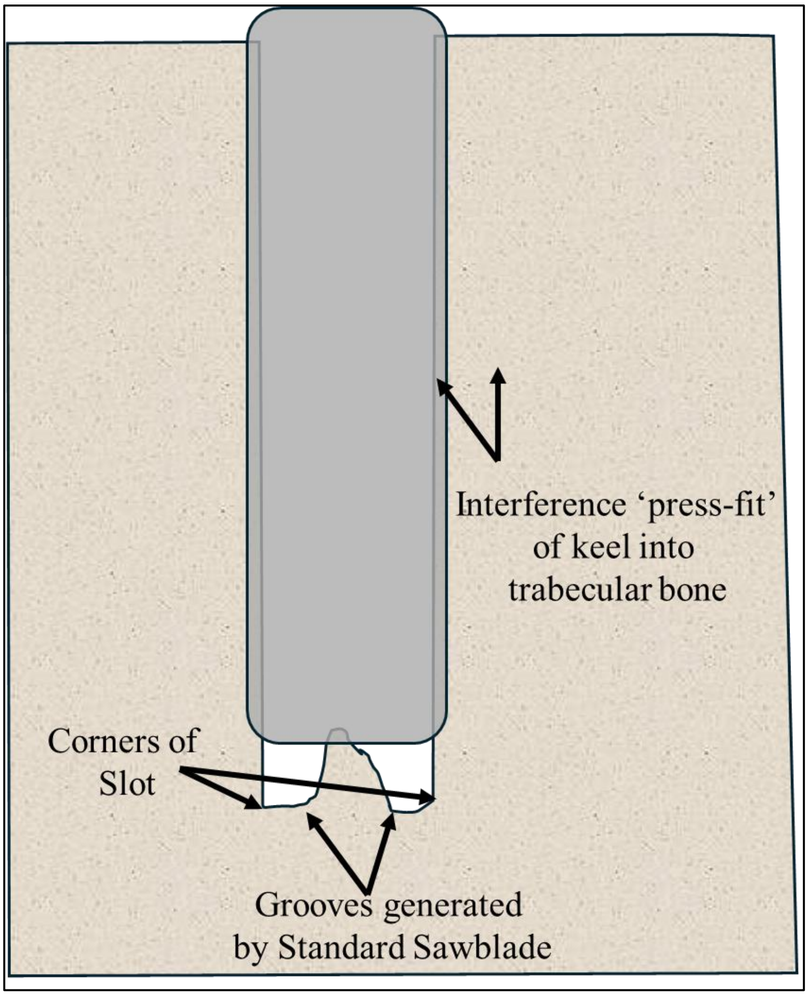


Figure 7.1 A diagram of a coronal section of the keel (grey) of a cementless Oxford Unicompartmental Knee Replacement implanted in a keel slot in the proximal tibial bone with potential stress risers indicated.

In contrast, the role of keel slot geometry in TPF risk has not been studied previously. Rahman's thesis explored whether changes in the design of the keel could reduce LTF in a small tibial fracture model (like the machined tibias described in **Section 6.2.5**). He found that reducing keel size, or replacing the keel with two pegs as the fixation element, significantly increased the LTF [360]. However, Rahman did not explore how changes in slot preparation effect LTF.

It is hypothesised that a rounder geometry will eliminate stress risers and decrease the risk of OUKR TPF. Therefore, the experiments in this Chapter aimed to:

1. Determine if the keel slot saw, with or without the use of adjuvant instruments, can be modified to produce a rounder slot.
2. Investigate whether a rounder geometry can reduce the risk of OUKR TPF.
3. Investigate whether changes to the slot geometry compromise primary fixation of the OUKR tibial component.

7.2 METHODS

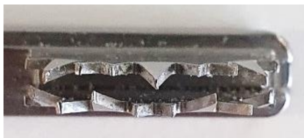
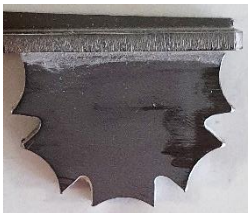
7.2.1 Testing Material

As in **Chapter 6,** Sawbones (20PCF solid rigid polyurethan foam, discussed in **Section 6.2.1**) was used for the mechanical testing completed in this Chapter.

7.2.2 Slot Preparation Instruments

The instruments shown in **Table 7.1** were used, either individually or in combination, to prepare keel slots in Sawbones. The dimensions of these instruments are included in **Table 7.2**. All instruments, except for the cemented pick, were used through a cutting template (**Figure 7.2**).

Table 7.1 Oxford Unicompartmental Knee Replacement Tibial Keel Slot Preparation Instrument Images

Instrument	Description	Lateral Profile	Inferior Profile
Standard Sawblade	Double blade sawblade recommended for keel slot preparation by the manufacturer. Manufactured by Synvasive from stainless steel.		
Prototype Round Sawblade	Double blade sawblade based on the design of the Standard Sawblade but with a semi-circular lateral profile and teeth of the double blades curved inwards with the aim of generating a ‘rounder’ slot profile.		
Gomina Standard Sawblade	A single blade sawblade designed to minimise the risk of tibial periprosthetic fracture without increasing the rate of tibial component loosening compared to the Standard Sawblade. Different widths (2.50 mm, 2.65 mm, and 2.75 mm) were trialled, with the 2.75 mm-wide design found to lower the rate of fracture without increasing the rate of loosening by one retrospective study [205]. Manufactured by Gomina (Niederwald, Switzerland) from stainless steel.		
Gomina Narrow Sawblade	Same design as Gomina Standard Sawblade, but 0.25 mm narrower.		
Manual Rasp	Semi-circular sawblade with 18 small, 2 mm-deep teeth all curved towards the handle. Designed to be used manually as an adjuvant for the standard sawblade. 3D-printed in titanium.		
Powered Rasp	Identical design to the Manual Rasp other than the anterior nine teeth face forward and the posterior nine teeth towards the hub which connects to a reciprocating saw. Designed to be used under reciprocating power. 3D-printed in titanium.		

Instrument	Description	Lateral Profile	Inferior Profile
Aggressive Rasp	Based on the Powered Rasp, but with fewer (12) 3 mm-deep teeth. Designed to be used under reciprocating power. 3D-printed in titanium.		
Cemented Pick	Included in the standard OUKR instrument set provided by the manufacturer. Originally designed to clear out the keel lot for the cemented tibial keel. However, many surgeons now use this instrument clinically to widen the keel slot for the cementless tibial keel.		
Buffer Sawblade	A modified version of the Standard Sawblade with ~5 mm stainless steel ‘buffers’ added on the anterior and posterior ends of the sawblade. This design prevents the saw from reaching the anterior and posterior ends of the slot in the cutting template, resulting in a slot that is ~5 mm shorter at each end.		

Table 7.2 Tibial Keel Slot Preparation Instrument Measurements

Instrument	Length (mm)	Width (mm)	Depth (mm)
Standard Sawblade	15.0	2.8	12.4
Prototype Round Sawblade	19.0	2.8	11.8
Gomina Standard Sawblade	18.0	2.75	12.8
Gomina Narrow Sawblade	18.0	2.7	12.8
Manual Rasp	18.7	2.5	12.4
Powered Rasp	18.7	2.5	12.4
Aggressive Rasp	19.6	2.8	12.5
Cemented Pick	2.5	3.3	12.4
Buffer Sawblade	15.0 (blade only) 26.3 (with buffers)	2.8	12.4

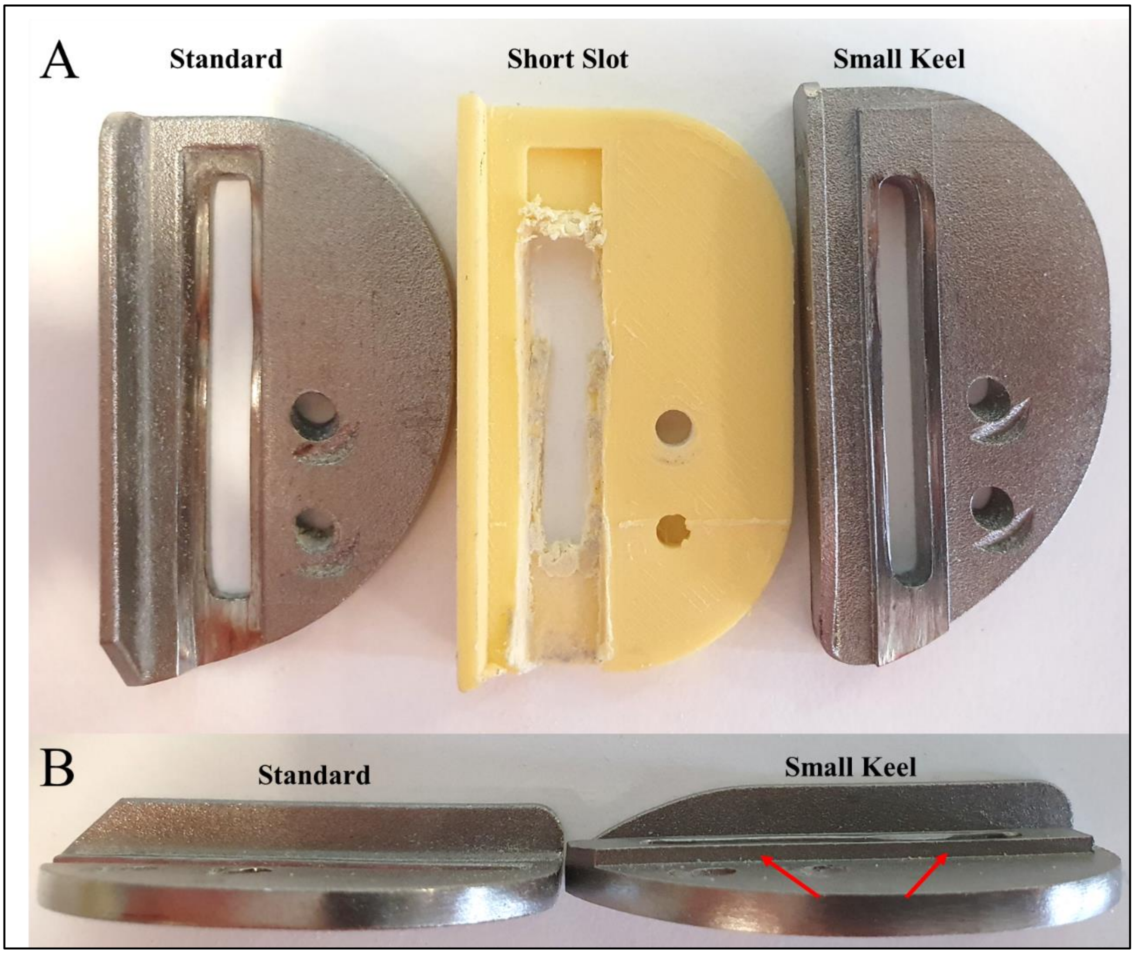


Figure 7.2 Superior view of keel slot cutting templates. **A** From left to right, the Standard Size A tibial keel slot cutting template, the **'**Short slot' tibial keel slot cutting template and Modified Size A tibial keel slot cutting template compatible with the small keel component. **B** Lateral view of the standard and small keel variant of the keel slot cutting template. Red arrows indicate the 3 mm raised slot on the small keel variant which creates a shallower slot when the Standard Sawblade is used.

7.2.3 Tibial Components

For LTF experiments, the Standard Size A cementless and 'No Keel' Size A cementless components were used (**Figure 7.3)**. In addition, a 'No Interference' Size A cementless component (**Figure 7.3A**) and 'Small Keel' Size A cementless component (**Figure 7.3B**) were used. The no interference component had a thinner keel (2.9 mm) compared to the standard component (3.55 mm), which meant that in a slot cut with the Standard Sawblade it had no interference. The small keel component had the same keel width (3.55 mm) as the standard component, so had the same interference. However, the keel was shorter (24 mm) and shallower (6 mm) than the standard component. Rahman optimised the small keel design by proportionately reducing the size of the keel and ensuring its surface area of the keel remained the same as the standard keel (**Figure 7.3B**) [360].

There are seven tibial component sizes from AA (smallest) to F (largest). The tibial component is scaled across all tibial component sizes except for the width (3.7-3.8 mm for hydroxyapatite-coated, clinically-used components) and depth (9 mm) of the keel which are constant across all sizes. Constant keel width allows the same instruments to be used to prepare the keel slot for all tibial component sizes, while the constant depth was designed to ensure adequate fixation across all sizes. Consequently, in smaller components the keel is relatively deeper. This relatively deeper keel means there will be less bone volume below the keel when smaller tibial component sizes are used which may increase TPF risk with the cementless OUKR. To minimise risk of TPF with the cementless OUKR in small tibias without compromising fixation, the keel size was scaled down from a Size F component (which is known to have adequate fixation) to a Size A component. To avoid compromising fixation, the same keel surface area was retained by removing the window feature.

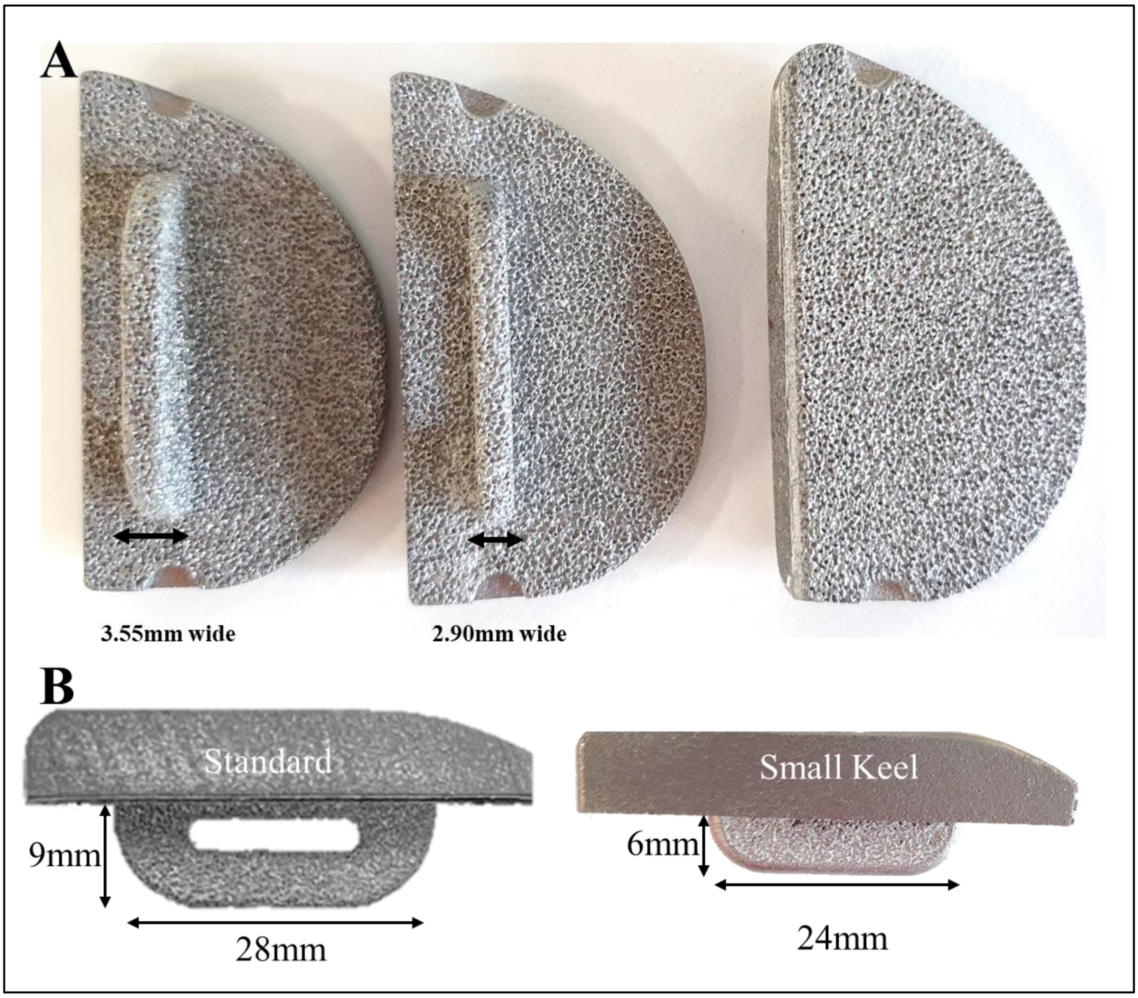


Figure 7.3 A The inferior surface of the Standard Size A cementless tibial component (left) compared to the 'No Interference' Size A cementless tibial component (middle) and 'No Keel' Size A cementless tibial component (right). All have a porous titanium coating on their undersurface and/or keel. **B** Lateral view of the Standard Size A cementless tibial component (left) and 'Small Keel' Size A cementless tibial component (right). The Small Keel component has a shorter and shallower keel than the standard component, but the keel is the same width. The inferior surface of the Small Keel is smooth titanium rather than porous.

7.2.4 Slot Dimension Analysis

Slots were made in Sawbones using the instruments listed in **Table 7.2**. and sectioned into 2 mm coronal slices from anterior to posterior or a single sagittal slice using a micro bandsaw (MBS 240/E, Proxxon Micromot System). Photos were taken of these slots on a black cotton cloth background. The images were inspected and described by the author and processed using a custom MATLAB program written by Jack Tu. This program used edge detection to create an outline of the slot sections from which slot dimensions were calculated (**Figure 7.4**). The roundness of slots was also estimated by the MATLAB program using an algorithm described in **Appendix A7.1.**

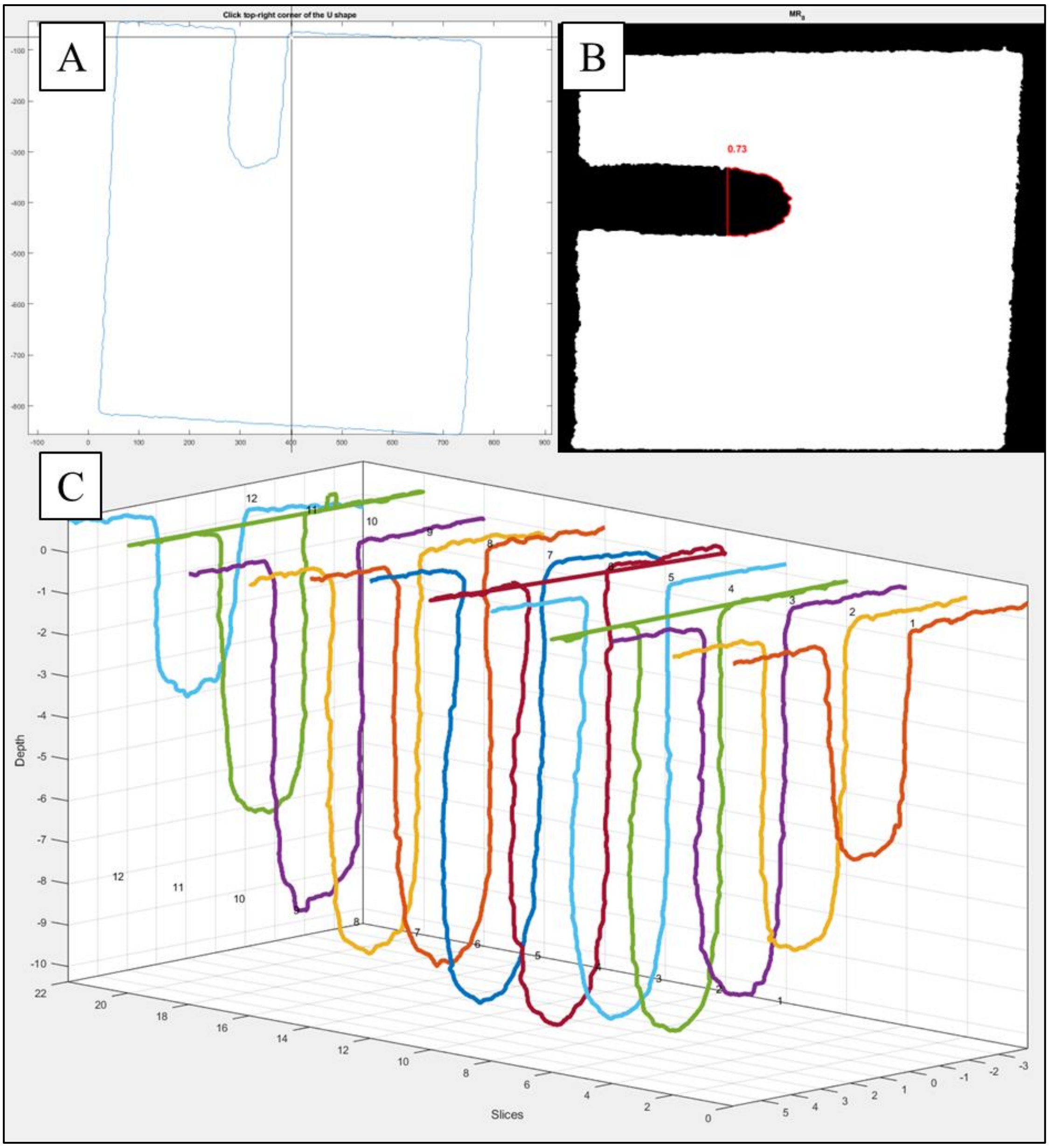


Figure 7.4 Example of Slot Dimension Analysis using the custom MATLAB program. **A** Edge detection to measure slot width and depth from a coronal slice. **B** Measurement to estimate roundness of the bottom of a slot. **C** A reconstructed slot geometry based on coronal slices of the slot.

7.2.5 Compact Tensile Testing

Compact Tensile Testing (CTT) was used as a preliminary test to evaluate the impact of slot geometry on LTF. This testing was conducted as per ASTM E399 the standard for plane-strain fracture toughness of metallic materials. Keel slots made in Sawbones were long enough to prepare three coronal specimens per slot of the required dimensions (**Figure 7.5**). Square and round slots were machined using 3.175 mm (1/8 inch) square-nose or round-nose end mill cutters, respectively.

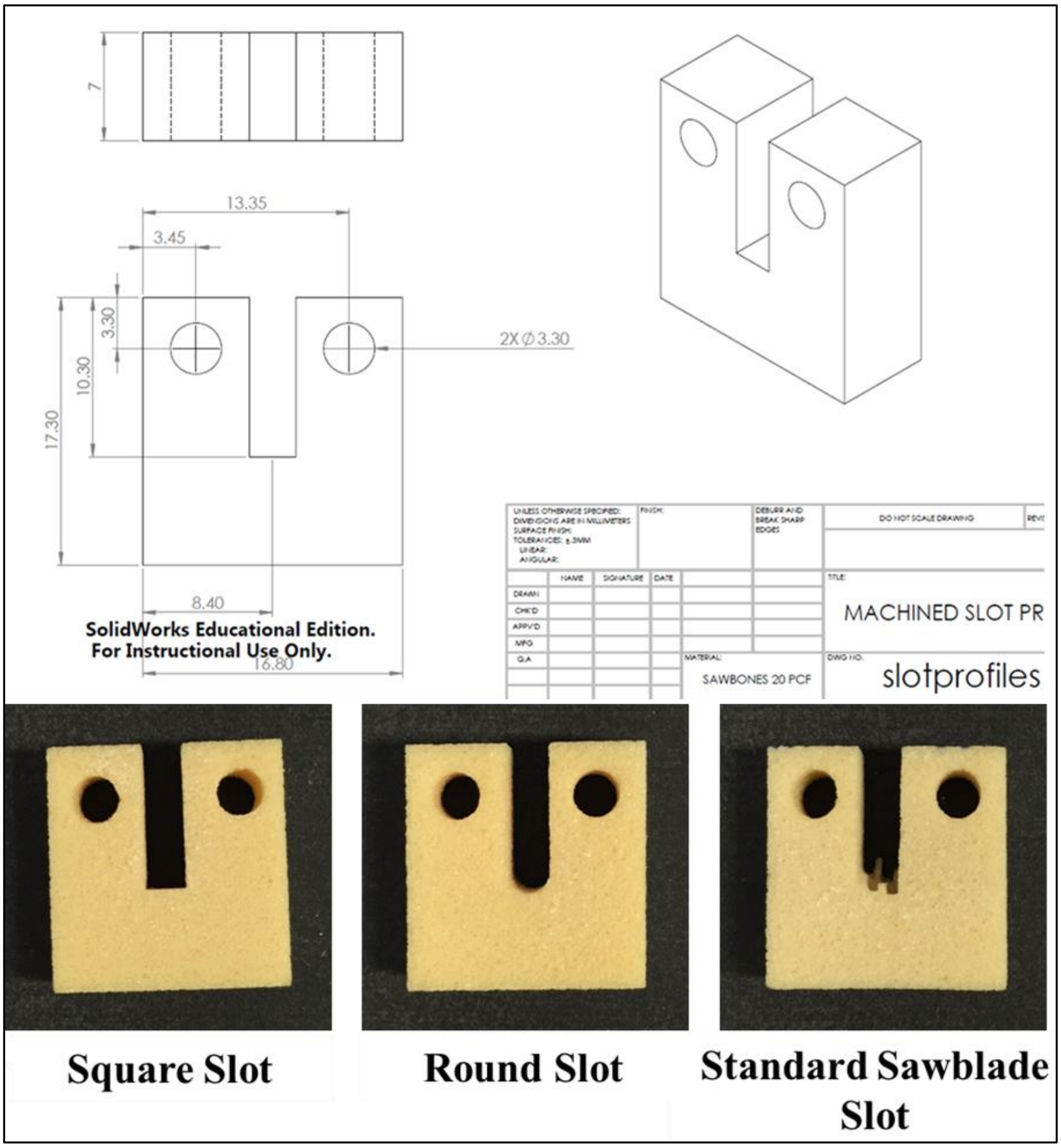


Figure 7.5 Top: Drawings for compact tensile testing specimens to be made in 20PCF solid rigid polyurethane foam with dimensions as required by ASTM E399. All measurements are in millimetres. **Bottom:** Examples of compact tensile testing specimens.

Once prepared, the specimens were loaded into a Materials Testing Machine (Proline Z005, ZwickRoell Ltd. Worcester, UK) with the specimens held by custom built holders that have a metal rod passing through each of the holes in the CTT specimens (**Figure 7.6**). Once positioned, the specimens were loaded to fracture using the protocol outlined in **Table 7.3**. Vertical force and displacement were measured by the materials testing machine.

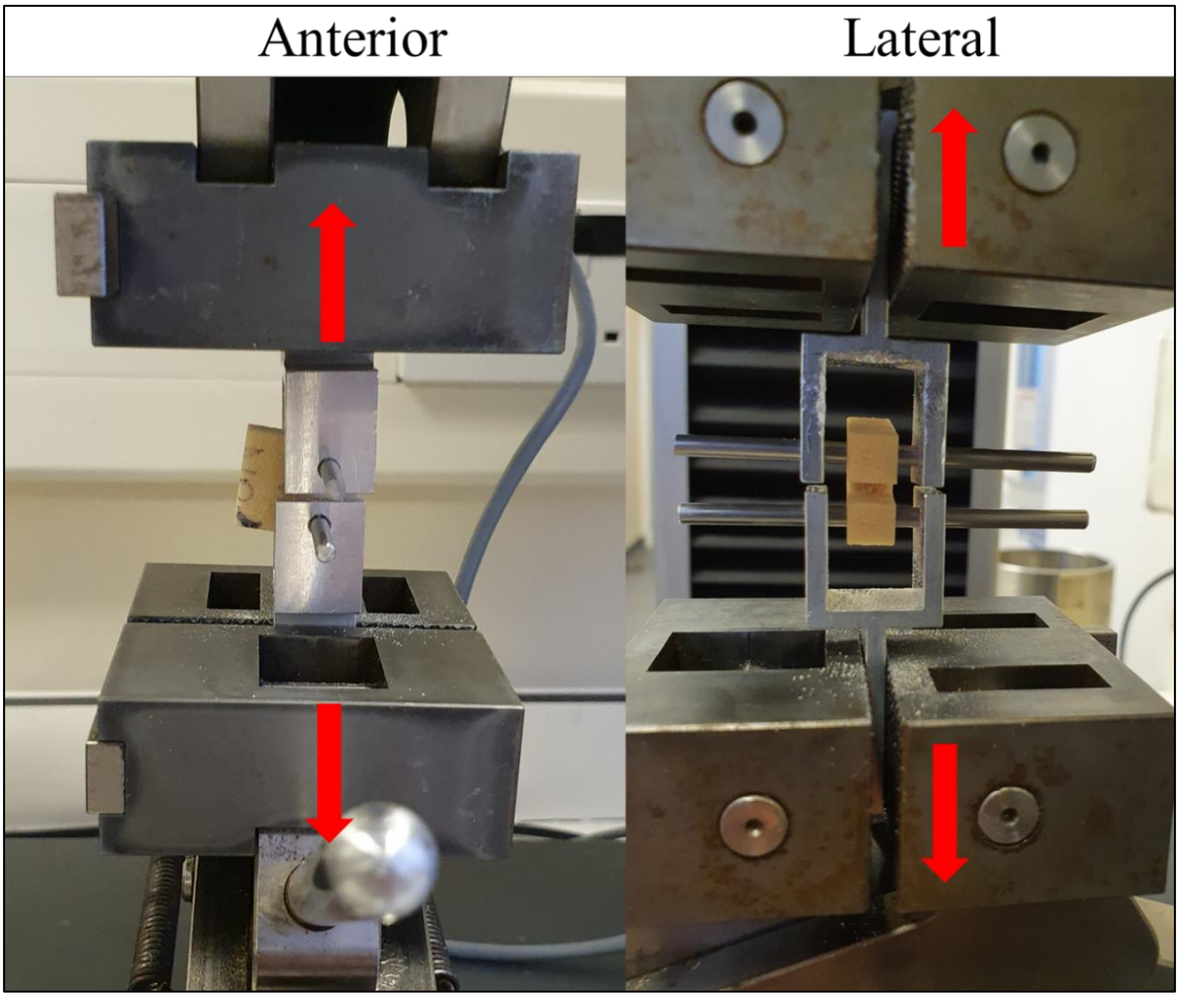


Figure 7.6 Experimental set-up for the compact tensile testing experiments showing an anterior and lateral view of a specimen loaded into the materials testing machine. The red arrows indicate the direction of the tensile load applied to the specimen.

Table 7.3 Compact tensile testing load to fracture protocol.

Test Step	Step Description
Step One – Position Loading Grips	The operator manually positions the loading grips so that they are spaced appropriately for the specimen to be positioned in the materials testing machine
Step Two – Preload	The loading grips separate at 1 mms^{-1} until a load of 1N is applied to the specimen.
Step Three – Load to Failure	The operator approves the test to continue. The loading grips separate at 1 mms^{-1} until the specimen fails.
Step Four – End Test	The test ends when a vertical force less than 75% of the maximum force is reach (i.e. the specimen has failed).

An attempt was made to validate the CTTs using bovine tibias. These experiments ultimately served as a demonstration of how unsuitable bovine tibias are for LTF testing. The results of these experiments are displayed and discussed in **Appendix A7.2.**

7.2.6 Load to Fracture Testing

LTF testing was completed using the method described in **Section 6.2.3.3**.

The standard tibial component was fully seated in slots cut in Sawbones blocks using a benchtop vice. The 'No Interference' component was implanted with finger pressure and the 'No Keel' component was simply positioned above on the block in the same location a component with a keel would be.

7.2.7 Push In Pull Out Testing

Campi et al., Mohammad et al., and Rahman have all previously used Push In Pull Out (PIPO) testing to assess the interaction between the keel and the slot of the cementless OUKR [204, 322, 360]. To complete PIPO testing, Slots were prepared using the instruments in **Table 7.1** in rectangular Sawbones blocks. A custom attachment connected to the Standard Size A cementless OUKR tibial component was fitted to the S-beam 2.5kN load cell and servo-hydraulic arm of the Dartec (**Figure 7.7**). The tibial component was implanted into to the full depth of the keel and then fully retracted from the slot as per the protocol outlined in **Table 7.4**. Force, displacement, and time data was recorded at 250Hz during the protocol.

Table 7.4 Push In Pull Out testing protocol for the servo-hydraulic testing machine and S-beam load cell

Test Step	Step Description
1 – Find Zero	A metal plate of known thickness (5.12 mm) is placed on top of the Sawbones. The servo-hydraulic arm lowers at 1 mms^{-1}. When a force >5N is detected by the load cell, the displacement of the servo-hydraulic arm is recorded.
2 – Remove Metal Plate	The servo-hydraulic arm retracts 5 mm at 10 mms^{-1} once a force is detected in Step 1 so that the metal plate can be removed by the test operator.
3 – Down to Zero	Once the metal plate is removed, the test operator then authorises the test to proceed. The servo-hydraulic arm lowers at 10 mms^{-1} to the upper surface of the slot (i.e. the zero point where the keel has not yet entered the slot).
4 – Push In	The servo-hydraulic arm extends at 0.17 mms^{-1} until it reaches 9 mm (6 mm for Small Keel components) below the zero level. At this level, the keel is fully implanted, but the baseplate of the tibial component should be slightly proud of the Sawbones block.
5 – Dwell for 10s	The component is left to dwell in the slot for 10 seconds.
6 – Retract to Look for Bounce Back	The servo-hydraulic arm retracts slowly at 0.017 mms^{-1} until the component is unloaded. This unloading phase was included to decouple the push in phase (where a force pushes the keel into the slot) and pull out phase (where a force is pulling the keel into the slot).
7 – Dwell for 10s	When the net vertical force on the servo-hydraulic arm is 0N, it stops moving and the keel dwells for 10 seconds.
8 – Pull Out	The servo hydraulic arm retracts at 0.17 mms^{-1} until the bottom of the keel is at the zero level.
9 – End of Test	The servo-hydraulic arm retracts 5 mm so that the Sawbones block can be easily positioned to test the next slot or be removed.

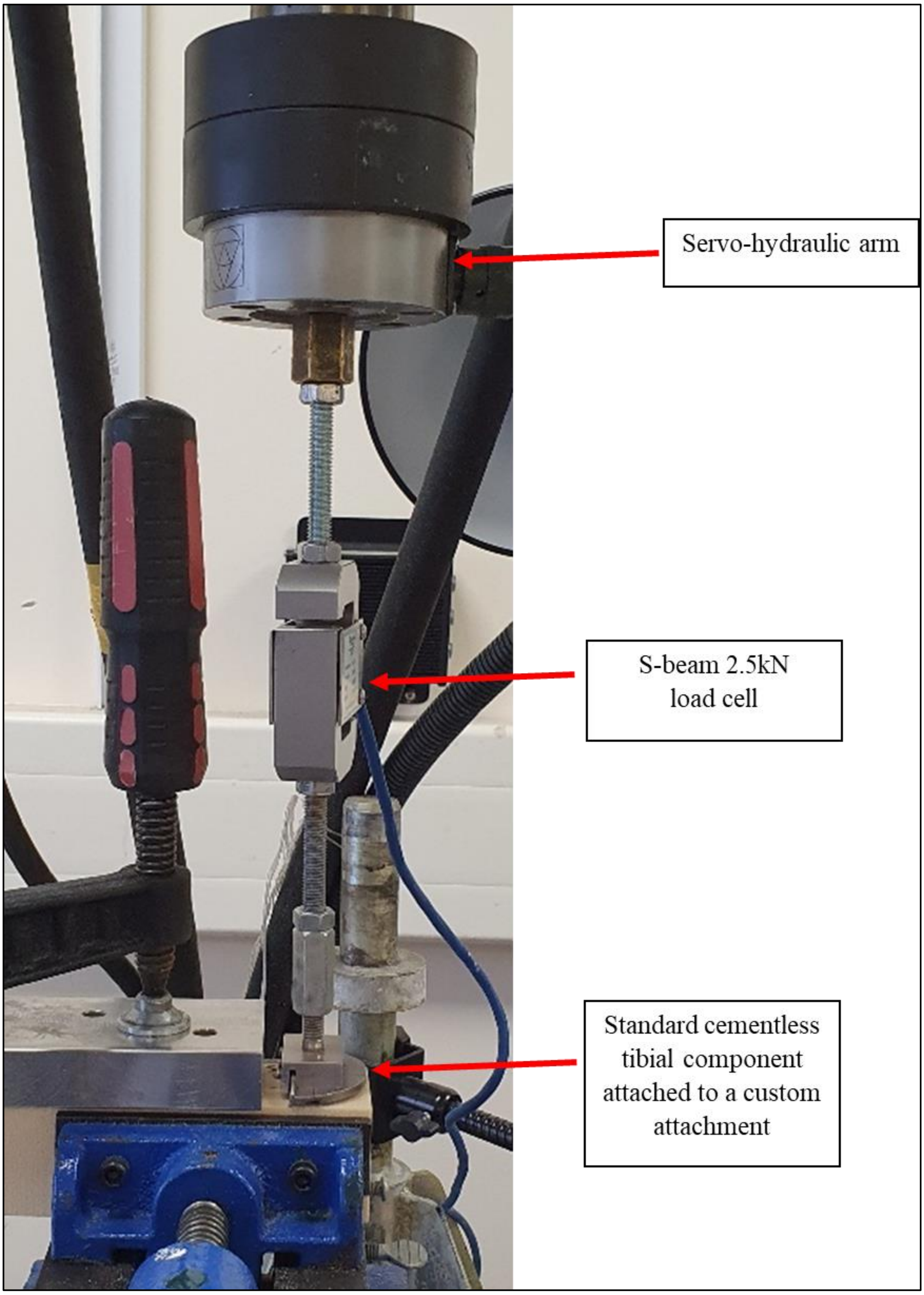


Figure 7.7 The typical Push In Pull Out test set-up. The Sawbones block is clamped horizontally and vertically while the standard cementless tibial Oxford Unicompartmental Knee Replacement component is completely pushed in and pulled out of a slot prepared in the block.

7.2.8 Statistical Analysis

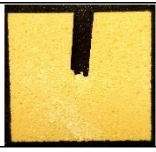
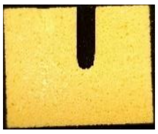
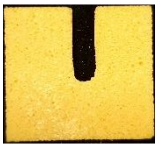
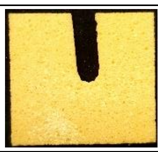
GraphPad Prism (version 10.2.0 for Windows, GraphPad Software, Boston, Massachusetts USA) was used for statistical analysis. When comparing the means of two groups, unpaired T-tests (Shapiro-Wilk $p>0.05$) were used for parametric data and the Mann-Whitney U-tests for non-parametric data (Shapiro-Wilk $p<0.05$). When comparing three or more groups, One-way ANOVA was used with Brown-Forsythe and Welch's ANOVA used when standard deviations were unequal. To compare the means of multiple groups to a control mean, Dunnett's T3 multiple comparisons test was used while Tukey's multiple comparisons test was used to compare the mean of each group with every other mean.

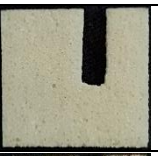
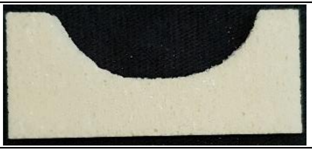
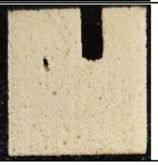
7.3 RESULTS

7.3.1 Keel Slot Dimension Analysis

Visual inspection of coronal slices of keel slots revealed it was possible to make rounder slots, particularly by using rasps, either manual or powered (**Table 7.5**). This observation was confirmed by roundness analysis, which indicated that all methods of slot preparation tried produced significantly rounder slots in the axial plane compared to the standard sawblade (**Table 7.6**). The slot prepared with the standard sawblade had a mean width of 3.0 mm (95%CI 2.7 to 3.0), a mean maximum depth of 10.5 mm (95%CI 10.4 to 10.6), length of 30 mm at a depth of 4 mm, and mean roundness of 0.62 out of 1 (95%CI 0.59 to 0.64). In comparison, use of the manual rasp (3.3 mm, $p<0.05$) and cemented pick (3.3 mm, $p<0.01$) in addition to the standard sawblade increased the mean slot width. The powered rasp produced significantly narrower slots (2.5 mm, $p<0.0001$) as did the aggressive rasp (2.9 mm, $p<0.05$). Compared to the standard sawblade the Gomina sawblade produced a significantly deeper slot (11.7 mm, $p<0.0001$) while the prototype round sawblade (10.0 mm, $p<0.0001$) and powered rasp produced shallower slots (9.0 mm, $p<0.0001$).

Table 7.5 Axial and Sagittal Cross Sections of Different Slot Preparations

Slot Preparation	Coronal Cross Section	Sagittal Cross Section (Anterior = Left, Posterior = Right)
Standard Sawblade		
Prototype Round Sawblade		
Gomina Standard Sawblade		
Manual Rasp		
Standard Sawblade + Manual Rasp		
Prototype Round Sawblade + Manual Rasp		
Powered Rasp		
Aggressive Rasp		
Standard Sawblade + Cemented Pick		
Standard Sawblade (Short Template) + Manual Rasp		
Standard Sawblade (Small Keel Template)		

Slot Preparation	**Coronal Cross Section**	**Sagittal Cross Section (Anterior = Left, Posterior = Right)**
Buffer Sawblade + Manual Rasp		
Buffer Sawblade + Manual Rasp (Small Keel Template)		

As intended, the use of the small keel template with both the standard saw (7.8 mm, $p<0.001$) and buffer saw (7.7 mm, $p<0.0001$) produced significantly shallower slots. Slots prepared with the manual rasp, standard sawblade (short template) and manual rasp, or buffer sawblade and manual rasp all tended to have shorter slot lengths at a depth of 8 mm compared to standard sawblade slots.

Table 7.6 Slot Dimensions and Roundness. P-values shown are for Dunnett's T3 multiple comparisons test comparing measurements of the different slot preparations to the standard sawblade slots. 'ns' indicates a non-significant value of p>0.05.

Slot Preparation	**Mean Width, mm (95%CI) [p-value, comparison with Standard Sawblade]**	**Mean Maximum Depth, mm (95%CI) [p-value, comparison with Standard Sawblade]**	**Length (mm) at 4mm Depth**	**Length (mm) at 8 mm Depth**	**Mean Roundness, 0 = a line to 1 = a perfect circle (95%CI) [p-value, comparison with Standard Sawblade]**
Standard Sawblade	3.0 (2.7 to 3.0)	10.5 (10.4 to 10.6)	30.0	20.2	0.62 (0.59 to 0.64)
Prototype Round Sawblade	3.0 (2.9 to 3.1) [ns]	10.0 (9.9 to 10.1) [**p<0.0001**]	26.2	NA	0.74 (0.71 to 0.76) [**p<0.0001**]
Gomina Standard Sawblade	2.9 (2.7 to 3.0) [ns]	11.7 (11.4 to 12.0) [**p<0.0001**]	29.6	21.2	0.71 (0.69 to 0.73) [**p<0.001**]
Manual Rasp	3.2 (3.1 to 3.3) [ns]	10.0 (9.4 to 10.5) [ns]	28.8	15.1	0.70 (0.66 to 0.74) [**p<0.01**]
Standard Sawblade + Manual Rasp	3.3 (3.1 to 3.4) [**p<0.05**]	10.6 (10.6 to 10.7) [ns]	30.8	24.3	0.74 (0.73 to 0.75) [**p<0.0001**]
Prototype Round Sawblade + Manual Rasp	3.1 (3.0 to 3.2) [ns]	10.3 (10.2 to 10.4) [ns]	31.5	24.5	0.74 (0.73 to 0.75) [**p<0.0001**]
Powered Rasp	2.5 (2.5 to 2.6) [**p<0.0001**]	9.0 (8.9 to 9.2) [**p<0.0001**]	29.6	17.8	0.78 (0.76 to 0.80) [**p<0.0001**]
Aggressive Rasp	2.9 (2.8 to 2.9) [**p<0.05**]	10.0 (9.5 to 10.6) [ns]	25.8	16.8	0.75 (0.73 to 0.77) [**p<0.0001**]
Standard Sawblade + Cemented Pick	3.3 (3.2 to 3.5) [**p<0.01**]	10.5 (10.3 to 10.6) [ns]	30.5	19.7	0.70 (0.67 to 0.73) [**p<0.01**]
Standard Sawblade (Short Template) + Manual Rasp	2.9 (2.8 to 3.0) [ns]	10.4 (9.9 to 10.8) [ns]	29.3	16.4	0.72 (0.69 to 0.74) [**p<0.001**]
Standard Sawblade (Small Keel Template)	3.1 (3.0 to 3.2) [ns]	7.8 (7.3 to 8.3) [**p<0.001**]	26.2	NA	0.69 (0.66 to 0.72) [**p<0.01**]
Buffer Sawblade + Manual Rasp	3.1 (2.9 to 3.3) [ns]	10.1 (9.7 to 10.5) [ns]	29.8	16.4	0.71 (0.69 to 0.74) [**p<0.001**]
Buffer Sawblade + Manual Rasp (Small Keel Template)	3.1 (3.0 to 3.2) [ns]	7.7 (7.3 to 8.1) [**p<0.0001**]	20.6	NA	0.72 (0.70 to 0.74) [**p<0.0001**]

7.3.2 Compact Tensile Testing

Compared to CTT specimens from slots prepared using the standard sawblade (20.5N), CTT specimens from both square (26.4N, $p<0.0001$) and round (29.6N, $p<0.0001$) machined slots had a higher tensile LTF (**Figure 7.8**). The LTF of round specimens was also significantly ($p<0.01$) higher than square specimens. The fractures of the standard sawblade and square specimens occurred at stress riser locations. Standard sawblade fractures tended to occur at the deepest point of the slot grooves while fractures of the square specimens occurred at the slot corners (**Figure 7.8**). In comparison, the round specimens tended to fracture through the centre of the slot.

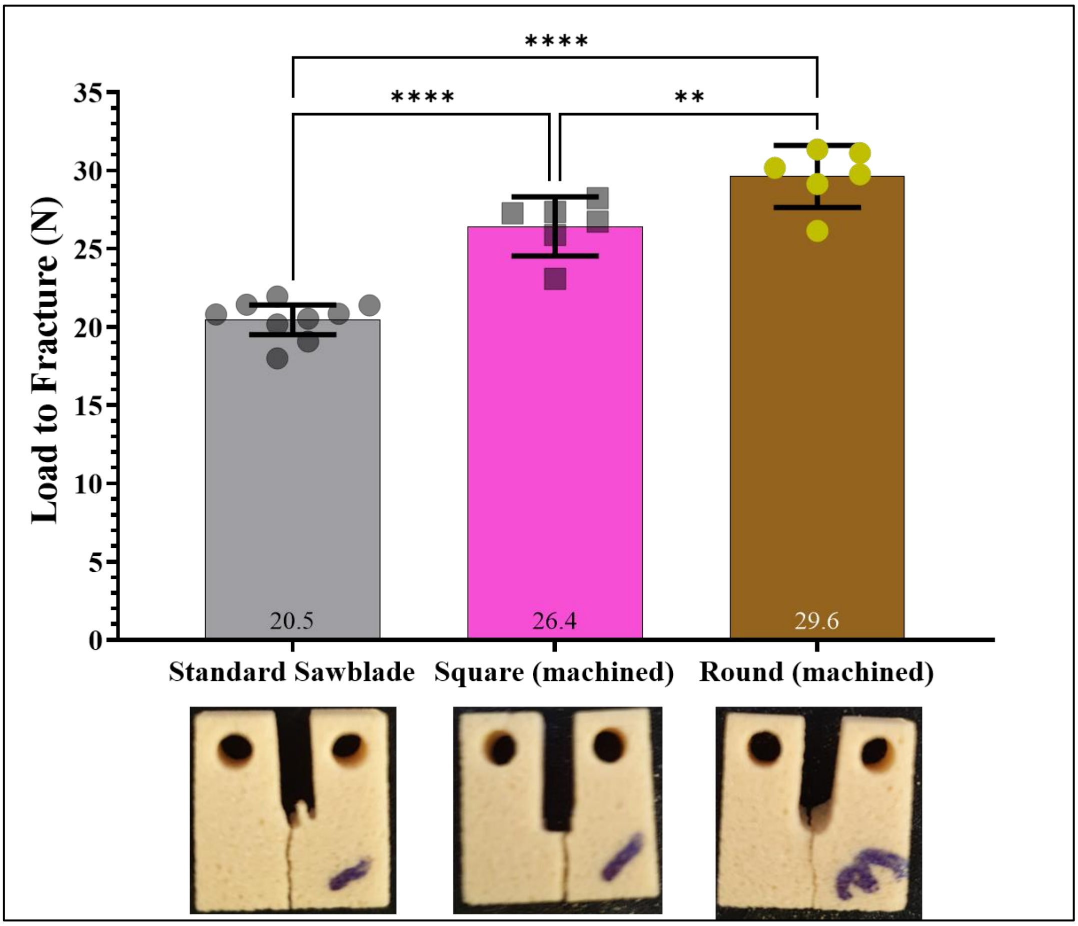


Figure 7.8 Load to fracture (mean ± 95% confidence intervals, individual results shown) of compact tensile testing specimens from standard sawblade, square machined, and round machined slots. Examples of fractured testing specimens are shown beneath the results for each preparation. Annotations indicate p-values for Tukey's multiple comparisons test: **$p<0.01$, ****$p<0.0001$.

Despite being rounder than the standard sawblade slots (**Table 7.6**), CTT specimens from slots prepared using the standard sawblade and rasp and prototype round sawblade did not have a significantly higher LTF than the standard sawblade CTT specimens (**Figure 7.9**). However, the LTF of the prototype round sawblade and rasp specimens (23.8N, $p<0.01$) was significantly higher than the standard sawblade. As shown in **Figure 7.9**, the fractures for the slots prepared with adjuvant use of the rasp tended to pass through the centre of the slot in the absence of stress risers. In comparison, slots prepared with either the standard or prototype round sawblades tended to fracture through the deepest groove in the slot.

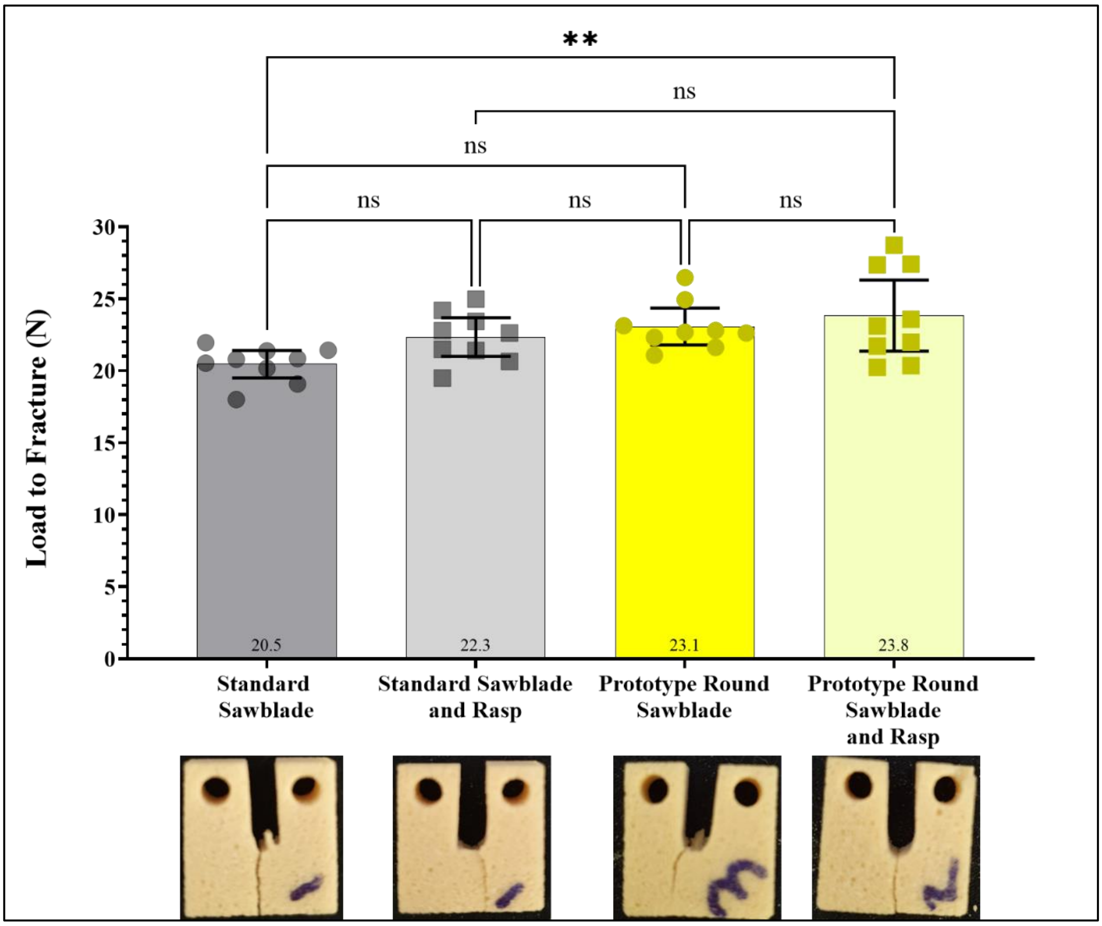


Figure 7.9 Load to fracture (mean ± 95% confidence intervals, individual results shown) of compact tensile testing specimens from standard sawblade, standard sawblade and rasp, prototype round sawblade, and prototype round sawblade and rasp. Examples of fractured testing specimens are shown beneath the results for each preparation. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates $p>0.05$, $^{**}p<0.01$.

7.3.3 Load to Fracture Testing

The interference between the keel of the standard cementless tibial component (3.6 mm wide) and a keel slot prepared with the standard sawblade (3.0 mm) is approximately 0.6 mm. Using the cemented pick widens the slot to 3.3 mm and therefore decreases the interference to approximately 0.3 mm. This decrease in interference significantly ($p<0.01$) increased LTF from 776N (95%CI 757 to 798) with the standard sawblade to 893N (95%CI 834 to 952) when the cemented pick was used as an adjuvant for slot preparation (**Figure 7.10**). When using a component with a thin (2.9 mm), zero interference keel that was narrower than the standard sawblade slot (3.0 mm) the LTF increased further to 974N (95%CI 904 to 1044). When a component with no keel was used the LTF increased again to 1042N (963 to 1121), however this was not significantly greater than the LTF of the component with the thin 'zero interference' keel. These results indicate that decreasing interference increases the LTF, and that the presence of a keel alone does not increase risk of fracture, given there is no significant difference in LTF between the zero interference keel and no keel components. Similar results were found with the Gomina sawblade, which had a significantly higher LTF when a 2.75 mm wide sawblade was used compared to 2.5 mm wide (**Figure 7.11**).

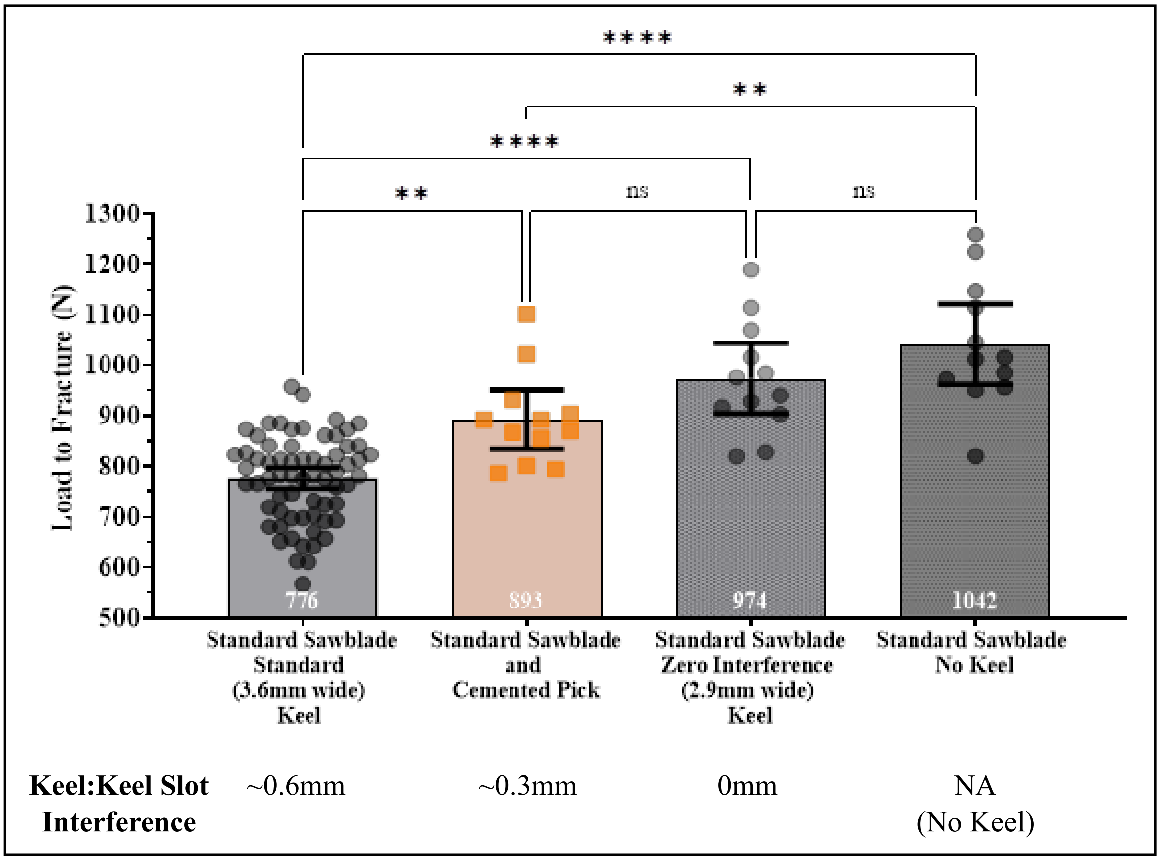


Figure 7.10 Load to fracture (mean ± 95% confidence intervals, individual results shown) of specimens with different interferences. The keel to keel slot interference is indicated below each slot preparation. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates p>0.05, **p<0.01, ****p<0.0001.

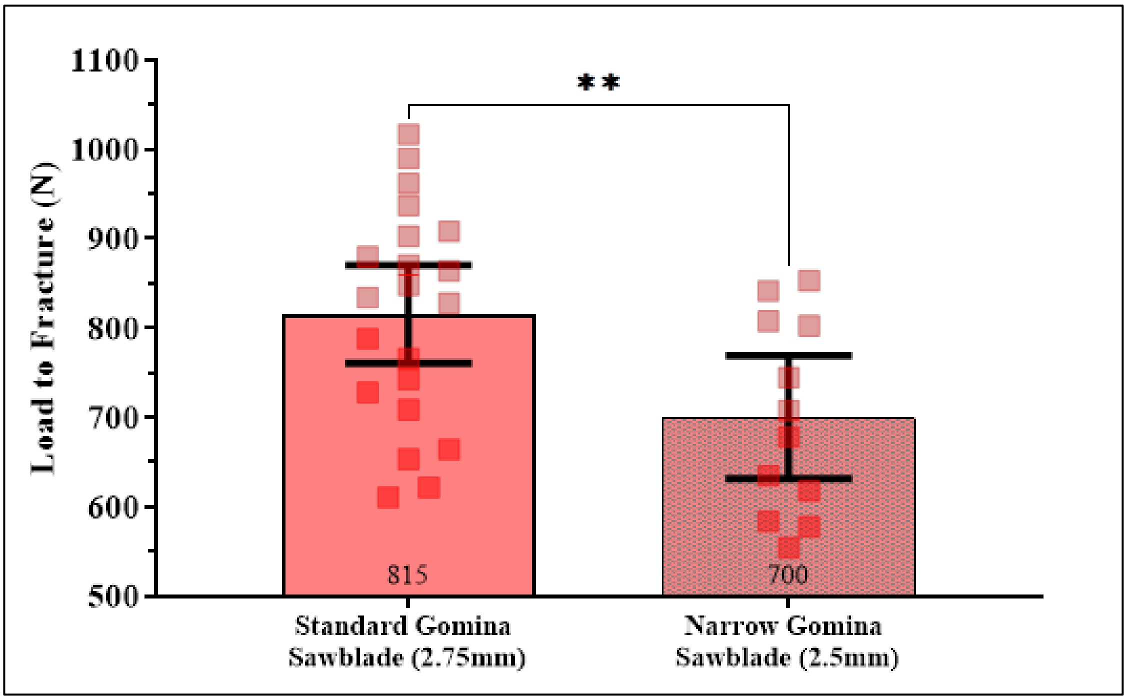


Figure 7.11 Load to fracture (mean ± 95% confidence intervals, individual results shown) of standard Gomina sawblade (2.75 mm wide) and narrow Gomina sawblade specimens (2.50 mm wide). Annotations indicate p-values for Welch's T-test: **p<0.01.

Given the rounder prototype round sawblade and rasp CTT specimens had a higher LTF compared to the standard sawblade specimens (**Figure 7.9**), it was hypothesised that they would also have a higher LTF when loaded with a cementless OUKR tibial component. However, there was no significant difference in LTF between slots prepared using the standard sawblade, standard sawblade and rasp, prototype round sawblade, or prototype round sawblade and rasp (**Figure 7.12**).

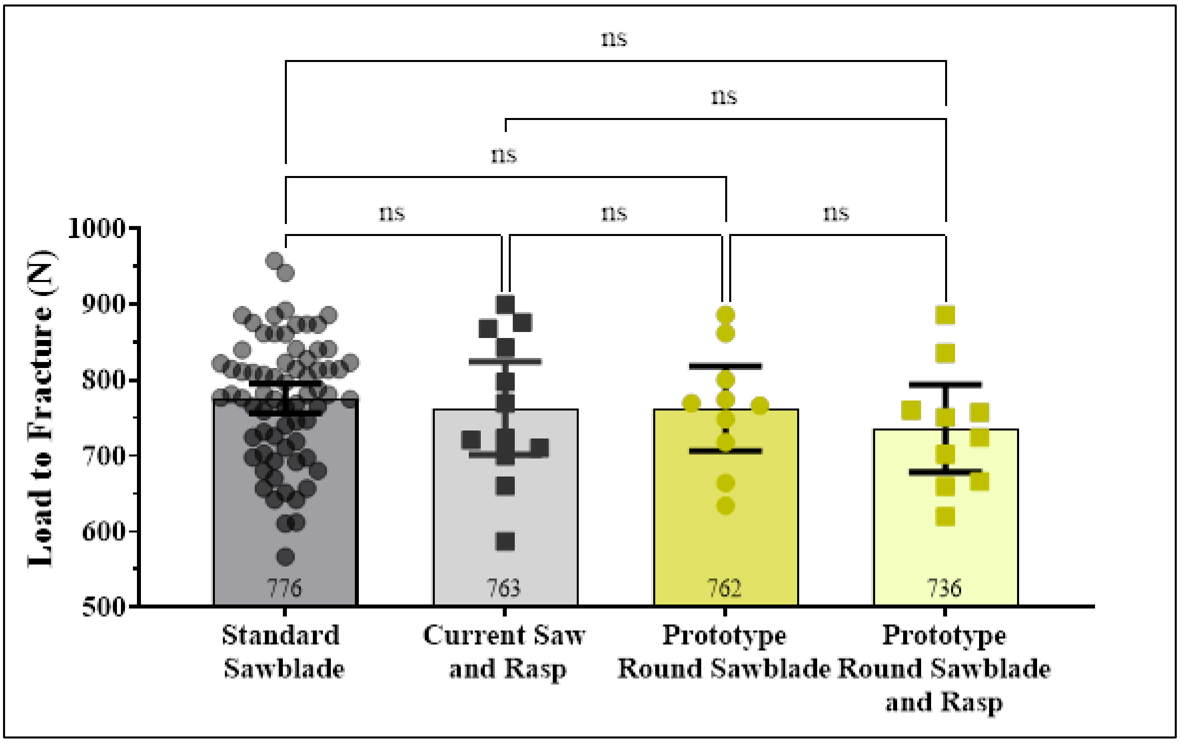


Figure 7.12 Load to fracture of slots prepared using the standard sawblade, standard sawblade and rasp, prototype round sawblade, and prototype round sawblade and rasp. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates $p>0.05$.

As altering the shape of the bottom of the slots (**Figure 7.12**) did not increase the LTF, the effect of altering the geometry at the anterior and posterior ends of the slot was investigated. As seen in **Table 7.5**, the Gomina sawblade creates a deeper slot but also leaves more material at the anterior and posterior ends of the slot with a step-like geometry that reflects the shape of the sawblade (see **Table 7.1**). The mean LTF for slots prepared with the Gomina sawblade was slightly higher (815N, 95%CI 761 to 870) than the LTF for the standard sawblade slots, but not significantly higher ($p>0.05$). In comparison, slots prepared with the manual rasp retained material at the anterior and posterior ends of the slot while also creating a round geometry in the sagittal plane (**Table 7.5**). The manual rasp slots had a significantly higher LTF (859N, 95%CI 817 to 902, $p<0.01$) compared to the standard sawblade slots (**Figure 7.13**). The limitation of the manual rasp slots were that they took much longer to produce (>4 minutes) than the standard sawblade slots (~20 seconds). Therefore, to recreate the geometry of the manual rasp slots in less time, producing a shorter slot with the current saw and then rasping the ends was proposed. This was done by combining the standard sawblade with a cutting template that was 5 mm shorter at the anterior and posterior ends (**Figure 7.2**) of the slot or by using a modified standard sawblade that 5 mm stainless steel buffers on the anterior and posterior ends of the sawblade (the buffer sawblade). After the initial cut, the manual rasp was used through the standard cutting template to remove material at the anterior and posterior ends of the slot. As shown in **Table 7.5**, both the standard sawblade (short template) with the manual rasp and the buffer sawblade with the manual rasp produced a slot geometry almost identical to the slots produced using the manual rasp only. Both short template (842N, 95%CI 802 to 883, $p<0.05$) and buffer sawblade methods (865N, 95%CI 831 to 899, $p<0.001$) significantly increased the LTF compared to the standard sawblade slots and had a LTF that was not significantly different compared to slots prepared with the manual rasp only (**Figure 7.13**).

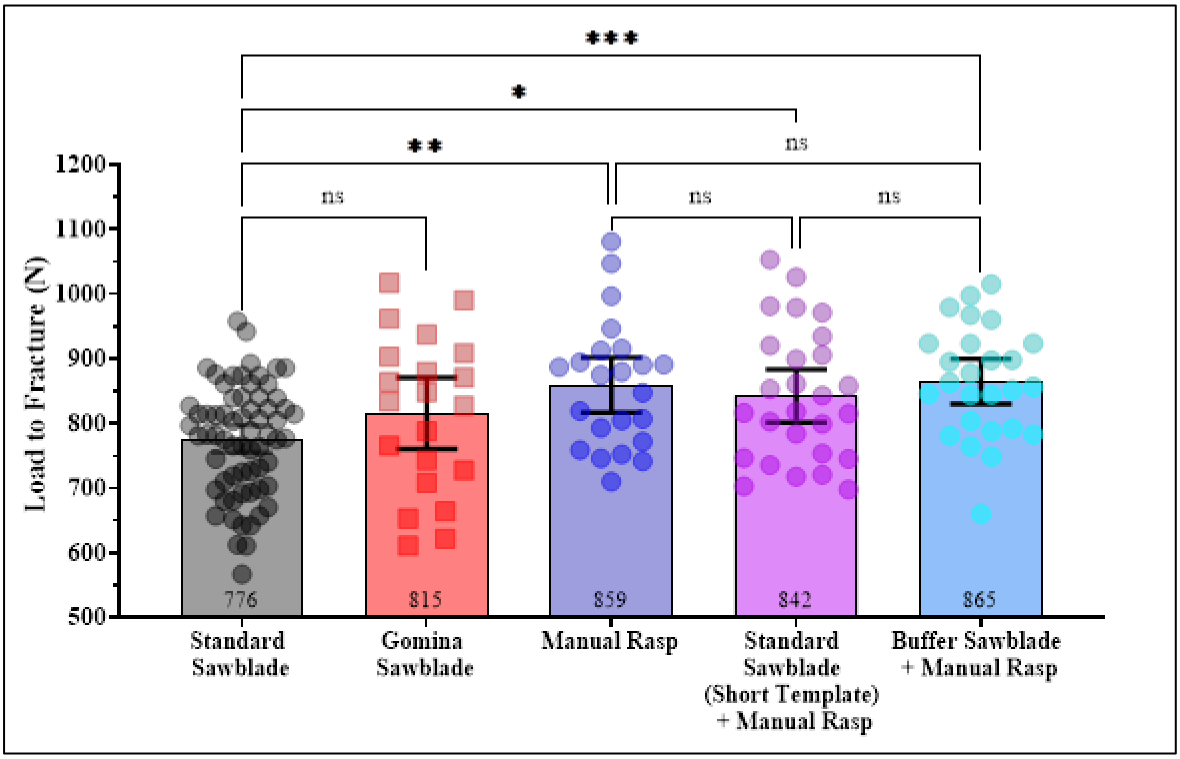


Figure 7.13 The load to fracture (mean ± 95% confidence intervals, individual results shown) of keel slots produced using different sawblade and rasp combinations compared to the standard sawblade. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates p>0.05, *p<0.05, **p<0.01, ***p<0.001.

While investigating ways to generate a similar slot geometry to the manual rasp slots, using rasps under reciprocating power were investigated. An aggressive rasp with larger teeth was also designed. Slots produced with the powered rasp (692N, 95%CI 635 to 750, p>0.05) were not significantly different than the standard sawblade while the aggressive rasp (656N, 95%CI 614 to 697, p<0.01) produced slots that had a significantly lower mean LTF compared to standard sawblade slots. An incidental finding was that when used manually, both the manual rasp and aggressive rasp produced slots that had a significantly higher mean LTF compared to when the powered rasp and aggressive rasp were used under reciprocating power (**Figure 7.14**).

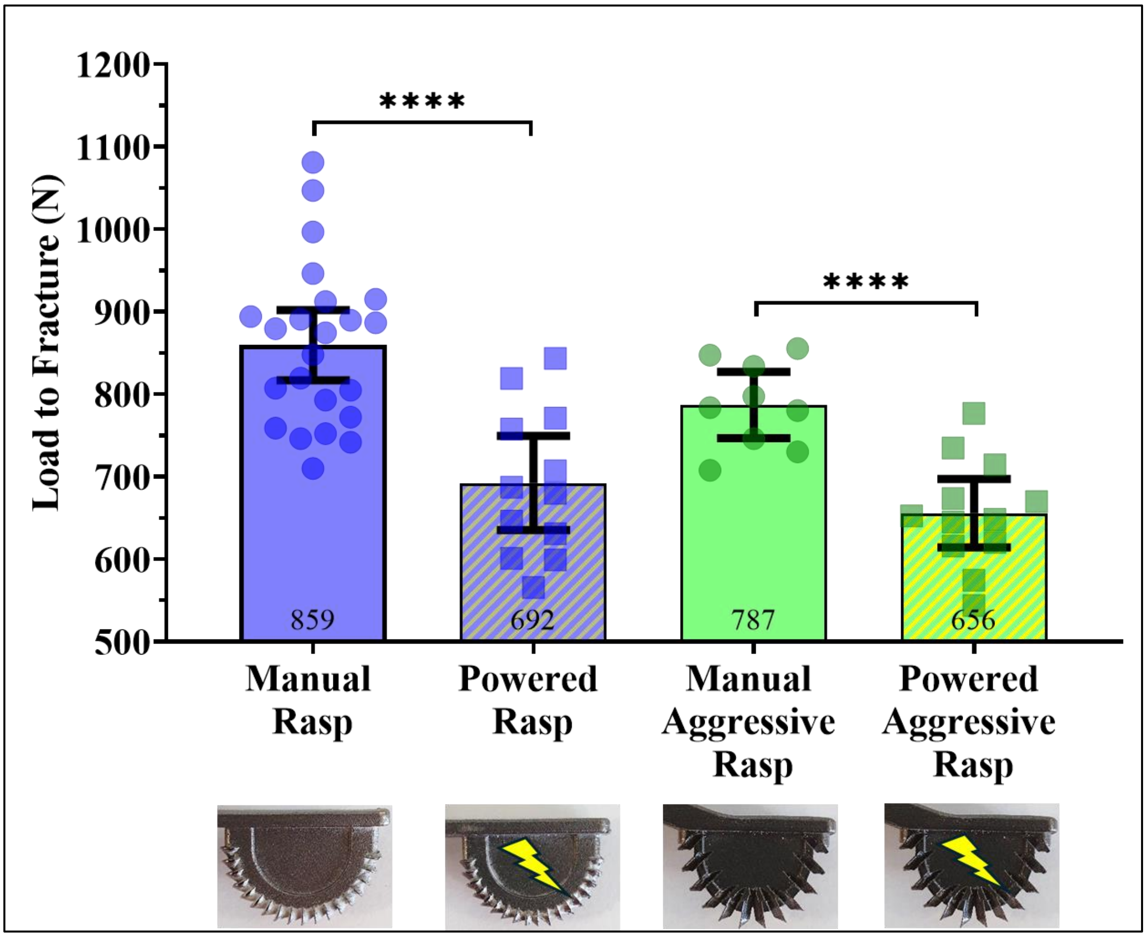


Figure 7.14 Comparison of the load to fracture (mean ± 95% confidence intervals, individual results shown) of slots prepared using rasps when used manually and under reciprocating power. Annotations indicate p-values for Welch's T-test: ****$p<0.0001$.

From the slot preparation methods tested, the most practical methods that increase LTF are using the cemented pick as an adjuvant to the standard sawblade and using the buffer sawblade with the manual rasp to remove material at the ends of the slot. There was no significant difference in the LTF for either of these methods (**Figure 7.15**). However, the use of a small keel component and a standard sawblade slot (1072N, 95%CI 996 to 1148) significantly ($p<0.0001$) increases the LTF compared to the standard sawblade slots as well as both improved slot preparation methods. Interestingly, when the buffer sawblade and manual rasp are used to prepare a small keel slot (1068N, 95%CI 1022 to 1114), there is no significant difference compared to when the standard sawblade alone is used to prepare a small keel slot.

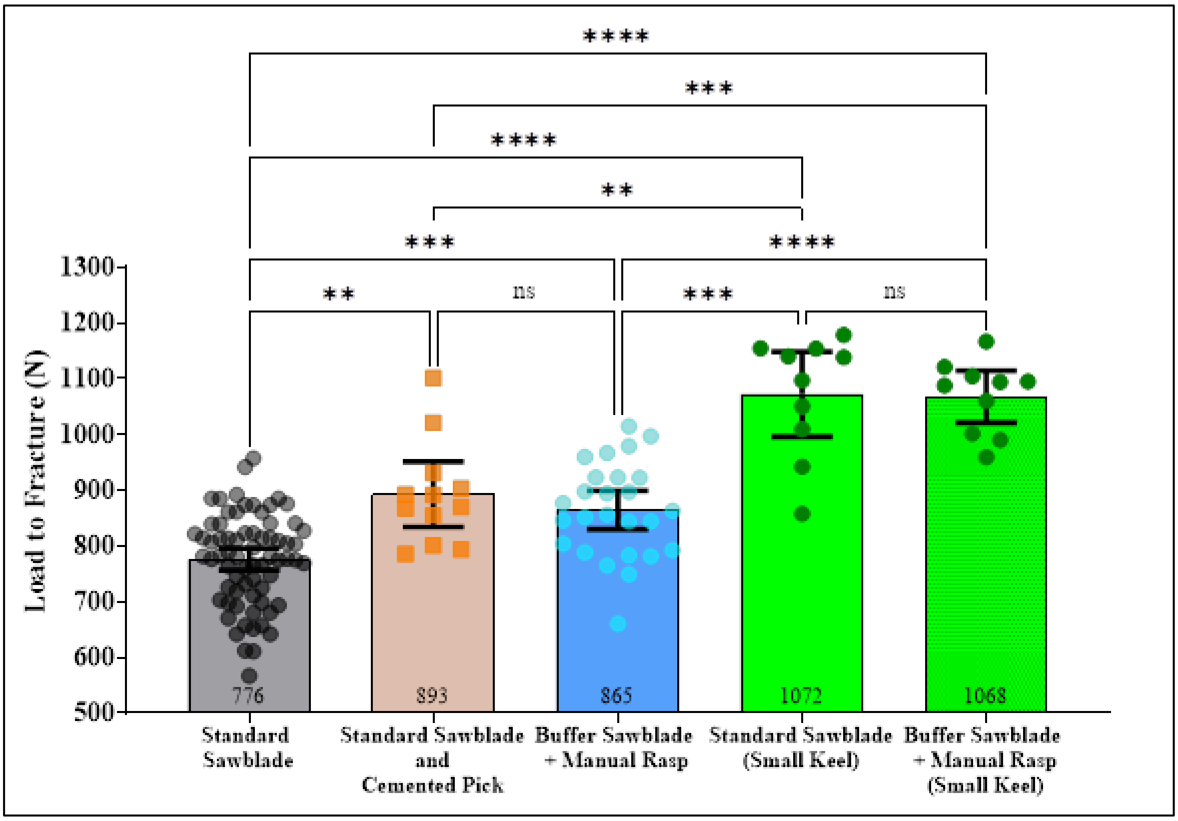


Figure 7.15 Comparison of the load to fracture (mean ± 95% confidence intervals, individual results shown) for slots made with the most practical slot preparation methods compared to the standard sawblade and use of the small keel component with both standard and buffer sawblade created slots. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates p>0.05, *p<0.05, **p<0.01, ***p<0.001, ****p<0.0001.

7.3.4 Push In Pull Out Testing

Compared to the standard sawblade slot (569N, 95%CI 466 to 672), the push in force required to implant a standard component was significantly lower (p<0.0001) when the cemented pick was used as an adjuvant (172N, 95%CI 131 to 212). However, there was no change in push in force between the standard slot and slots prepared using the buffer sawblade with manual rasp, Gomina sawblade or the small keel (**Figure 7.16A**).

As with push in force, there was no change in pull out force between the standard slot and slots prepared using the buffer sawblade with manual rasp, Gomina sawblade or the small keel. However, adjuvant use of the cemented pick significantly decreased the pull out force (**Figure 7.16B**).

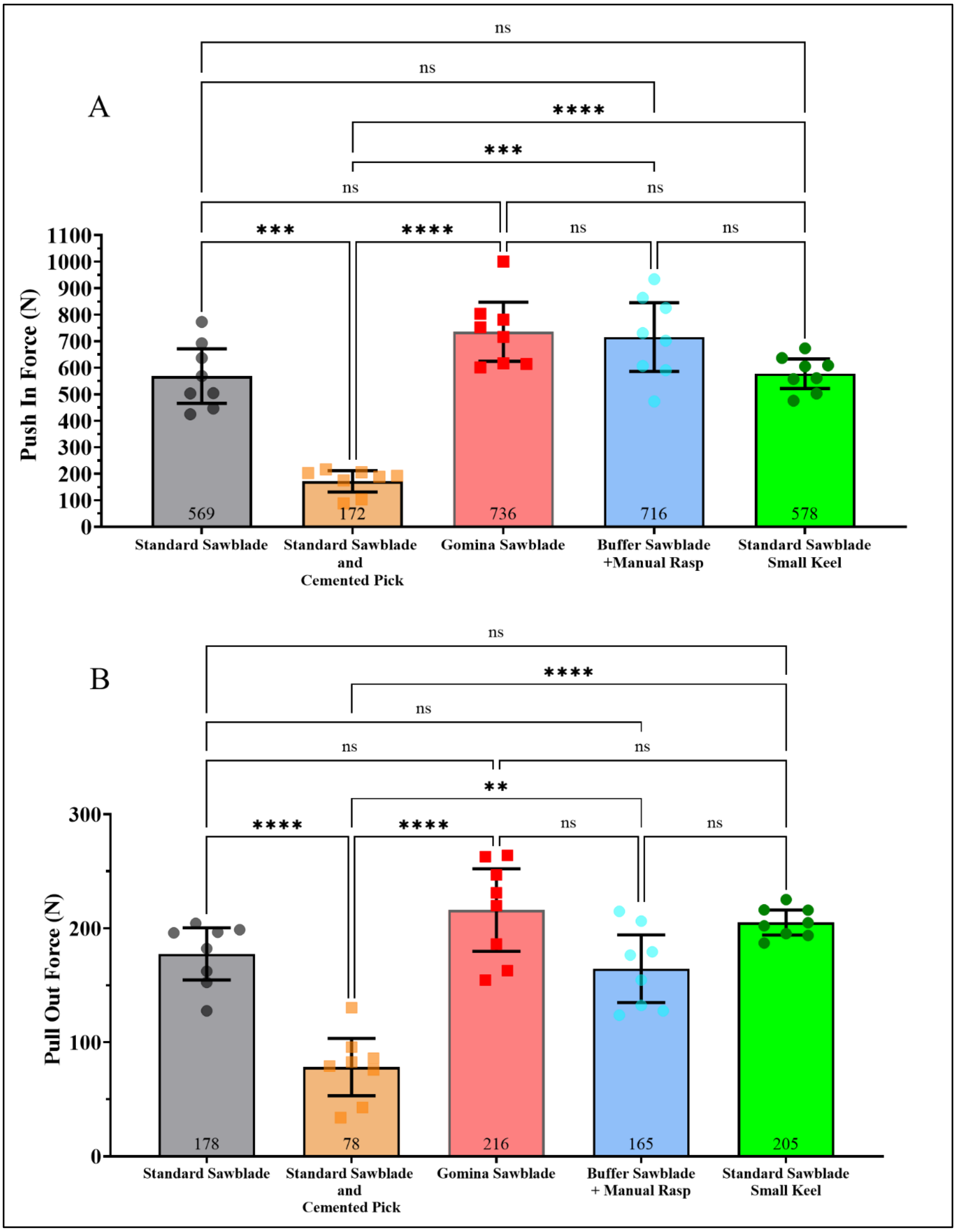


Figure 7.16 Results of Push In Pull Out testing. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates p>0.05, ***p<0.001, ****p<0.0001. **A** Push in forces (mean ± 95% confidence intervals, individual results shown) for different slot preparations. **B** Pull out forces (mean ± 95% confidence intervals, individual results shown) for different slot preparations.

7.4 DISCUSSION

This study demonstrated that the use of different saw blades and rasps could minimise stress risers and produce slots that are significantly rounder than slots produced with the standard sawblade that is used clinically (**Table 7.6**). CTT suggested rounding the bottom of the slot could increase LTF (**Figure 7.8**, **Figure 7.9**). However, when slots with round bottoms, such as when the manual rasp was used as an adjuvant to the standard sawblade or prototype round sawblade, were loaded with a cementless OUKR tibial component there was no significant difference in LTF (**Figure 7.12**). As CTT results did not correlate with LTF results, CTT may not be a good method to investigate how slot geometry is related to the LTF for cementless OUKR.

When slots were loaded anatomically with a cementless OUKR tibial component, LTF was increased both by decreasing the interference (i.e. widening the slot or narrowing the keel, **Figure 7.10**) or retaining material at the anterior and posterior ends of the slot with a rounded shape produced by a rasp (**Figure 7.13**). However, the increase in LTF achieved through optimising the instrumentation was dwarfed by the LTF improvement that could be achieved by reducing the size of the tibial component keel (**Figure 7.15**). Altering slot geometry with the small keel by using the buffer sawblade in combination with the manual rasp did not improve the LTF further. PIPO test results suggest LTF can be increased without compromising the strength of primary fixation for the tibial component (**Figure 7.16**).

The most practical changes that could be made clinically to increase the LTF were identified as using the cemented pick as an adjuvant to the standard sawblade or modifying the standard sawblade to have 5 mm buffers at the anterior and posterior ends of the saw (the buffer sawblade) and then using a rasp to remove the remaining material at the ends of the slot. The cemented pick is already available and included in the standard OUKR instrumentation while the buffer sawblade would require minor modifications to the sawblade that is currently used clinically [190]. These proposed changes to slot preparation both significantly increased the LTF compared to the standard sawblade (**Figure 7.15**), however, use of the cemented pick significantly decreased the pull out force of the tibial component from the slot while the buffer sawblade did not (**Figure 7.16**).

Pull out force was used in this study as a surrogate measure for the strength of primary fixation. The interference press-fit of the cementless OUKR tibial keel creates friction with the trabecular bone surrounding the keel slot. A combination of this friction and contact stress is the primary force holding the tibial component in place until the bone surrounding the implant remodels and there is bony ingrowth into the component's porous surface and secondary fixation occurs. If the frictional force is overcome, micromotion of the implant relative to the surrounding bone can occur. It has been suggested in the literature that bone ingrowth can only occur when micromotion is less than approximately 150μm [361-363]. It is reasonable to assume that maximum pull-out force is proportional to the magnitude of the frictional force holding the tibial component in place. Therefore, a slot preparation that lowers pull out force would increase the likelihood that a tibial component has micromotion beyond the acceptable level of 150μm and be at risk of complications such as aseptic loosening and possibly TCS [361-363].

The RSA study in **Chapter 2** identified that despite cementless OUKR tibial components migrating more than cemented components in the early post-operative, all cementless components were securely fixed in the long-term. Cementless OUKRs in this study were implanted using the standard instrumentation. Therefore, if a slot preparation reduces the maximum pull out force to a level significantly below that of the standard sawblade, such as when the cemented pick is used, it may compromise primary fixation. Theoretically, this could increase micromotion, preventing secondary fixation and increase the risk of aseptic loosening. The threshold for the maximum pull out force that correlates with aseptic loosening is not known. Rahman performed PIPO and micromotion testing with Sawbones and concluded that it was unclear how maximum pull out force relates to micromotion of the cementless OUKR tibial component in vitro [360]. No published studies have compared in vitro maximum pull out force and clinical incidence of aseptic loosening for the cementless OUKR. Despite this, the mean pull out force decreased by over 50% from 178N with the standard saw to 78N when the cemented pick was used as an adjuvant which was significant ($p<0.0001$). Mohammad et al. also found that use of the cemented pick significantly decreased pull out forces compared to the standard sawblade [204]. Yet surgeons are known to use the cemented pick for slot preparation when preparing the keel slot for cementless OUKR, including those completing the survey in **Chapter 5**. There are anecdotal reports of surgeons using the cemented pick with success, but there have been no large studies comparing rates of tibial aseptic loosening with and without pick use. Given the results in this Chapter, the theoretical potential for the use of the cemented pick to increase the risk of aseptic loosening cannot be ignored.

In addition to potentially increasing the risk of aseptic loosening, the cemented pick carries the additional risk of damage to the posterior tibial cortex. The range of the cemented pick is not restrained by a cutting template like the sawblades or rasps used in this study. Therefore, if not used carefully by the surgeon the sharp, pointed end of the cemented pick can damage the posterior tibial cortex. This concern was also raised in the surgeon survey discussed in **Chapter 5** (**Figure 5.2D**) and has been cited as a risk factor for TPF in the literature [204, 334]. Therefore, of the instruments tested, use of the buffer sawblade with adjuvant use of the rasp is the best option for slot preparation as it increases LTF and does not decrease maximum pull out force relative to the standard sawblade.

Push in force has been used previously as a surrogate measure for the force required to implant a cementless OUKR tibial component, with a higher push in force indicative of a greater risk of TPF [204, 322]. In this study, push in force did not necessarily correlate with LTF. For example, the maximum push in force of slots prepared standard sawblade and the buffer sawblade with manual rasp were not significantly different (**Figure 7.16**), despite the latter having a significantly higher LTF (**Figure 7.15**). These results suggest a higher push in force does not necessarily indicate a higher risk of TPF. Rahman also found that push in force was not correlated with LTF [360]. However, it is likely that push-in force correlates with how hard a surgeon needs to strike the tibial component impactor to fully seat the cementless OUKR tibial component. The effect of the incredibly high strain rates induced by hammer blows on the risk of OUKR TPF is not fully understood.

A study by Keppler et al. proposed that using the Gomina sawblade decreases the risk of cementless OUKR TPF without increasing the risk of aseptic loosening [205]. In this single-centre retrospective study of 1258 cementless OUKRs, the keel slots were prepared either using the standard sawblade and a pick or a Gomina sawblade (thicknesses of 2.5 mm, 2.65 mm, or 2.75 mm used). Significantly fewer fractures occurred in patients with the Gomina sawblade compared to the standard sawblade and there was no difference in the rate of aseptic loosening between the two slot preparations. The results of this study suggest that there is no difference in the risk of fracture between slots prepared with the standard sawblade and Gomina sawblade as the LTF and push in forces are not significantly different (**Figure 7.13, Figure 7.16A**). The study also found that the risk of fracture lowered as the width of the Gomina sawblade was increased from 2.5mm to 2.75 mm, which is supported by the results of this study which found decreasing interference increased LTF (**Figure 7.11**). The pull out forces are also not significantly different, supporting the finding by Keppler et al. that the Gomina sawblade does not increase the risk of aseptic loosening. Given the standard sawblade was used for only the first 126 (10%) cases in the study which occurred over a seven year period, it is suggested that increased surgeon experience with the cementless OUKR across the following 1132 cases is more likely to have contributed to the decreased risk of TPF. No details of the suspected cause of individual TPF cases are provided by Keppler et al., but it would be interesting to know whether any of the TPFs were associated with damage to the posterior tibial cortex, especially given the adjuvant use of a pick for slot preparation, was cited by the authors as a risk factor for TPF [205].

The increase in LTF achieved by optimising the slot preparation instrumentation is minor compared to the increase achieved by reducing the keel size. Compared to the standard sawblade slots, using the buffer saw with manual rasp increased mean LTF by 11% (776N to 865N) while using a small keel component increased mean LTF by 38% (776N to 1072N). Rahman's thesis reported that a smaller keel reduced the LTF by 75% compared to the standard keel in LTF tests using Sawbones tibial models based on the CT scans of a Japanese patient, similar to those used to evaluate the impact of component position on LTF in Chapter 6 [360]. This may indicate that the simple fracture model used in this study underestimates the improvement that slot preparation may have. Conversely, it could indicate that the slot changes may have a larger effect in small tibias that are known to be most at risk of TPF.

The results of this study suggest the main determinant for LTF in mechanical testing is the amount of material between the keel and the edge of the Sawbones block. As demonstrated in **Figure 7.17,** the buffer sawblade retains more material at the anterior and posterior ends of the slot compared to the standard sawblade. This is also true for the small keel slot preparation, particularly at the posterior end of the slot. This theory aligns with clinical studies that have identified that patients with a shorter distance between the keel of the tibial component and tibial cortex are at higher risk of TPF [342, 343]. This theory is further supported by the fact that using the buffer saw and manual rasp for small keel slot preparation did not significantly increase the LTF to the standard sawblade small keel slot preparation (**Figure 7.15**). Additionally, the speed of the surgical reciprocating saw is controlled by the surgeon but has a maximum speed of 12500 cycles per minute. As most surgeons do clinically, in this study the saw was used at, or near, full speed. Therefore, when the sawblade hits the end of the template it rams the end of the slot hundreds to thousands of times in a matter of seconds. It is proposed that hitting the ends of the slot with the saw creates microfractures or cracks that then propagate when loaded. These microfractures then have a shorter distance to propagate to the edge of the block and become a complete fracture when less material is retained at the end of slots, such as when the slots are rasped or when the small keel is used. When a slot is made shorter and a rasp is used, such as with the buffer saw, these microfractures are removed by rasping out the ends of the slots (**Figure 7.17**). This theory is supported by the fact that rasped slots have a significantly higher LTF when used manually compared to when they are used under reciprocating power (**Figure 7.14**). It is suggested the rasps generate microfractures at the ends of the slots when used under power as they ram into the slot ends, while this does not occur when the rasps are used manually.

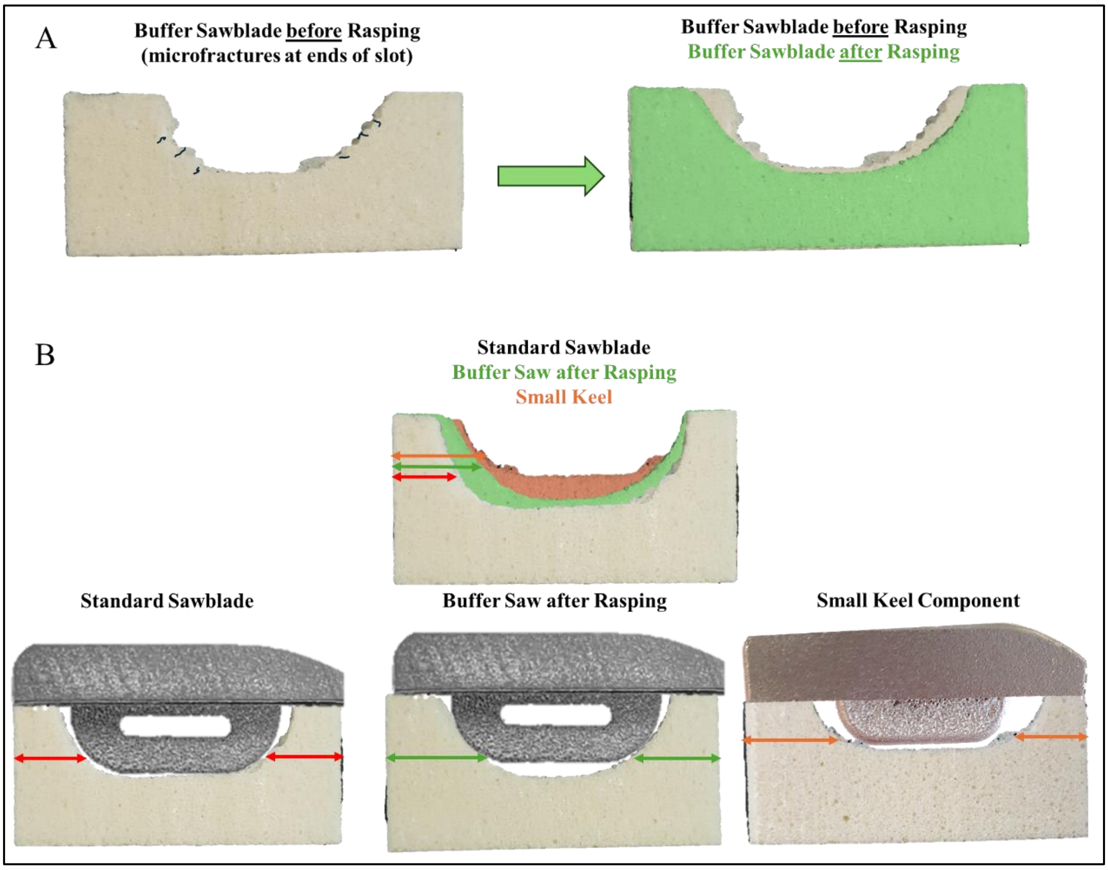


Figure 7.17 Diagrams explaining the hypothesised reasons for differences observed in load to fracture testing. **A** Before rasping, stress risers in the form of jagged edges are present at the ends of the slot. Microfractures (black lines) may also occur at the end of the slots due to the saw ramming the end of the slot. After, rasping (green outline) the stress risers and region where the stress risers occur is removed. **B** A comparison of the amount of material between the keel slot and the edge of the Sawbones block for slots prepared with the standard sawblade (red arrows), buffer sawblade and manual rasp (green), and small keel tibial component (orange). Note that slot preparation for the small keel component and standard slot preparation with the buffer sawblade and rasp retains more material at the posterior end of the slot.

7.4.1 Limitations

The general limitations of using simplified Sawbones models for LTF and the LTF protocol used also apply to the LTF testing in this Chapter. These limitations are discussed extensively in **Section 6.4.1**. Despite these limitations, Sawbones allow for controlled comparison of variables that may affect LTF and give insight into how these factors could reduce the risk of TPF clinically. Size A tibial components were used for LTF testing in this Chapter and therefore the results may not be generalisable to all component sizes.

Polyurethane foam has been widely used for PIPO testing in orthopaedic fixation studies and have been validated for this purpose [204, 322]. However, it is uncertain whether Sawbones can replicate the PIPO forces that the implant would experience in a clinical setting where liquids such as blood and fat are likely to affect the friction. Unlike LTF testing, PIPO testing is likely to be generalisable to all tibial component sizes as the keel size is the same for all component sizes.

7.5 CHAPTER SUMMARY

The LTF testing in this Chapter suggests that the amount of material retained to the posterior of the keel during keel slot preparation is an important factor for LTF of the cementless OUKR. Therefore, maximising the amount of material posterior to the keel is likely to reduce the risk of TPF. In the short-term, it is recommended that the buffer saw with the manual rasp is adapted for clinical keel slot preparation as it is likely to decrease the risk of TPF with the cementless OUKR without compromising primary fixation. This would require a relatively minor change to the manufacturing of the standard sawblade and the addition of the manual rasp to the standard OUKR instrumentation. It is also recommended that the cemented pick not be used due to the potential risks of damaging the posterior tibial cortex, which may contribute to TPF, and widening the slot, which may contribute to aseptic loosening. The longer-term aim should be to obtain approval for a tibial component with a shorter and shallower keel, as the small keel component tested in this study increased LTF to a level significantly higher than the buffer sawblade slots without reducing the maximum pull out force.

CHAPTER 8 – CONCLUSION

8.1 SUMMARY OF FINDINGS

To understand the risk of late aseptic loosening, **Chapter 2** reported the 10-year results of an RCT comparing cemented and cementless fixation of the Phase III OUKR, which is the longest known follow-up for an RSA study of the Phase III OUKR. Despite the femoral and tibial components of the cementless OUKRs migrating more than the cemented OUKRs in the first six months, the cementless components were all solidly fixed in the long-term and there were no significant differences in long-term migration. However, two cemented tibial components that migrated early continue to migrate at 10 years and therefore have an increased chance of loosening. No cementless tibial components were continuing to migrate at 10 years. Cementless fixation was also associated with fewer tibial radiolucent lines than cemented fixation at 10 years. It was therefore concluded that OUKR cementless tibial fixation is likely to be as good, if not better, than cemented beyond 10 years.

The same data from the same RCT was used to study 10-year polyethylene wear of the cemented and cementless Phase III OUKRs in **Chapter 3** to better understand the risk of bearing fracture in the long-term. Creep penetration (mean 0.08 mm) occurs during the first six months post-operatively followed by linear penetration at a mean rate of 0.06 mm/year from six months to 10 years. There was no difference in wear rate between cemented and cementless OUKRs. Bearings positioned further away from the tibial wall and femoral components positioned such that there was a lower percentage of the superior bearing surface in contact with the femoral component had higher rates of wear. The linear wear rate for Phase III OUKRs is significantly higher than Phase II, for reasons not fully explained by the factors studied. To minimise the risk of bearing fracture given the higher wear rate for Phase III, it is recommended careful surgery be performed to position the bearing approximately 2 mm from the tibial wall and neutrally align the femoral component to maximise the bearing surface in contact with the femoral component. Surgeons should aim to use Size 4 bearings in younger, active patients to avoid the risk of bearing fracture in the second decade and beyond with the thinner Size 3 bearings.

Chapter 4 reports the results of a radiographic study which investigated TCS, a rare phenomenon of the cementless OUKR. Five of the 94 OUKRs were found to have TCS, an incidence of 5%. There were no patient, implant, or surgical factors found to be associated with TCS, but this may be due to the small number of cases identified. Two (2%) subsiders had moderate pain at five years, although their pain was likely related to other comorbidities and not TCS. All patients with TCS in this study had an acceptable five-year clinical and radiographic outcome. This study contributes to the growing body of evidence suggesting TCS patients have acceptable outcomes and therefore patients with TCS should be treated conservatively and not revised immediately.

The results of the first survey to assess limitations of the OUKR instrumentation from the perspective of surgeons were reported in **Chapter 5**. One hundred and six OUKR surgeons (90 consultants and 16 non-consultants) responded to the survey. The greatest proportions of respondents identified the instruments for patient positioning (36%), tibial resection (51%), femoral preparation (41%), and tibial keel slot preparation (29%) as the instruments with limitations that required improvement. It was concluded that the instruments for these steps should be optimised and **Chapters 6 and 7** went on to optimise instruments for the tibial resection and keel slot preparation, respectively. The other significant finding was that most surgeons (63%) believed that CAS would benefit the OUKR procedure. Given that CAS is not routinely used with the OUKR, this is an interesting direction for future research.

Results of mechanical experiments in **Chapters 6 and 7** identified risk factors of OUKR TPF related to the tibial resection and keel slot, respectively. Through understanding these risk factors, instruments were optimised instruments to prevent them. Vertical overcut was found to reduce LTF by 19%. A prototype drill bit resection guide increased LTF compared to vertical overcut specimens by 37% and the standard resection method by 15%. Therefore, it was recommended that the prototype guide be adopted for clinical use to prevent vertical overcut and minimise the risk of TPF. LTF was reduced by 9% when two tibial nail holes were made beneath the horizontal resection level and 8% when a single nail hole was made beneath the position of the vertical cut compared to if no holes were made. When a single hole was made near the keel, there was no significant decrease in LTF. As at least one nail is required to fix the OUKR resection guide to the proximal tibia, it was recommended that the nail be positioned near the position of the keel slot to minimise the risk of TPF. In patients with small tibias, positioning the cementless OUKR tibial component more medially, distally, or valgus significantly reduced the LTF. It appears the driving factor behind the decrease in LTF is the distance between the keel slot and tibial cortex. To minimise the risk of cementless OUKR TPF surgeons should aim to make the vertical cut immediately medial to the medial tibial spine, make a conservative tibial resection using the 3G clamp, and implant the component in slight (<5°) varus.

Experiments in **Chapter 7** found that decreasing interference, either by making the keel slot wider with the cemented pick or making the keel narrower, increased LTF. Making the bottom of the keel slot rounder did not significantly alter the LTF, however using a rasp to round the ends of the slot and retain more material did significantly increase LTF. The use of a buffer sawblade, which cuts a slot that is 5 mm shorter at the anterior and posterior ends compared to the standard sawblade, followed by rasping of the slot ends was found to be the most practical method to create the desired slot geometry. Preparing the slot with the buffer sawblade and manual rasp significantly increased LTF by 11% compared to the standard sawblade without decreasing pull out force. Comparatively, use of a small keel component increased LTF by 38% also without decrease pull out force. Therefore, it was recommended that the buffer saw should be adopted clinically in the interim as it may decrease the risk of TPF without effecting fixation. Approval for use of small keel tibial component for cementless OUKR should be sought as its use is likely to decrease the risk of TPF far more than any changes to slot preparation ever could.

This final chapter reflects on the overall limitations of the findings presented in this thesis. The further work required to translate the findings of this thesis to clinical practice and future directions are also discussed.

8.2 THESIS LIMITATIONS

The limitations of individual studies are detailed in their respective chapters. However, the overarching limitation of **Chapters 2, 3 and 4** is that all the OUKRs in these studies were implanted by one of 4 designer surgeons, or a surgeon under their supervision, at the designer centre. It is known high volume surgeon and centres achieve better results with the OUKR [21-23]. Therefore, it is possible that the migration, polyethylene wear, and incidence of TCS found in these studies do not reflect of the results of the average OUKR surgeon. There is the added possibility of bias in the RCT cohort both due to patients self-selecting themselves into the study and the Hawthorne effect on the surgeons knowing that the OUKRs they were performing would be closely monitored with RSA [364].

Similarly, the respondents to the survey presented in **Chapter 5** were largely experienced, high-volume OUKR surgeons. This is partly due to the recruitment method which advertised the survey directly to known OUKR users and surgeons who had recently published OUKR-related research. The innate limitation of anonymous online surveys is that biased respondents can select themselves into the sample, and for this study it is likely that opinionated, experienced OUKR surgeons were more likely to respond [330].

Except for push in pull out testing [204, 322, 360], the other biomechanical fracture tests used in **Chapters 6 and 7** are novel and were developed for this thesis. While they were useful for comparative testing of several factors thought to be related to cementless OUKR TPF, the tests have not yet been validated with cadaveric or clinical experiments. It is therefore unclear how the suggested changes will improve the risk of TPF clinically. How the findings of these experiments can be translated to clinical practice is discussed in **Section 8.3**.

8.3 FURTHER WORK AND FUTURE DIRECTIONS

There are a lack of long-term RSA studies published in the literature, particularly for UKR [244]. The most successful orthopaedic application of RSA has been the prediction of long-term failure of implants based on migration that occurs in the first two post-operative years [229, 230]. For this reason, few studies collect results beyond 2-years and even fewer publish these results. The most applied early migration threshold linked to long-term failure due to aseptic loosening, >0.2 mm of MTPM between 12 and 24 months post-operatively, is based on data from TKRs [239, 243]. UKRs have been found to have similar migration profiles to TKRs, but generally have higher levels of migration at one- and two-years post-operatively, and there is scepticism about whether TKR MTPM cut-offs are appropriate for UKR RSA [244].

The study in **Chapter 2** applied a tibial MTPM cut-off of 1 mm at six months for early migration and 0.2 mm between five and 10 years. Both cemented early migrators exceeded the late migration cut-off, the only cemented cases to do so. Meanwhile, six cementless OUKRs exceeded the early migration cut-off but none of the 16 cementless OUKRs studied exceeded the late cut-off. It was therefore suggested that early migration was indicative of ongoing migration for cemented OUKR tibial components and indicates an increased risk of long-term aseptic loosening, but early migration was acceptable for cementless OUKRs as they all seem to be solidly fixed in the long-term.

Late aseptic loosening with the cementless OUKR has so far been extraordinarily rare, with no cases reported among the first 1000 cementless OUKRs performed by the designer surgeons and only one case of early femoral loosening [20]. As none of the components were revised for aseptic loosening in this study, it is impossible to correlate migration with the risk of aseptic loosening. As it is suspected the two cemented OUKRs with ongoing migration are thought to be at risk of becoming loose, it is important follow-up of the patients in this study is continued. If a case of aseptic loosening is identified, this would help to correlate certain OUKR migration patterns with aseptic loosening. Continuing to follow-up the patients and report their outcomes, if ethical approval and patient consent can be obtained, is also an important contribution to the field given the lack of long-term RSA studies published, particularly for UKRs [244].

Continuing the RSA study for the analysis of wear would also be beneficial to understand the relationship between bearing thickness and risk of bearing fracture. It has been suggested that bearings worn to less than approximately 2 mm thick, are at higher risk of fracture [37, 269, 276]. This thought is founded on data from a retrieval study that found five of 10 fractured OUKR bearings were less than 2.5 mm thick [225]. Two bearings (5%) studied in **Chapter 3**, both Size 3, were projected to be less than 2 mm thick by 20 years. Extending the study to determine how bearing thickness is related to fracture as with a mean wear rate of 0.06 mm/year, the average Size 3 bearing will be 2.3 mm thick at 20 years, and therefore close to inherent risk of fracture if the 2 mm thickness hypothesis holds true. Such a finding would further support the recommendation that Size 4 bearings be used in younger patients.

The results of **Chapter 4** contribute to the growing body of evidence that suggests that TCS does not impair the long-term outcome of cementless OUKRs [32-35, 219]. However, no patient, implant, or surgical factors were able to be correlated with TCS due to only five TCS cases being identified. To overcome this limitation, a larger radiographic study is underway using the first 1000 cementless OUKRs implanted by the designer surgeons [20]. However, just as in Chapter 4, this larger radiographic study is also limited by the need to exclude poor quality radiographs, which dramatically reduces the sample size, and the difficulty of accurately and efficiently measuring TCS using radiographs. Like Kamenaga et al., this thesis suggests that external rotation of the tibial component may contribute to TCS but it is not possible to determine tibial component external/internal rotation accurately from an anteroposterior radiograph [33]. Using CT images for analysis, like Kamenaga et al., is one way accurately determine the 3D location of the component, but is expensive, exposes the patient to high levels of radiation, and is not routinely performed for OUKR at most centres. Another limitation of the TCS study in this thesis is that the earliest timepoint migration was able to be measured at was one year as there were no radiographs at earlier timepoints. It is suspected that TCS occurs within the first six months post-operatively, therefore imaging within this period would help to understand TCS migration and possible give insight into the cause. This could be done with plain radiographs, but to study the migration accurately, a prospective study with RSA would be the most appropriate method. RSA cohorts are usually small given the high accuracy of RSA systems, however, given the relatively low incidence of TCS (~5%) a larger cohort would be required. Although uncommon, RSA studies with several hundred patients have been performed and would be possible at the designer centre given the high volume of cementless OUKRs performed and access to an RSA system validated for the OUKR.

The major future direction arising from **Chapter 5** is the need to investigate the development of a CAS system for the OUKR given 63% of survey respondents believe it will improve the procedure. Two of the surgical steps that surgeons found most difficult were the orientation of the vertical cut and the position of the intramedullary rod / femoral drill guide, steps which determine the orientation of the tibial and femoral components, respectively. Surgeons also identified that these two steps of the procedure would benefit the most from CAS. Although development of CAS technology was deemed beyond the scope of this thesis, it will be an area of ongoing research with a proposed strategy outlined in **Appendix 8**. Preliminary experiments exploring the potential for the use of inertial measurement units, optical tracking of quick response (QR) codes, or object/marker tracking as potential technologies to form the basis of an OUKR CAS system have been conducted (see **Appendix 8**). Development of an improved OLH, which was identified as having limitations by 36% of survey respondents, has been ongoing and prototype leg holders have been tested by the designer surgeons. A meta-analysis has found the Microplasty instrument has improved femoral component alignment [28]. Nevertheless, 41% of survey respondents had issues with the femoral component. Some modifications to the manual instruments used femoral preparation have been experimented with in Sawbones. These experiments were outside the scope of this thesis but warrant further study.

Chapters 6 and 7 determined several factors, vertical overcut, tibial resection guide nail number and position, component position, and keel slot preparation. Some recommendations do not require further study or regulatory approval to implement. These include using one nail to fix the OUKR resection guide and positioning that nail near the tibial keel slot, making the vertical resection immediately medial to the medial tibial spine, making a conservative tibial resection using the 3G clamp in patients with small tibias, and using the cemented pick with caution for keel slot preparation. Surgeon education, preferably with support from the designer surgeons and manufacturer should be sufficient to incorporate these changes and then long-term surveillance (i.e. joint registry data, cohort studies) will reveal if the changes have had any significant effect. Instrumentation changes will require some further study and regulatory approval. The process for clinical translation of such innovations is clearly laid out by the IDEAL recommendations (**Table 8.1)** [365].

The prototype drill bit resection guide and buffer sawblade and rasp are both currently in Stage 1, the idea stage, of surgical innovation. Both have had proof of concept in the form of preclinical mechanical experiments using Sawbones. The prototype drill bit resection guide has also been tested in cadavers, received regulatory approved for clinical use, and is in use by designer surgeons with early data and surgeon feedback being collected. Provided no major flaws of the guide are identified, it will soon be ready to move to Stage 2a with use expanding to some collaborating surgeons. During Stage 1 some limitations have been identified from surgeon feedback. As the guide restrains the vertical cut, surgeons need to ensure they select the appropriate medial-lateral position and internal/external rotation before locking the guide in place. This will require education of surgeons before moving to Stage 2. It was also identified early on that the standard drill bit supplied by the OUKR instrumentation is often not long enough to reach the posterior tibial cortex when used in the corner of the prototype guide. Therefore, a longer drill bit needs to be included to ensure it reaches the posterior cortex and prevents vertical overcut at this location.

Table 8.1 Outline of the stages of surgical innovation, as per the IDEAL recommendations, applied to the clinical translation of OUKR instrumentation from pre-clinical experiments. Adapted from [365].

Stage	(1) Idea	(2a) Development	(2b) Exploration	(3) Assessment	(4) Long-term study
Purpose	Proof of concept	Development	Learning	Assessment	Surveillance
Number and types of patients	Single digits; patients with low tibial periprosthetic fracture (TPF) risk No patients required for preclinical studies)	Few; selected patients with low TPF risk	Many; may expand to mixed; broadening indication	Many; expanded indications	All patients meeting OUKR indications eligible
Number and types of surgeons	Designer surgeons at designer centre	Few; designer surgeons and some collaborating experienced OUKR surgeons	Many; designer surgeons, collaborating experienced OUKR surgeons, other experienced OUKR surgeons	Many; all experienced OUKR surgeons or surgeons under experienced supervision	All OUKR surgeons eligible, including trainees
Output	Description	Description	Measurement; comparison	Comparison; complete information for non-RCT participants	Description; audit, regional variation; quality assurance; risk adjustment
Intervention	Design Evolving	Design Evolving	Design evolving; community learning	Stable	Stable
Method	Preclinical studies, Structured case reports, Feedback from designer surgeons	Prospective development studies, Feedback from surgeons	Research database; explanatory or feasibility RCT (efficacy trial), surgeon survey	RCT with or without additions/modifi cations; alternative designs	National Joint Registry, cohort studies, rare-case reports
Outcomes	Proof of concept; technical achievement; disasters; dramatic successes	Mainly safety; technical and procedural success	Safety; clinical outcomes (specific and graded); short-term outcomes; patient-centred (reported) outcomes; feasibility outcomes	Clinical outcomes (specific and graded); middle-term and long-term outcomes; patient-centred (reported) outcomes; cost-effectiveness	Rare events; long-term outcomes; quality assurance
Ethics required	Sometimes	Yes	Yes	Yes	No
Examples	Sawbones and Cadaveric Studies, Use by Designer Surgeons	Expanded use by designer surgeons, their colleagues and	Single-centre RCT	Multi-centre RCT	Rate of TPF in national joint registries

The buffer sawblade and rasp are in an earlier stage of development, having only been used in preclinical sawbones studies (**Chapter 7**). To progress the buffer sawblade and rasp to clinical use, they first need to be manufactured to clinical standard and approved by the appropriate regulator. In the UK, this is the MHRA (see **Section 1.6.5)**. Once approved for clinical use, designer surgeons can begin using the instruments and they can progress through the stages of surgical innovation (**Table 8.1**).

Before moving to an RCT, it may be worth considering whether instrumentation changes will be grouped or tested independently. Combining multiple instruments makes it more difficult to discern which instrument is responsible for changes in clinical outcome but saves time and money by running a single trial. As the instrumentation changes are all aimed at lowering the incidence of TPF, it seems reasonable to combine them in a trial. Given cementless OUKR TPF is rare in Caucasian populations, it would be appropriate to conduct a feasibility RCT in a population where the incidence of TPF is higher, such as Japan [228]. This would provide a higher chance of a significant difference in the primary outcome of TPF incidence being identified. Secondary outcomes of such an RCT may include early migration (potentially measured using RSA), incidence of aseptic loosening, and PROMs.

Chapter 7 concluded that the reduction in TPF risk achieved by modifying instruments is likely to be minimal compared to introducing a small keel component. Rahman's thesis tested small keel components in depth and the small keel component used in this thesis had the 'porous with smooth edge' keel determined to have the best performance in terms of minimising fracture risk without compromising primary fixation [360]. The results of this thesis support those of Rahman's thesis and indicate that the small keel tibial component is clearly the way forward to minimise the risk of cementless OUKR TPF. However, as an implant, the small keel component receives the highest risk Class III designation will take many years to obtain regulatory approval [207, 208]. In comparison, surgical instruments are given the lowest risk designation Class I and can be approved for clinical use within months. Therefore, introducing optimised instrumentation provides a short-term solution to TPF while awaiting the approval of the small keel tibial component.

8.4 THESIS CONCLUSIONS

This thesis aimed to investigate poorly understood complications of the OUKR and optimise instrumentation to minimise the risk of complications, with a particular focus on the cementless OUKR and its known risk of TPF.

From the results this thesis, it was concluded that the cementless OUKR has as good, if not better, fixation at 10 years compared the cemented Phase III OUKR and therefore an equivalent, or lower, risk of long-term aseptic loosening. Similarly, there is no significant difference in linear polyethylene bearing wear at 10 years between cemented and cementless OUKRs. However, the wear rate is high compared to the Phase II OUKR so to prevent the risk of bearing fracture in the long-term, surgeons should aim to position the bearing close to the tibial wall, neutrally align the femoral component, and avoid the use of the thinnest Size 3 bearings in young patients. While long-term migration of cemented and cementless OUKRs is similar, 5% of cementless OUKRs were found to have TCS. All TCS patients had acceptable radiographic and clinical outcomes at five-years, which supports findings in the literature that suggest TCS patients should be treated conservatively and not be revised immediately.

Surgeons are happy with most of the OUKR instrumentation; however, many would like improved instruments for the patient positioning, tibial resection, femoral preparation, and tibial keel slot preparation. Most believe CAS would improve the OUKR procedure.

Therefore, it is recommended that instruments for the key steps identified are optimised, with the viability of CAS for the OUKR to also be investigated.

Both the tibial resection and tibial keel slot preparation can be optimised to minimise the risk of TPF. To minimise the risk of TPF, surgeons should use one pin placed near the position of the keel slot to fix the resection guide to the proximal tibia and use the prototype drill bit resection guide to minimise the risk of vertical overcut, which is a known risk factor for TPF. Surgeons should make the vertical cut immediately medial to medial tibial spine and make a conservative tibial resection to minimise the risk of TPF in patients with small tibias. Patients with small tibias may also benefit from a varus resection, as positioning the component in valgus increases the risk of TPF.

Preparing the tibial keel slot with the buffer sawblade and manual rasp reduce the risk of TPF without compromising fracture, and therefore should be developed for clinical use. However, the risk of TPF can be reduced significantly more by using a small keel tibial component. The longer-term goal should be to develop the small keel component for clinical use so that the cementless OUKR, with its known benefits and improved survival compared to the cemented OUKR, can be used widely in all patients without fear of TPF.

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APPENDICES

APPENDIX 1: AWARDS AND RESEARCH OUTPUT

Awards

2021 Rhodes Scholarship for South Australia – Rhodes Trust (full funding and stipend for three years of DPhil studies)

2022 Best Student Presentation – Australian Orthopaedic Association ACT Annual Scientific Meeting

2023 Best Second Year Student Presentation – Botnar Institute Student Symposium

2022 – 2024 Competitive Conference and Fieldwork Funding – Green Templeton College

2023 Warden’s Discretionary Fund – Rhodes Trust

2023 Awarded Associate Fellowship of the Higher Education Academy (AFHEA) in recognition of completing the Advanced Teaching and Learning Course with the University of Oxford Centre for Teaching and Learning

Peer-reviewed Publications

Received: 18 October 2023 | Accepted: 11 December 2023
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KNEE ARTHROPLASTY

Knee Surgery, Sports Traumatology, Arthroscopy WILEY

Polyethylene bearing wear is comparable for cemented and cementless Oxford unicompartmental knee replacements: Ten-year results of a randomized controlled trial

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Abstract

Purpose: There is concern that using cementless components may increase polyethylene wear of the Oxford unicompartmental knee replacement (OUKR). Therefore, this study aimed to measure bearing wear at 10 years in patients from a randomized trial comparing Phase 3 cemented and cementless OUKRs and to investigate factors that may affect wear. It was hypothesized that there would be no difference in wear rate between cemented and cementless OUKRs.

Methods: Bearing thickness was determined using radiostereometric analysis at postoperative, 3-month, 6-month, 1-year, 2-year, 5-year and 10-year timepoints. As creep occurs early, wear rate was calculated using linear regression between 6 months and 10 years for 39 knees (20 cemented, 19 cementless). Associations between wear and implant, surgical and patient factors were analysed.

Results: The linear wear rate of the Phase 3 OUKR was 0.06 mm/year with no significant difference ($p = 0.18$) between cemented (0.054 mm/year) and cementless (0.063 mm/year) implants. Age, Oxford Knee Score, component size and bearing thickness had no correlation with wear. A body mass index ≥ 30 was associated with a significantly lower wear rate ($p = 0.007$) as was having ≥80% femoral component contact area on the bearing ($p = 0.003$). Bearings positioned ≥1.5 mm from the tibial wall had a significantly higher wear rate ($p = 0.002$).

Conclusions: At 10 years, the Phase 3 OUKR linear wear rate is low and not associated with the fixation method. To minimize the risk of wear-related bearing fracture in the very long-term surgeons should consider using 4 mm bearings in very young active patients and ensure that components are appropriately positioned, which is facilitated by the current instrumentation.

Level of Evidence: Level III, Retrospective Comparative Study.

Conference Presentations

Work from this thesis has been presented in the UK at the British Association for Surgeons of the Knee Annual Meetings, British Orthopaedic Association Annual Congresses, Oxford Surgical Innovation Conference, and the 60th Anniversary Scientific Meeting Girdlestone Orthopaedic Society. Internationally the work has been presented at the 2022 Australian Orthopaedic Association ACT Annual Scientific Meeting, 2023 European Orthopaedic Research Society Meeting, and 2023 SICOT Orthopaedic World Congress.

BASK 2022

Orthopaedic Proceedings

KNEE

FULL ACCESS

INVESTIGATING PRIMARY AND LONG-TERM FIXATION OF THE OXFORD UNICOMPARTMENTAL KNEE ARTHROPLASTY TIBIAL COMPONENT: TEN-YEAR RESULTS OF A RANDOMIZED CONTROLLED TRIAL COMPARING CEMENTED AND CEMENTLESS FIXATION USING RADIOSTEREOMETRIC ANALYSIS

The British Association for Surgery of the Knee (BASK) May 2022 Meeting, Newport, Wales, 17–18 May 2022.

L. Arthur, S. Campi, B. Kendrick, W. Jackson, C. Dodd, A. Price, S. Mellon, D. Murray

BOA 2022

283 - Investigating Primary and Long-Term Fixation of the Oxford Unicompartmental Knee Replacement Tibial Component: Ten-year results of a Randomised Controlled Trial Comparing Cemented and Cementless Fixation Using Radiostereometric Analysis

Lachlan Arthur[1], Stefano Campi[1], Benjamin Kendrick[1,2], William Jackson[2], Christopher Dodd[2], Andrew Price[1,2], Stephen Mellon[1], David Murray[1,2]

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Australian Orthopaedic Association ACT Annual Scientific Meeting 2022

Lachlan Arthur	Primary and Long-Term Fixation of the Oxford Unicompartmental Knee Replacement: Ten-year results of a Randomised Controlled Trial Comparing Cemented and Cementless Fixation

Oxford Surgical Innovation Conference

Polyethylene Bearing Wear of the Oxford Unicompartmental Knee Replacement: Ten-year results of a Randomised Controlled Trial Comparing Cemented and Cementless Fixation

Authors: Lachlan Arthur, Priyanka Ghosh, Hasan Mohammad, Stefano Campi, Benjamin Kendrick, William Jackson, Andrew Price, David Murray, aStephen Mellon

Presenting author: Lachlan Arthur

BASK 2023

Orthopaedic Proceedings

KNEE

FULL ACCESS

POLYETHYLENE BEARING WEAR OF THE OXFORD UNICOMPARTMENTAL KNEE ARTHROPLASTY: TEN-YEAR RESULTS OF A RANDOMIZED CONTROLLED TRIAL COMPARING CEMENTED AND CEMENTLESS FIXATION

The British Association for Surgery of the Knee (BASK) May 2023 Meeting, London, England, 16–17 May 2023.

Lachlan Arthur, Priyanka Ghosh, Hasan Mohammad, Stefano Campi, David Murray, Stephen Mellon

Orthopaedic Proceedings

KNEE

FULL ACCESS

EARLY TIBIAL SUBSIDENCE OF THE CEMENTLESS OXFORD UNICOMPARTMENTAL KNEE ARTHROPLASTY

The British Association for Surgery of the Knee (BASK) May 2023 Meeting, London, England, 16–17 May 2023.

Lachlan Arthur, Ali Amin, Azmi Rahman, Shihfan Jack Tu, Stephen Mellon, David Murray

60th Anniversary Scientific Meeting Girdlestone Orthopaedic Society 2023

Ten-Year Results of a Randomised Controlled Trial Comparing Migration of Cemented and Cementless Oxford Unicompartmental Knee Replacement Using Radiostereometric Analysis	**Lachlan Arthur**

BOA 2023

A Surgeon Survey to Identify Instrumentation Improvements for the Oxford Unicompartmental Knee Replacement Procedure

Lachlan Arthur[1], Xiaoyi Min[1], Barbara Marks[1], Coral Milburn-Curtis[2], Stephen Mellon[1], David Murray[1]
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EORS 2023

Orthopaedic Proceedings

RESEARCH

OPTIMIZING THE TIBIAL KEEL SLOT FOR THE OXFORD UNICOMPARTMENTAL KNEE ARTHROPLASTY

The European Orthopaedic Research Society (EORS) 31st Annual Meeting, Porto, Portugal, 27–29 September 2023. Part 2 of 2.

L. Arthur · X. Min · S.J. Tu · S. Campi · S. Mellon · D. Murray

SICOT 2023

Short Free Paper

A Surgeon Survey to Identify Instrumentation Improvements for the Oxford Unicompartmental Knee Replacement Procedure

Free Paper

Early Subsidence of the Cementless Oxford Unicompartmental Knee Replacement Tibial Components

Free Paper

Polyethylene Bearing Wear of the Oxford Unicompartmental Knee Replacement: Ten-year results of a Randomised Controlled Trial Comparing Cemented and Cementless Fixation

APPENDIX 2: VALIDATION OF METHODS

A2.1 Validation of Migration Measurements Using Radiostereometric Analysis Used in Chapter 2

To validate the RSA method that was used to measure implant migration of the OUKR, the measurements for five sets of radiographs were double-analysed and compared with measurements from analysis by Stefano Campi, who performed the five-year RSA for the RCT comparing cemented and cementless Phase III OUKRs [216]. The results of the comparison for both femoral and tibial component migration is shown below. They are compared to the accuracy of the RSA system for the OUKR, expressed as the SD of translations, rotations, and MTPM from double exposure experiments of five patients by Benjamin Kendrick [217]. As shown in **Figure A-1**, the error in measurement was consistent with the accuracy of the system determined by Kendrick with little error in translation measures and larger errors in rotations and MTPM. Therefore, the technique used was considered sufficient for analysis. Of note, there was considerably more variability in the measurement of rotations, particularly for the femoral component. This was consistent with lower accuracy of femoral rotation measurements for the OUKR with the RSA system [217].

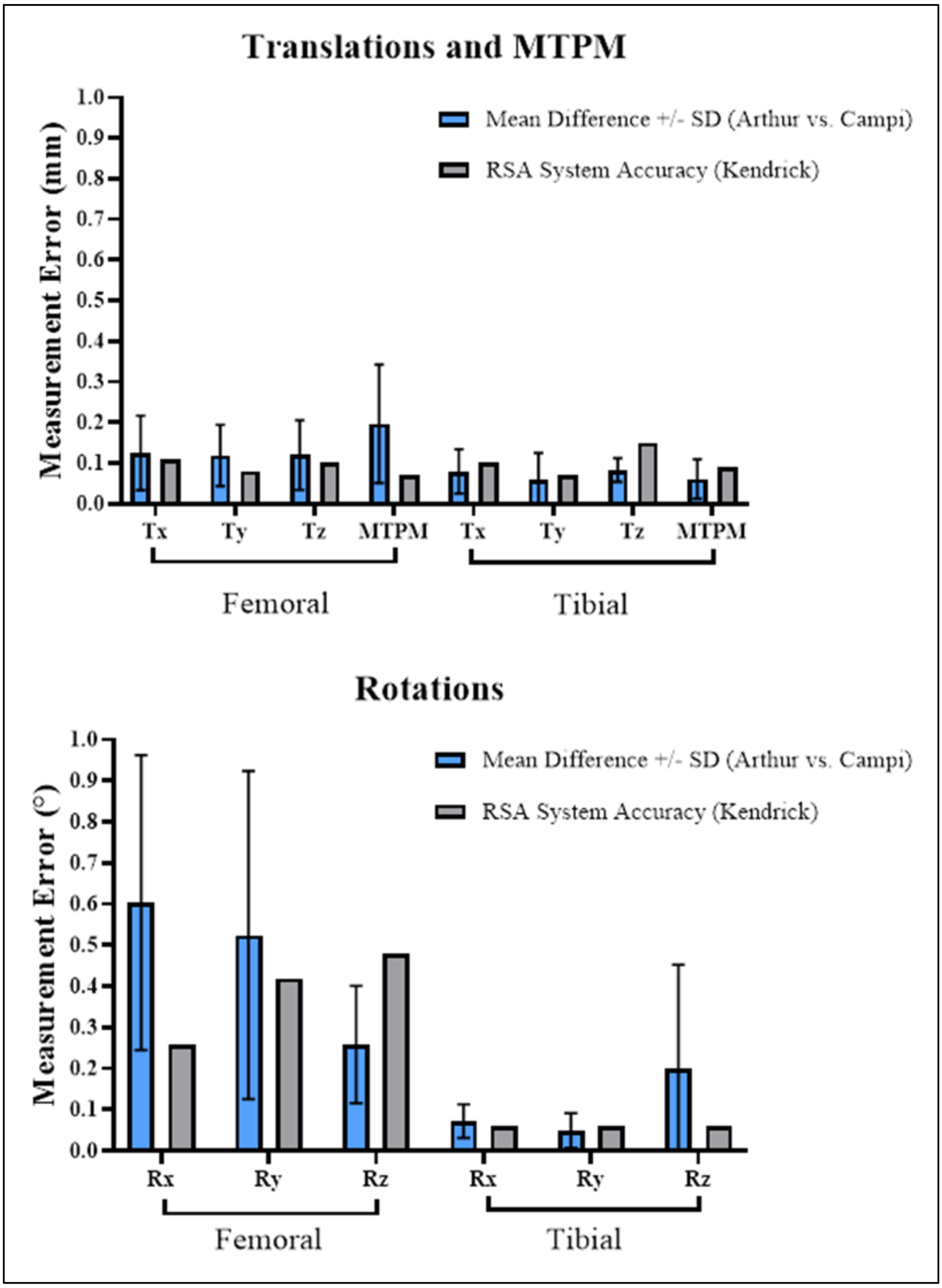

Figure A-1: Measurement error for the radiostereometric analysis method used to analyse migration for the Oxford Unicompartmental Knee Replacement in Chapter 2. The error between the method used in Chapter 2 and that of a previous author are shown in blue (mean ± SD) while the RSA system accuracy is shown in grey, for both femoral and tibial components. The top graph demonstrates the error in translations and MTPM (measured in millimetres, mm) while the bottom graph shows error in rotations (measured in degrees, °)

A2.2 Validation of Bearing Thickness Measurements Used in Chapter 3

Like the validation of the technique used to measure migration with RSA, the method used to measure bearing thickness from RSA data was validated by double-analysis of 11 sets of radiographs from three patients at different time points and compared with previous results from Stefano Campi [216]. The results from this validation are shown in **Figure A-2**. The mean error in bearing thickness was approximately 0.05 mm which is substantially less than the RSA system accuracy of 0.1 mm [217]. When the five-year wear rate was calculated using linear regression and compared with Campi's data, the error was approximately 0.01 mm/year, which is substantially less than the clinically significant difference of 0.025 mm/year. Therefore, the RSA method used to calculate bearing thickness for **Chapter 3** was determined to be acceptable.

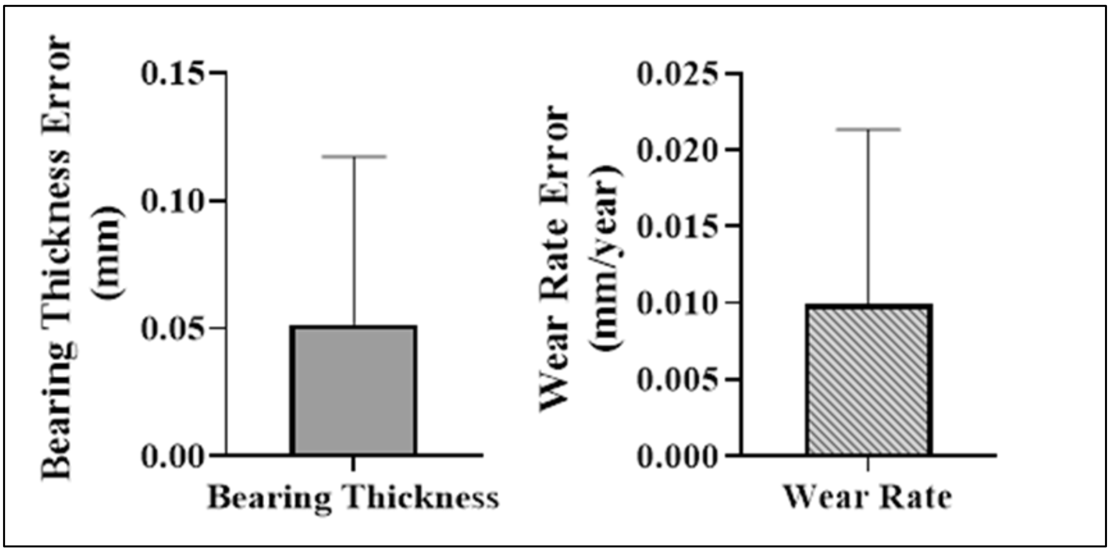

Figure A-2: Measurement error for the radiostereometric analysis method used to analyse bearing thickness for the Oxford Unicompartmental Knee Replacement in Chapter 3. The error in bearing thickness (left, solid grey) and wear rate (right, grey-striped), calculated by linear regression, are shown.

A2.3 Validation of Radiographic Analysis Technique Used in Chapter 4

Several steps were taken to validate the radiographic analysis technique used in Chapter 4. Firstly, after receiving instructions from a trainer familiar with the software (Azmi Rahman) the ability of the two observers for the study (Lachlan Arthur and Ali Amin) to identify key component and bony landmarks using the selected MATLAB program was compared. This process was repeated until the two observers were consistently identifying the same landmarks as shown in **Figure A-3**.

Figure A-3: Example of the analysis to ensure the observers were consistently identifying the same component and bony landmarks. The points observed by one observer are shown as yellow circles and those observed by the other are shown as cyan crosses.

The analysis of 30 patients by both observers was completed to determine the inter-observer error of the method. These results were analysed using Bland-Altman plots. The intra-observer error was analysed by comparing measurements for 20 sets of radiographs across the five subsiders, again using Bland-Altman plots.

Table A-1: Inter- and Intra-observer error as calculated by Bland-Altman plot analysis

Measure	**Inter-Observer (Arthur vs. Amin)**		**Intra-Observer (Arthur vs. Arthur)**	
	Bias	95% Limits of Agreement	Bias	95% Limits of Agreement
Tibial Component Varus/Valgus Angle (°)	-0.02	-3.2 to 3.2	0.65	-1.4 to 2.7
Tibial Component Axis to Fibula Head Distance (mm)	0.09	-2.9 to 3.1	-0.25	-6.7 to 6.1
Tibial Component Anterior/Posterior Tilt Angle (°)	-0.12	-3.8 to 3.5	-0.72	-5.1 to 3.7

4 of the patients in the cohort studied in **Chapter 4** were also in the RSA cohort studied in **Chapters 2** and **3**. Given RSA is the gold-standard for implant migration, the results of the RSA and radiographic analysis were compared to assess the accuracy of the radiographic analysis method. Across 15 sets of radiographs (both anteroposterior and lateral) which allowed calculation of migration over 11 timepoints, the average errors between RSA and MATLAB data were 1.7° (SD 1.1) for tibial varus/valgus angle and 1.6° (SD 1.1) for anterior/posterior tibial tilt.

APPENDIX 3: ETHICS

A3.1 Cemented Versus Cementless Unicompartmental Knee Arthroplasty (UKA) – A single-blind randomised controlled trial

NHS

Oxfordshire REC B
2nd Floor, Astral House
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Telephone: 01869 604047
Facsimile: 01869 604055
Email: jo.franklin@orh.nhs.uk

21 June 2006

Prof. David Murray
Oxford Orthopaedic Engineering Centre
Nuffield Dept of Orthopaedic Surgery
Botnar Research Centre
Nuffield Orthopaedic Centre
Oxford
OX3 7LD

Dear Prof. Murray

Full title of study: **Cemented Versus Cementless Unicompartmental Knee Arthoplasty UKA A single blind randomised controlled trial**
REC reference number: **C02.101**

The REC gave a favourable ethical opinion to this study on 5th June 2002.

Notification(s) of no objection to the conduct of this research have been received from local site assessor(s), following site-specific assessment. The Chair of this REC has confirmed the extension of the favourable opinion to the new site(s) listed below:

Principal Investigator	Title	*Research site*	*Site assessor*
Prof David Murray	Consultant Orthopaedic Surgeon	Nuffield Orthopaedic Centre	Oxfordshire REC B
Mr Peter Adrian Butler-Manuel	Consultant Orthopaedic Surgeon	East Sussex Hospitals NHS Trust	East Sussex Local Research Ethics Committee

Conditions of approval

The favourable opinion is given for the study to be conducted at the above site(s) provided that you comply with the conditions set out in your previously issued approval letter. You are advised to study the conditions carefully.

Research governance approval

The Chief Investigator or sponsor should inform the principal investigator at each site of the favourable opinion by sending a copy of this letter. The research should not commence until research governance approval from the relevant host organisation has been confirmed at each site.

Statement of compliance

An advisory committee to Thames Valley Strategic Health Authority

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

C02.101	**Please quote this number on all correspondence**

Yours sincerely

J Franklin

Miss Jo Franklin
Committee Co-ordinator

Copy: Lynden Guiver, R&D Coordinator, Nuffield Orthopaedic Centre

A3.2 A Survey of Surgeons to Identify Instrumentation Improvements for the OUKR Procedure

MEDICAL SCIENCES INTERDIVISIONAL RESEARCH ETHICS COMMITTEE
Research Services, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB
Tel: +44(0)1865 616575
ethics@medsci.ox.ac.uk

UNIVERSITY OF OXFORD

CONFIDENTIAL

Professor David Murray & Lachlan Arthur
NDORMS
University of Oxford
Nuffield Orthopaedic Centre
Windmill Road
Oxford

20 July 2022

Dear Professor Murray and Lachlan,

Research Ethics Approval - CUREC 1

Ethics Approval Reference: R81755/RE001

Study title: A survey of surgeons to identify instrumentation improvements for the Oxford Unicompartmental Knee Replacement Procedure

Short title: Oxford UKR Instrumentation Survey

The above application has been considered on behalf of the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) in accordance with the University's procedures for ethical approval of all research involving human participants.

I am pleased to inform you that, on the basis of the information provided to the IDREC, the proposed research has been judged as meeting appropriate ethical standards, and approval has been granted for a period of **1 year**, commencing on **20th July 2022.**

Amendments
Should there be any subsequent changes to the study, you should submit details to the MS IDREC for consideration and approval. Details of changes must be listed on an amendment form.

Yours Sincerely
DocuSigned by:
Leah Butts
9F14880C2BC546A...
Mrs Leah Butts
Research Ethics Administrator

for
Dr Helen Barnby-Porritt
Research Ethics Manager

APPENDIX 4: RANDOMISED CONTROLLED TRIAL REGISTRATION

The RCT "Cemented Versus Cementless Unicompartmental Knee Arthroplasty UKA A single blind randomised controlled trial" was retrospectively registered with ClinicalTrials.gov on the 6th of July 2023 as Oxford University Hospitals NHS Trust Protocol Record PID7088 and ClinicalTrials.gov Identifier NCT05935878. Evidence of the registration is below.

ClinicalTrials.gov Protocol Record PID7088

ClinicalTrials.gov Registration <register@clinicaltrials.gov>
Thu 7/6/2023 7:48 PM

Message generated by ClinicalTrials.gov Protocol Registration and Results System

---

ClinicalTrials.gov Identifier: NCT05935878

Oxford University Hospitals NHS Trust Protocol Record PID7088,
Cemented Versus Cementless Unicompartmental Knee Arthroplasty,
is registered and will be posted on the ClinicalTrials.gov public website.

RECORDS USUALLY APPEAR ON ClinicalTrials.gov WITHIN 2 BUSINESS DAYS
of the receipt of this message.

QUESTIONS? Contact us at: register@clinicaltrials.gov

Thank you,

PRS Team
ClinicalTrials.gov

APPENDIX 5: SCORING SYSTEMS

A5.1 Oxford Knee Score (OKS)

PROBLEMS WITH YOUR KNEE

During the past 4 weeks.. ✓**tick one box for every question**

1	***During the past 4 weeks........*** How would you describe the pain you usually have from your knee? None ❑ / Very mild ❑ / Mild ❑ / Moderate ❑ / Severe ❑
2	***During the past 4 weeks........*** Have you had any trouble with washing and drying yourself (all over) because of your knee? No trouble at all ❑ / Very little trouble ❑ / Moderate trouble ❑ / Extreme difficulty ❑ / Impossible to do ❑
3	***During the past 4 weeks........*** Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you would tend to use) No trouble at all ❑ / Very little trouble ❑ / Moderate trouble ❑ / Extreme difficulty ❑ / Impossible to do ❑
4	***During the past 4 weeks........*** For how long have you been able to walk before pain from your knee becomes **severe**? (*with or without a stick)* No pain/ More than 30 minutes ❑ / 16 to 30 minutes ❑ / 5 to 15 minutes ❑ / Around the house only ❑ / Not at all - pain severe when walking ❑
5	***During the past 4 weeks........*** After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee? Not at all painful ❑ / Slightly painful ❑ / Moderately painful ❑ / Very painful ❑ / Unbearable ❑
6	***During the past 4 weeks......*** Have you been limping when walking, because of your knee? Rarely/ never ❑ / Sometimes, or just at first ❑ / Often, not just at first ❑ / Most of the time ❑ / All of the time ❑

/P.T.O

During the past 4 weeks...

✓tick **one** box for **every** question

7 *During the past 4 weeks........*

Could you kneel down and get up again afterwards?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

8 *During the past 4 weeks........*

Have you been troubled by pain from your knee in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
❑	❑	❑	❑	❑

9 *During the past 4 weeks........*

How much has pain from your knee interfered with your usual work *(including housework)*?

Not at all	A little bit	Moderately	Greatly	Totally
❑	❑	❑	❑	❑

10 *During the past 4 weeks........*

Have you felt that your knee might suddenly 'give way' or let you down?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
❑	❑	❑	❑	❑

11 *During the past 4 weeks........*

Could you do the household shopping on your own?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

12 *During the past 4 weeks........*

Could you walk down one flight of stairs?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

A5.2 American Knee Society Score (AKSS)

5940547318 Page 1/7

KNEE SOCIETY SCORE: POST-OP

DEMOGRAPHIC INFORMATION **(To be completed by patient)**

1- Today's date
☐☐ / ☐☐ / ☐☐☐☐

Enter dates as: mm/dd/yyyy

2- Date of birth
☐☐ / ☐☐ / ☐☐☐☐

3- Height (ft' in")
☐ ☐☐

4- Weight (lbs.)
☐☐☐

5- Sex
O Male O Female

6- Side of this (surgically treated) knee
O Left O Right

If both knees have been operated on, please use a different form for each knee

7- Ethnicity
O Native Hawaiian or other Pacific Islander O American Indian or Alaska Native O Hispanic or Latino
O Arab or Middle Eastern O African American or Black O Asian O White

8- Please indicate date and surgeon for your knee replacement operation

Date
☐☐ / ☐☐ / ☐☐☐☐
Enter dates as: mm/dd/yyyy

Name of Surgeon
☐

9- Was this a primary or revision knee replacement?
O Primary O Revision

To be completed by surgeon

10- Charnley Functional Classification **(Use Code Below)** ☐

A Unilateral Knee Arthritis
B1 Unilateral TKA, opposite knee arthritic
B2 Bilateral TKA
C1 TKR, but remote arthritis affecting ambulation
C2 TKR, but medical condition affecting ambulation
C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR

OBJECTIVE KNEE INDICATORS (To be completed by surgeon)

ALIGNMENT

1- Alignment: measured on AP standing Xray (Anatomic Alignment) **25 point max**

Neutral: 2-10 degrees valgus	(25 pts)
Varus: < 2 degrees valgus	(-10 pts)
Valgus: > 10 degrees valgus	(-10 pts)

INSTABILITY

2- Medial / Lateral Instability: measured in full extension **15 point max**

None	(15 pts)
Little or < 5 mm	(10 pts)
Moderate or 5 mm	(5 pts)
Severe or > 5 mm	(0 pts)

3- Anterior / Posterior Instability: measured at 90 degrees **10 point max**

None	(10 pts)
Moderate < 5 mm	(5 pts)
Severe > 5 mm	(0 pts)

JOINT MOTION

4- Range of motion (1 point for each 5 degrees)

Deductions

Flexion Contracture **Minus Points**

1-5 degrees	(-2 pts)
6-10 degrees	(-5 pts)
11-15 degrees	(-10 pts)
> 15 degrees	(-15 pts)

Extensor Lag **Minus Points**

<10 degrees	(-5 pts)
10-20 degrees	(-10 pts)
> 20 degrees	(-15 pts)

SYMPTOMS (To be completed by patient)

1- Pain with level walking (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

2- Pain with stairs or inclines (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

3- Does this knee feel "normal" to you? (5 points)

O Always (5 pts) O Sometimes (3 pts) O Never (0 pts)

Maximum total points (25 points)

PATIENT SATISFACTION

1- Currently, how satisfied are you with the pain level of your knee while sitting? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

2- Currently, how satisfied are you with the pain level of your knee while lying in bed? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

3- Currently, how satisfied are you with your knee function while getting out of bed? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

4- Currently, how satisfied are you with your knee function while performing light household duties? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

5- Currently, how satisfied are you with your knee function while performing leisure recreational activities? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

Maximum total points (40 points)

PATIENT EXPECTATION (To be completed by patient)

Compared to what you expected before your knee replacement:

1- My expectations for pain relief were... **(5 points)**

- ○ Too High- "I'm a lot worse than I thought" (1 pt)
- ○ Too High- "I'm somewhat worse than I thought" (2 pts)
- ○ Just Right- "My expectations were met" (3 pts)
- ○ Too Low- "I'm somewhat better than I thought" (4 pts)
- ○ Too Low- "I'm a lot better than I thought" (5 pts)

2- My expectations for being able to do my normal activities of daily living were... **(5 points)**

- ○ Too High- "I'm a lot worse than I thought" (1 pt)
- ○ Too High- "I'm somewhat worse than I thought" (2 pts)
- ○ Just Right- "My expectations were met" (3 pts)
- ○ Too Low- "I'm somewhat better than I thought" (4 pts)
- ○ Too Low- "I'm a lot better than I thought" (5 pts)

3- My expectations for being able to do my leisure, recreational or sports activities were... **(5 points)**

- ○ Too High- "I'm a lot worse than I thought" (1 pt)
- ○ Too High- "I'm somewhat worse than I thought" (2 pts)
- ○ Just Right- "My expectations were met" (3 pts)
- ○ Too Low- "I'm somewhat better than I thought" (4 pts)
- ○ Too Low- "I'm a lot better than I thought" (5 pts)

Maximum total points (15 points) ☐

FUNCTIONAL ACTIVITIES (To be completed by patient)

WALKING AND STANDING (30 points)

1 - Can you walk without any aids (such as a cane, crutches or wheelchair)? **(0 points)**

O Yes O No

2 - If no, which of the following aid(s) do you use? **(-10 points)**

O wheelchair (-10 pts) O walker (-8 pts) O crutches (-8 pts) O two canes (-6 pts)

O one crutch (-4 pts) O one cane (-4 pts) O knee sleeve / brace (-2 pts)

O other

3 - Do you use these aid(s) because of your knees? **(0 points)**

O Yes O No

4 - For how long can you stand (with or without aid) before sitting due to knee discomfort? **(15 points)**

O cannot stand (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

5 - For how long can you walk (with or without aid) before stopping due to knee discomfort? **(15 points)**

O cannot walk (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

Maximum points (30 points)

STANDARD ACTIVITIES (30 points)

How much does your knee bother you during each of the following activities?	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	I never do this	
1 - Walking on an uneven surface	O	O	O	O	O	O	O	
2 - Turning or pivoting on your leg	O	O	O	O	O	O	O	
3 - Climbing up or down a flight of stairs	O	O	O	O	O	O	O	
4 - Getting up from a low couch or a chair without arms	O	O	O	O	O	O	O	
5 - Getting into or out of a car	O	O	O	O	O	O	O	
6 - Moving laterally (stepping to the side)	O	O	O	O	O	O	O	

Maximum points (30 points)

ADVANCED ACTIVITIES (25 points)

1 - Climbing a ladder or step stool	O	O	O	O	O	O	O	
2 - Carrying a shopping bag for a block	O	O	O	O	O	O	O	
3 - Squatting	O	O	O	O	O	O	O	
4 - Kneeling	O	O	O	O	O	O	O	
5 - Running	O	O	O	O	O	O	O	

Maximum points (25 points)

DISCRETIONARY KNEE ACTIVITIES (15 points)

Please check 3 of the activities below that you consider *most important* to you.
(Please do not write in additional activities)

Recreational Activities

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (>30mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)

Workout and Gym Activities

- ☐ Weight-lifting
- ☐ Leg Extensions
- ☐ Stair-Climber
- ☐ Stationary Biking / Spinning
- ☐ Leg Press
- ☐ Jogging
- ☐ Elliptical Trainer
- ☐ Aerobic Exercises

Please copy all 3 checked activities into the empty boxes below.

How much does your knee bother you during each of these activities?

Activity (Please write the 3 activites from list above)	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	
1.	○	○	○	○	○	○	
2.	○	○	○	○	○	○	
3.	○	○	○	○	○	○	

Maximum points (15 points)

Maximum total points (100 points)

A5.3 Intermittent and Constant Osteoarthritis Pain (ICOAP)

A Measure of Intermittent and Constant Osteoarthritis Pain, ICOAP: KNEE Version

People have told us that they experience different kinds of pain (including aching or discomfort) in their knee. To get a better sense of the different types of knee pain you may experience, we would like to ask you about any "constant pain" (pain you have all the time) separately from any pain that you may experience less often, that is, "pain that comes and goes". The following questions will ask you about the pain that you have experienced in your knee in the PAST WEEK. Please answer ALL questions.

A) CONSTANT PAIN

For each of the following questions, please select the response that best describes, on average, your *constant knee pain* in the PAST WEEK.

1. In the past week, how intense has your *constant knee pain* been?

☐$_0$	☐$_1$	☐$_2$	☐$_3$	☐$_4$
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

2. In the past week, how much has your *constant knee pain* affected your sleep?

☐$_0$	☐$_1$	☐$_2$	☐$_3$	☐$_4$
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

3. In the past week, how much has your *constant knee pain* affected your overall quality of life?

☐$_0$	☐$_1$	☐$_2$	☐$_3$	☐$_4$
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

4. In the past week, how frustrated or annoyed have you been by your *constant knee pain?*

☐$_0$	☐$_1$	☐$_2$	☐$_3$	☐$_4$
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

5. In the past week, how upset or worried have you been by your *constant knee pain*?

☐$_0$	☐$_1$	☐$_2$	☐$_3$	☐$_4$
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

B) PAIN THAT COMES AND GOES

For each of the following questions, please select the response that best describes your *knee pain that comes and goes, on average,* in the PAST WEEK.

6. In the past week, how intense has your most severe *knee pain that comes and goes* been?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

7. In the past week, how frequently has this *knee pain that comes and goes* occurred?

☐0	☐1	☐2	☐3	☐4
Never/ No knee pain that comes and goes	Rarely	Sometimes	Often	Very Often

8. In the past week, how much has your *knee pain that comes and goes* affected your sleep?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

9. In the past week, how much has your *knee pain that comes and goes* affected your overall quality of life?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

10. In the past week, how frustrated or annoyed have you been by your *knee pain that comes and goes*?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

11. In the past week, how upset or worried have you been by your *knee pain that comes and goes*?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

THANK YOU!

APPENDIX 6: SURVEY INSTRUMENT

A survey of surgeons to identify instrumentation improvements for the Oxford Unicompartmental Knee Replacement Procedure

Medial Oxford Unicompartmental Knee Replacement Instrumentation Survey

Research Title: A survey of surgeons to identify instrumentation improvements for the Oxford Unicompartmental Knee Replacement Procedure

Central University Research Ethics Committee Approval Reference: R81755/RE001

Researchers: Lachlan Arthur and David Murray
Contact: lachlan.arthur@ndorms.ox.ac.uk / david.murray@ndorms.ox.ac.uk

You are being invited to take part in a research project that aims to identify potential improvements for the instrumentation used for the medial Oxford Unicompartmental Knee Replacement (hereby Oxford UKR) procedure from the perspective of surgeons. This research will form part of Lachlan Arthur's DPhil (Doctor of Philosophy) Project, and your participation is greatly appreciated.

The survey will take approximately 10 minutes to complete. **All responses are anonymous.**

Please follow this link to view the full Participant Information Sheet:
https://bit.ly/InstrumentationSurveyPIS

Section 1 ...

Consent

1

By checking the following box you are indicating that you have read and understood the Participant Information Sheet (above) and provide consent for your responses to be recorded and published as described. *

○ Proceed to survey

Section 2 ...

Demographic Information

2

What stage of your orthopaedic surgical career are you in? *

- ◯ Trainee
- ◯ Consultant
- ◯ Other

3

For how many years have you been performing the Oxford UKR Procedure? *

The value must be a number

4

Of your current knee replacement caseload (both partial and total knee replacements) **what proportion** are Oxford UKRs? (enter number as a percentage) *

The value must be a number

5

How many Oxford UKR procedures do you perform **per year?** *

The value must be a number

Section 3 ...

Patient Set Up, Incision and Osteophyte Removal

Please indicate whether the instruments for each stage of the Oxford UKR procedure listed have any limitations or perform sub-optimally in your experience:

6

Do you find the Oxford Leg Holder difficult to use? *

◯ Yes

◯ No

7

Are there any additional instruments or equipment that would help with the patient set up? (please list below)

Enter your answer

8

Patient Positioning, Incision and Osteophyte Removal *

◯ Instrumentation for this stage of the procedure has limitations and/or performs sub-optimally

◯ No instrumentation changes are required for this stage of the procedure

Section 4 ...

Patient Set Up, Incision and Osteophyte Removal

You have indicated that instruments used for Patient Set Up, Incision, and Osteophyte removal for the Oxford UKR procedure have limitations and/or perform sub-optimally

9

Please select the instrument(s) that have limitations and/or perform sub-optimally *

- [ ] Oxford Leg Holder
- [ ] Narrow (6mm) Chisel
- [ ] Rongeur
- [ ] Other

10

Please elaborate on the limitations and/or sub-optimal performance of the instrument(s) that you selected

Enter your answer

Section 5 ...

Tibial Preparation and Resection

Please indicate whether the instruments for each stage of the Oxford UKR procedure listed have any limitations or perform sub-optimally in your experience:

11

Tibial Preparation and Resection *

◯ Instrumentation for this stage of the procedure has limitations and/or performs sub-optimally

◯ No instrumentation changes are required for this stage of the procedure

Section 6 ...

Tibial Preparation and Resection

You have indicated that instruments used for the Tibial Preparation and Resection for the Oxford UKR procedure have limitations and/or perform sub-optimally

12

Please select the instrument(s) that have limitations and/or perform sub-optimally *

- ☐ Femoral Sizing Spoons
- ☐ G-clamp
- ☐ Extramedullary Tibial Resection Guide
- ☐ Oxford Tibial Shim
- ☐ Oxford Tibial Slotted Shim
- ☐ Bone Pin
- ☐ Pin Inserter/Extractor
- ☐ Medial Collateral Ligament Retractor (a.k.a. 'Curly Wurly')
- ☐ Reciprocating Saw and Blade (Vertical Cut)
- ☐ Oscillating Saw and Blade (Horizontal Cut)
- ☐ 'Boomerang' shim
- ☐ Other

13

Please elaborate on the limitations and/or sub-optimal performance of the instrument(s) that you selected

Enter your answer

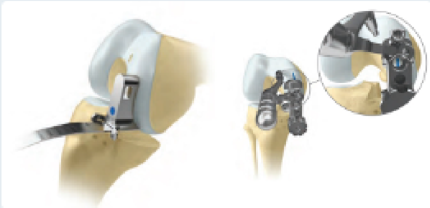
Section 7 ...

Femoral Preparation and Posterior Resection

Please indicate whether the instruments for each stage of the Oxford UKR procedure listed have any limitations or perform sub-optimally in your experience:

14

Femoral Preparation and Posterior Resection *



○ Instrumentation for this stage of the procedure has limitations and/or performs sub-optimally

○ No instrumentation changes are required for this stage of the procedure

Section 8 ...

Femoral Preparation and Posterior Resection

You have indicated that instruments used for the Femoral Preparation and Posterior Resection for the Oxford UKR procedure have limitations and/or perform sub-optimally

15

Please select the instrument(s) that have limitations and/or perform sub-optimally *

- [ ] 5mm Awl
- [ ] Intramedullary (IM) Rod / Rod Pusher
- [ ] Oxford IM Link
- [ ] Femoral Drill Guide
- [ ] Oxford IM Rod Removal Hook
- [ ] Femoral Posterior Resection Guide
- [ ] Oxford Slap Hammer
- [ ] Other

16

Please elaborate on the limitations and/or sub-optimal performance of the instrument(s) that you selected

Enter your answer

Femoral Milling and Balancing the Flexion/Extension Gaps

Please indicate whether the instruments for each stage of the Oxford UKR procedure listed have any limitations or perform sub-optimally in your experience:

17

Femoral Milling and Balancing the Flexion/Extension Gaps
*

◯ Instrumentation for this stage of the procedure has limitations and/or performs sub-optimally

◯ No instrumentation changes are required for this stage of the procedure

Section 10 ...

Femoral Milling and Balancing the Flexion/Extension Gaps

You have indicated that instruments used for Femoral Milling and Balancing the Flexion/Extension Gaps in the Oxford UKR procedure have limitations and/or perform sub-optimally

18

Please select the instrument(s) that have limitations and/or perform sub-optimally *

- ☐ Spherical Femoral Mill
- ☐ Spigots for Femoral Mill
- ☐ Bone Collar Remover
- ☐ Femoral Impactor
- ☐ Trial Femoral Component
- ☐ Tibial Template
- ☐ Feeler Gauge
- ☐ Other

19

Please elaborate on the limitations and/or sub-optimal performance of the instrument(s) that you selected

Enter your answer

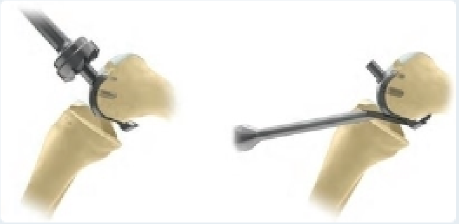
Section 11 ...

Impingement Prevention using the Anti-Impingement Guide

Please indicate whether the instruments for each stage of the Oxford UKR procedure listed have any limitations or perform sub-optimally in your experience:

20

Impingement Prevention using the Anti-Impingement Guide *



○ Instrumentation for this stage of the procedure has limitations and/or performs sub-optimally

○ No instrumentation changes are required for this stage of the procedure

Section 12 ...

Impingement Prevention using the Anti-Impingement Guide

You have indicated that instruments used for Impingement Prevention using the Anti-Impingement Guide in the Oxford UKR procedure have limitations and/or perform sub-optimally

21

Please select the instrument(s) that have limitations and/or perform sub-optimally *

- [ ] Anterior Mill
- [ ] Oxford Anti-Impingement Guide
- [ ] Oxford Posterior Osteophyte Chisel
- [ ] Other

22

Please elaborate on the limitations and/or sub-optimal performance of the instrument(s) that you selected

Enter your answer

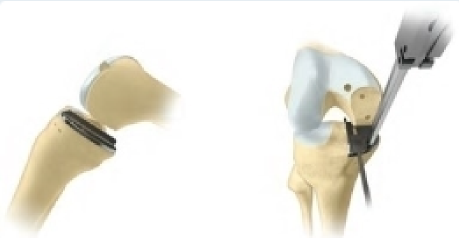
Section 13 ...

Final Tibial Preparation and Keel Cut

Please indicate whether the instruments for each stage of the Oxford UKR procedure listed have any limitations or perform sub-optimally in your experience:

23

Final Tibial Preparation and Keel Cut *



◯ Instrumentation for this stage of the procedure has limitations and/or performs sub-optimally

◯ No instrumentation changes are required for this stage of the procedure

Section 14 ...

Final Tibial Preparation and Keel Cut

You have indicated that instruments used for the Final Tibial Preparation and Keel Cut in the Oxford UKR procedure have limitations and/or perform sub-optimally

24

Please select the instrument(s) that have limitations and/or perform sub-optimally *

- ☐ Trial Bearing
- ☐ Trial Bearing Removers
- ☐ Tibial Template
- ☐ Oxford Tibial Template Nail
- ☐ Tibial Keel Cut ("Toothbrush") Saw
- ☐ Trial Tibial Component
- ☐ Tibial Gouge / Pick
- ☐ Other

25

Please elaborate on the limitations and/or sub-optimal performance of the instrument(s) that you selected

Enter your answer

Section 15

Implantation/Removal of Trial Components and Bearing

Please indicate whether the instruments for each stage of the Oxford UKR procedure listed have any limitations or perform sub-optimally in your experience:

26

Implantation/Removal of Trial Components and Bearing *

- ◯ Instrumentation for this stage of the procedure has limitations and/or performs sub-optimally
- ◯ No instrumentation changes are required for this stage of the procedure

Section 16 ...

Implantation/Removal of Trial Components and Bearing

You have indicated that instruments used for the Implantation/Removal of Trial Components and Bearing in the Oxford UKR procedure have limitations and/or perform sub-optimally

27

Please select the instrument(s) that have limitations and/or perform sub-optimally *

- [ ] Femoral Impactor
- [ ] Trial Femoral Component
- [ ] Right-Angled Tibial Impactor
- [ ] Trial Tibial Component
- [ ] Trial Bearing
- [ ] Trial Bearing Removers
- [ ] Other

28

Please elaborate on the limitations and/or sub-optimal performance of the instrument(s) that you selected

Enter your answer

Section 17 ...

Insertion of Final Components

Please indicate whether the instruments for each stage of the Oxford UKR procedure listed have any limitations or perform sub-optimally in your experience:

29

Insertion of Final Components

◯ Instrumentation for this stage of the procedure has limitations and/or performs sub-optimally

◯ No instrumentation changes are required for this stage of the procedure

Section 18 ...

Insertion of Final Components

You have indicated that instruments used for the Insertion of the Final Components in the Oxford UKR procedure have limitations and/or perform sub-optimally

30

Are the instruments that have limitations and/or perform sub-optimally required for cemented fixation or cementless fixation, or both? *

◯ Cemented

◯ Cementless

◯ Both

Section 19 ···

Cemented Instruments

31

Please select the CEMENTED instrument(s) that have limitations and/or perform sub-optimally *

- ○ Right-Angled Tibial Impactor
- ○ Cement Removal Chisel to adjust tibial component position
- ○ Oxford Cement Key Drill
- ○ Femoral Impactor
- ○ Woodson Cement Curette
- ○ Other

32

Please elaborate on the limitations and/or sub-optimal performance of the instrument(s) that you selected

Enter your answer

Section 20 ···

Cementless Instruments

33

Please select the CEMENTLESS instrument(s) that have limitations and/or perform sub-optimally *

- [ ] Cementless Tibial Introducer
- [ ] Right-Angled Tibial Impactor
- [ ] Cement Removal Chisel to adjust tibial component position
- [ ] Femoral Impactor
- [ ] Other

34

Please elaborate on the limitations and/or sub-optimal performance of the instrument(s) that you selected

Enter your answer

Section 21

Both Cemented and Cementless Instruments

35

Please select the CEMENTED instrument(s) that have limitations and/or perform sub-optimally *

- Right-Angled Tibial Impactor
- Cement Removal Chisel to adjust tibial component position
- Oxford Cement Key Drill
- Femoral Impactor
- Woodson Cement Curette
- Other

36

Please elaborate on the limitations and/or sub-optimal performance of the CEMENTED instrument(s) that you selected

Enter your answer

37

Please select the CEMENTLESS instrument(s) that have limitations and/or perform sub-optimally *

- [ ] Cementless Tibial Introducer
- [ ] Right-Angled Tibial Impactor
- [ ] Cement Removal Chisel to adjust tibial component position
- [ ] Femoral Impactor
- [ ] Other

38

Please elaborate on the limitations and/or sub-optimal performance of the CEMENTLESS instrument(s) that you selected

Enter your answer

Section 22 ...

Computer-Assisted Surgery for the Oxford UKR

The following questions relate to the potential introduction of Computer-Assistance for the Oxford UKR procedure

39

Do you believe the Oxford UKR procedure would be improved by the use of Computer-Assisted Surgery (CAS)? This could include, but is not limited to:

- Image-based Navigation
- Model-based Navigation
- Accelerometer Guided Instruments
- Robotic Surgery *

◯ Yes

◯ No

40

If yes, what steps of the procedure do you believe would benefit most from the introduction of computer assistance?

Enter your answer

41

What type/s of computer assistance would improve the Oxford UKR procedure?

Enter your answer

APPENDIX 7: EXTRA MECHANICAL TESTING INFORMATION AND RESULTS

A7.1 Slot Bottom Roundness Algorithm

The roundness metric used to evaluate the roundness of the bottom of keel slots cut in Sawbones is detailed below. The MATLAB code for the algorithm was written by Jack Tu based on instructions on how to identify round objects from the MathWorks Help Centre (https://uk.mathworks.com/help/images/identifying-round-objects.html). The edge of the bottom of coronal slices of slots were detected as shown in **Figure 7.4B**. The below algorithm was then applied to the shape using its calculated area and perimeter from edge detection. This resulted in a value of 0 (a line) to 1 (a perfect circle) being calculated. Examples of objects and their associated roundness metric values are shown in **Figure A-5**.

$$Roundness\ Metric = \frac{4\pi \times Area}{Perimeter^2}$$

$$Area\ of\ a\ Circle = \pi r^2$$

$$Perimeter\ of\ a\ Circle = 2\pi r$$

$$Therefore\ if\ the\ shape\ is\ a\ perfect\ circle, the\ roundness\ metric\ equals\ 1:$$

$$Roundness\ Metric = \frac{4\pi \times \pi r^2}{(2\pi r)^2} = \frac{4\pi^2 r^2}{4\pi^2 r^2} = 1$$

$$As\ area\ of\ a\ shape\ approaches\ 0\ (i.e.\ a\ line), the\ Roundness\ Metric\ approaches\ 0.$$

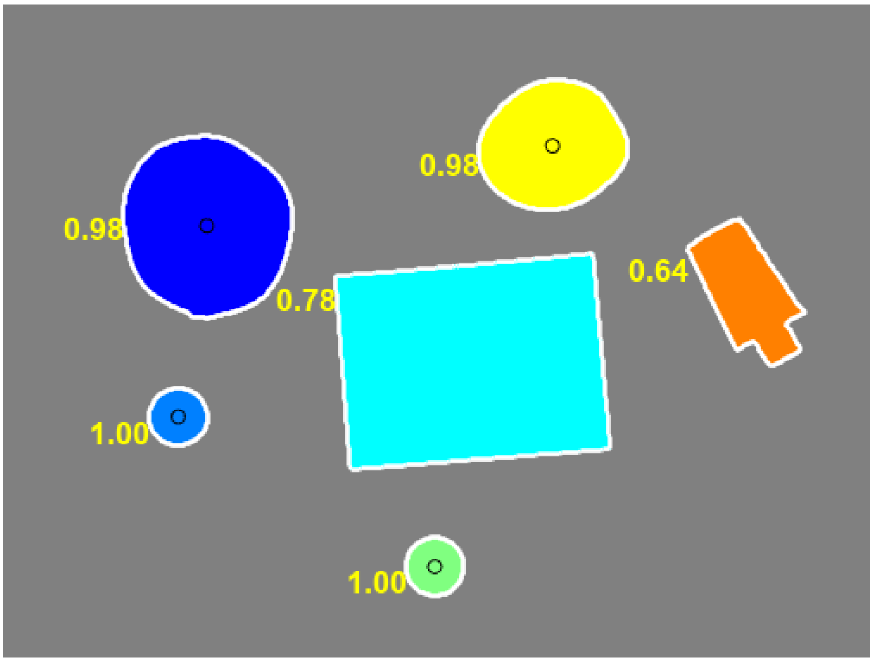


Figure A-5: Examples of objects and their associated roundness metric values. Taken from https://uk.mathworks.com/help/images/identifying-round-objects.html.

A7.2 Compact Tensile Testing with Bovine Tibial Bone

The aim of these experiments was to repeat the CTT experiments performed in **Chapter 7** to validate the Sawbones experiments using trabecular bone from bovine tibiae as the testing material. Testing was conducted as per **Section 7.2.5**, except the slots were prepared in trabecular bone from bovine tibiae. The results of these tests are shown in **Figure A-6**.

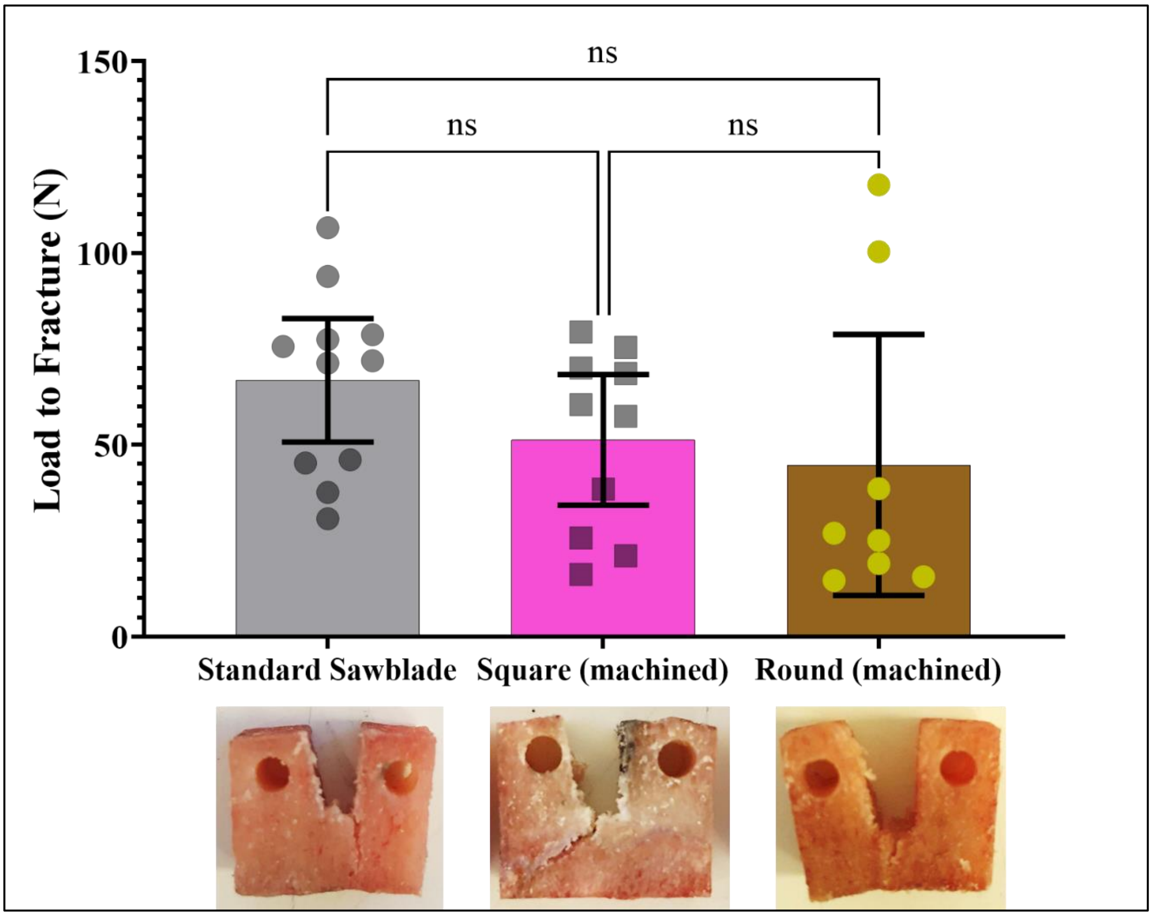


Figure A-6: Load to fracture (mean ± 95% confidence intervals, individual results shown) of compact tensile testing specimens made in bovine tibia from standard sawblade, square machined, and round machined slots. Examples of fractured testing specimens are shown beneath the results for each preparation. Annotations indicate p-values for Tukey's multiple comparisons test: ns indicates p>0.05.

As with the Sawbones specimens, fractures tended to originate from stress risers in the slot: the deepest groove for the standard sawblade slots and the corners of the square slots. There was a high amount of variability in the LTF results, which resulted in no significant difference being identified between slot preparations. The variability was thought to be due to the inconsistency in the bone, as it was clear that the density of the bone varied, and the epiphyseal plate was present in some specimens (**Figure A-7**). The bone was also difficult to work with and produce consistent specimens.

Unfortunately, the CTT results using Sawbones were unable to be validated. However, these experiments also highlighted the limitations of bovine tibia as a testing specimen and therefore validated the choice to use Sawbones for mechanical testing.

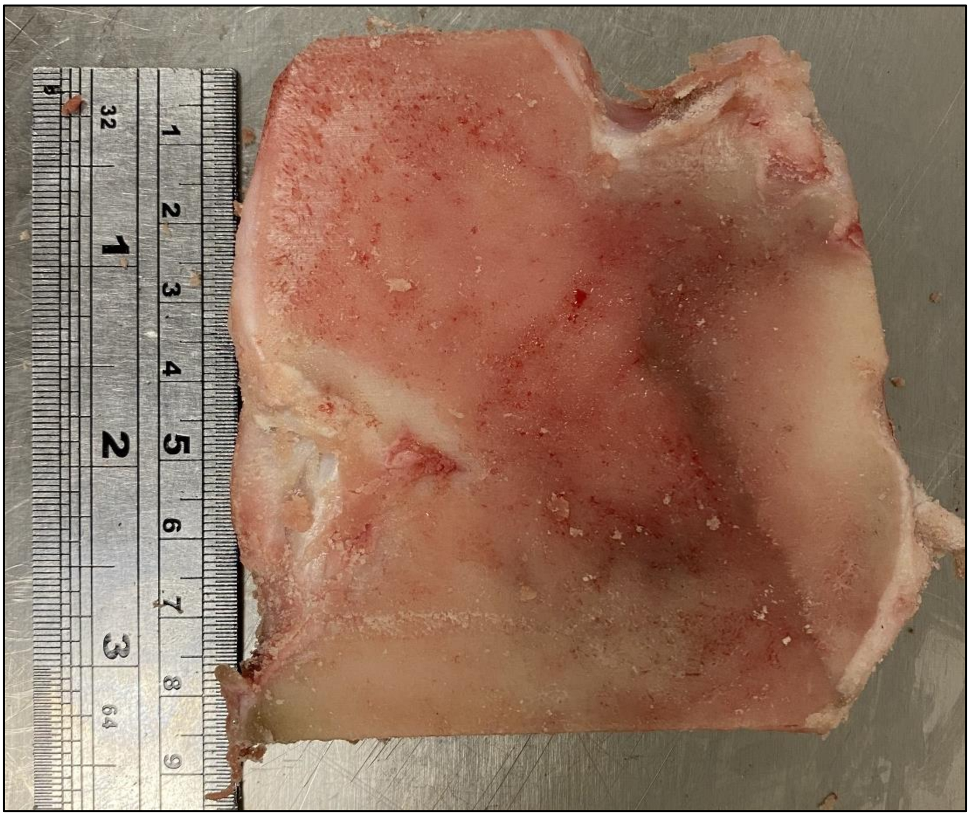


Figure A-7 Image of a slice of trabecular tibial bovine bone. Note the variability of colour and texture throughout the slice.

APPENDIX 8: COMPUTER ASSISTED SURGERY FOR THE OUKR

This proposal was the result of the findings of this thesis and a collaboration between the author, Kukhokuhle Tsengwa, Jack Tu, Stephen Mellon, and David Murray. Preliminary experiments validating the ability of QR codes to track the necessary surgical steps was underway at the time of writing this thesis.

Overall Aim

To use computer assistance to position the tibial and femoral components of the Oxford Unicompartmental Knee Replacement (OUKR) to recreate the native knee kinematics of patients with anteromedial osteoarthritis.

Background

The use of computer assisted surgery (CAS) for knee arthroplasty is increasing rapidly. There is currently no CAS systems designed specifically for the OUKR. We are not aware of any CAS systems for knee arthroplasty which aim to capture the patient's native knee kinematics intraoperatively and recreate the patient's kinematics through the operation. Aiming to recreate the patient's pre-disease kinematics is unique to the OUKR and intraoperative tracking of kinematics is a novel aspect of this project.

A survey of 106 OUKR surgeons found that 63% of surgeons believe CAS would improve the OUKR procedure (**Chapter 5**). Two of the surgical steps that surgeons found most difficult were the orientation of the vertical cut and the position of the intramedullary rod / femoral drill guide, steps which determine the orientation of the tibial and femoral components, respectively. Surgeons also identified that these two steps of the procedure would benefit the most from CAS.

Steps to Receive Computer Assistance

1) Track the native kinematics of the medial compartment of the knee, i.e. identify the instant centre of rotation (the point of contact between the medial femoral condyle and the tibia) and track its path on the medial tibial plateau.

    a) Assumption: Lateral compartment is normal and therefore if the knee is flexed/extended in valgus this is representative of the 'normal' kinematics. This should hold true if the recommended indications of OUKR are followed, as the patient should have a 'normal' lateral compartment.

2) Guide the surgeon to make the vertical tibial resection parallel to path of the instant centre of rotation, with the cut passing immediately medial to the tibial spine.

3) Guide positioning of femoral components so that it is:

    a) Neutrally aligned (90° to the tibial component)

    b) Positioned so that the bearing will be ~1mm from the tibial wall.

Materials

Current Approach: QR codes that are attached to the patient and/or instrumentation will be tracked using an Intel® RealSense™ Depth Camera D435i. Through motion tracking of the patient and instruments, real-time feedback will be given to the surgeon (initially via a computer screen) to provide them with information and guide key steps of the procedure.

Methods

1) Proof of Concept: Proving that the QR the surgeon to direct the vertical cut towards the anterior superior iliac spine (ASIS).

    a) To prove the concept that the system can track objects, a simple set up with a marker on the ASIS and surgical saw will be used with fixed position cameras.
    b) Validate the accuracy of the camera tracking using a Vicon Marker system (a Gold Standard system with sub millimetre accuracy).
    c) Repeat validation with mobile cameras (i.e. fixed to a surgeon's headset).
2) Tracking the kinematics of the knee to determine the instant centre of rotation – likely the most difficult step to achieve.
    a) This will be explored in plastic bones initially and possibly in cadavers and live subjects (if markers can be attached non-invasively).
3) Guide the surgeon to
    a) Make the vertical tibial resection parallel to path of the instant centre of rotation, with the cut passing immediately medial to the tibial spine.
    b) Position the femoral drill guide so that the femoral component will be neutrally aligned (90° to the tibial component) and so the bearing will be ~1 mm from the tibial wall.
4) Testing in Plastic Bones and Cadavers with surgeons
    a) Validate the system with multiple users and optimise the user interface.
5) Clinical Trial of the System to compare it to Microplasty instrumentation.
6) Future development and optimisation
    a) Optimising the system to utilise Augmented Reality

   i) Rather than displaying data and guidance to surgeon on a separate screen, augmented reality technology could be used to project information/guidance onto the patient with the surgeon wearing Google glasses, or similar.
   ii) Some systems use augmented reality on mobile phones which use the phone's camera to provide surgical guidance.

b) Optimising camera system for best line of sight (likely to be mounted to a headset on the surgeon, but could be affixed to the surgical light or another location in the operating room if a fixed-mount camera is found to be better than mobile)

c) Guiding further steps of the procedure, such as the varus/valgus angle of the tibial component if an adjustable ankle yoke is used.