Imperial College London

TOTAL KNEE REPLACEMENTS:

DESIGN AND PRE-CLINICAL TESTING METHODS

Camilla Halewood

A Thesis Submitted for the Degree of

Doctor of Philosophy

The Biomechanics Group

Department of Mechanical Engineering

Imperial College London

April 2016

Declaration of Originality

I declare that all the work in this thesis is my own, except that which has been appropriately referenced.

Copyright Statement

Some of the work in this thesis has been presented elsewhere, in peer-reviewed journal articles and as conference presentations (Appendix D). In cases where necessary, permission for reproduction of those works has been granted; these cases are summarised in Appendix E.

Abstract

Total knee replacement (TKR) is a common and successful treatment for severe osteoarthritis of the knee. However, a large minority of people remain dissatisfied after the operation, despite adequate pain relief. Over 50 designs of TKR are used in the UK each year, but differentiating between these devices in terms of patient function and making the right choice for each patient remains challenging. The aim of this research was to characterise designs of TKR in the laboratory, using pre-clinical testing methods, in order to better understand TKR function, and make suggestions for improved implant design and testing. Conventional, medial-pivot, guided-motion and bicruciate retaining (BCR) TKRs were tested. Standard ASTM test methods used for CE-marking purposes were demonstrated to differentiate between devices, but did not produce enough information to adequately understand how a new device will behave clinically, or what the potential benefits of a new device would be to patients. Guided-motion devices are meant to replicate normal knee motion, but there has been concern that they might cause too much rotation of the knee, leading to anterolateral knee pain. Results from cadaveric testing suggest that they do not adequately mimic normal knee motion and small design changes may have little impact on performance. A BCR TKR, designed to improve stability in the replaced knee joint, was also tested. Knee kinematics were measured for three design phases and surgical feasibility was also assessed for this more complicated procedure. BCR TKR was shown to lead to more normal levels of anteroposterior tibiofemoral laxity, compared to a conventional, anterior-cruciate-ligament-sacrificing TKR. Inherent variability between people's anatomy and osteoarthritis pathology suggests there will never be a single, perfect, TKR, but more comprehensive pre-clinical testing could improve the regulatory approval process and inform better device selection, leading to improved patient outcomes.

Contents

List of Figures

List of Tables

Glossary

ACL	anterior cruciate ligament
ADL(s)	activity(ies) of daily living
AMTI	Advanced Mechanical Technology, Inc.
AP	anterior-posterior (translational direction)
arthroplasty	surgical reconstruction or replacement of a degenerated joint
ARUK	Arthritis Research UK, a charity
BCR	bi-cruciate retaining - (TKR)
BCS	bi-cruciate substituting (manufacturer specific TKR, Smith & Nephew)
bench-top	an experiment using testing rigs in the laboratory but without human or animal cadaver tissue
BW	body weight
CoCr	cobalt chrome alloy
CR	(posterior) cruciate retaining (type of TKR where the PCL is retained)
CS	condylar or cruciate stabilised (types of TKR where the PCL tends to be resected)
dMCL	deep medial collateral ligament
DoF	degree of freedom
FE	flexion-extension (primary rotation of the knee)
FEA	finite element analysis
FMA	femoral mechanical-anatomical (angle)
HTO	high tibial osteotomy
ICLH	Imperial College/London Hospital Total Knee Replacement
IE	internal-external (secondary rotation of the knee)
IM	intramedullary
in silico	computational (literally "in silicon")

in vitro	experimental (literally "in glass", used in place of "ex vivo")
in vivo	clinical (literally "in body")
ITB	the ilio-tibial band
KSS	The Knee Society Score, a SROM
LCL	lateral collateral ligament
M:L	medial:lateral tibiofemoral loading distribution
MCL	medial collateral ligament
MIS	minimally invasive surgery
ML	medial-lateral (translational direction)
MRI	magnetic resonance imaging
MTM	materials testing machine
NHS	The National Health Service
OA	osteoarthritis
OKR	Oxford Knee Rig, a dynamic knee squatting rig
OKS	Oxford Knee Score, a PROM
PCL	posterior cruciate ligament
PD	proximal-distal (translational direction)
PE	polyethylene
PFJ	patellofemoral joint
PFJR	patellofemoral joint replacement
PLC	(the soft tissue structures in the) posterior lateral corner (of the knee)
PMC	(the soft tissue structures in the) posterior medial corner (of the knee)
PMMA	polymethylmethacrylate (bone cement)
PPI	public patient involvement
PROM	patient reported outcome measure
PS	PCL-substituting (type of total knee replacement)
PT	patella tendon (ligament)
ROM	range of motion - describes the range of flexion-extension of the knee joint
SROM	surgeon reported outcome measure
STL	stereolithography

TKA	total knee arthroplasty
TKR	total knee replacement
UHMWPE	ultra high molecular weight polyethylene
UKR	unicondylar knee replacement
VV	varus-valgus (secondary rotation of the knee, also known as adduction-abduction)

CHAPTER 1

INTRODUCTION

1.1 Research motivations

Osteoarthritis (OA) of the knee is a debilitating, painful disease which affects hundreds of millions of people worldwide and is a major source of socio-economic cost. Total knee replacement (TKR) is a successful treatment for severe OA of that joint, relieving pain and restoring function in the vast majority of patients. However, clinical outcome after TKR surgery is inconsistent and a large minority of pain-free patients remain unhappy after surgery, despite the pain relief that is afforded to them by the device. It is believed that this dissatisfaction is partly due to functional inadequacies that patients experience with their device(s) and that these, in turn, are due to a combination of factors, including: design of the TKR; removal of one or both of the cruciate ligaments; and alteration of the other soft tissues in the knee joint.

There have been many designs of TKR over the years, reflecting attempts to solve the clinically observed problems and improve levels of satisfaction among TKR patients. Pre-clinical testing (that is, testing that is performed in the laboratory) of new devices can assist in the understanding of the functional inadequacies of TKR designs and aid in the development of better ones. The work described in this thesis was motivated by the continuing introduction of new devices by implant manufacturers; do design differences between TKRs contribute to improved knee biomechanics, and how can this be assessed in the pre-clinical setting?

1.2 Research aims

The work in this thesis had several research aims:

- – Examine the biomechanics of the replaced knee;

- Investigate the laboratory-based pre-clinical assessment options for knee replacements;

- Compare different TKR designs in the pre-clinical setting;

- Inform better test methods;

- Suggest improved/different implant solutions.

1.3 Clinical relevance

All TKRs aim to alleviate pain and, to a certain extent, restore function to the severely osteoarthritic knee. But some may do it better than others and some devices might suit certain types of patient more than others. Pre-clinical testing of these implants has huge clinical significance; proof of the performance of a device in the laboratory setting has the potential to prevent ineffective or unsafe new devices from being implanted into living patients. Knee joints and, therefore, their replacements, require the correct combination of stability and laxity in order to function properly, permitting the user to navigate different terrains and activity types. A better understanding of TKR motion and how different design features interact with the remaining soft tissue structures in the knee is essential if implants are to achieve that combination successfully. There has long been a hope that total joint arthroplasty would by now be obsolete, replaced by regenerative techniques and disease prevention. But the numbers of TKRs being implanted is steadily increasing and while we await a truly disruptive technology in the field of severe knee osteoarthritis treatment, or better early OA treatment, better functioning TKRs continue to be an important target for engineers and surgeon designers. The work described in this thesis is part of the ongoing efforts to improve the design and the pre-clinical assessment of these devices.

1.4 Thesis overview

A comprehensive review of the literature is presented in Chapters 2, 3 and 4, with the anatomy of the human knee, its simplified biomechanics and pathology presented in Chapter 2; total knee replacements explored in Chapter 3 and existing pre-clinical assessment methods for these devices examined in Chapter 4.

Three separate TKR studies, with relevant background, methodology, results and discussions, are presented in Chapters 5, 6 and 7.

The stability characteristics of TKRs are investigated in Chapter 5, using bench-top test methods.

Instability of the knee joint is a common complaint amongst TKR patients and although this subjective, clinical feeling of instability is separate from the precise stability (or constraint) measurement defined by engineers as the knee's ability to resist translations or rotations, the two are inextricably linked to one another. Instability is a frequent cause for revision so it is an important characteristic to quantify for TKR designs and to understand how implant stability in different directions varies with design changes. Recommendations are made for improvements to the standard test methods, so that more information about implant performance can be elucidated from the results.

Chapter 6 explores the idea of "guided-motion" total knee replacements and examines whether these modern devices accurately mimic natural knee kinematics and how their guided-motion behaviour affects the soft tissue structures surrounding the knee. Guided-motion knees have more complex articular geometries than "conventional" TKRs, in an effort to match normal knee motion, but it has been suggested that these high-performance knees may have implications for the surrounding soft tissues of the knee. This study examined changes in ligament lengths following arthroplasty and also evaluated how much impact small, incremental design changes to devices affected the kinematics of the replaced knee.

Chapter 7 describes the development and testing of a bicruciate retaining (BCR) TKR. The vast majority of TKRs implanted in the world require the resection of the anterior cruciate ligament (ACL) and 25% of those also remove the posterior cruciate ligament (PCL) prior to implantation. While the action of the PCL is supposedly compensated for via a cam-post mechanism in posterior-substituting (PS) designs of TKR, the action of the ACL is meant to be mimicked via the geometry of the tibiofemoral articulation. It has been suggested that these substitutions do not compensate adequately for cruciates' absence and that ACL deficiency in TKRs could be partly responsible for poorly functioning devices and unhappy patients. The study tested three different designs of BCR TKR in the laboratory to examine the potential kinematic benefits and surgical feasibility of such a design.

Chapter 8 summarises the work done in the three studies and suggests improvements that could be made to the pre-clinical testing methods described, which testing methods should be made a mandatory part of the product development and route to market process, and suggests further work

to be done in the TKR research sphere.

In light of the work done in the three studies and the conclusions drawn in Chapter 8, Chapter 9 considers the future of and the alternatives to TKR surgery.

Finally, some of the additional work done as part of this PhD and information relating to publications is presented in the following Appendices.

Appendix A contains additional data from the work done in the studies described in Chapters 6 & 7.

Appendix B summarises the findings from a small public and patient involvement (PPI) study that aimed to understand better some of the reasons behind patient dissatisfaction with TKR surgery.

A small finite element study was conducted in support of the work in Chapter 7, this is described in Appendix C.

Some of the work in this thesis has been presented in a number of peer-reviewed journal articles and at a number of conferences. These are highlighted in Appendix D.

Appendix E contains a summary of permission for third party copyright works.

CHAPTER 2

THE HUMAN KNEE JOINT

2.1 Anatomy

2.1.1 Introduction

The relevant anatomy of the human knee, based on Gray (2008) and Scott (2011), is discussed in this section and standard terms for the planes of the body are used (Figure 2.1). The human knee is a complex synovial joint and is the largest in the body, consisting of four bones (the femur, tibia, fibula and patella) and three joints: the articulation between the tibial plateau and the distal femur (tibiofemoral joint); the articulation between the posterior of the patella and the anterior aspect of the distal femur (patellofemoral joint) and the articulation between the inferior lateral tibial condyle and the head of the fibula (the superior tibiofibular joint) (Figure 2.2). The tibiofemoral joint is by far the biggest joint in the human body and the one that causes the most problems in terms of injury and disease (Bollen, 2000).

The main function of the knee is to enable standing, walking and running over different terrains while controlling a person's centre of mass. The second function is to transmit both internal forces, which are largely caused by muscle tensions around the joint, and external forces, which result from impact between the foot and the ground. Most of the loading in the knee is due to the muscle tensions compressing the joint surfaces together (Taylor *et al.*, 2004); indeed, during an activity such as getting up from a chair, tibiofemoral joint forces can exceed three times the person's body weight (BW) (Kuster *et al.*, 1997). All the articulating surfaces in the joints are covered with hyaline cartilage, which has an ultra-low coefficient of friction, enabling, in combination with the synovial fluid that provides lubrication, smooth sliding and rolling of the surfaces over one another (Wright and Dowson, 1976).
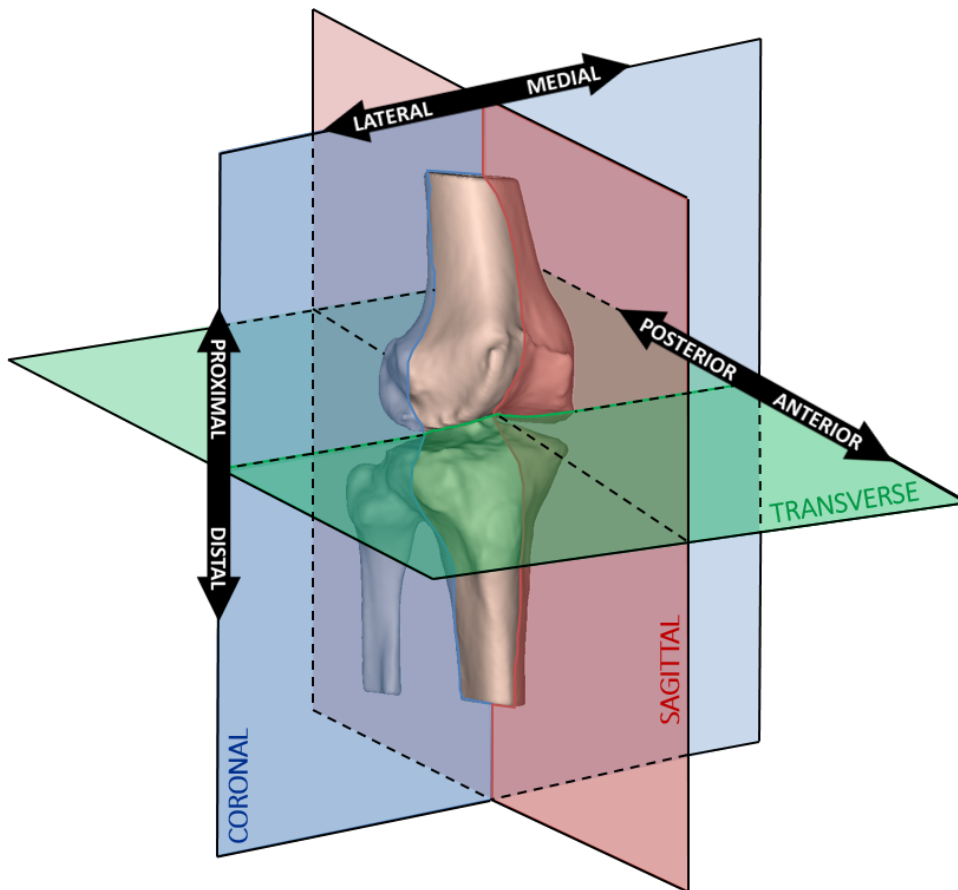
Figure 2.1   An illustration of the three main planes of the human body and anatomical terms of location using a right sided knee model as reference.

2.1.2 The geometry of the articulating surfaces in the tibiofemoral joint

The work described in this thesis is focused on the tibiofemoral joint. The distal end of the femur is the bearing surface for load transmission to the tibia (Scott, 2011). Its two condyles are largely covered by hyaline, or articular, cartilage. The condyles articulate with the plateaux of the proximal tibia. The tibiofemoral joint is thought of as two distinct compartments: the medial and the lateral. The medial plateau is longer and more congruent in its articulation with the medial femoral condyle than the lateral side, where the tibial plateau is almost convex in its centre in the sagittal plane (Figure 2.3). This articular geometry, together with the main tibiofemoral ligaments, guide the passive (that is, without consideration of the actions of the muscles) flexion kinematics of the knee (Wilson *et al.*, 1998).
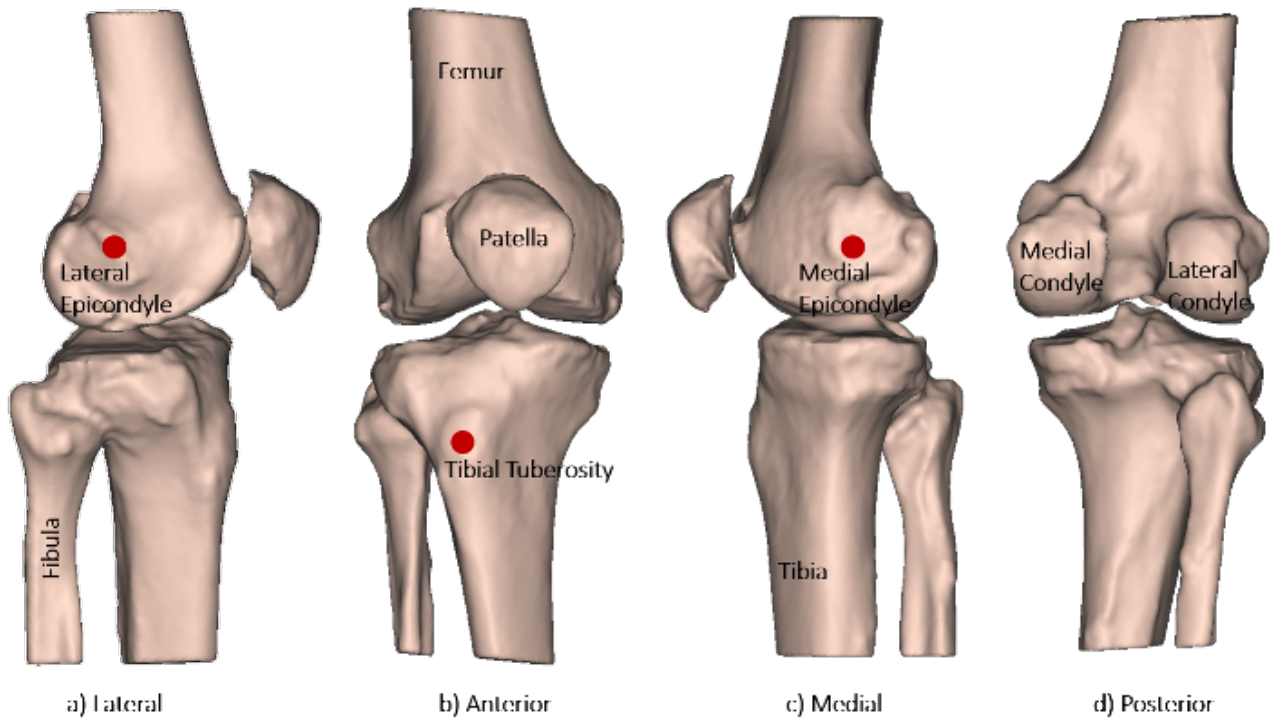
Figure 2.2   An illustration of the bones of a right sided knee joint, shown from four different aspects
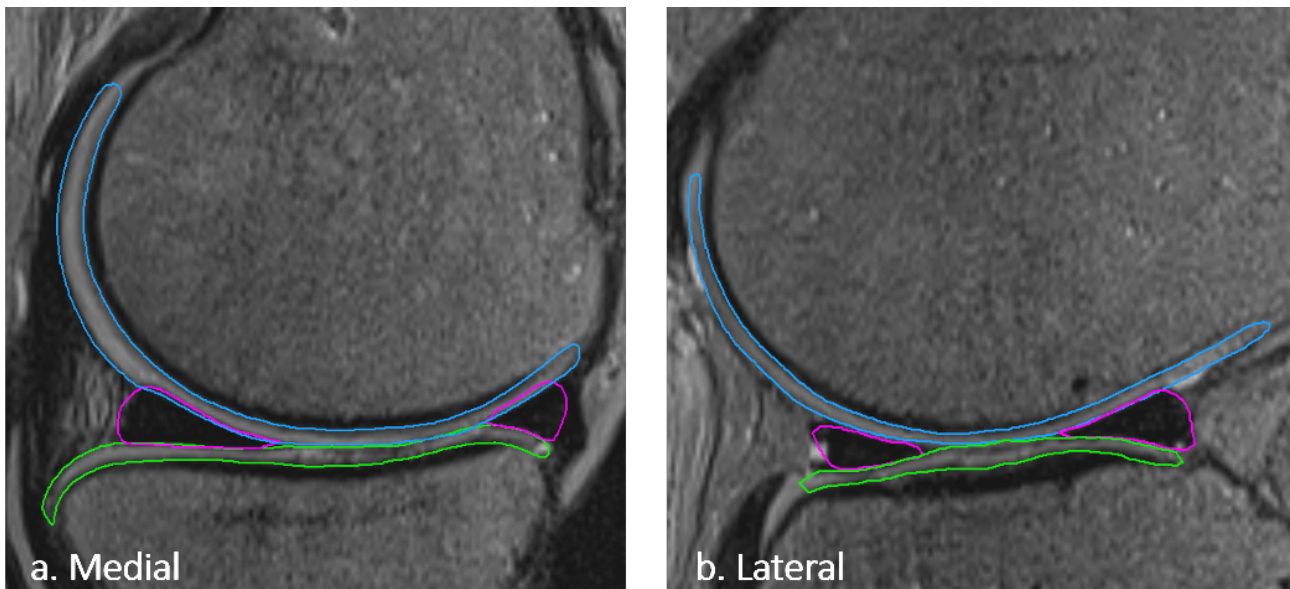
Figure 2.3   Sagittal slices of an MRI scan of a right sided cadaver knee.The femoral articular cartilage is outlined in blue, the menisci outlined in pink and the tibial articular cartilage is outlined in green. The difference in the articulating geometry between the concave medial and convex lateral sides can be clearly seen.

2.1.3 The ligaments of the knee joint

The femur and tibia are connected to each other by three main ligaments: the ACL, the PCL and the medial collateral ligament (MCL). Despite connecting the femur to the head of the fibula (rather than the tibia), the lateral (or fibular) collateral ligament (LCL) also plays a role in tibiofemoral joint motion (Sugita and Amis, 2001).   The ilio-tibial band (ITB), the posteriomedial corner (PMC) and posteriolateral corner (PLC) of the knee's soft tissues all contribute to normal tibiofemoral biomechanics (Merican and Amis, 2009; Robinson *et al.*, 2006; Miyatake *et al.*, 2011). In addition, the lateral meniscus is attached to the femur via the anterior and posterior meniscofemoral ligament and the medial meniscus is connected to the deep MCL (dMCL) as it passes between its attachment points on the femur and tibia.   There is also a large intra-articular fat-pad that sits outside the synovium at the anterior of the knee, between the infra-patellar portion of the patella tendon (PT) and the front of the tibia (Gray, 2008). The fat pad is highly innervated and vascularised, although its function is a matter of debate.   It probably protects the knee when kneeling and there is some evidence to suggest that removing the fat pad leads to poorer outcomes after TKR surgery (Moverley *et al.*, 2014). It can also be a source of pain in some athletes (Bohnsack *et al.*, 2005).

2.1.4 The menisci

The menisci, once thought of as purpose-less "remnant vestiges" (Bland-Sutton, 1897), are now recognised as vital fibrocartilaginous structures, deserving of their own section in any discussion of knee anatomy. They are found in both the medial and lateral compartments of the tibial plateau (Figure 2.4) and cover approximately two thirds of each compartment. Long considered erroneously as "shock-absorbers" (Andrews *et al.*, 2011), they in fact absorb less energy than the underlying articular cartilage and instead serve to distribute the joint load across the plateau and provide some stability to the joint; damage or meniscectomy will inevitably lead to altered loading in the joint and the potential development of OA (Figure 2.5). As many as 12 ligaments are connected to the two menisci in the knee joint (not all are present in every person), including ones whose functions are still not really understood: the intermeniscal ligament and the coronary ligaments. There are 3 ligaments which have been frequently studied in order to understand their biomechanical function: the dMCL, which provides secondary varus-valgus and anterior translational restraint to the knee joint (Arno *et al.*, 2013); and the 2 meniscofemoral ligaments (Humphry and Wrisberg), which connect the posterior horn of the lateral meniscus to the femur and have been shown to be secondary restraints to posterior

translation and external rotation of the tibia at certain angles of flexion (Gupte *et al.*, 2003).
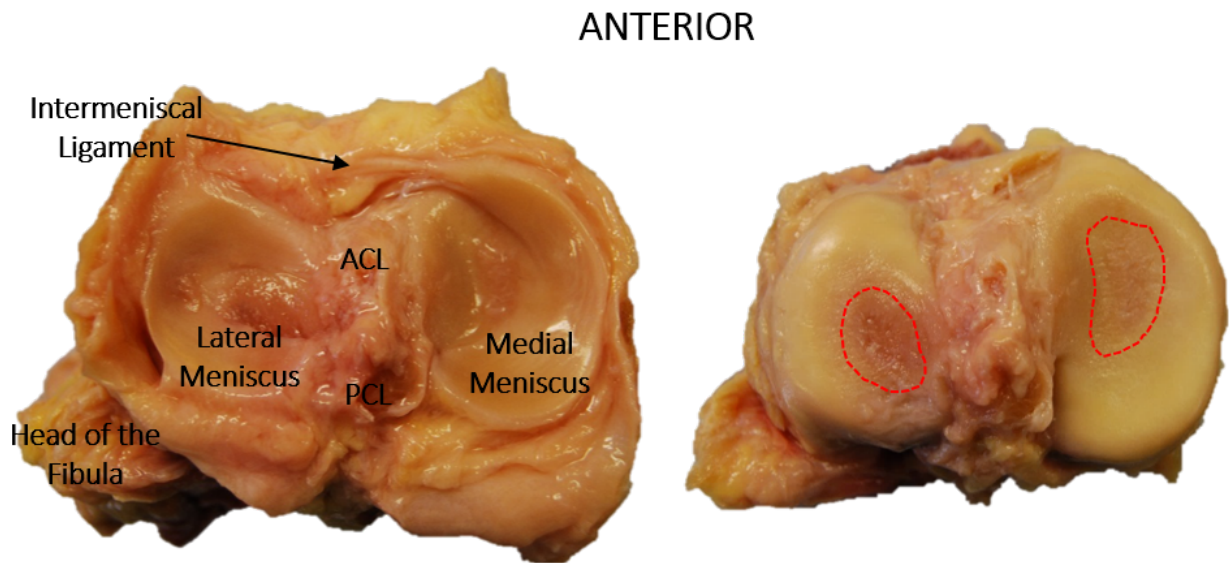
Figure 2.4   Photographs of a left sided tibial plateau of a 65 year old female with moderate patellofemoral (PFJ) OA and mild tibiofemoral OA. In the left hand image the menisci are intact: the longer, "C" shaped medial meniscus is on the right, the smaller, more "c" shaped lateral meniscus on the left. In this image the intermeniscal ligament is also visible, as are the attachment points of the ACL and PCL. The right hand image shows the same tibial plateau with the menisci removed. Areas of cartilage damage where the menisci were not protecting the articular cartilage in the medial and lateral compartments are outlined by the red dotted lines.
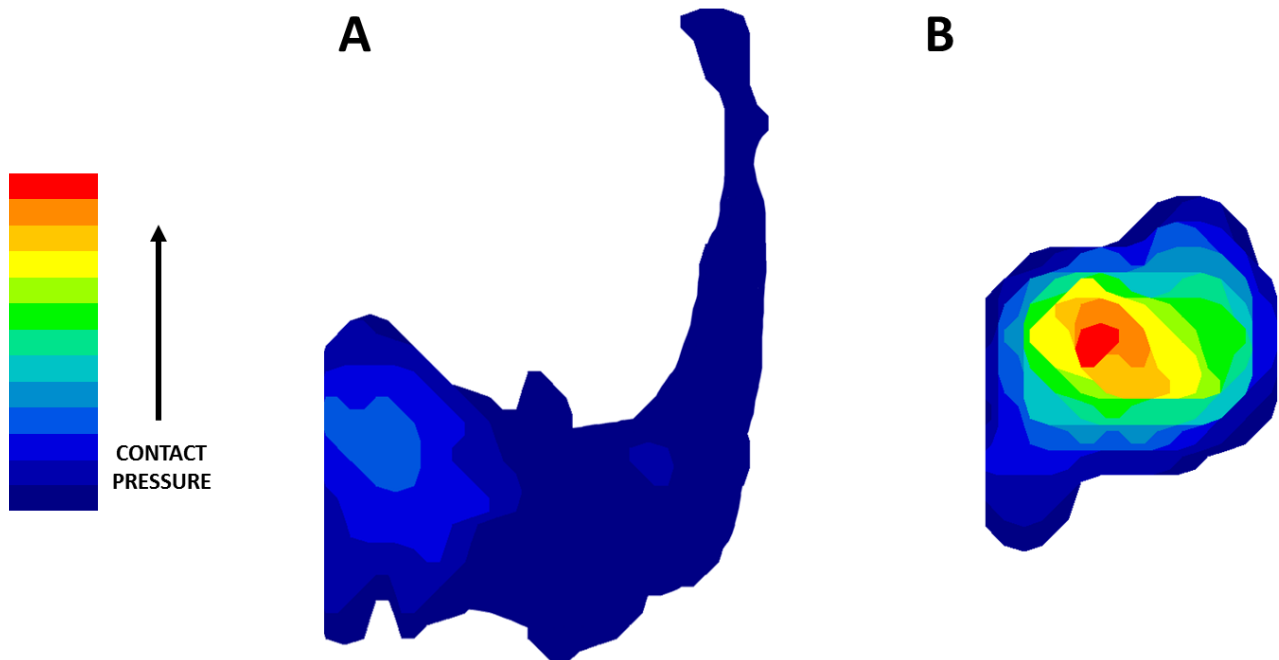
Figure 2.5   Contact pressure maps using Tekscan of the medial tibiofemoral compartment of a cadaver knee at 60° flexion and 1000 N axial loading. Pressure maps with (A) an intact medial meniscus and (B) post-meniscectomy; the function that the meniscus is performing is clear.

2.2 Biomechanics of the knee

The knee has a large range of rotational motion in the sagittal plane, flexion-extension, and smaller translations and rotations in all 3 planes, giving 6 degree of freedom (DoF) motion (Figure 2.6). This normal knee motion is a result of a complicated relationship between the muscles (active stablisers), ligaments, menisci (both passive stabilisers) and the geometry of the articulation between the femur and tibia. Knee extension is provided mainly by the quadriceps femoris muscles, helped by the tensor fasciae latae. The biceps femoris, semitendinosus and semimembranosus (the hamstrings muscles) cause knee flexion, along with the gracilis, sartorius and gastrocnemius. These muscles are active stabilisers of the joint. Large movements of the joint in directions other than these are prevented by the actions of the ligaments and the iliotibial band (ITB), which are passive stabilisers, and the geometry of the articulating surfaces (Morrison, 1970) as well as by the stabilising actions of the menisci.

In 1836 the Weber brothers described knee joint motion as a combination of rolling and sliding (Müller, 1983) and much research exploring knee movement followed over the next 150 years. It was well understood that because of the knee's range of motion, it did not operate like a pure hinge joint but despite human gait being the most frequently studied of all activities (Kozanek *et al.*, 2009), it wasn't until the late 20th Century that improved imaging and computational methods allowed more accurate three dimensional (3D) modelling of the knee, enabling us to better understand the 6 DoF motion of the knee joint, rather than just considering it in 2 dimensions in one plane at a time.

By the turn of this century, there seemed to be agreement about how the normal knee moves. The "medial rotation" concept of knee movement during non-ambulatory weight bearing and non-weight bearing flexion suggested by the series of studies by Freeman and colleagues in 2000 (Iwaki *et al.*, 2000; Hill *et al.*, 2000; Nakagawa *et al.*, 2000) became widely accepted by knee surgeons and researchers alike. Similar studies looking at knee motion during squatting confirmed these findings and guided-motion TKR designs such as the Medial Rotation Knee (MRK; MatOrtho, Leatherhead, UK) and the Advance Medial Pivot Knee (Wright Medical Technology, Inc. Memphis, TN, USA) made some headway into the TKR market (NJR, 2014a). The more conforming nature of the medial compartment, together with the fact that the lateral meniscus appears to be more mobile than the medial one (Figure 2.7), adds weight to the medial rotation theory.
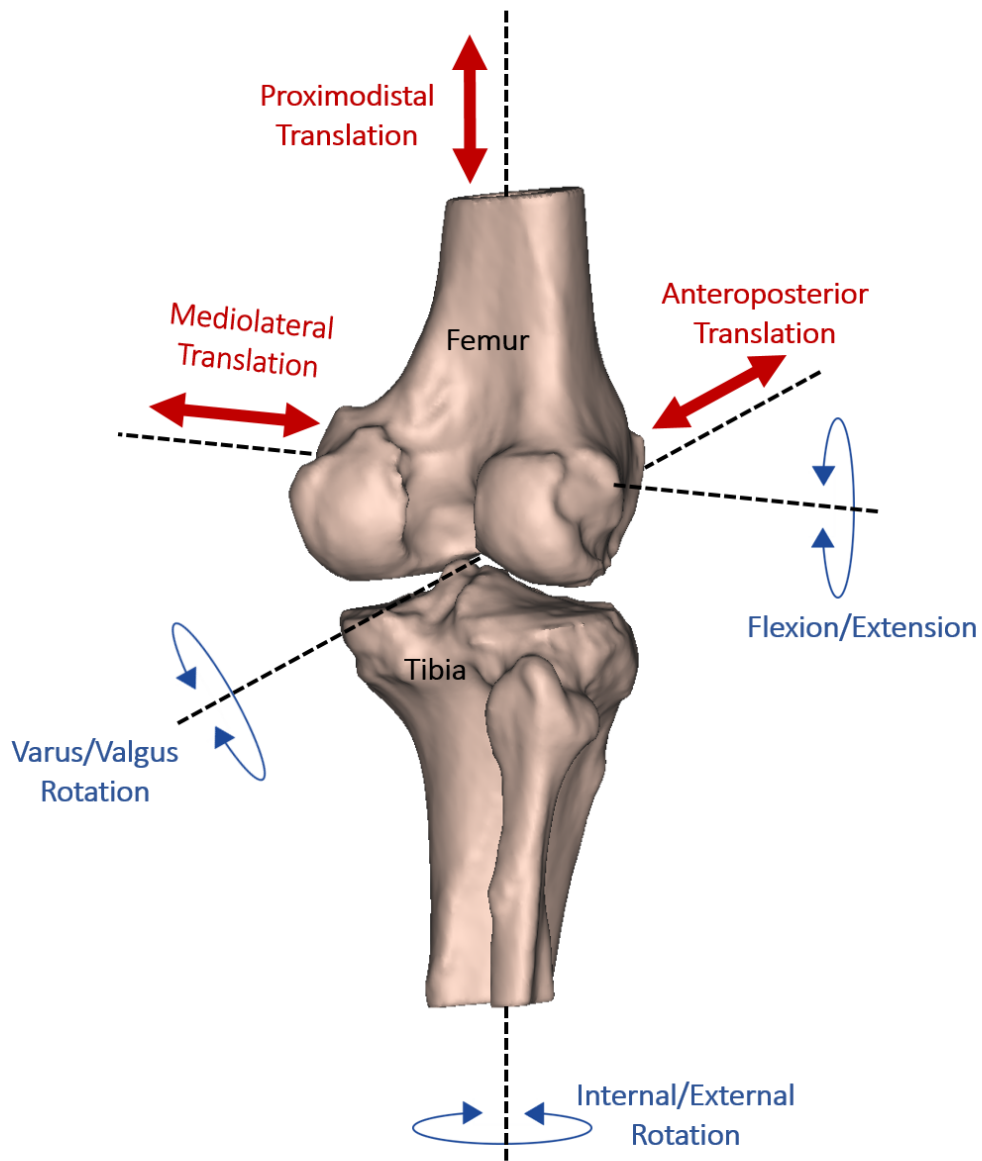
Figure 2.6 An illustration of the six degrees of freedom of the tibiofemoral joint, looking towards the posterolateral corner of a right sided knee. There are three translational directions: anterior-posterior (anteroposterior; AP); medial-lateral (mediolateral; ML) and proximal-distal (proximodistal; PD). The main rotation is flexion and extension (FE) and the secondary rotations are internal-external (IE) and varus-valgus (VV). The soft tissues and patella are left out of this diagram for clarity.

In the last decade, however, knee motion during essential activities of daily living (ADL(s)) such as walking, running and ascending and descending stairs, rather than in pure flexion, has been analysed. Koo and Andriacchi (2008) used gait analysis to see whether the knee rotated around the medial side of the joint during stance phase (heel strike to toe off) of gait and found that it actually rotates around the *lateral* side of the knee (with the centre of rotation often being located in an extra-articular position) for a majority of the stance phase in all of their 46 subjects. Other studies by Kozanek *et al.* (2009), Isberg *et al.* (2011) and Hoshino and Tashman (2012) appear to confirm that the centre of rotation of the knee is activity dependent. Banks (2014) suggests that the knee rotates around the medial compartment during flexion and the lateral compartment during extension activities and points out that if this is true, designing better functioning TKRs, which strive to restore "normal" knee motion, could be a very difficult task. Perhaps this makes the "forgotten knee" (Behrend *et al.*, 2012) an unachievable ambition.
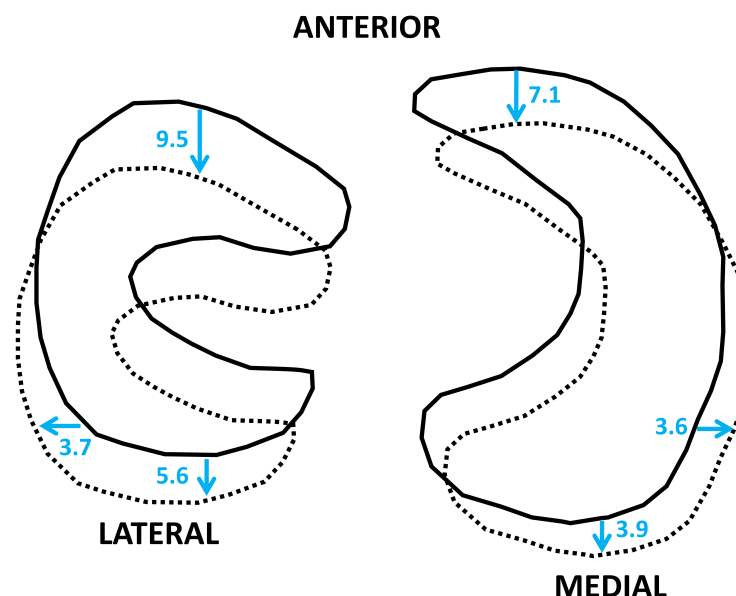
Figure 2.7   The motion of the menisci during weight bearing knee flexion from full extension to 90° measured in patients using dynamic magnetic resonance imaging (MRI). The menisci move a similar amount in the peripheral direction but the lateral meniscus moves more in the AP direction. The diagram was made using data from Vedi *et al.* (1999). (Not to scale)

2.3 Pathology and failure

One of the reasons there is such interest in the biomechanics of the knee joint is the frequency with which it is injured or diseased. The epidemiology of knee injury is a complex subject matter, but it has been estimated that, in the United States of America, the incidence of knee injury is 2.29 per 1,000

population per annum (Gage *et al.*, 2012). One of the reasons that the knee is susceptible to injury is that there exists some compromise in order to maintain both mobility and stability in the joint. If the knee was too stable, certain activities would be unachievable. Too mobile and the knee would be more susceptible to pain and even dislocations, as seen in hyperlaxity syndrome (Adib *et al.*, 2005). Tears to the menisci occur in approximately 70 per 100,00 people every year (Maffulli *et al.*, 2010) and knee ligament reconstruction surgery is carried out in around 46 people per 100,000 population, with a further 1150 people per 100,000 injuring a ligament in the knee but not undergoing surgery at the time (Gianotti *et al.*, 2009).

Common functional disorders of the knee include trochlear dysplasia, which can lead to chronic patellar instability and dislocation; knee hyperextension, which can lead to increased stresses on the ACL and the posterolateral corner of the knee; joint misalignment, leading to one of the knee's compartments being overloaded; unequal leg lengths; and inadequate recruitment of certain muscle groups, such as the quadriceps, which can result in reduced range of motion during walking gait and hamstring muscle over activity. It is these injuries and disorders and the resulting alteration in knee biomechanics that may lead to the development of knee OA later in life.

OA is the most common pathology of the knee and a study published in the Lancet in 2012 showed that it is the 23rd most common global sequela, with over 250 million people (3.64% of the global population) suffering from the disease worldwide, making up over 14% of all musculoskeletal disorder sufferers (Vos *et al.*, 2012). In 1997, the World Health Organisation (WHO) World Health Report found that up to 40% of people over the age of 70 suffered from OA of the knee and that almost 80% of these patients were limited in some way in terms of knee movement and 25% could not perform their major activities of daily life (World Health Organization, 1997). Diseases of the knee, OA in particular, are a cause of great suffering to millions and present a massive economic burden for health providers across the globe. According to Arthritis Research UK (ARUK), nearly one quarter of people over the age of 75 and over 4 million people in total in the UK have sought treatment for knee OA, costing the National Health Service (NHS) around £15billion per year. Knee replacement (partial and total) surgery alone costs the NHS (excluding Scotland) in the region of £600million (Dakin *et al.*, 2012; Willis-Owen *et al.*, 2009; NJR, 2014a).

A complicated relationship exists between knee biomechanics, injury, OA and surgical treatment.

Research that will lead to better understanding of the nature of knee biomechanics and treatments of OA is of profound importance. It is now well understood that OA is not simply "wear and tear" of the articular cartilage but is a complex condition affecting the whole of the joint. Progression of the disease requires activation of inflammatory response genes and biological pathways which are mechanosensitive (Little *et al.*, 2009). These mechanical stimuli are an important aspect of OA development and explain not only why trauma, such as rupture of cruciate ligaments or tears in the menisci, which can lead to unnatural knee kinematics, cause OA, but also why the occurrence of the disease increases with obesity (Burleigh *et al.*, 2012) and is also commonplace in people with abnormal anatomy or functional limitations such as those described earlier. These biomechanical factors operate alongside systemic ones such as old age; being female; bones being of high mineral density; or having one of the 11 genetic loci associated with osteoarthritis, all of which appear to increase the likelihood of developing the disease (Glyn-Jones *et al.*, 2015). If OA or its causes can be diagnosed early, the disease can sometimes be prevented from progressing but if it is not, there are various treatment options depending on the severity of the disease manifestation.

2.4 Treatment options, techniques and limitations

2.4.1 Non surgical interventions

For certain knee pathologies, non-surgical treatment options are the preferred route to improvement. An excessively mobile tibiofemoral or patellofemoral joint, for example, can be successfully treated with muscle strengthening exercises. Patients presenting with symptoms suggestive of knee OA will be advised to exercise as a core treatment in the first instance, before more invasive treatment options are considered (NICE, 2014). Indeed, even for traumatic injury such as ACL tears or rupture, there is still a lack of evidence to support systematic surgical intervention; in some studies the incidence of OA does not differ between the surgically treated patients and the non-surgically treated ones in the long-term (Tsoukas *et al.*, 2015; Delincé and Ghafil, 2012). This may be due to the inadequacies in current ACL reconstruction techniques, the fact that a reduction in laxity in one direction (in the case of the ACL, the AP direction) does not necessarily mean that the knee is restabilised, or the fact that concomitant injuries, such as meniscal tears, are often left unrepaired during ACL reconstruction procedures.

2.4.2 Ligament reconstruction and meniscus repair

For the serious athlete, injury to one or more of the ligaments of the knee, requires surgical repair for the best chance of returning to sport quickly. The ligaments surrounding the knee, particularly those connecting the femur and tibia, are passive stabilisers and act to either control the path of motion of the knee or to restrict the total range of motion in a particular direction. The ligaments serve as either primary or secondary restraints, stretching under force, keeping the joint stable (Masouros *et al.*, 2010; Halewood and Amis, 2015). An injury to one of these ligaments can cause a mechanical instability and alter the tibiofemoral kinematics, potentially leading to OA later in life (Lohmander *et al.*, 2007). The ACL is the most frequently reconstructed ligament in the knee because it has the greatest influence on tibiofemoral biomechanics and symptomatic instability (Gianotti *et al.*, 2009). Reconstruction can be achieved via autograft (using semitendinosus tendon, semitendinosus plus gracilis tendons or bone-patella-tendon-bone (BPTB)), allograft or using synthetic grafts such as the LARS ligament (Machotka *et al.*, 2010). It can be a single bundle or double bundle reconstruction and the tunnels used for fixing the graft can be put in a variety of positions.

There is great debate about which is the best ACL reconstruction technique. However, it is probably the case that, at the moment, none of the options perfectly restores the kinematics of the knee to its pre-injured state, and although reconstruction appears to lower the rate of early onset OA compared to conservative, non-surgical treatment of the ACL deficient knee, it has been reported that as many as 50% of patients with a reconstructed ACL go on to develop early onset OA in that knee (Lohmander *et al.*, 2007).

A recent meta-analysis suggests that OA caused by isolated ACL injury is not as prevalent as once thought (closer to 30% than 50%), but that it is meniscectomy combined with ACL reconstruction that dramatically increases the risk for developing OA in the knee (Claes *et al.*, 2012).

Meniscal tears are commonplace and those that are less severe can be repaired with sutures or the defect can simply be resected. Menisci too severely damaged to be repaired with sutures or treated by partial meniscectomy can be reconstructed either partially or in their entirety using allografts, biodegradable scaffolds, collagen based implants or totally synthetic meniscal replacements. It has been suggested that even an isolated meniscal tear (either degenerative or traumatic) treated with a limited meniscectomy can lead to tibiofemoral OA and that a degenerative meniscal tear should be

treated as the first sign of knee OA (Englund *et al.*, 2003). Correct treatment of meniscal injury is therefore critical. We do not yet understand the long term benefits of the various kinds of meniscus repair and replacement procedures in terms of OA (and therefore arthroplasty) prevention (Verdonk *et al.*, 2012; Van Der Straeten *et al.*, 2014).

2.4.3 Joint realignment

If localised OA occurs in a single tibiofemoral compartment, leading to or as a result of either a varus or valgus joint, an opening or closing wedge osteotomy on either the tibia or the femur, can be performed. Most commonly, this will be an opening wedge on the tibia - so-called high tibial osteotomy (HTO) - performed to unload the medial compartment and prevent the progression of OA that may occur due to the increased forces in the varus knee (Amis, 2013). The limb should be left in valgus after an osteotomy for medial compartmental osteoarthritis, but without so much overcorrection that would lead to accelerated degeneration of the lateral compartment of the tibiofemoral joint (Hui *et al.*, 2011). A keen understanding of the difference between a misaligned knee joint, an oblique joint line and the entire lower limb being in varus or valgus, is required. These osteotomies are becoming more methodical with the use of patient specific cutting guides and 3D printed fixation plates (Victor and Premanathan, 2013).

2.4.4 Arthroplasty

While ligament reconstruction and meniscus repair are still being perfected, knee OA will continue to reach an advanced stage in these patients, in addition to those people with non-traumatic OA, caused by obesity and old age. In these cases, knee arthroplasty might be the only remaining option to try to relieve pain and restore function to the joint. There are different types of knee arthroplasty, the main three being: unicompartmental knee replacement (UKR); patellofemoral joint replacement (PFJR) and total knee replacement (TKR). A UKR can replace either the medial or lateral compartments of the knee and can have either a fixed ultra-high molecular weight polyethylene (UHMWPE) bearing (either on its own or fixed into a metal tibial tray) or a mobile bearing on a metal tibial tray. A UKR retains both cruciate ligaments and sacrifices much less bone than a TKR. UKR patients tend to function better than TKR patients (Wiik *et al.*, 2013) and it is also a more cost-effective procedure (Willis-Owen *et al.*, 2009). There is also some evidence to suggest that the kinematics with a UKR are closer to those of the normal knee (Patil *et al.*, 2005) although the indications for the two procedures can be conflicting. A PFJR replaces the articulating surface of the patella, usually with UHMWPE in

the form of a dome or a button and the trochlea of the femur, most commonly with a cobalt-chrome (CoCr) component. A TKR replaces all three compartments of the knee joint; this type of arthroplasty will be discussed at length in Chapter 3.

2.5 Conclusions

The knee, so essential to human locomotion, has fascinated and frustrated surgeons and engineers alike. In some ways a much more complex joint than the hip, replacement of the knee has presented more of a technical challenge than of the ball and socket joint and is still striving to achieve the "forgotten joint". Better repair after injury in the younger patient could delay OA disease progression and reduce the need for total joint replacement but, as it stands, this is still a necessary treatment option for hundreds of thousands of people worldwide every year.

CHAPTER 3

TOTAL KNEE REPLACEMENTS

3.1 Introduction & history

Although the concept of TKR, also known as total knee arthroplasty (TKA), can be traced back as far as Themistocles Gluck's 1891 ivory hinged knee (Figure 3.1), modern, condylar (where the femoral and tibial articulating ends of bones are both replaced but are unconnected to each other) TKR development, of the sort that is recognisable in today's devices, only began in earnest in the 1970s. With the development of UHMWPE in 1963 and the FDA approving the use of polymethyl-methacrylate (PMMA) cement in 1971 (Robinson, 2005), the hinged knees and inter-positional arthroplasty devices of the 1940s and 50s were forgotten and two broad approaches to primary TKR - functional and anatomic - dominated design during the complicated upsurge of innovation during the 1970s, with several devices being developed simultaneously in Europe, Japan and America (Figure 3.2).

The first cemented knee replacement made from metal and plastic was the Polycentric Knee, designed by Frank Gunston and John Charnley and first implanted in the late 1960s (Gunston, 1971). It wasn't a true "total" knee replacement however, having 2 femoral and 2 tibial components, and therefore resembling what would now be called a "bi-uni" procedure. This device was used predominantly in rheumatoid arthritis patients and survivorship was poor, but condylar TKR had arrived. Clinical Orthopaedics and Related Research devoted over half of its July 1973 issue to a symposium on TKR (Kettelkamp and Leach, 1973) and development of this type of prosthesis has continued ever since in the quest for the "perfect" device.
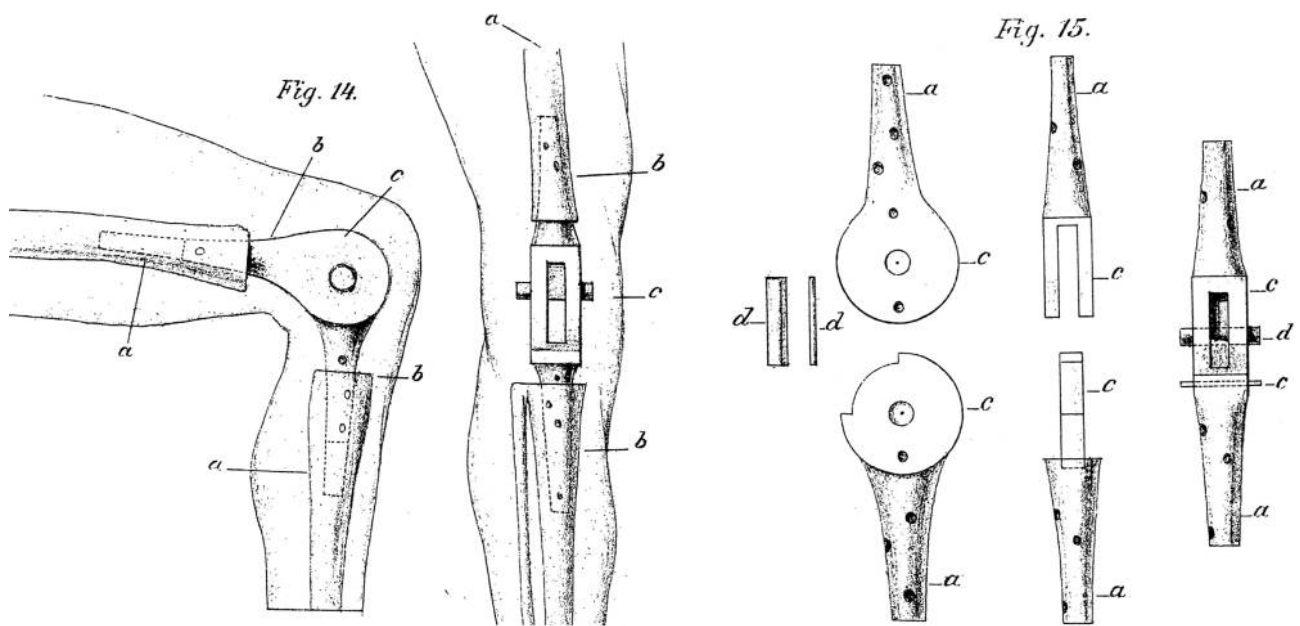
Figure 3.1   Illustrations of a knee joint suggested by Gluck (1891)

3.1.1 Anatomic TKRs

Anatomic TKRs aimed to be tissue preserving, retaining both of the cruciate ligaments and resecting as little bone away from the femur and tibia as possible, while still removing the arthritic portions of the articulating surfaces. They were essentially resurfacing devices, conservative in terms of bony resections but ambitious with regards to surgical technique and skill, with polyethylene (PE) only tibial components and metal femoral components. They were designed to have low articular conformity, the thinking being that the soft tissues in the knee would control the kinematics of the joint. Examples of early anatomic knee include: the Anatomic Total Knee, designed by Charles Townley; the Geomedic Knee, by Mark Coventry; the Duocondylar Knee, developed by Peter Walker, Chitranjan Ranawat and John Insall; the Leeds knee, by Bahaa Seedhom and the Kodama-Yamamoto knee (Ranawat, 2001; Yamamoto, 1979). All of these had a monoblock, horseshoe-shaped tibial component designed to fit around the ACL attachment on the tibial plateau, except for the Duocondylar device, which had two polyethylene inserts that were placed either side of the tibial eminence (Figure 3.3).

3.1.2 Functional TKRs

Functional TKRs paid small regard to the anatomy of the native knee. These devices were designed to relieve pain and reproduce some function in the knee via the much more conforming articulating geometry of the plastic and metal components, resecting both cruciate ligaments (Freeman and

44

ANATOMIC   FUNCTIONAL

1970   1st Anatomic TKR   1st Cemented   1st Functional TKR
       Kodama-   cruciate sparing   Freeman-Swanson
       Yamamoto   Geomedic   ICLH Mark I
       Mark I   Duocondylar

1972   1st Cemented
            anatomic TKRs
            Leeds   ICLH Mark II
            Anatomic   Geometric II

1974   Total Condylar
                         Duopatellar
       Mark II

            Cloutier   Total Condylar II
1976

                                                1st mobile
                                               bearing TKR
1978   Kinematic   Insall-Burstein PS   LCS
                         CR and PS

1980   Freeman-Samuelson

                                     PFC Sigma
                                      (1984)

       Hermes 2C
        (1991)   Biopro (1992)   Medial Rotation
                                                   Knee (1994)

                    Vanguard XP
                      (2013)

Figure 3.2   Early innovation of the total knee replacement, adapted and simplified from Robinson (2005)

Swanson, 1975). Michael Freeman and Alan Swanson developed the Imperial College/London Hospital (ICLH) knee which was first implanted in April 1970 (Freeman *et al.*, 1977).

Freeman developed his own rules for TKR design strategy (Freeman *et al.*, 1973), and it is striking how many of the aims hold true today. He stated that a TKR should:

1. Require minimal bone cuts, leaving large flat surfaces of cancellous bone;

2. Minimise chances of loosening by ensuring that:

   a) The femoral and tibial surfaces are minimally constrained so that rotational moments are not transferred to the cement (or bone fixation);

   b) There is low friction between the femoral and tibial parts;

   c) That while hyperextension should be minimised, this action should be gradual, not sudden;

   d) Both components are attached to the bone via the largest possible area;

3. Minimise wear debris and where debris is produced, that debris should be as innocuous as possible;

4. Have a low infection risk;

5. Mitigate the effects of infection with small intramedullary (IM) rods and no IM cementing;

6. Have a standard procedure for surgeons to follow;

7. Have a range of motion (ROM) of around -5° to at least 90°;

8. Control rotation so that it isn't completely free;

9. Prevent excessive movement in any direction by way of soft tissues restraint, particularly the collateral ligaments;

10. Not rely on the cruciate ligaments for the correct functioning of the prosthesis due to the condition of the knees for which TKR surgery is appropriate;

11. Should not require patella replacement to be mandatory and

12. Be affordable, by only offering the smallest number of sizes of implant.

The ICLH was a roller-in-trough design and tried to over simplify knee motion, restricting almost all rotation around the mechanical axis of the tibia and, to a large extent, AP translation of the femur, but it had no mediolateral constraint built into the design. The first release of the implant was not a success but it went through several design iterations and the present day MRK (MatOrtho, Leatherhead, UK) is a descendant of it.

The Total Condylar knee, which evolved from the Duocondylar design, was another functional TKR developed at the same time as the ICLH. This prosthesis resembled more closely today's TKRs than the ICLH and would eventually lead, in 1980, to the first TKR to have a metal-backed tibial component: the Insall-Burstein prosthesis, which also had the option of being posterior-cruciate ligament substituting, via a cam-post design (Figure 3.3).

The evolution of these early design iterations, although not always successful, paved the way for the development of modern day TKRs.

Figure 3.3   Examples of early TKRs. Top: "anatomic TKRs", from left to right: Anatomic, Kodama-Yamamoto, Duocondylar. Bottom: "functional TKRs", from left to right: The ICLH Mark I; the Total Condylar Knee; The Insall-Burstein PS.

3.2 Present day TKRs

The distinction between the functional and anatomical approaches to knee replacement became blurred as engineers and surgeons strove to improve TKR design and outcomes after the pioneering developments during the 1970s. It was not long before most devices shared many of the same features and although there are still categories which devices fall into, there are a lot of similarities across the different types of modern day TKRs in both design and function. There are three main features of a total knee replacement: 1) its materials; 2) whether or not it sacrifices the PCL and 3) the geometry of its articulating surfaces.

3.2.1 Materials

In the majority of TKRs, the tibial plateau is replaced with a CoCr tray and an UHMWPE bearing (this is occasionally a component made entirely of UHMWPE but this is uncommon, particularly in the UK). The distal part of the femur is replaced with a metal component, again this is usually CoCr, although it can also be made from CoCr coated in ceramic (titanium nitride) or it can be entirely ceramic. More recently, some femoral components have been made from "Oxinium", a metal alloy with the surface transformed to a ceramic; this, combined with cross-linked UHMWPE, appears to offer superior wear resistance in regulatory testing (Figure 3.4). Oxinium and ceramic components also have the benefit

of having lower nickel and and chromium levels than CoCr components, thereby reducing the risk of metal sensitivity problems (ASTM, 2010; ASTM, 2012b).

The posterior, articulating surface of the patella can be resurfaced with a patella "button" or dome, which is normally made of UHMWPE alone, although it can also have a CoCr back. The UHMWPE tibial bearing can either be "snapped" into place on the metal tray (fixed) or sits on top of a polished metal tray and able to rotate and/or translate (mobile).
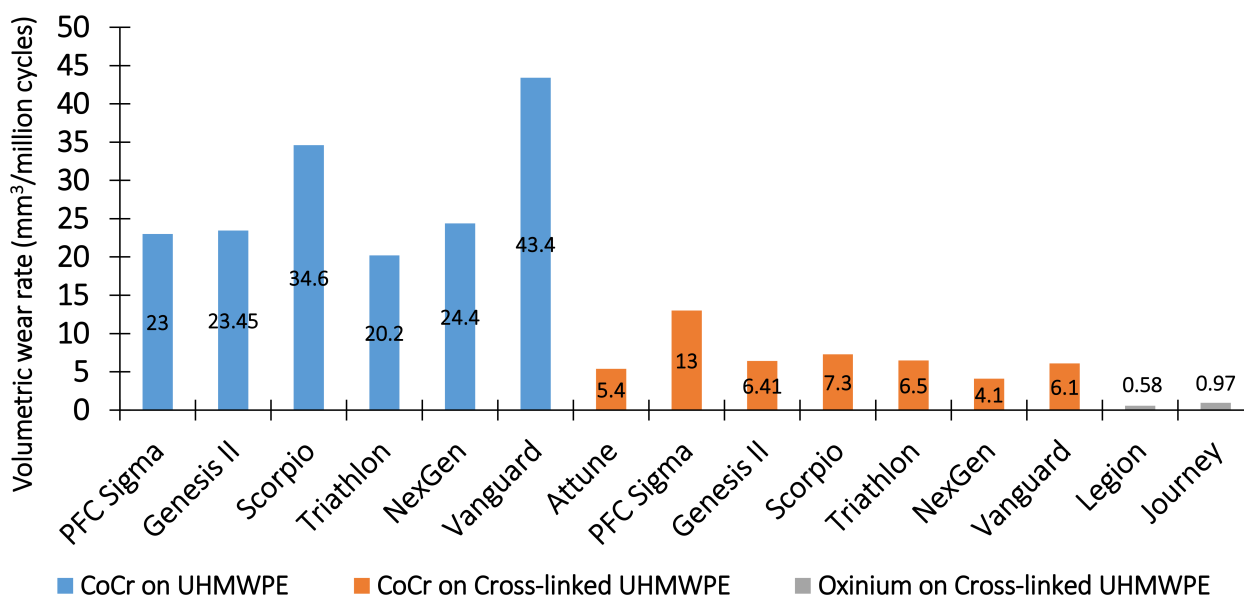
Figure 3.4 Mean volumetric wear rates of CoCr against UHMWPE, CoCr against cross-linked UHMWPE and Oxinium against cross-linked UHMWPE using standard wear testing described by ISO 14243-1 (ISO, 2009). The results for the same device with conventional and cross-linked UHMWPE can be directly compared as they are from the same study but comparisons between different devices should be made with caution as they were produced using different machines and published in different studies (McEwen *et al.*, 2005; Parikh *et al.*, 2007; Essner *et al.*, 2005; Herrera *et al.*, 2008; Schaerer *et al.*, 2010; Biomet, 2013; DePuy, 2010; Papannagari *et al.*, 2012; Smith & Nephew, 2014).

3.2.2 Ligaments and geometry

TKRs have different levels of built-in constraint and can be: PCL-retaining (CR); or PCL-sacrificing but with some constraint built in to the geometry of the UHMWPE bearing (condylar or cruciate stabilised (CS)); or PCL-substituting, (PS) where the action of the PCL is replaced by a cam (femur) and post (tibia) mechanism.

The vast majority of TKRs are ACL-sacrificing, although there are three bi-cruciate retaining (BCR)

devices currently in clinical use: the TKO (BioPro, Inc., Port Huron, MI USA); the Hermes 2C (Ceraver, Paris, France); and the Vanguard XP (Zimmer Biomet, Warsaw, IN USA). There is some evidence that patients prefer ACL-retaining TKRs (Pritchett, 2011; Pritchett, 2004) and that these implants result in closer to normal knee kinematics during activities of daily living (ADL(s)) (Andriacchi *et al.*, 1982; Stiehl *et al.*, 2000) but their use at the moment is limited by only a very small number of surgeons offering this procedure and it is not currently practiced at all in the United Kingdom. Balancing of the soft tissues (the collateral ligaments in particular) is vital for all successful TKR surgery (Nowakowski *et al.*, 2011; Kuster *et al.*, 2004); the more ligaments that are left intact the harder that correct balancing is to achieve. The BCR TKR concept will be explored in Chapter 7.

Since the ACL and both menisci are removed during TKR surgery, the articulation between the femoral and tibial components is meant to compensate for the loss in stability, with the "dish" shape of the UHMWPE providing some resistance to anteroposterior translation and rotation of the femoral component. This constraint can be symmetrical, with the shapes of the medial and lateral compartments and condyles being the same, or asymmetrical. Examples of the latter case include medial-pivot type TKRs, which are designed to rotate around the medial compartment, with more translation and rotation permissible in the lateral compartment which is shallower, and so-called guided-motion knees which can have concave medial compartments, convex lateral compartments combined with a cam-post system in an effort to replicate normal knee motion.

3.3 Epidemiology of present day primary knee replacement

In England, Wales and Northern Ireland, 33% of primary TKRs in 2013 were carried out using the fixed-bearing version of the Sigma Total Knee System (DePuy, Warsaw, IN, USA). This is a device based on the PFC Total Knee, which was introduced to the market in 1984. This device can either be CR or PS. Despite the advent of guided-motion devices, medial pivot knees, mobile bearing TKRs and bicruciate retaining implants, the most popular device in the UK is one that has been available for over 3 decades. With 10 year postoperative survivorship at over 97% (the highest in the NJR for 10 year follow-up) and over 210,000 procedures carried out in total over the 10 years in this country alone, the Sigma has a proven track record and has been the most implanted device annually in the UK since the registry started (Figure 3.5). Why this is the case is not completely clear but is likely to be related to the fact that senior surgeons teach more junior surgeons using their preferred device

and so it makes sense that the most used device would carry on being so. In addition, the PFC Sigma may suit more patients adequately than a medial pivot device such as the Medial Rotation knee (MRK), which may only match the biomechanics of a smaller cohort of patient. There may also be a financial aspect to this with more modern designs of TKR being more expensive.
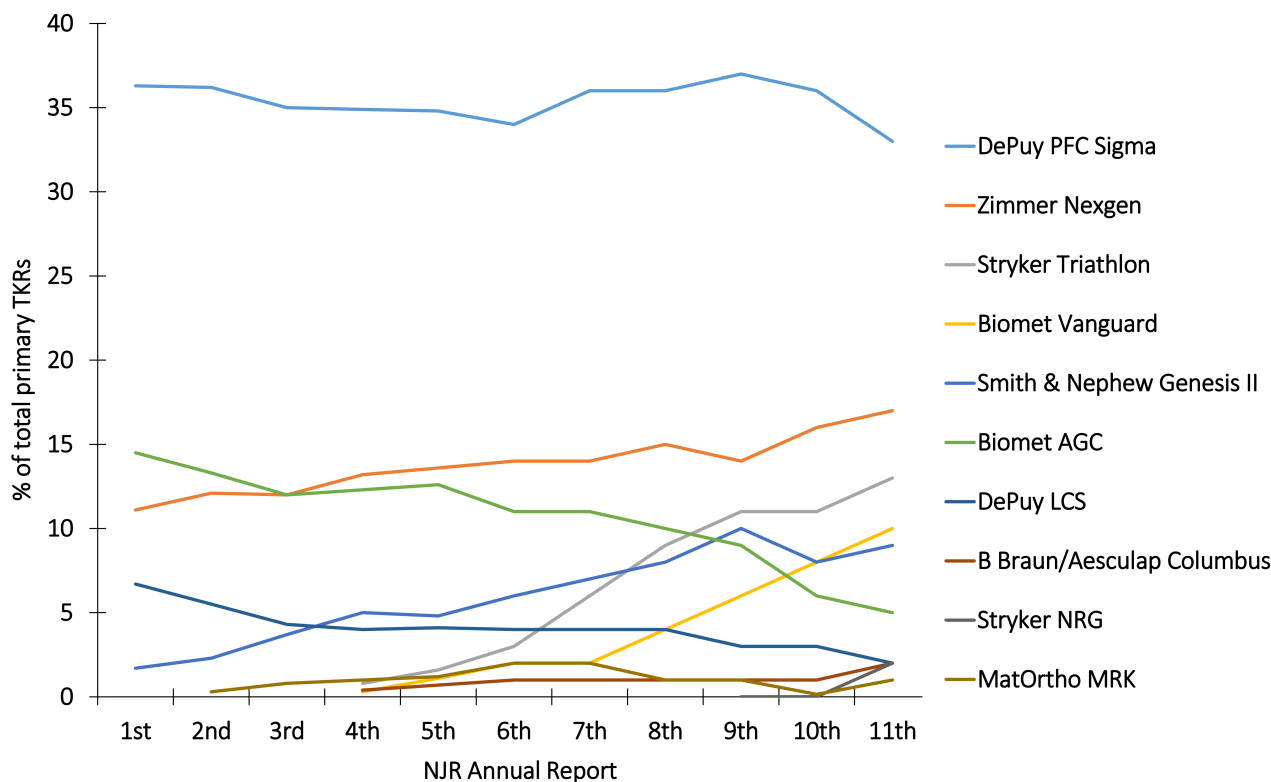
Figure 3.5 **The 10 most commonly used TKRs in England, Wales and Northern Ireland in 2013, with their % usage for the previous 10 reports. The first report was produced in 2004 and covered procedures for 2003. The most recently published report, the 11th, was produced in 2014 and covers procedures for 2013.**

In 2013, according to the National Joint Registry, 56 different designs of TKR produced by 23 different implant manufacturers were used in 77,781 primary procedures in England, Wales and Northern Ireland (NJR, 2014a). The number of primary TKRs has been steadily increasing since 2005 and if numbers continue to rise at the same rate, around 120,000 primary TKR procedures will be performed in 2027 (Figure 3.6). This increase must be due partly to an increasing overall population, (the UK population has increased from 60.18 million in 2005 to 64.77 million in 2014), but is is also likely to be linked to factors that very familiar; more people living longer, a greater rate of obesity, etc..

Over the 11 years of the National Joint Registry, some of the statistics have remained relatively

50

static: osteoarthritis has been the indication in 96-98% of cases; TKRs have made up 91% of all primary knee replacements in every year of the NJR, with UKRs consisting of 8% and PFJRs the remaining 1% of primary knee patients. Of the TKRs implanted, just under 75% have been CR devices. Something that has changed over the years is the proportion of TKRs that are implanted without using cement; this has fallen from nearly 9% in 2003 to less than 3% of cases in 2013. The number of mobile bearing TKRs being used has also fallen, from a peak of 17% in 2005, to a low of 7% in the most recent NJR.
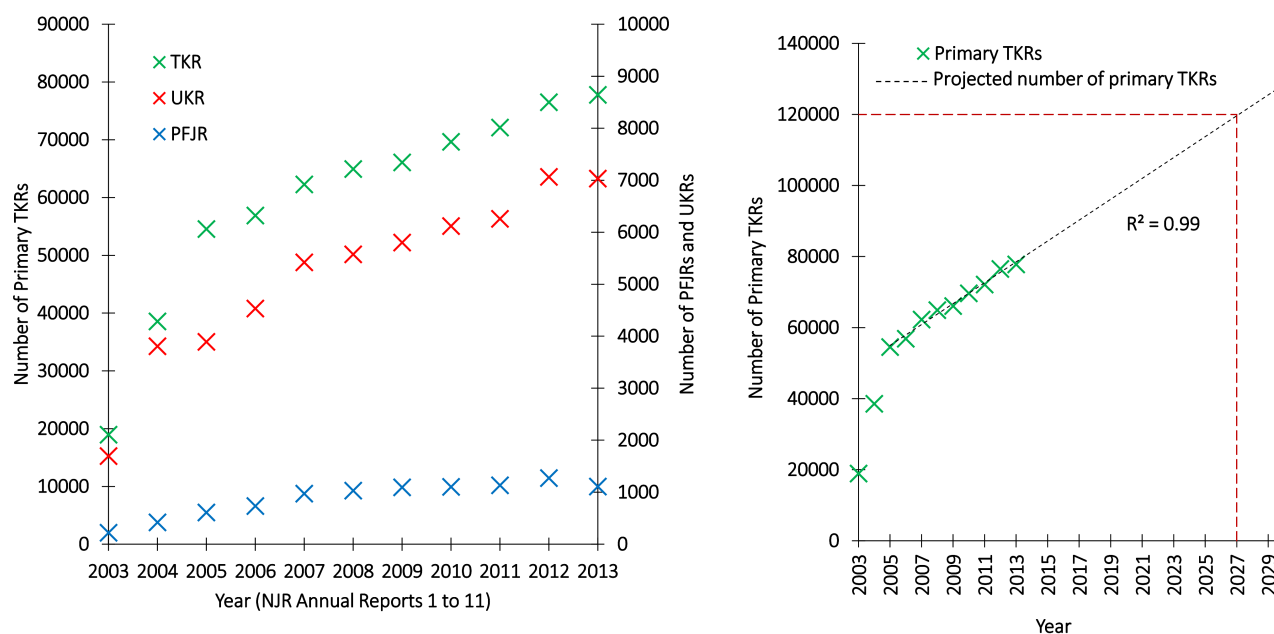
Figure 3.6 TKR numbers. On the left, the number of primary knee procedures performed in England, Wales and Northern Ireland 2003-2013 according to the National Joint Registry database. Low compliance in the first two years of the registry probably explains the apparent large increase in procedures between 2004 and 2005. The percentage split between the three procedures has stayed roughly the same over this 11 year period, with TKRs accounting for around 91%, UKRs 8% and PFJRs the remaining 1% of primary knee replacements operations.
On the right, the projected number of primary TKR procedures in England, Wales and Northern Ireland 2014-2030, linear fit to data from 2005 to 2013. Data taken from the National Joint Registry Annual Reports 2003 to 2014 (NJR, 2014a).

3.4 Alignment in TKR surgery

Traditionally, a TKR is implanted so that the horizontal resections of the distal femur and proximal tibia are perpendicular to the mechanical axes of those bones in the coronal plane (Gu *et al.*, 2014). This method will restore the joint line to "normal" in the coronal plane if the patient had a pre-arthritic

neutral hip-knee-ankle mechanical axis. But most people do not have a neutral axis, nor is their joint line parallel with the ground (Bellemans *et al.*, 2012). This "mechanical" alignment can lead to a trapezoidal space between the femoral and tibial cuts, and soft tissue releases may be required to create a parallel space for the implant, leading to the joint line being further rotated (Howell *et al.*, 2013).

It has been suggested that this change in joint line obliquity may explain the high dissatisfaction rates in pain-free patients who have good surgeon reported outcomes (Bellemans *et al.*, 2012) and that it may be beneficial to leave the patient in varus or valgus (matching their contralateral, healthy knee) or use "kinematic alignment", a method which retains the joint line obliquity and appears to improve functional outcomes in TKR patients (Dossett *et al.*, 2012). These alignment considerations will be discussed further in Chapter 9.

3.5 Failure of TKRs

Survivorship of TKRs is excellent, with fewer than 5% having to be revised (at least one component of the TKR being replaced) at some stage (NJR, 2014a; SKAR, 2013; NZJR, 2014; AOANJRR, 2014). When modern TKRs do fail, it is now seldom due to wear of the UHMWPE bearing on the tibia; improvements in the chemistry and the manufacturing of the bearings means that polyethylene wear is no longer the problem it once was. The biggest reason for failure of TKRs, across 4 registries and two peer-reviewed studies, is aseptic loosening (with or without associated osteolysis; Figure 3.7).

Discounting long-term pain and infection, the next most common reason for a TKR to fail is instability. This instability is defined as *"excessive and unnatural movement of the implant components"* (Athwal *et al.*, 2014). It is obviously a somewhat subjective event, felt and reported by the patient, but is almost certainly related to the tibiofemoral articulation of the TKR, any soft tissue releases made during surgery and any pre-existing pathologies the patient might have (Rodríguez-Merchán, 2015). It is suggested that instability can be avoided with correct choice of implant; for example, a patient with weak collateral ligaments or an insufficient PCL, might require a more constrained type of TKR (by way of a cam-post or more congruent tibiofemoral geometry). Making this choice might have other implications, however; a more conforming UHMWPE bearing is more likely to pass stresses onto the underlying proximal tibia, with the potential to increase the risk of component loosening. Although the registries have revision rates for specific devices, it does not break down the revision into reasons for

each device (NJR, 2014a; NZJR, 2014; AOANJRR, 2014; SKAR, 2013). This could be very useful data to try to link failure to implant model and manufacturer (which is presumably exactly why the registries do not publish this data).
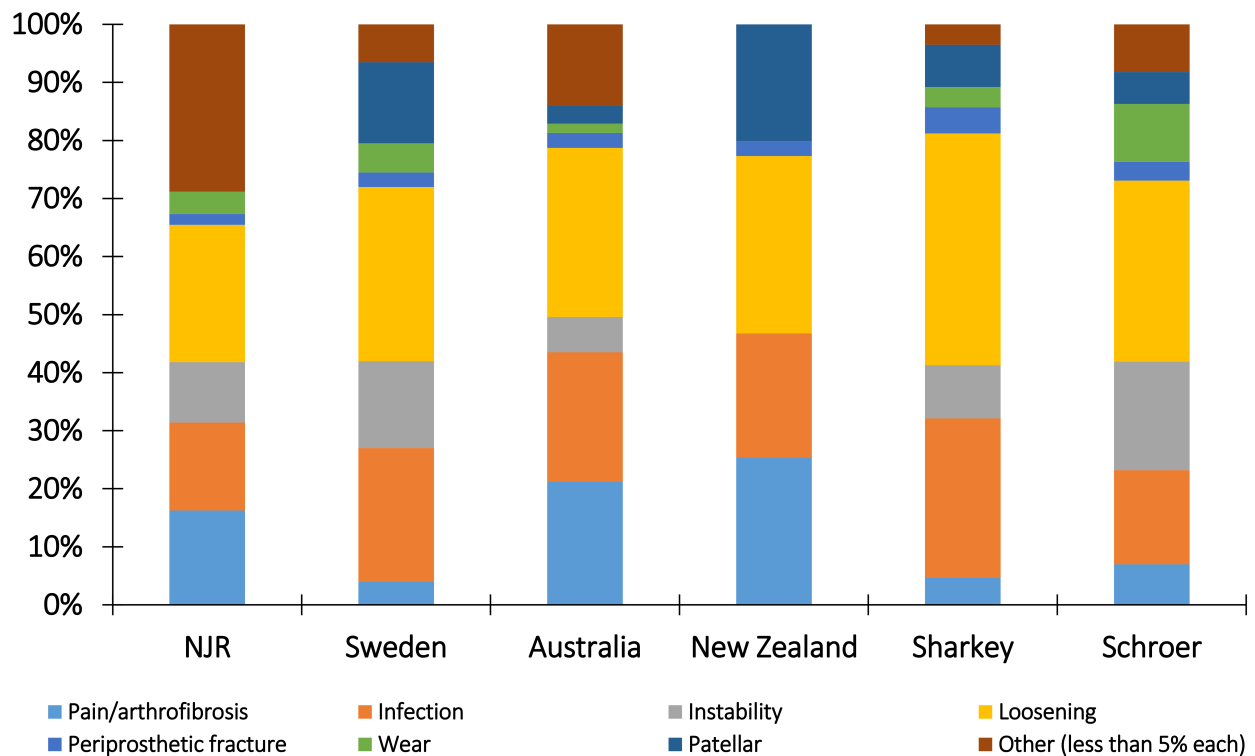
Figure 3.7 Reasons for revision of primary TKR. Data presented from 4 national joint registries (NJR, 2014a; NZJR, 2014; AOANJRR, 2014; SKAR, 2013) and two peer-reviewed publications (Sharkey *et al.*, 2014; Schroer *et al.*, 2013).

3.6 Patient (dis)satisfaction with TKRs

Success of a TKR can be evaluated via several different metrics:

1. Survivorship rates, with surgical revision of the device being regarded as the failure point;
2. SROMs, such as the Knee Society Score KSS (Insall *et al.*, 1989);
3. PROMs such as the Oxford Knee Score OKS (Dawson *et al.*, 1998).

There is a large minority of patients who are not satisfied with their TKR implant. The percentage of dissatisfaction varies from study to study but can be as high as 20% using patient reported outcome (PROM) measures such as the Oxford Knee Score (OKS)(Bourne *et al.*, 2010). In addition, as few as 10% of patients feel that their replaced knee is "normal" (Noble *et al.*, 2006; Beverland, 2010) and

a high percentage of TKR patients have significant difficulty performing certain functions, compared to control subjects of the same age (Figure 3.8, (Noble *et al.*, 2005)). When considering the reasons and solutions for post-operative dissatisfaction in knees that do not actually fail, it is important to distinguish between post-operative pain, surgeon satisfaction and patient satisfaction. Patient dissatisfaction is linked to many variables, including pre-operative expectation and post-operative perceptions (Baker *et al.*, 2013) but it can also be linked to the functional problems described by Figure 3.8. Why do patients with a TKR find it harder to perform activities such as these? TKR design is likely to play a part; if a patient feels that their knee is not stable, due to the actual device not having enough stability built into its design, or there is paradoxical femoral translation anteriorly, then they will find it harder to do certain movements, such as squatting and walking downstairs. It may be that TKR designs with more constraint built into the UHMWPE bearing, such as a medial conforming knee, feel more stable, giving more confidence to the patient and better functional outcomes (Shimmin *et al.*, 2015). Loss of muscle strength and proprioception after TKR surgery are probably also factors to be considered. It would require high numbers of patients and excellent patient matching to control other variables, but it would be interesting to extend Figure 3.8 so that different designs of TKR are compared side by side in terms of patient function. Could there be one type of TKR that does out perform the others?
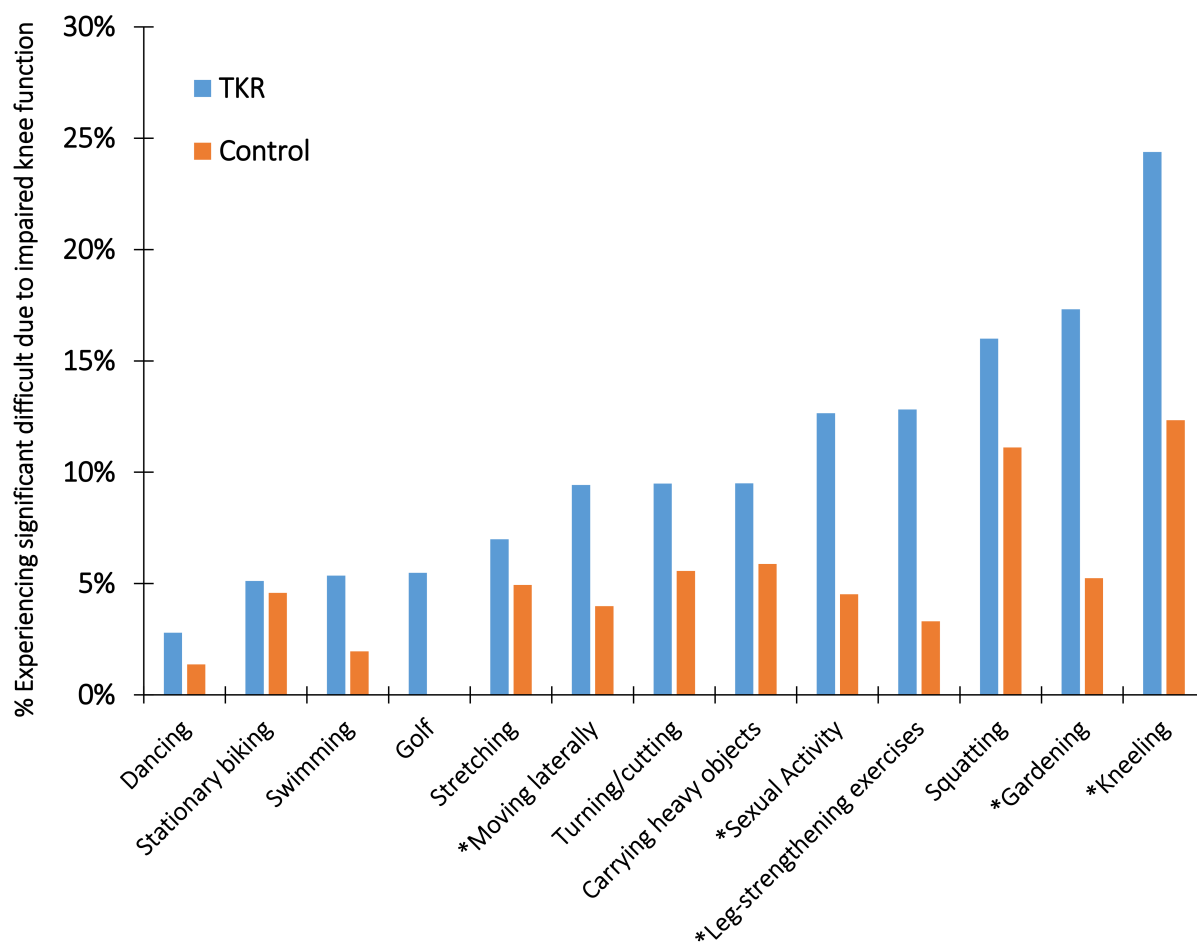
Figure 3.8   Percentages of TKR patients and control subjects who had significant difficulty performing certain activities due to impaired knee function. * indicates a significant difference between the TKR group and the control group (Noble *et al.*, 2005).

There are patients who experience pain after TKR which leads to dissatisfaction. But this pain can, for the most part, be explained and is linked most commonly to aseptic loosening, misalignment, polyethylene wear, infection, patellofemoral problems and instability (Dennis, 2004) and will result in a revision procedure. Unexplained long-term pain after TKR surgery is very rare (Elson and Brenkel, 2007; Brander *et al.*, 2007; Mont *et al.*, 1996), but might also result in a revision. While it is obviously important to tackle the issue of postoperative pain, the focus of the work in this thesis is TKR function and how that can be improved.

Age is often cited as one of the reasons that this dissatisfaction exists: TKRs are supposedly being put into younger, more active patients who expect more from their implant. The data on TKR demographics do not demonstrate this, however: since 2003 the mean age of patients undergoing primary TKR surgery has remained static at around 70 years of age (Figure 3.9). However, although the average age of the patients has not changed over the years, it may be the case that 70 year olds in the present day are more active and have higher expectations of their device than previous generations (this is hard to prove).
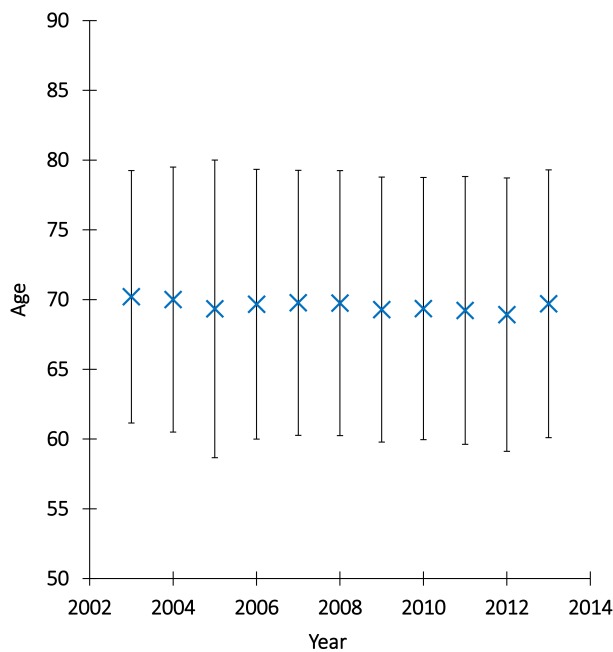
Figure 3.9 Ages and outcomes of TKR patients. Mean age ($\pm$ 1 standard deviation) of patients undergoing primary TKR procedures in England, Wales and Northern Ireland from 2003 to 2013. Data taken from the National Joint Registry Annual Reports 2003 to 2014 (NJR, 2014a).

3.6.1 Reported outcomes

There are 2 types of reported outcome measure that are used to assess TKRs in patients, in an effort to understand patient satisfaction levels: clinician completed (surgeon reported outcome measure - SROM) and patient completed (patient reported outcome measure - PROM). The (new) Knee Society Score (KSS) is the most widely used SROM and assesses the clinical outcome of TKR surgery via pain, flexion contracture, ROM, alignment and stability in AP and ML. There are many more PROMs to choose from, including: Oxford Knee Score (OKS); Knee Injury and Osteoarthritis Outcome (KOOS); Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC); International Knee Documentation Committee (IKDC); and The High Activity Arthroplasty Score (HAAS). In total, 47 different PROMs for assessing TKR surgery have been described in the literature (Ramkumar *et al.*, 2015).

One of the reasons that so many PROMs have been developed is that there has traditionally been a mismatch between what the surgeon considers to be a successful TKR procedure and how happy the patient is (Harris *et al.*, 2013a) - with surgeons generally being more pleased with the clinical outcome than patients are with their functional abilities post surgery. More and more scores have been developed in order to iron out this discrepancy, as well as to combat language and cultural differences that occur in different countries. Another problem is the existence of floor and ceiling effects, where a significant proportion of patients who answer the PROM surveys score either the minimum or the maximum score, making it very difficult to discriminate between subjects in these regions. PROMs are generally crude measurements, biased towards pain and low demand activities which, while essential to daily living, are often easy to achieve, even with a TKR that isn't performing very well. The HAAS and the activity and participation questionnaire supplement of the OKS (OKS-APQ) have been developed to evaluate those patients who would like to achieve a higher level of function and activity than is assessed in traditional PROM questionnaires (Dawson *et al.*, 2014; Talbot *et al.*, 2010).

Implant manufacturers point to the very good PROM scores; these may be be due, in part, to the fact that the questionnaires are generally carried out soon after surgery (about 6 months post-operation), when the patient is still becoming accustomed to the device and how it feels and so any longer term functional deficits have not yet been realised. Publicly available Health Episode Statistics (HES) data demonstrate that improvement in the Oxford Knee Score post TKR is sensitive

to the pain elements of the questionnaire - functional improvements are not so clear-cut, particularly in the younger patient (Figure 3.10). There is a more in depth analysis of the OKS and its pain and function subscores in Appendix A.

In 2013, the NJR for England, Wales and Northern Ireland for the first time linked PROM data to the registry data, but only catalogued the data by cementation type and, unsurprisingly, there was no difference between scores in the cemented and uncemented groups of patients (the authors could have linked OKS data to constraint type or even to specific devices). The analysis was not repeated in the 2014 annual report.
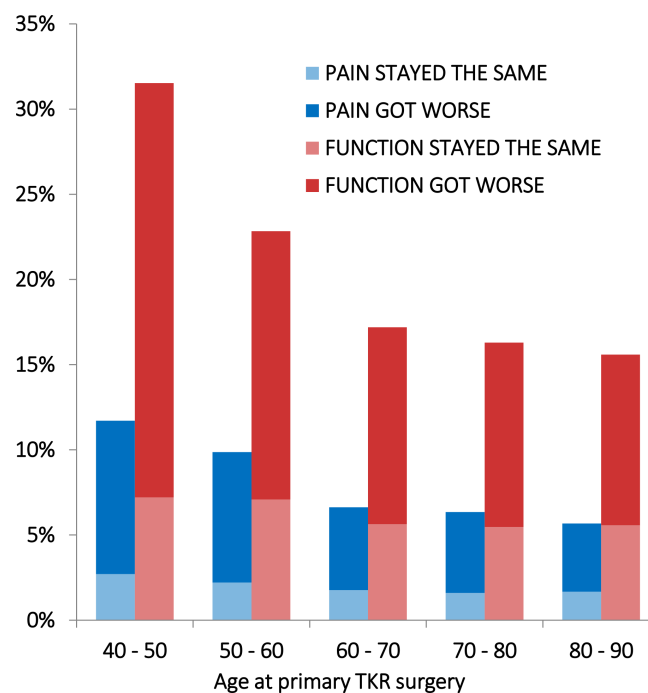
Figure 3.10   Change in Oxford Knee Score after TKR, split into pain and function subscores and arranged by age of patient. Data taken from (HSCIC, 2013). The pain and function subscores are discussed in Appendix B

3.7 Conclusions

TKRs have advanced hugely since Gunston's Polycentric Knee design developed during the 1960s. Survivorship is above 95% after 10 years in all the national joint registries. It is a safe and relatively long lasting procedure. TKRs relieve pain and in the most part people are happy with their device.

However, most people with TKRs do not forget that they have an artificial knee and a large minority

of TKR patients remain dissatisfied with their device, particularly when trying to achieve more demanding activities than merely walking on a flat surface. This means that implant manufacturers, design engineers and surgeons alike continue in the pursuit of the "perfect" TKR. As new designs are developed, so must effective pre-clinical assessment techniques in order to ensure that the updated models are in the patients' best interests.

CHAPTER 4

PRE-CLINICAL FUNCTIONAL ASSESSMENT METHODS FOR TOTAL KNEE REPLACEMENTS

4.1 Introduction

Knee reconstructions and replacements must not only treat the injury or disease and relieve pain but must also aim to replicate the normal motion and function of the knee. There is a plethora of choice when considering pre-clinical assessment of knee reconstruction techniques and devices. As new devices and techniques have been developed over the years, so have the methods by which to evaluate them. Well planned pre-clinical analysis is vital to establish safety and efficacy of devices prior to first in man implantation (and, in some cases, live animal studies). These tests range in type, from the relatively simple mechanical testing of biomaterials to implant stability testing to complex biomechanical testing using cadaver specimens, physiological muscle loading and bespoke testing rigs and fixtures. There are also computational methods that can be used to assess implant performance, including finite element analysis (FEA) and musculoskeletal models (Ishikawa *et al.*, 2015; Pianigiani *et al.*, 2012).

All of these methods have their inherent limitations and it is likely that to be able to properly quantify a device's performance in the pre-clinical setting, a combination of these methods will be required. The regulatory framework in both Europe and the USA requires that, among others, the pre-clinical tests described by ASTM standard F2083-12 (ASTM, 2012c) are carried out as part of the pre-market approval process for all new total knee replacements. The review here focusses on the assessment of the functional biomechanical performance of TKRs in the laboratory, but excludes the evaluation of safety considerations such as wear and fatigue which are also covered by international standards.

4.2 Isolated implant testing

4.2.1 Single degree of freedom testing

For quick and relatively easy assessment of TKRs, isolated tests of the implant itself can be a useful tool as part of the pre-clinical testing process. They represent a "common sense check" of new design considerations, such as the geometry of the articulation of the tibiofemoral joint.

One such test is ASTM F1223-08: "Standard Test Method for Determination of Total Knee Replacement Constraint" (ASTM, 2008), which defines the methods by which the inherent uni-axial or uni-rotational mechanical stability (or laxity, or constraint – the three terms are used interchangeably in the literature) of the TKR prosthesis itself can be measured. Stability in this context is defined as the magnitude of force or torque required to translate or rotate the tibial component of the TKR away from its neutral position while it is articulating with the femoral component under an axial compressive force. This constraint measurement is independent of patient pathology or the surgical implantation process (Figure 4.1). This information may help the surgeon in choosing the most appropriate TKR for each patient, while also considering factors such as the intrinsic stability of the native knee, which is affected by the condition of the soft tissues surrounding it and is therefore highly variable between different patients (Kakarlapudi and Bickerstaff, 2000). The ASTM standard aims to:

> *"provide a database of product functionality capabilities that is hoped to aid the physician in making a more informed total knee replacement selection".*

In the United Kingdom National Health Service (NHS), this "database" is unlikely to empower the surgeon to make better implant choices: she or he will be limited by their hospital or primary care trust's contracts with the implant manufacturer(s). These manufacturers must still perform these standard tests, however: it was made mandatory in March 2010 for all new TKRs before they are marketed and used clinically if CE marking is required (The EU, 2007). The testing specifications of this standard will be discussed further in Chapter 5.

Another type of implant-only test for TKRs is the measurement of contact pressure and area in the tibiofemoral joint. This is another standard test described by ASTM (ASTM, 2012c) and can act as an inspection test to highlight potential regions of high contact stresses (and related reduced contact

areas) which could potentially lead to problems with UHMWPE wear, without having to conduct lengthy wear assessments, which take weeks or even months to perform. The standard does not describe the testing specifications, but instructs the reader to follow one of several test methods in the literature. In order to measure the contact area and pressure in the joint, some kind of pressure-measuring systems must be used, together with a test rig that can compress the implant axially at different knee flexion angles. There are three different pressure measuring devices mentioned in the biomechanics literature: 1) Pressure sensitive conductive rubber; 2) FujiFilm prescale pressure-sensitive film (Fujifilm, Tokyo, Japan) and 3) Tekscan piezo-electric pressure sensitive film (Tekscan, Inc. South Boston, MA USA) (Hara *et al.*, 1992; Harris *et al.*, 1999).

These ASTM tests have been designed to try to approximate in vivo conditions but bench-top tests of isolated implants such as these have obvious limitations. This kind of testing is most powerful when used to compare different devices to one another and a known predicate device must also be tested as a control when performing these procedures for regulatory approval. It could be argued that this type of test is more of a safety check, as opposed to a functional assessment. None of them really enables the researcher to predict how the device would perform in vivo.
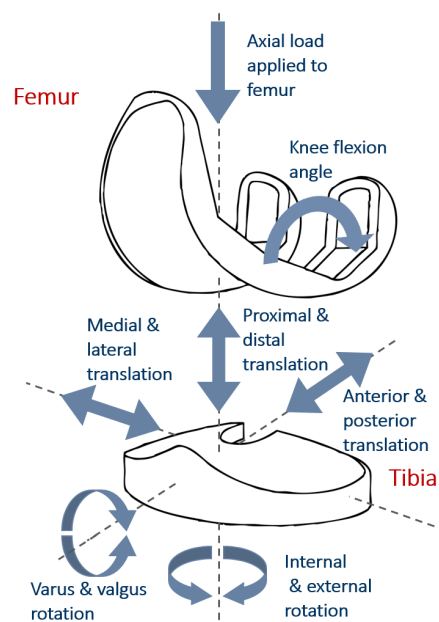
Figure 4.1 A schematic of TKR stability testing, showing the two components of the implant, the direction of the compressive load used during testing and the 6 degrees of freedom of the native knee.

4.2.2 6 degree of freedom testing

Another form of isolated implant testing that can be done is by way of a force-controlled knee simulator, such as the Instron-Stanmore knee simulator, described by Walker *et al.* (1997) and Haider *et al.* (2006), for example. This type of simulator controls the flexion/extension movement of the knee joint and imposes an axial load, AP forces and IE moments by way of springs representing the various passive soft tissues surrounding the knee joint during a simulated gait cycle. The magnitudes of these forces and moments were based on the in vitro work done over 3 decades ago by Fukubayashi *et al.* (1982). Simulators of this sort are the same as those that are used for long-term wear testing of TKRs (ISO, 2009); they make the assumptions that the external forces on the knee are independent of TKR design and that the kinematics displayed by the knee in the simulator will be a function of the design of the TKR. This type of test may tell you what the kinematics of a replaced knee will be in a single, "average" patient, whose ligament resistances during gait are modelled by the springs in the rig.

Like the single DoF stability tests described previously, these simulators can provide a comparison between devices but do not appear to be well suited to predicting how they will perform in different types of patient. Indeed, the kinematic patterns produced by these simulators are not reproduced in vivo (using the same TKRs) and, in addition, there is high variability in kinematics between patients with the same TKR implanted (DesJardins *et al.*, 2007; Ngai *et al.*, 2009). This suggests that this type of assessment cannot really predict how a TKR will behave in clinical use and that a TKR's characteristics cannot be determined from its articular geometry and the passive resistance provided by the ligaments alone. Variations in surgical technique, implant positioning and patient anatomy and/or pathology clearly all have an effect on the functional outcome of a TKR and it is possible that this kind of implant simulator should only be used to conduct pre-clinical wear tests as part of the regulatory process and that they should not be used to try to predict how different TKR designs will behave in vivo or used to show improvement in function due to design changes.

Recently, the AMTI "Vivo" has been developed. (White and Carignan, 2012). It has a similar design philosophy behind it as the Stanmore simulator, but is more sophisticated: the applied forces are controlled by "virtual soft-tissues" and these can be adjusted to have non-linear responses depending on the displacement or rotational position of the knee and some muscle forces are also included (White *et al.*, 2006). It is possible that this type of simulator could be tuned to simulate

different patient pathologies, thereby giving much more information about a device's potential performance in vivo.

4.3 In vitro testing

While the implant-only tests described in the previous section are robust, simple to perform and low-cost, they have the obvious limitation of not being influenced by patient and surgeon variability. While this makes them more repeatable, and reproducible so that different users and laboratories will produce similar results, it also means that they are less representative of in vivo conditions. The use of in vitro testing methods, which utilise cadaver knee specimens, some realism can be added to the pre-clinical testing process.

4.3.1 Single degree of freedom testing

The isolated implant testing described in the previous section could be expanded to include stability testing of cadaver knees before and after TKR implantation, such as that described by Walker *et al.* (2011).   In this study, low-cost polyurethane TKR components were manufactured from stereolithography (STL) files and tested using a "desktop" testing machine, with drawer forces and rotational torques applied to produce stability data for different TKR designs.   Unfortunately, the authors of this study only used intact cadaver knees in a pilot study, to give a set of baseline "anatomic" results for AP and IE stability. They then proceeded to test the implants in isolation and compare laxity results to the anatomic baseline; a more powerful study would have tested the cadaver knees implanted with the TKRs.

Another limitation of this study was the very low axial compressive load that was used during the stability testing (58 N, compared to around 2 kN maximum during walking gait). However, this type of testing could be a powerful tool for assessing the effects of small design changes, such as the shape or position of the peg in a PS device, or the amount of PCL damaged by the surgical insertion of the tibial baseplate (Van Opstal *et al.*, 2014). A repeated measures test design would be ideal, so that the stability of the replaced knee could be directly compared to that of the native knee.

4.3.2 Six degree of freedom testing

The uni-directional tests described previously are a relatively quick and cheap ways to assess TKRs in the pre-clinical setting. But the knee moves in three dimensions and, as described in Chapter 2, has 6 degrees of freedom. Modern TKRs aim to replicate these 3D motions of the knee joint and 6 DoF kinematic testing can aid in determining whether or not they achieve this.

4.3.2.1 Passive testing rigs

The simplest kind of 6 DoF kinematic testing method for the knee is passive flexion/extension of the joint. There are many different kinds of specially designed rigs that can be used to examine the rotations and translations in the knee joint as it is flexed and extended (Bull *et al.*, 2008; Ghosh *et al.*, 2010; Heever *et al.*, 2012; Barnes *et al.*, 2012; Hunt *et al.*, 2014), utilising the fact that the position of the knee as it is passively moved through flexion angles is controlled by the ligaments, menisci and the articular geometry of the tibiofemoral joint (Wilson *et al.*, 1998). Although slightly variant to each other, all of these rigs simulate an open-chain flexion of the knee, with none, some or all of the heads of the quadriceps loaded to provide the extensor moment. Some of the rigs additionally load the hamstrings to provide a more realistic co-contraction, which also limits the amount of anterior translation of the tibia (Hunt *et al.*, 2014).

The design and manufacture of some of these rigs can still be relatively "low-tech", with manual movement of the knee and weights and/or pneumatic actuators providing muscle loading and drawer forces and rotational torques. In some cases the drawer forces and torques are applied by hand until a "subjective end point" is felt (Hunt *et al.*, 2015): this is akin to the intra-operative stability assessment that is performed during TKR surgery, but it may be the case that this is not repeatable and in addition does not allow secondary motions of the tibia to occur naturally because of the way in which the tibia has to be held for forces and torques to be applied. This kind of evaluation should be considered alongside the controlled loading scenarios.

The tracking of the femur and tibia in this type of test is fairly complex because both bones are usually in motion simultaneously. An electromagnetic or optical tracking system is therefore normally used to record the movement of each bone during the experiment – similar in style to the motion capture techniques used in gait analysis, with the advantage of being able to attach trackers directly to the bones, so soft tissue artefact does not present a problem (as is also the case in computer

assisted/navigated surgery). This kind of test and the associated measurement techniques and limitations will be discussed further in Chapters 6 & 7.

4.3.2.2 Dynamic or active knee testing rigs

The logical addition to make to the open-chain exercises described above is a ground reaction force, creating a closed-chain motion. This will better approximate weight bearing activities such as squatting, walking, cycling and rising from a chair. This type of "dynamic" knee testing rig has its origins in the Oxford Knee Rig (OKR) which was developed in the late 1970s by John O'Connor and colleagues with a view to studying different designs of knee arthroplasty (Bourne *et al.*, 1978). Since then, many others have followed over the years, all with slightly different design features, levels of sophistication and methods of operation. What they all have in common is that the angle of flexion of the knee is controlled by a force at the hip joint, balanced by quadriceps (and sometimes hamstrings) muscle loading, rather than relying on one of the bones being manually controlled. Although quasi-static measurements during activities such as squatting are routinely captured using this type of system, continuous flexion-extension motions can also be produced and dynamic ADLs such as walking gait, stair climbing and rising out of a chair can be assessed, although most of the rigs currently only examine the relatively straightforward squat. A selection of such rigs has been summarised in Table 4.1. Similarly to the passive knee rigs described previously, some kind of 3D tracking system must be used in conjunction with these dynamic rigs in order to accurately measure tibiofemoral motion.

Table 4.1 Dynamic knee testing rigs being used in knee research. DoF: degrees of freedom, VI: vastus intermedius, quadriceps muscle, RF: rectus femoris, quadriceps muscle, VM: vastus medialis, quadriceps muscle, VL: vastus lateralis, quadriceps muscle, FE: flexion/extension of a joint, IE: internal/external rotation of a joint, VV: varus/valgus rotation of a joint, AP: anteroposterior translation, PD: proximodistal translation.

Location of Rig	Hamstrings loaded?	Which quadriceps loaded?	Downward squat?	Upward squat?	Other activities	DoF at hip	DoF at ankle	Reference
Bath	Yes	VI+RF	Yes	No	None	Universal joint	FE ,IE ,VV	Coles *et al.* (2014)
Clemson	Yes	VI+RF, VM, VL	Yes	No	None	PD,IE,VV	FE ,IE ,VV	Rusly *et al.* (2014)
Ghent	No	VI+RF	Yes	Yes	None	PD,FE,IE	FE,IE,VV (AP)	Van Haver *et al.* (2013)
Harvard	No	VI+RF	Yes	No	None	Universal joint	FE,IE,VV	Ramappa *et al.* (2006)
Kansas	No	VI+RF	Yes	Yes	Walking	PD,FE	FE,IE,VV	Guess and Maletsky (2005)
Leuven	Yes	VI+RF	Yes	No	None	PD,FE	FE,IE,VV	Victor *et al.* (2009)
LMU	Yes	VI+RF, VM, VL	Yes	Yes	None	PD,FE,VV	FE,IE,VV	Steinbrück *et al.* (2013)
NYU	Yes	VI+RF	Yes	Yes	None	Spherical bearing	FE,IE	Yildirim *et al.* (2009)
Oxford	No	VI+RF	Yes	No	None	PD,FE,VV	FE,IE,VV	Zavatsky (1997)
Scripps	No	VI+RF	Yes	Yes	Stair climbing	PD,FE,VV	FE,IE,VV	D'Lima *et al.* (2000)
Taylor	Yes	VI+RF, VM, VL	Yes	No	None	PD,IE,VV	FE ,IE ,VV	Oshea *et al.* (2014)
Tubingen	Yes	VI+RF, VM, VL	Yes	No	None	PD,FE,VV	FE,IE,VV	Wünschel *et al.* (2011)
UBC	No	VI+RF	Yes	Yes	Stair climbing	PD,FE,VV	FE,IE,VV	Anglin *et al.* (2008)

4.3.2.3 Robotic testing methods

Perhaps the most controllable method by which to measure native knee kinematics and comparing them to those of the replaced knee is a 6 DoF robot arm, or "manipulator". Pioneered by the Musculoskeletal Research Center at the University of Pittsburgh in the mid 1990s (Rudy *et al.*, 1996), this test utilises a high-precision 6 DoF robot arm, the sort that is seen in car manufacturing facilities (Figure 4.2). This kind of robot arm, fitted with a 6-axis force and moment sensor and a robotic controller, can be programmed to move the knee joint in flexion-extension, while simultaneously minimising the forces in the other degrees of freedom, allowing the secondary motions that occur naturally during passive knee flexion. One of the limitations of this type of assessment is that these relatively small robotic manipulators are not capable of providing joint loads above around 200 N, a fraction of what is seen during ADLs. This can be partly rectified by the inclusion of external actuators or weights attached directly to the muscles surrounding the knee to simulate the loads experienced by the knee during flexion and extension (Van de Velde *et al.*, 2009), most of which are a result of muscle action (Shelburne *et al.*, 2006). This would have the added benefit of some of the active stability afforded to the knee by the muscles, being simulated.
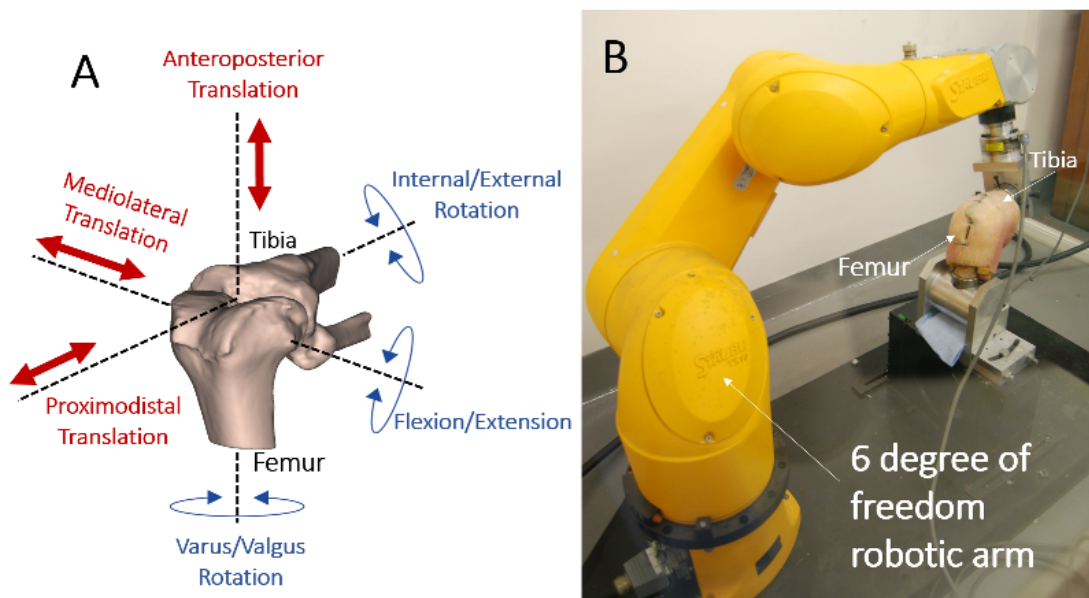
Figure 4.2   Knee testing with a robot.

4.4 Computational methods

Although this thesis is concentrated on experimental investigations, this review would be incomplete without mentioning the computational or "in silico" techniques that can be used as part of the pre-clinical testing process, particularly those that complement or replicate the laboratory based tests described above. The stability test described previously has been reproduced using rigid-body computational methods by Moran *et al.* (2008), who found good agreement between the experimental and virtual models. The Kansas knee rig has been duplicated in silico, using a finite element method (Baldwin *et al.*, 2012; Clary *et al.*, 2013) and although this presents a much more challenging modelling problem due to the use of cadaver specimens in the experimental model, the FE version of the simulator produced results in good agreement with those from the experimental testing. Computational methods are an attractive option; once they have been constructed and verified using experimental models, controlled loading regimes can be used on a variety of TKR designs, to extract small changes in kinematics.

In addition, they offer the opportunity to test TKRs under a variety of loading conditions and, for example, alignment options, allowing multiple comparisons that would be extremely time consuming using in vitro methods. This probabilistic or parametric modelling has the potential to be very powerful in the design phase of new TKRs, although that is dependent on powerful computers to keep the computational time at a realistic level (Strickland *et al.*, 2010).

CHAPTER 5

STABILITY ASSESSMENT OF TOTAL KNEE REPLACEMENTS

5.1 Overview

This chapter describes work done to examine the stability of different designs of TKR using bench-top testing. The objectives of the work were to: measure the stability characteristics of different designs of implant using the testing procedure described by the ASTM standard F1223-08 (ASTM, 2008); assess whether this type of test, the simplest of the functional assessment methods for TKRs, can adequately distinguish between devices and educate surgeons about performance; quantify some of the "coupled" or secondary motions (those that are in the other degrees of freedom from that which is being examined) that occur during testing; produce recommendations for how this ASTM standard test method could be improved to better characterise TKRs as part of the regulatory and pre-clinical testing process.

The following terminology is used throughout this document to describe the broad types of total knee replacement:

1. ACL is resected, PCL is retained: cruciate-retaining (CR);

2. ACL & PCL are resected and stabilisation is built into the condylar geometry: condylar-stabilised (CS);

3. ACL & PCL are resected and substitution built into a cam-post mechanism, posterior-substituting (PS);

4. ACL & PCL are both retained: bi-cruciate retaining (BCR).

5.2 Introduction

The study by Haider and Walker (Haider and Walker, 2005) used the test methods outlined in the 2005 version of the ASTM standard to assess the constraint – or stability – of three different designs of CR TKR that are currently on the market: the Nexgen (Zimmer, Warsaw, IN, USA); the Genesis II (Smith & Nephew, Memphis, TN, USA) and the PFC Sigma, (DePuy Synthes, Warsaw, IN, USA). Moran *et al.* (2008) assessed one TKR device experimentally in order to validate a computer simulation of the ASTM test methods. These studies looked at TKR anterior-posterior AP translational stability and internal-external IE rotational stability, but neglected to consider the effect on stability of the medial:lateral (M:L) tibiofemoral loading distribution, which varies depending on subject and activity (Varadarajan *et al.*, 2008; Mundermann *et al.*, 2008; Zhao *et al.*, 2007). Instability is a major cause of TKR revision and so is an important consideration.

The ASTM standard does not include guidance on this loading distribution and is worth examining. Haider and Walker (2005) did explore whether keeping secondary motions constrained during the translation and rotation tests led to anomalous results. They concluded that, other than flexion angle and the DoF being measured, all the other motions should be left unconstrained in order to obtain reliable results. Heim *et al.* (1996) and Heim *et al.* (2001) looked at AP, ML and IE stability of mobile bearing and posterior stabilised TKRs but constrained all of the DoF of motion other than the one being measured. That constraint most probably led to unrealistic measurements of laxity and edge-loading conditions, especially in asymmetric TKR designs where one might expect large secondary motions to occur during stability testing.

There also has not been an analysis of the effect of axial load magnitude on the stability of these devices. In the methods section of their paper, Haider and Walker (2005) defined "constraint" as

$$Constraint = \frac{F}{Wa} \tag{5.1}$$

where F is the load reached at a particular displacement, a, under an axial load W. However, the authors did not go on to use this definition to compare the constraint measured for the 3 devices that they were testing. This definition of constraint effectively normalises the stability relative to the applied axial load and so any effects of changing the load might not be obvious by analysis of this

constraint measurement (i.e. it is possible for the ratio $\frac{F}{a}$ to change as W is varied and the constraint remain the same, but the stability characteristics might be quite different so this measure could be misleading). It would seem more sensible to quote the force and translation (or torque and rotation) of the device as it approaches the point of instability/subluxation. This measurement can then be compared across different devices for the same axial load. Or, for the same device, the effect of changing the compressive axial load could easily be quantified.

Therefore, this study sought to examine the AP and ML translational and IE rotational stability at a range of flexion angles, M:L loading distributions and axial loads, using the ASTM standard test methods with all of the secondary motions unconstrained, for a range of different devices. It was hypothesised that altering the M:L load distribution would vary the relative constraint of each compartment of each prosthesis, leading to changes in the coupled rotations which accompany AP and ML translations and the AP translations and VV rotations that accompany controlled IE rotation. It was also hypothesised that increasing the axial compressive load would alter the devices' stability characteristics and that the TKRs would exhibit different stability characteristics depending on the flexion angle being tested.

5.3 Materials and methods

Two purpose-built rigs were used in conjunction with two Instron materials testing machines (MTM, Instron Ltd, High Wycombe, UK) for translational and rotational stability testing.

5.3.1 AP testing rig

A previously designed and constructed test rig, which could accommodate the femoral and tibial components of a TKR was used for testing (Figure 5.2). This rig fixed the flexion angle, AP, ML and IE position of the femoral component but allowed it to freely rotate in VV and translate proximodistally. The tibial component was constrained in flexion/extension, VV rotation and proximodistal translation, but free to rotate in IE and translate in ML, while the AP translations were imposed on the component. Therefore, all 6 DoF of the knee were present and, except for flexion, unconstrained during testing.

The femoral component was mounted using polymethylmethacrylate (PMMA) bone cement onto an aluminium alloy cross-bar, shaped to match the component's internal geometry, similar to the shape of the distal femur as prepared during surgery (Figure 5.1). The flexion angle could be adjusted by

rotating and then fixing the cross-bar into position. This rotation occurred around an axis parallel to the distal most aspect of the condyles, which was perpendicular to the line of action of the axial compressive force so this force was always acting along the same line in the sagittal plane. A pivoting frame was used so that the femoral component was free to rotate in varus-valgus, about an anterior-posterior axis at the level of the flexion axis, not far from the joint line. In previously used testing rigs in other studies, this VV rotation axis had been situated high above the joint line (Klein *et al.*, 2003; Moran *et al.*, 2008) which is not physiologically accurate.
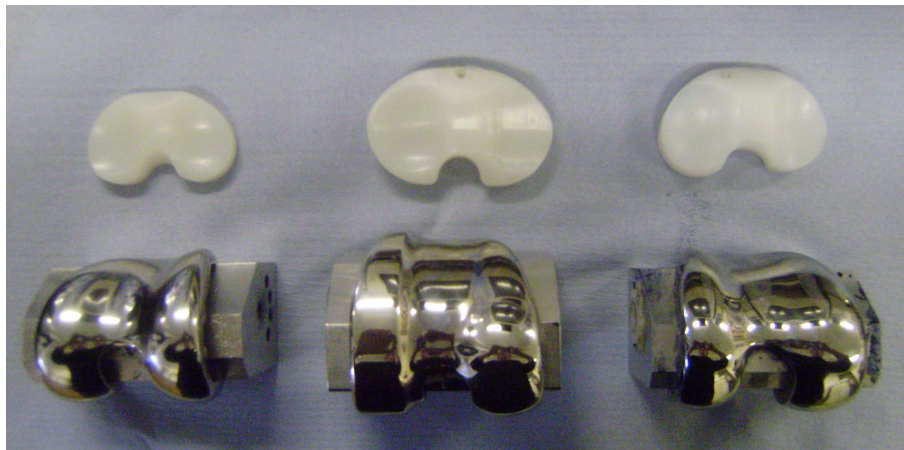
Figure 5.1   Three MatOrtho TKRs ready for testing. From left to right: mobile-bearing Saiph; MRK; fixed-bearing Saiph.

This pivot point could also be adjusted medially-laterally, thereby shifting the line of action of the axial load in the coronal plane, varying the load distribution between the medial and lateral compartments of the TKR, across the range 30:70% to 70:30% M:L. This was determined by measuring the distance between the lowest points on each femoral condyle – assuming that these would be the contact locations on the tibial bearing. The pivoting femoral frame was in turn mounted on a linear bearing, which allowed it to translate proximodistally during testing. A calibrated pneumatic cylinder forced the femoral fixture distally (horizontally in the test set-up) against the tibial component, providing the compressive joint force. A pneumatic cylinder was chosen so that any coupled proximal translations were not prevented from occurring during testing.

The tibial components were mounted onto the end of a freely-rotating shaft, which allowed internal-external rotation. A wedge could be placed in between the tibial tray and the shaft in order to adjust

the amount of posterior slope if required by the TKR operational technique. This assembly was mounted onto a linear bearing which allowed free medial-lateral translation in the horizontal plane. In turn, this whole tibial assembly was then mounted onto another linear bearing, which allowed anterior-posterior translation (a vertical motion in the experimental set-up). The tibial assembly was attached directly to the load cell of a single-axis Instron 5565 MTM which provided the AP motion and measured the force (N) required to translate the tibial component (mm).
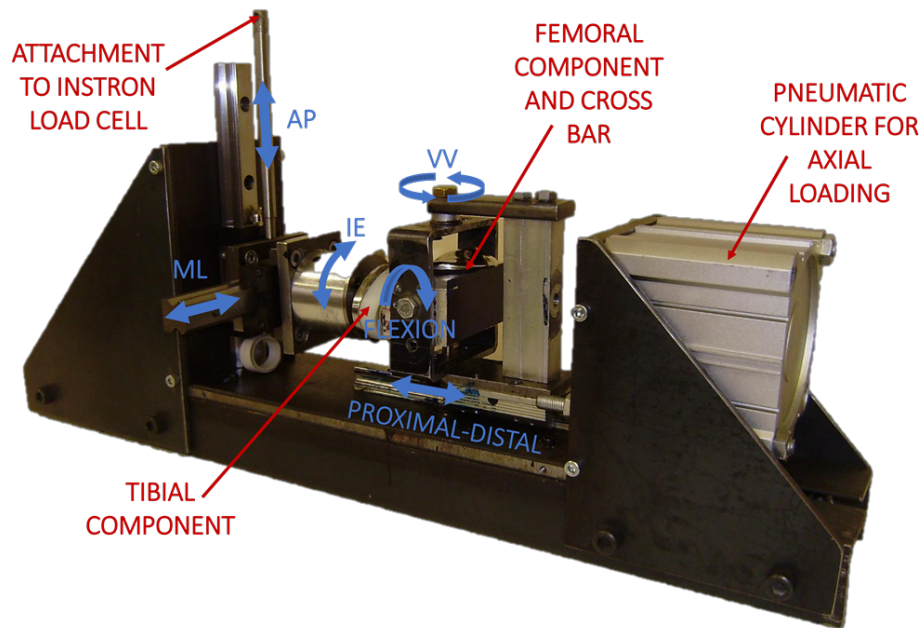
Figure 5.2   AP translational stability testing rig.
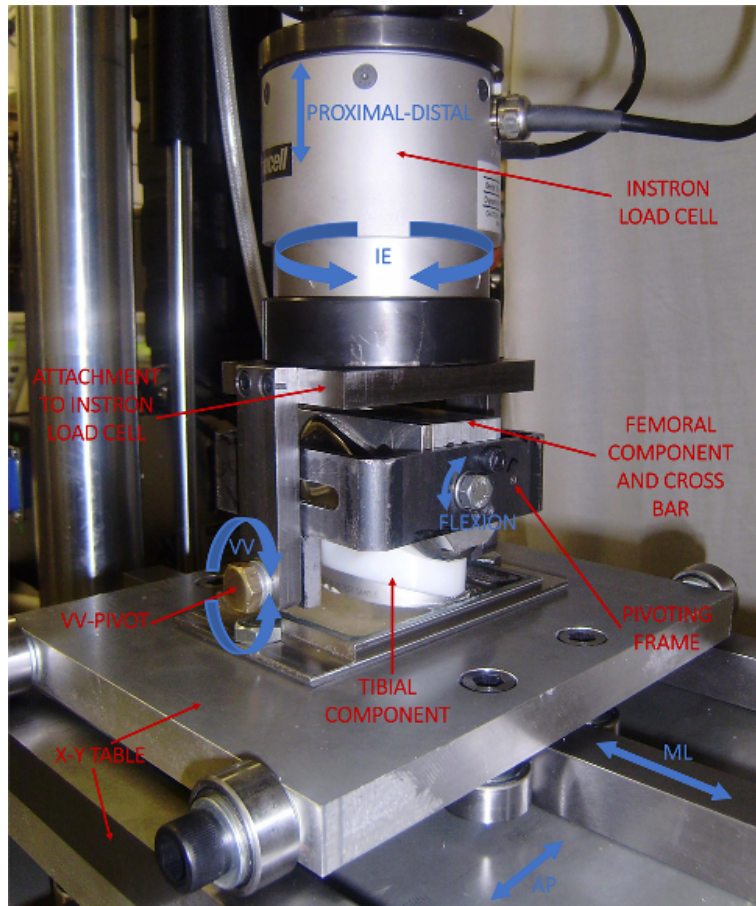
Figure 5.3   Rotational stability testing rig.

5.3.2 ML translation rig

The AP translation rig was adapted for the ML testing. The same pivoting frame was used to mount the femur, and the tibia was again attached to a rotating shaft and two linear bearings. So that the Instron imposed ML (rather than AP) translation to the tibial component, the whole femoral assembly was rotated by 90° around the line of action of the axial compressive load.

5.3.3 IE rotation rig

The tibial component was cemented into a shallow mounting on a low friction bearing X-Y translation table which prevented rotations and was bolted to the base of the servohydraulic dual-axis tension-torsion Instron (8874) (Figure 5.3). An aluminium alloy wedge could again be placed below the tibial tray to adjust the posterior slope (Figure 5.4). The femoral component was mounted using a similar cross-bar and VV pivot frame as in the translation tests, allowing free varus-valgus rotation about an anterior-posterior axis at the level of the joint line, but this was now mounted onto the end of the Instron load cell (Figure 5.4). The Instron imposed internal external rotation to the femoral component at the desired axial compressive force and angle of flexion, while the tibial component was able to translate in both AP and ML via the X-Y table and rotate in VV (Figure 5.3). The Instron measured the torque (Nm) and rotation (°) of the femoral component. With the Instron programmed to maintain a constant compressive joint force, the hydraulic crosshead lifted the femoral component to allow it to "climb" out of the concavities of the tibial bearing surfaces as required during the testing, in a similar way to the pneumatic cylinder in the AP stability tests.

5.3.4 Translational stability test method

The crossbar with the femoral component mounted onto it was fixed inside the pivoting frame at the desired flexion angle and then translated to the required M:L position for the loading distribution of interest.The vertical position of the tibial component was adjusted until an approximate "neutral" position of the TKR was found and the loadcell was balanced, to neutralise the weight of the tibial assembly. The more precise neutral position was then found by applying a 350 N axially compressive load and applying small AP/ML translations to the tibia ($\pm$2 mm for 5 cycles). The neutral position was then defined as the position where the hysteresis loop of the force versus displacement graph was symmetrical about the zero load axis (Figure 5.5). Once the components were in the precise neutral position, the axial load was then increased to the required level, and the AP/ML limits were found by translating the tibial component gradually until the force-displacement graph started to plateau,
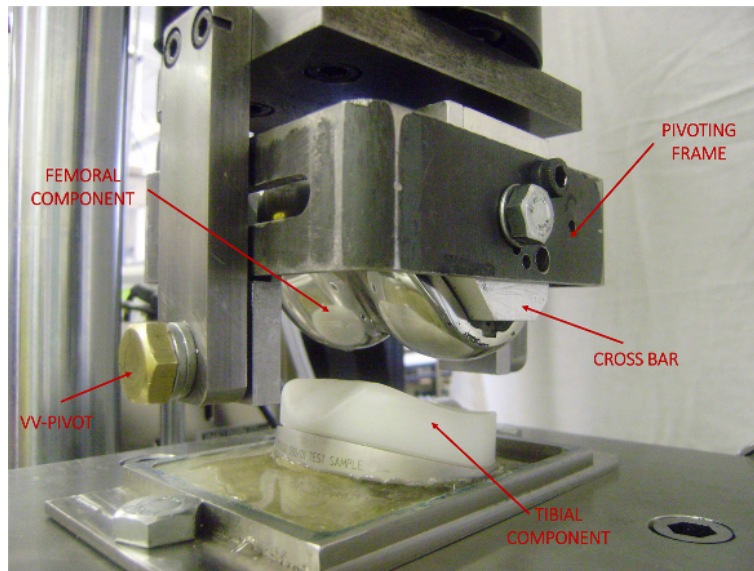
Figure 5.4   A close up image of the rotational stability testing rig.

first in the anterior/medial direction (the posterior/lateral limit of the UHMWPE bearing) and then in the posterior/lateral direction (the anterior/medial limit of the bearing). ASTM stipulates that the translation and rotation limits are defined as the point at which subluxation of the device is imminent. However, the plateau point was chosen instead in order to avoid any permanent deformation of the edge of the UHMWPE bearing caused by the components subluxing, which would have affected the results of future tests using the same implant. These displacement limits in both directions were recorded, the TKR was returned to the neutral position, lubricated with water, reloaded axially and cycled between the limits. Three "pre conditioning" cycles were completed and data were collected on the fourth cycle (Figure 5.6).

Each of these process (neutral location, limit finding and cyclic testing) was repeated for different flexion angles, M:L loading distributions and axial loads.

5.3.5 Rotational stability test method

The method for the IE stability testing was very similar to the AP testing. With the components mounted in the rig, the axial load was increased to 350 N via the Instron and the neutral point found. Then the internal and external rotational limits were found by rotating the femur until the torque-rotation curve started to plateau, or when 25° from the neutral rotation was reached, whichever occurred sooner. The components were then cycled between those limits. Again, each test was repeated for different flexion angles, axial loads and M:L loading distributions.
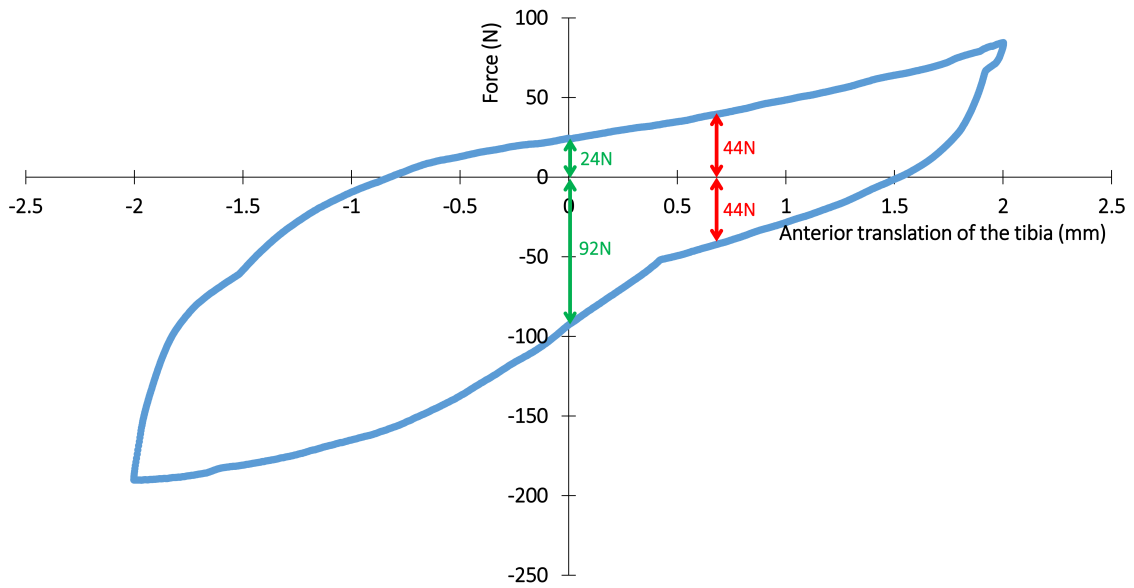
Figure 5.5   A graph showing the neutral point locating method for AP stability testing. The graph shows that the approximate neutral position (indicated by the green arrows at 0 mm translation) was around 0.7 mm posterior of the precise neutral position (shown by the red arrows).
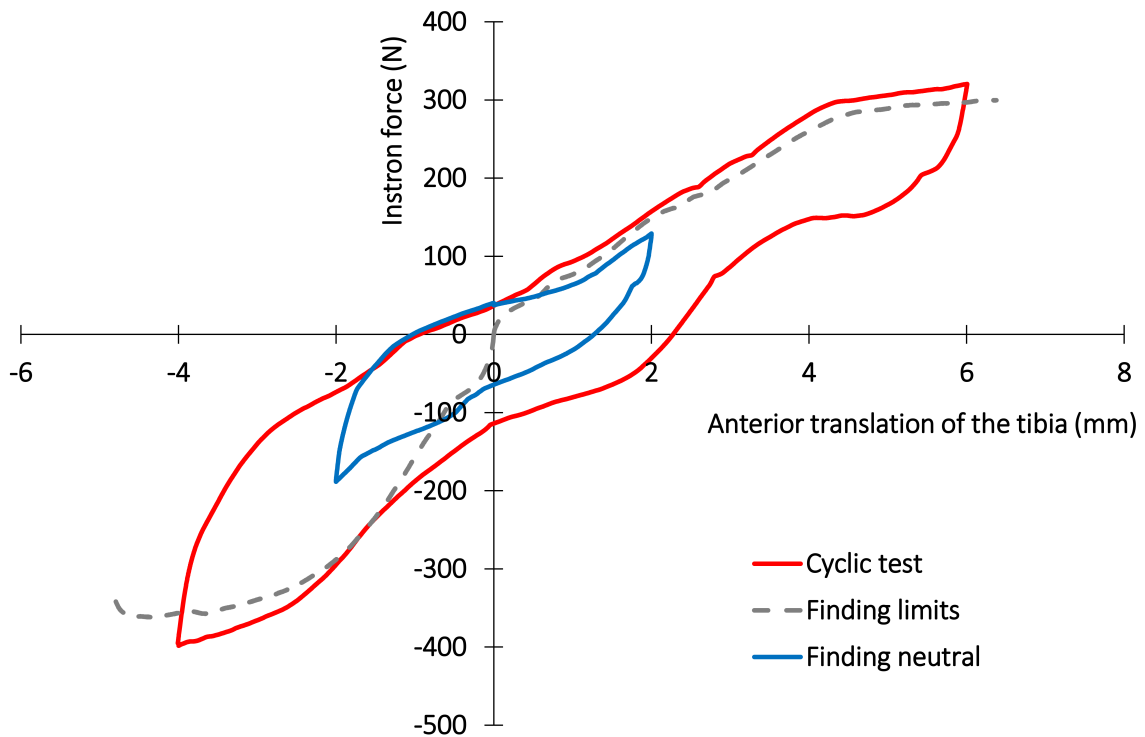
Figure 5.6   A graph showing the 3 stages of stability testing of TKRs. 1) Finding the neutral relative position of the femoral and tibial components. 2) Finding the anterior and posterior (or internal and external for rotational stability testing) limits. 3) The final cyclic stability test between the previously found limits.

5.3.6 Implants

Three TKRs were tested using the AP, ML and IE stability testing protocols. The Medial Rotation Knee (MRK) which has been in clinical use for over ten years and a fixed and mobile bearing version of a new device, the Saiph Knee (all 3 are manufactured by MatOrtho, Leatherhead, UK). These devices are medial-sphere, highly congruent condylar stabilised (CS) type TKRs, with asymmetrical condylar geometry (Figure 5.7). The mobile bearing version of the Saiph has the same femoral component as the fixed bearing device but has a more conforming lateral compartment on the UHMWPE bearing and is able to rotate 15° internally and externally around a post on the polished tibial tray without any translation (Figure 5.8). In addition to these devices, the AP stability of the Stryker Triathlon (Stryker Ltd., Kalamazoo, MI, USA) was measured using the same rig at a range of compressive loads and M:L loading distributions. The Triathlon is a conventionally designed, PCL-retaining, single-radius TKR with symmetrical condylar geometry. These results, as well as data from the literature, will be used to contextualise the stability results from the medial pivot devices.

Figure 5.7   MatOrtho total knee replacements. On the left, the Medial Rotation Knee (MRK) and a cross-section through the medial compartment showing the conformity. On the right, the Saiph Knee and a similar cross-section, where the built-in posterior slope of the device can also be clearly seen. Taken from the manufacturer's product brochures

Figure 5.8   The mobile bearing version of the Saiph Knee. Top left: the polished tibial tray with post. Top right: the backside of the UHMWPE tibial bearing with the rotation slot visible in its centre. Bottom: a right-sided bearing in place on top of the symmetrical tibial tray at the internal (left), neutral (centre) and external (right) limits of its rotation.

5.4 Results

5.4.1 Comparison between samples

Three samples of the Saiph knees from the same manufacturing batch were tested, in order to assess repeatability of results between supposedly identical devices. An example is shown in Figure 5.9, where the implants show good agreement between one another. This repeatability was consistent across the various tests, despite the inherent variability in implant cementing, mediolateral alignment and the subjective nature of defining the imminent subluxation point.
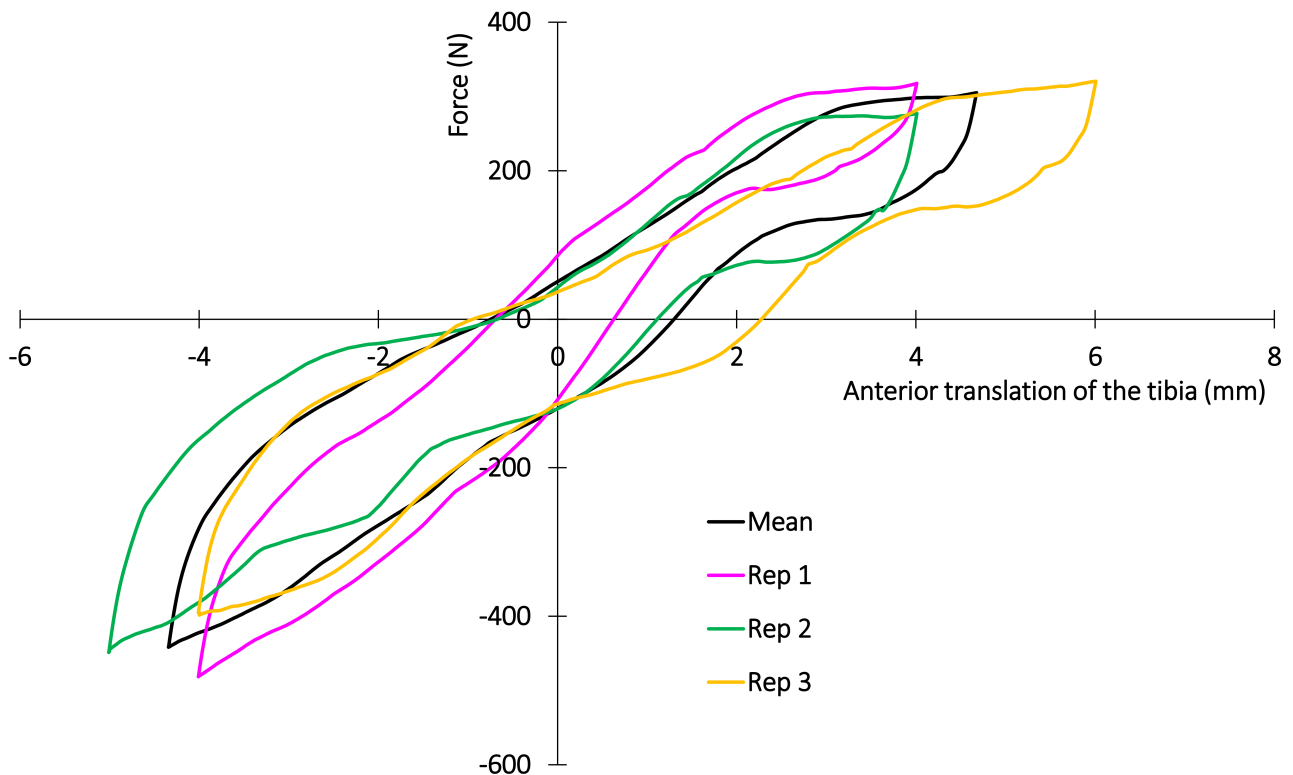
Figure 5.9   AP stability of three samples of the Saiph fixed bearing knee at 0° flexion and 50:50 M:L.

5.4.2 AP Stability and coupled tibial rotation

The AP stability characteristics varied between the four different TKR designs.   The AP force-displacement graphs for the tests at full extension (here defined as 0° flexion) for 50:50 M:L loading distribution are shown in Figure 5.10. The results were consistent with the geometry and congruency of the tibial bearings. The fixed bearing Saiph and the MRK had similar laxity in the posterior translation direction, but in the anterior direction, the MRK was much more constrained – needing 600 N to translate 4 mm compared to the Saiph, which required only 250 N to move the same amount. The relatively incongruent Triathlon, which has a shallow tibial bearing concavity in both the medial and lateral compartments, was less constrained in AP translation, with a shallow sloped force-displacement curve in both directions. It only remained stable for 3 mm in the posterior drawer direction – a reflection of the fact that it is designed to be a CR device.

At full extension and 50:50 M:L loading distribution, total AP translation between the instability limits ranged from 8.5 mm with the MRK to 15 mm with the Triathlon.

At 90° flexion, the MRK and Saiph again showed similar stability characteristics to each other, while

the Triathlon allowed a larger range of AP translation, 22 mm, largely in the anterior drawer direction. In all three cases, changing the M:L loading distribution to 60:40 had only a small effect on the AP stability characteristics, although the total AP translation did increase for both the MRK and fixed bearing Saiph devices, particularly at 90° flexion (Figure 5.11). This increase in total translation that could take place before subluxation appeared to be due to increased coupled tibial rotation that was observed during this test. Figure 5.12.
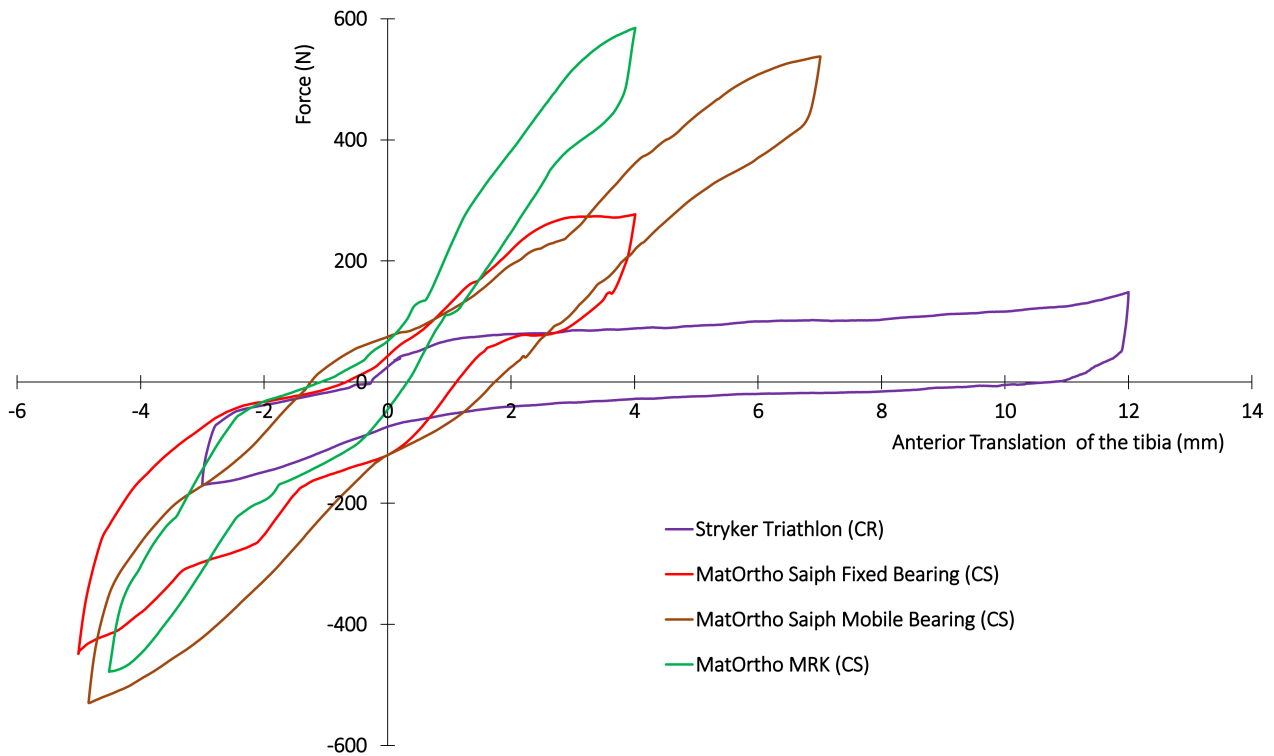
Figure 5.10   AP stability at 0° flexion and 50:50 M:L loading for 4 different TKRs.
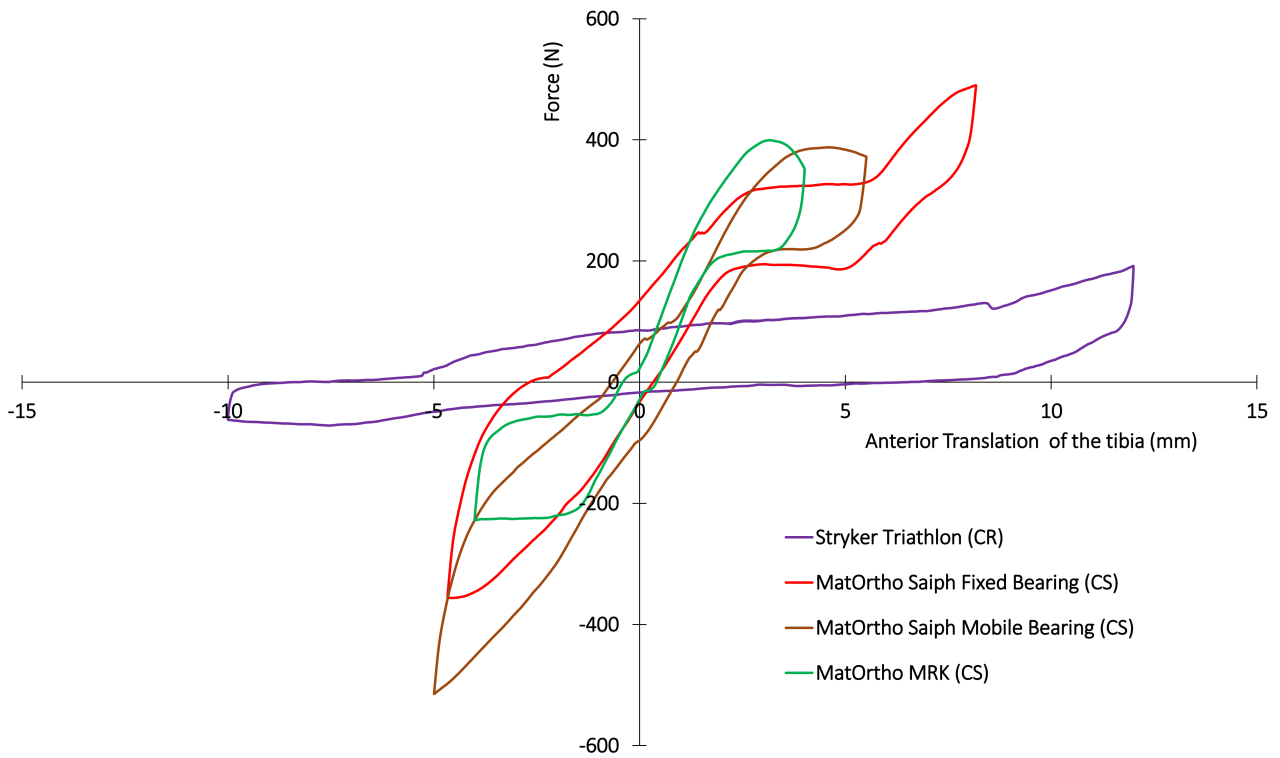
Figure 5.11   AP stability at 90° flexion and 60:40 M:L loading for 4 different TKRs.
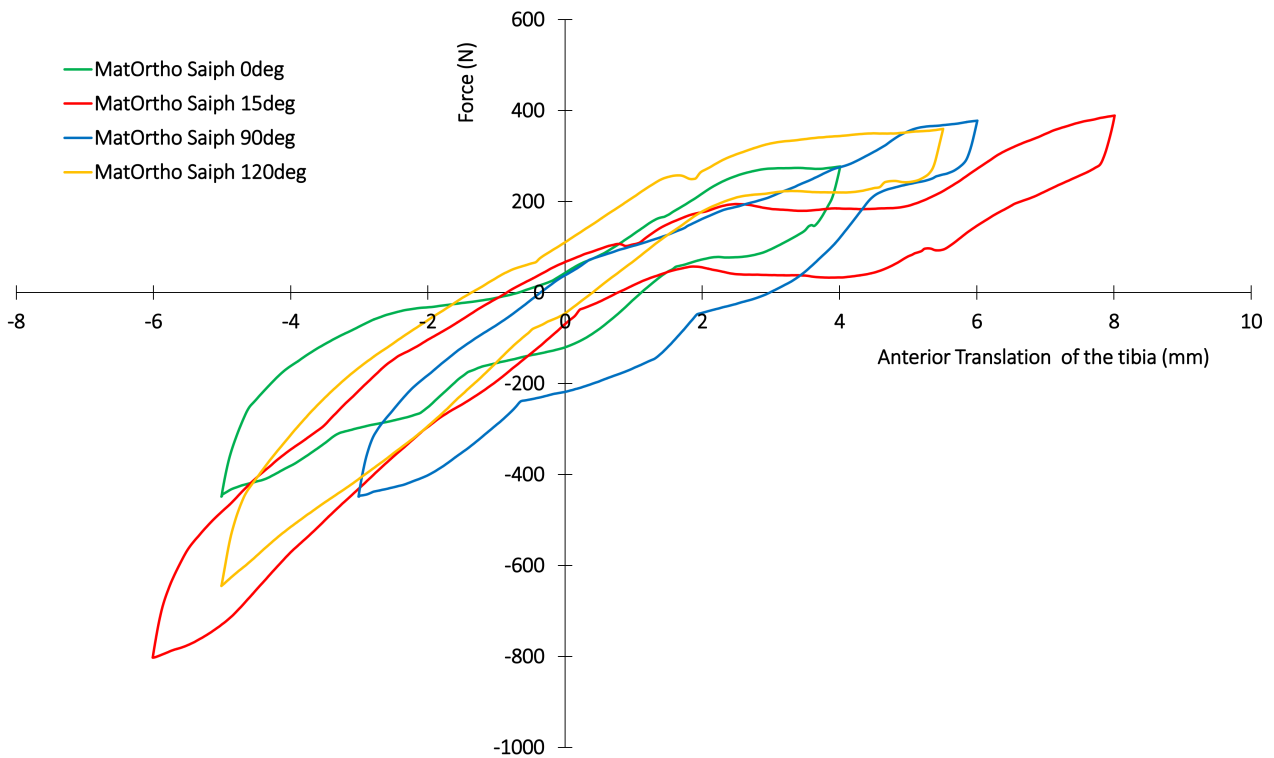
Figure 5.12   Stability of the Saiph TKR at different angles of flexion, 50:50 M:L loading distribution.

The medial-sphere type TKRs exhibited more coupled tibial IE rotation in AP translation at the 50:50 M:L loading distribution than the symmetrical Triathlon, which displayed almost 0° rotation in both translation directions at full extension and 90° flexion. This finding is consistent with the design objectives of the devices. Total tibial rotation at both 0° and 90° flexion for both the fixed bearing Saiph and MRK was 11° at the 50:50 M:L loading condition. For the mobile bearing Saiph, the tibial bearing only rotated a total of 5.5°. When the loading distribution was shifted towards the medial side to give a 60:40 loading condition, an increased amount of tibial rotation was observed with the MRK, fixed bearing Saiph and mobile bearing Saiph at 90° flexion, with total rotation increasing to 15°,19° and 10° respectively (Figure 5.13). This secondary tibial rotation in the MRK and fixed bearing Saiph resulted from greater movement in the less constrained lateral compartment (Figure 5.14).

At full extension, rotation only increased for the Saiph TKRs. It should also be noted that the direction of the majority of the rotation varied between the three devices. For the fixed bearing Saiph, most of the coupled rotation occurred during anterior tibial drawer in the internal direction; it was fairly balanced with the mobile bearing Saiph but with the MRK, it tended to be mainly external rotation during posterior tibial drawer. When the axial load was increased, there was an associated increase in the range of stability for the devices; not only were the subluxation limits further away from the neutral point of the implants, but the gradient of the force-displacement curve tended to be slightly steeper too (Figure 5.15)

The Triathlon TKR underwent AP stability tests at a range of different M:L loading distributions, from 30:70 to 70:30, at 0° and 90° flexion. Both the magnitude and direction of the associated tibial rotation were very sensitive to the M:L load balance (Figure 5.16). The Triathlon was also assessed for AP stability at different axial compressive loads at 90° flexion. The stability increased with the compressive load: for 5 mm anterior translation, the displacing force required was 43, 117 and 150 N, for compressive loads of 710 N, 2 kN and 3 kN, respectively, after frictional effects were considered (Figure 5.17).
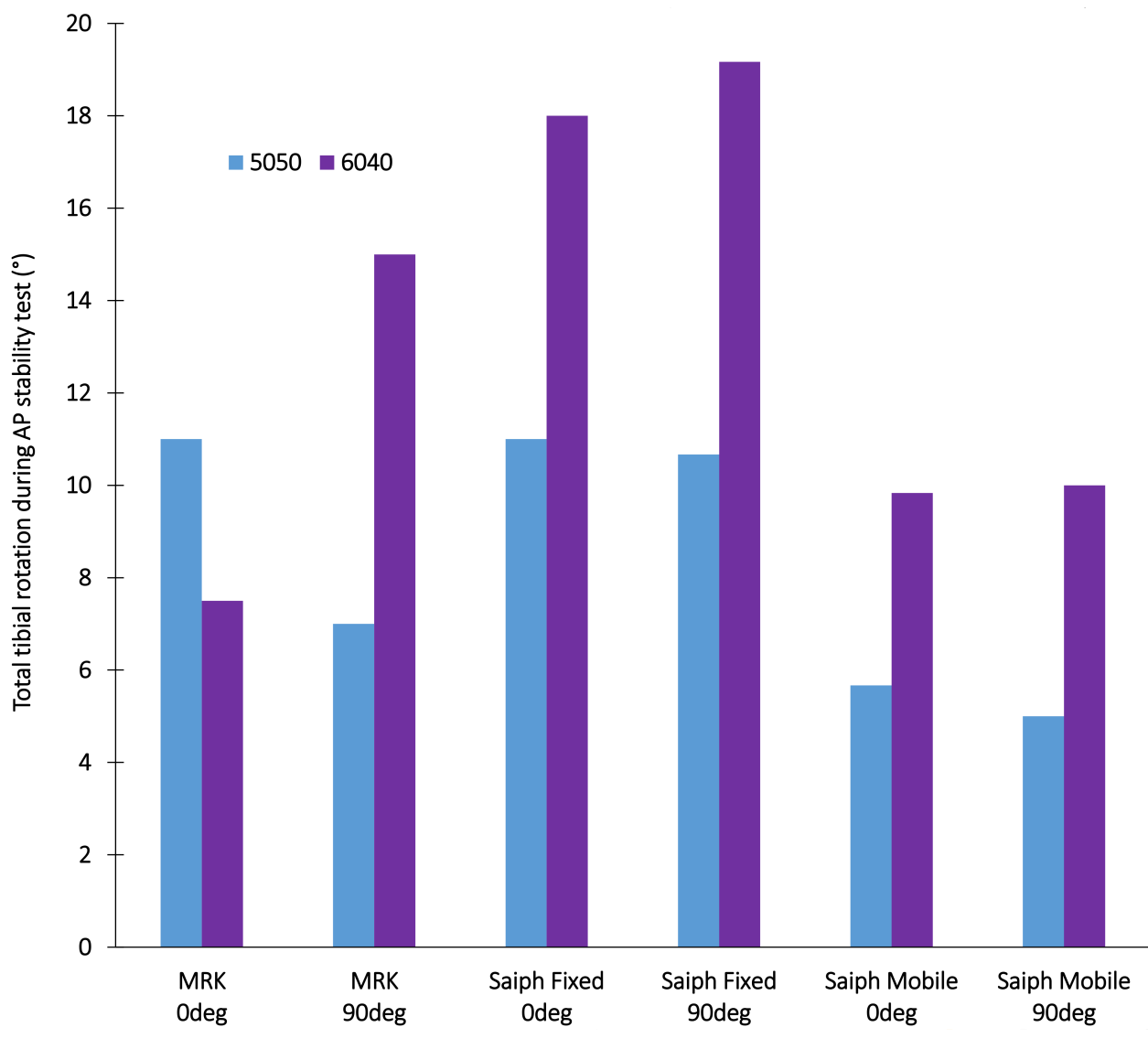
Figure 5.13 Total tibial rotation during AP translation.
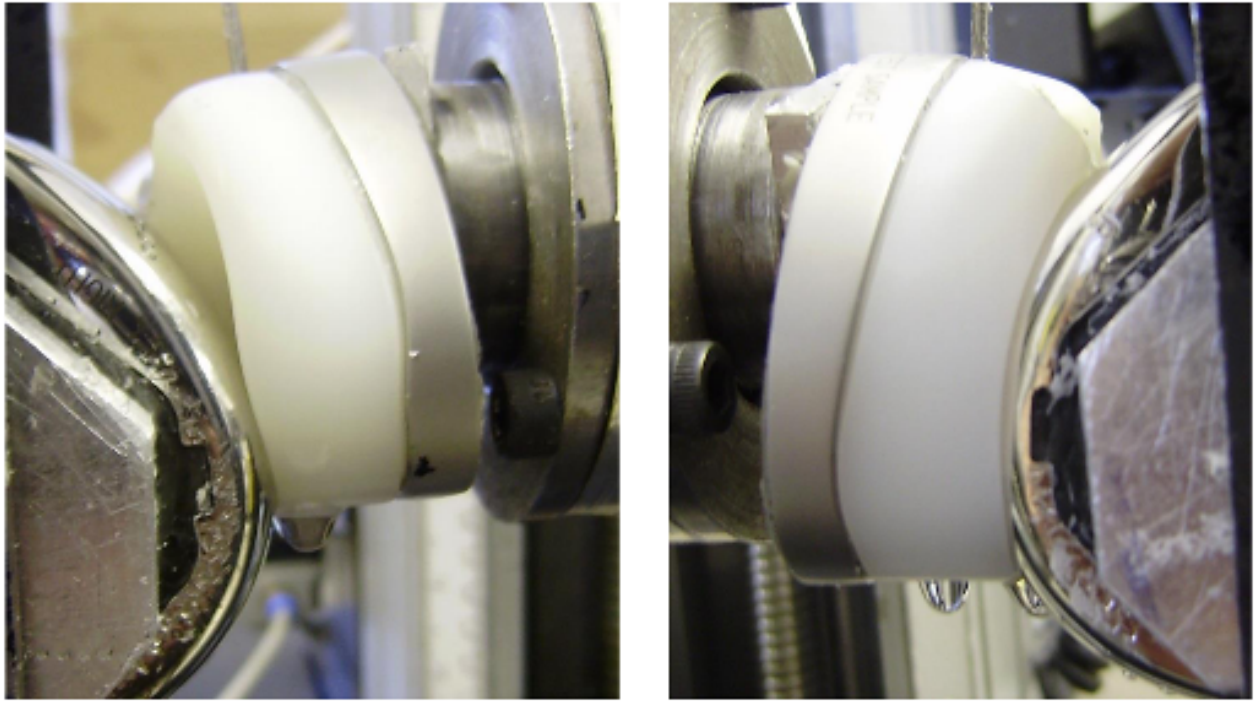
Figure 5.14 **Coupled tibial rotation of the MRK during AP translation. Left: the unconstrained lateral compartment approaching subluxation during anterior translation of the tibial component. Right: the medial sphere compartment in the same device at the same point of anterior tibial translation.**
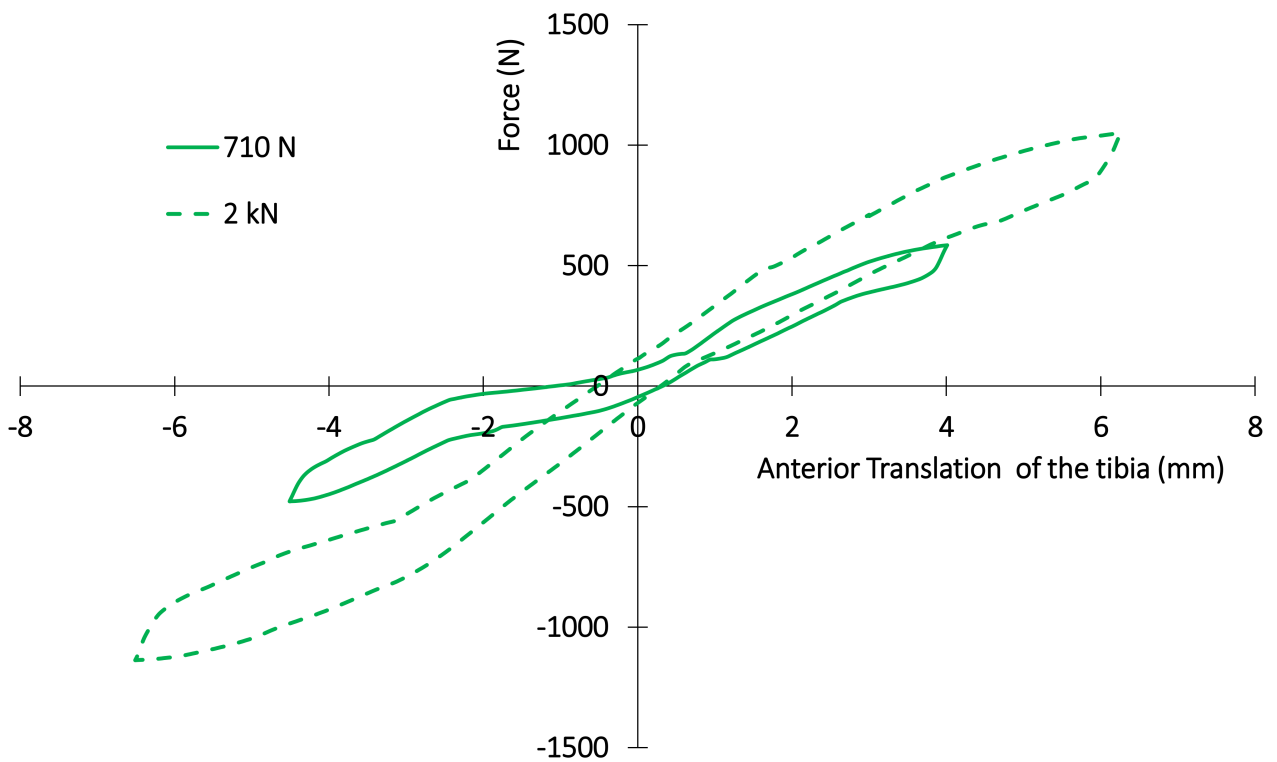
Figure 5.15 **AP stability of the MRK TKR under different axial loads.**
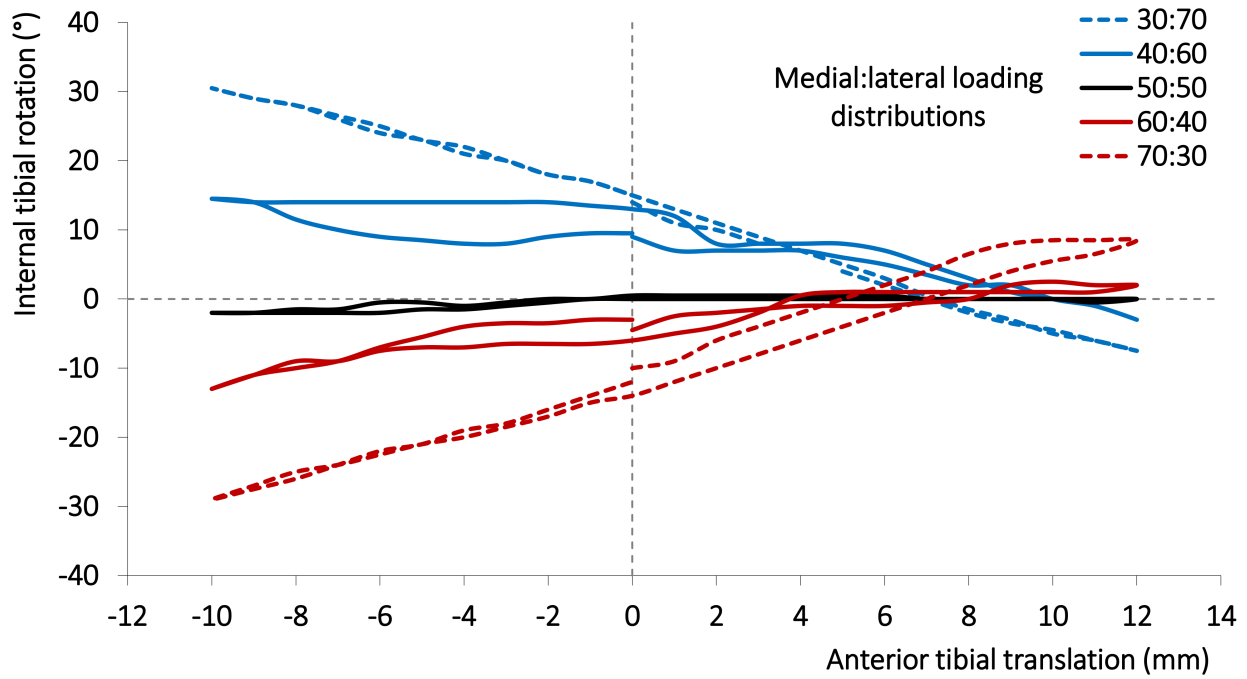
Figure 5.16   Variation of coupled rotation with M:L loading distribution for the Stryker Triathlon at 90° flexion.
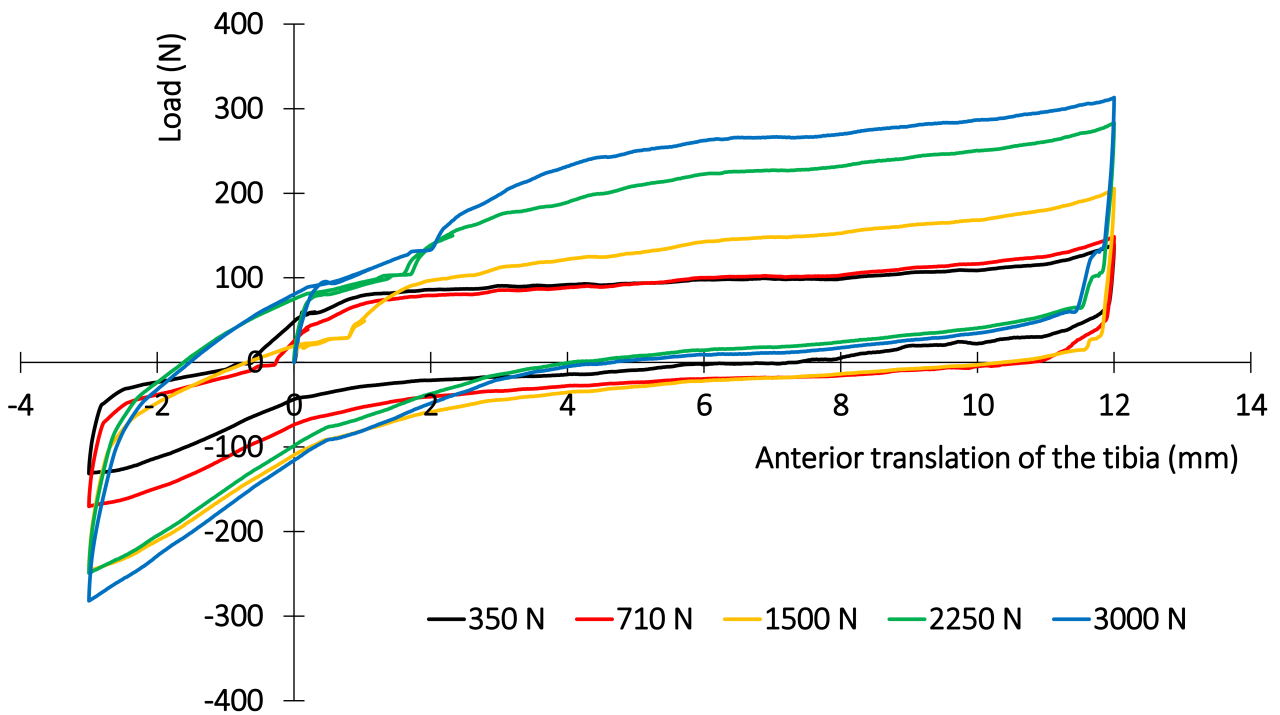
Figure 5.17   Variation of AP stability with compressive loads for the Stryker Triathlon at 0° flexion and 50:50 M:L loading distribution.

5.4.3 ML Stability

Stability in the medio-lateral direction did not vary greatly between devices, load distribution or flexion angle, with total ML translation only varying from 9 to 11 mm across the whole range of tests and devices. Both the MRK and both types of Saiph appeared to be stable in medial and lateral translation, although the MRK was slightly more laterally constrained than the Saiph, which may be due to the MRK's distinct lateral ridge. In medial tibial translation the Saiph design was less stable, reaching the limit of instability sooner (Figure 5.18).
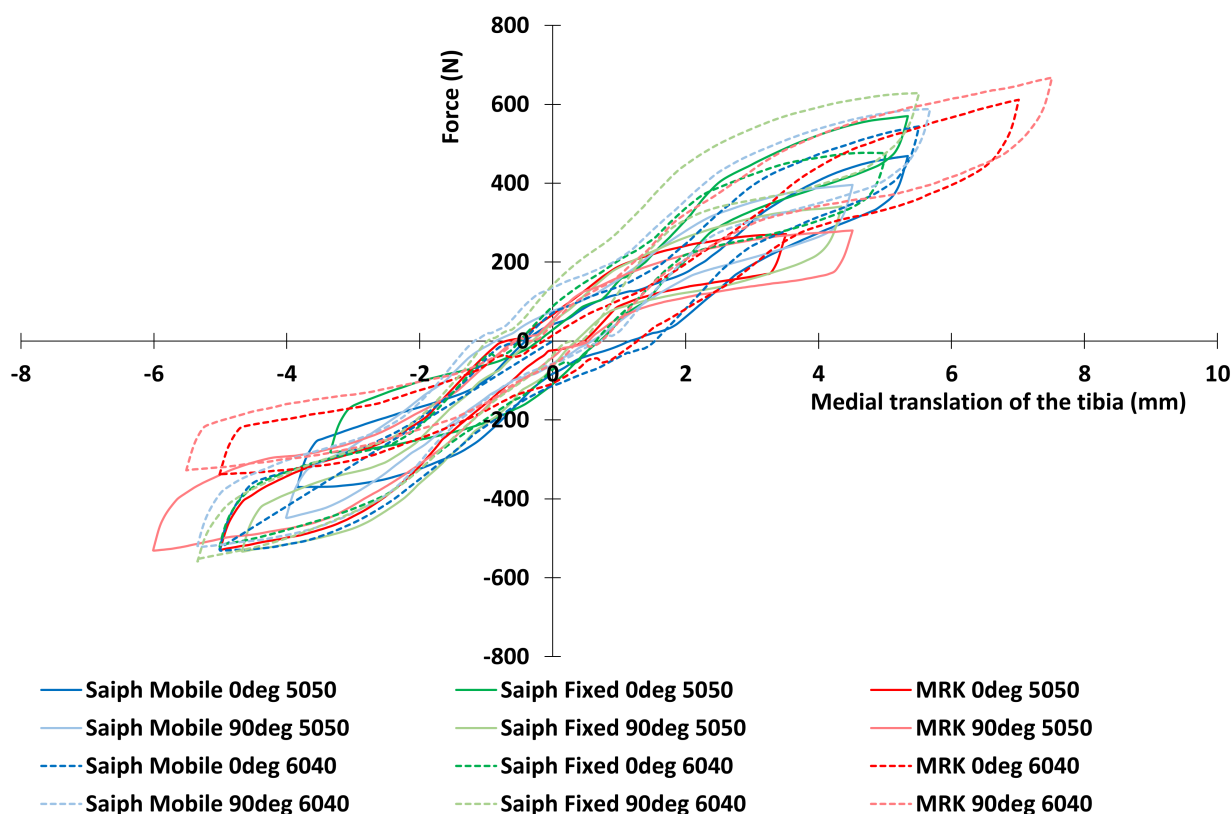
Figure 5.18   ML stability graphs for 3 different TKRs at 0° and 90° flexion and 50:50 and 60:40 M:L loading distribution

5.4.4 IE Rotational Stability

For the fixed bearing devices (MRK and Saiph), rotational stability was consistent with the secondary rotations observed during the AP stability tests. At full extension, the tibial component of the fixed bearing Saiph rotated internally at a very low torque, while the MRK was much more stable (Figure 5.19). The rotational stability also depended on flexion angle: the MRK could rotate further before instability at 90° flexion than at full extension, while the Saiph rotated much more at 0° flexion

(Figure 5.20). When the devices were tested in deep flexion (120° and 135°), the Saiph maintained low internal rotation stability, while the MRK remained more stable (Figure 5.21). During these rotation tests, the tibial component of both devices underwent coupled AP and ML translations of approximately ±5 mm. The mobile bearing Saiph, unsurprisingly, had very different IE stability characteristics compared to the fixed bearing TKRs, rotating at very low torque in both directions until the "stop point" of the mobile bearing where the torque then increased until the 20° rotation limit, stipulated by the standard, was reached (Figure 5.19). This device behaved very similarly at 90° flexion.
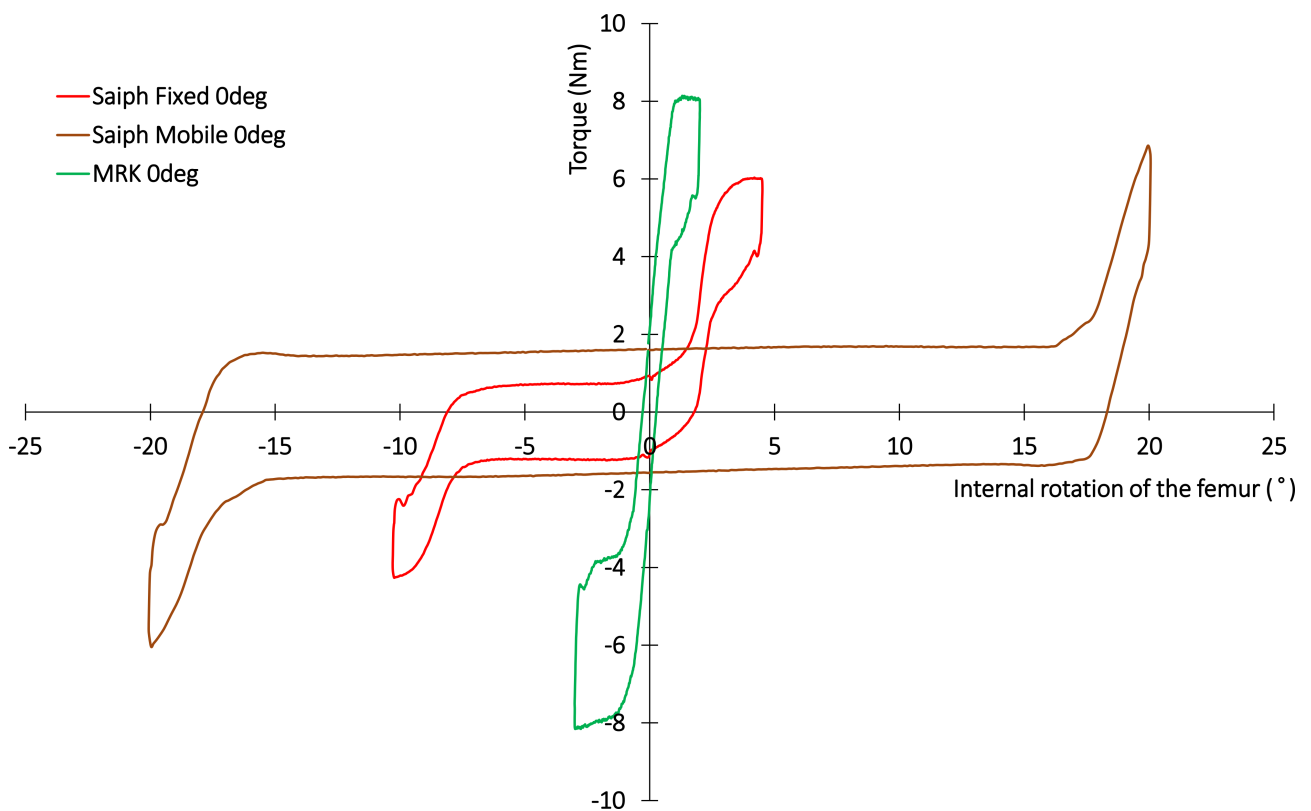
Figure 5.19   IE rotational stability at 0° flexion for 3 TKRs at 50:50 M:L loading and 710 N axial compression.
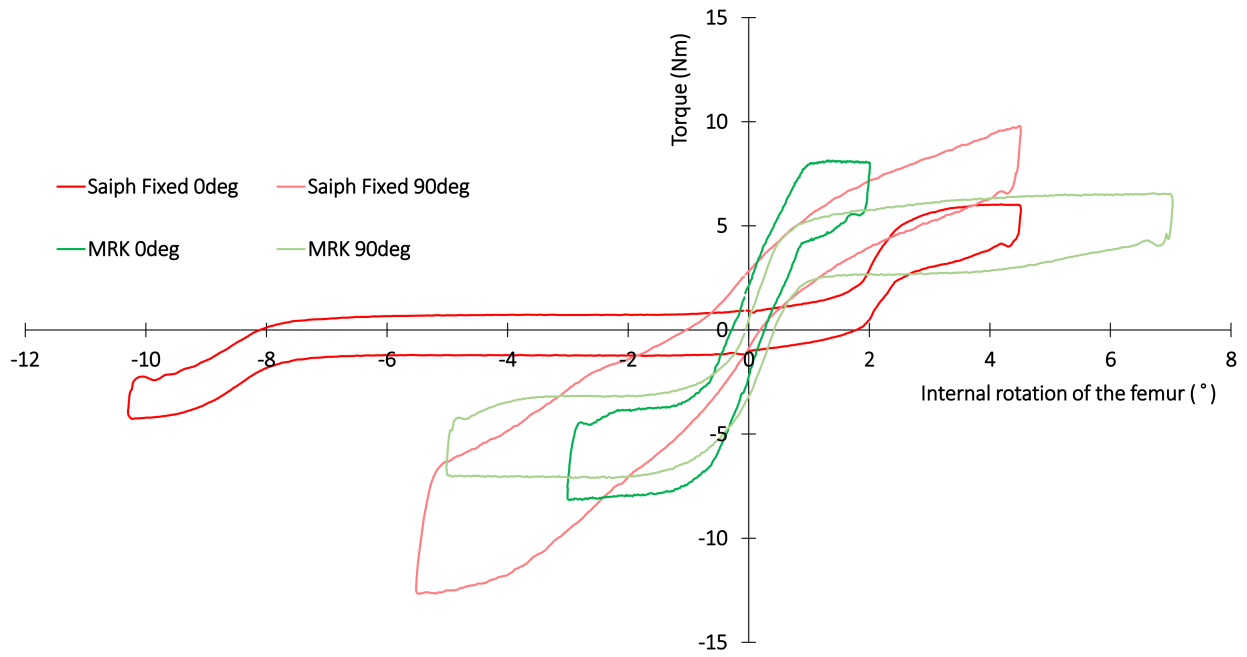
Figure 5.20 **IE rotational stability at 0° and 90° flexion for the fixed bearing Saiph and the MRK at 50:50 M:L loading and 710 N axial compression.**
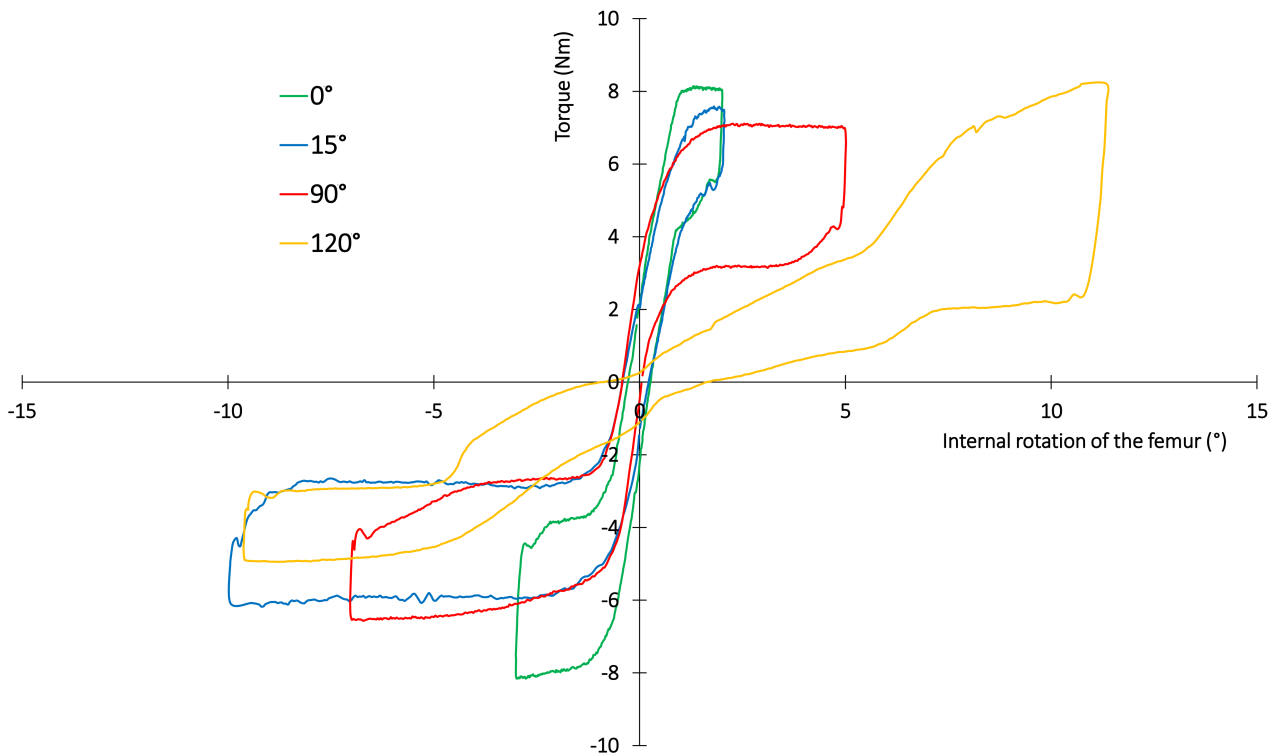
Figure 5.21 **IE rotational stability for the MRK at a range of flexion angles, 710 N axial loading and 50:50 M:L loading distribution.**

5.5 Discussion

Four total knee replacements were tested for AP, ML and IE stability at different flexion angles, M:L load distributions and compressive loads. The AP and IE constraint characteristics varied between TKRs and also depended on M:L load distribution, flexion angle and the magnitude of the axial compressive load being applied. ML stability characteristics did not vary much between devices or testing configurations.

The AP stability characteristics of the devices tested were compared to those in the literature. Haider and Walker (2005) tested 3 devices using their stability rig: the Zimmer Nexgen CR (Warsaw, IN, USA), the Smith & Nephew Genesis II CR (Memphis, TN, USA) and the DePuy PFC Sigma CR (Warsaw, IN, USA). Moran *et al.* (2008) did an experimental validation of a computational model using the Stryker Duracon PS TKR (Kalamazoo, MI, USA). A graph of all these results, together with those from this study, for 0° flexion at 710 N axial load and 50:50 M:L loading distribution, can be seen in Figure 5.22. The variation in AP stability among the different kinds of TKR is evident. It is obviously not reasonable to directly compare the stability results between the CR/CS devices and the PS devices. But these differences demonstrate that these tests do work as a measure of the intrinsic stability of a device, without the influences of soft tissues and other patient variables and therefore present a common sense check of the methods. The reduced stability in the posterior drawer direction for the CR devices is an obvious and predictable example (Figure 5.22). The lack of anterior stability demonstrated by the Stryker Triathlon, Stryker Duracon and Zimmer Nexgen was more surprising, however, as all of these TKRs are designed to be ACL sacrificing, with the articulating geometry of the devices playing the role of stabilising the knee in anterior drawer.
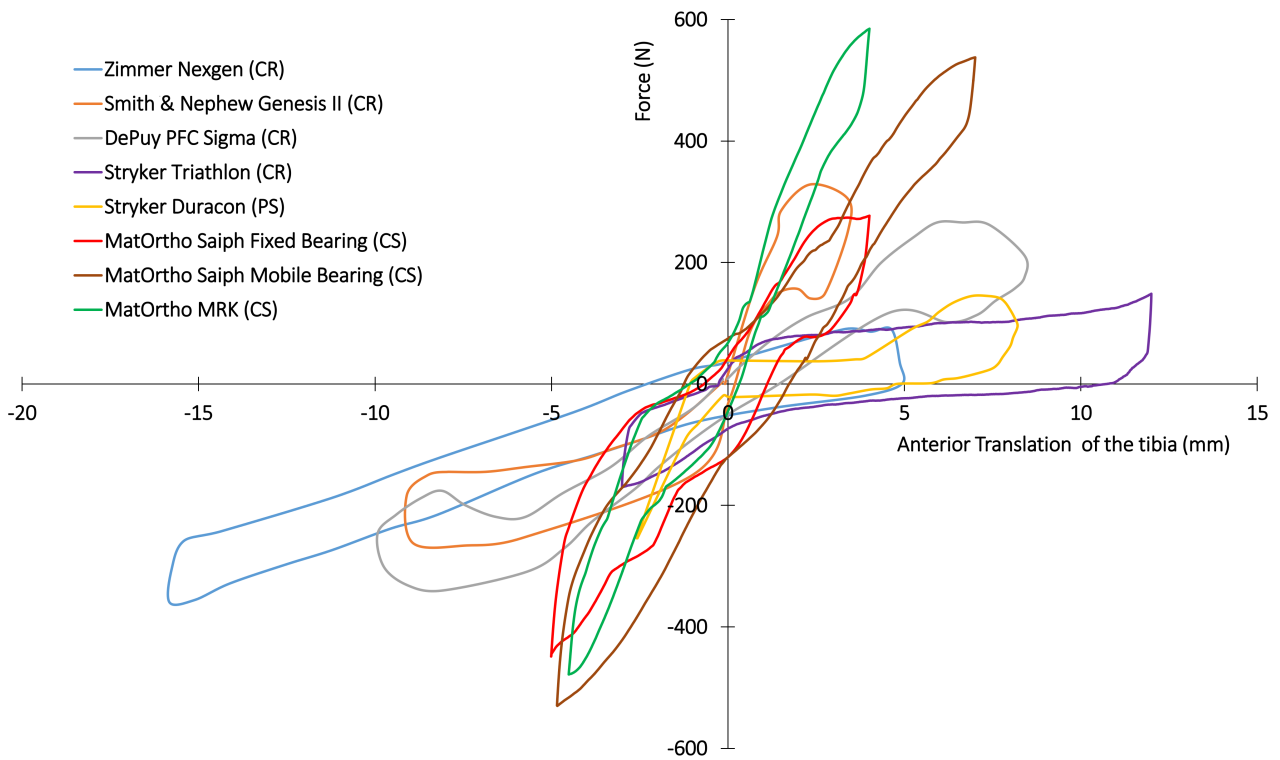
Figure 5.22   AP stability of 8 different TKRs. The devices were tested at 0° flexion, 710 N axial load and 50:50 M:L loading. The Nexgen, Genesis II and PFC Sigma data are reproduced from Haider and Walker (2005). The Duracon data are reproduced from Moran *et al.* (2008).

Coupled tibial IE rotation, a secondary motion in the AP translation tests, was found to be sensitive to the M:L loading distribution, confirming the initial hypothesis. The MRK and the fixed bearing Saiph demonstrated similar rotational behaviour to each other and to the Smith & Nephew Genesis II (Figure 5.23). It was surprising that the mobile bearing version of the Saiph TKR did not rotate more than it did during testing (in fact, it rotated less than the fixed bearing Saiph). This may have been due to the "rocking" that was observed during testing; instead of rotating internally and externally as expected, the tibial bearing would start to tilt away from the tibial tray as the tibia was translated away from the neutral point (Figure 5.24). It is not clear why this occurred but it may have been a result of higher than expected frictional forces between the femoral and tibial components or between the UHMWPE bearing and the tibia tray. The coupled tibial rotations, in response to AP translations, were particularly sensitive to the M:L load distribution with the Triathlon TKR; this author believes that this will be common in other symmetrical TKR designs. Mundermann *et al.* (2008) demonstrated that the resultant joint force in the knee may oscillate between the medial and lateral compartments during ADLs. Taken together with these recent results, it implies that secondary rotational instabilities may occur with these symmetrical, non-congruent TKR designs, which do not appear to have considered variations of M:L loading in their designs.
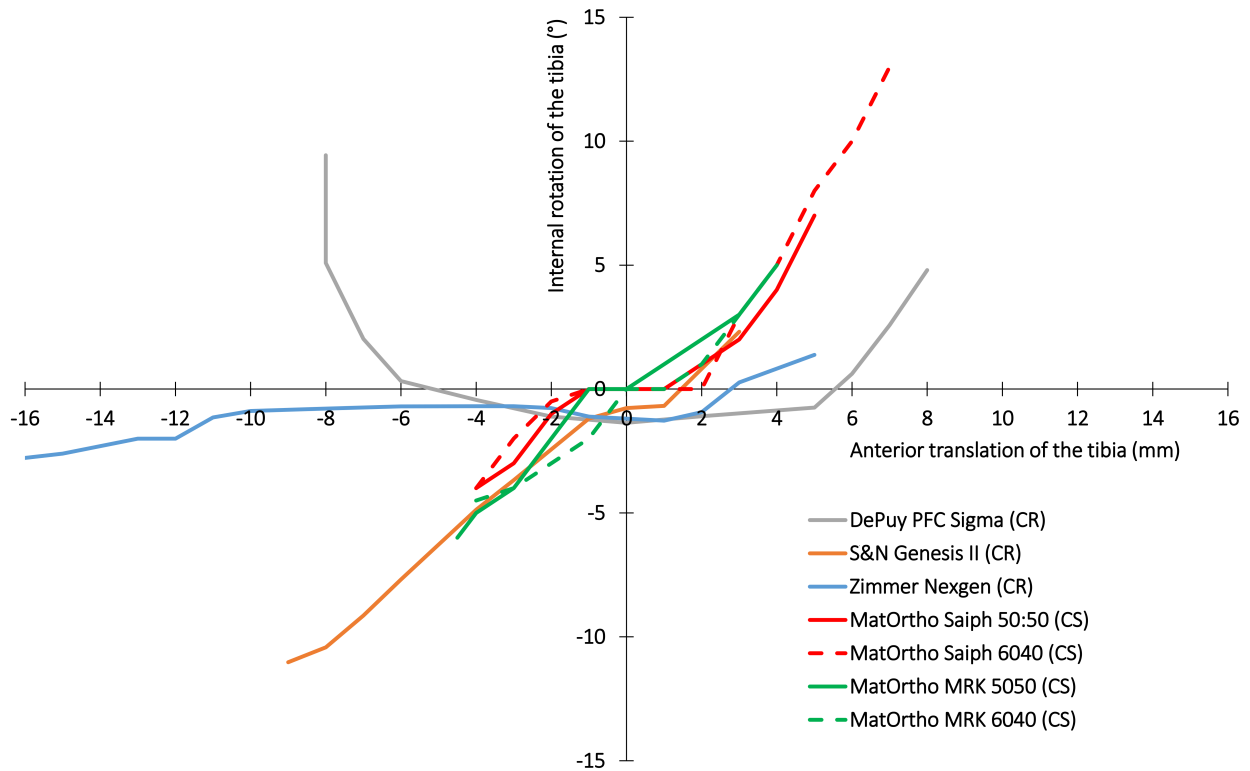
Figure 5.23   Coupled tibial rotation during AP stability testing. The devices were tested at 0° flexion, 710 N axial load and 50:50 M:L loading unless indicated. The Nexgen, Genesis II and PFC Sigma data are reproduced from Haider and Walker (2005).
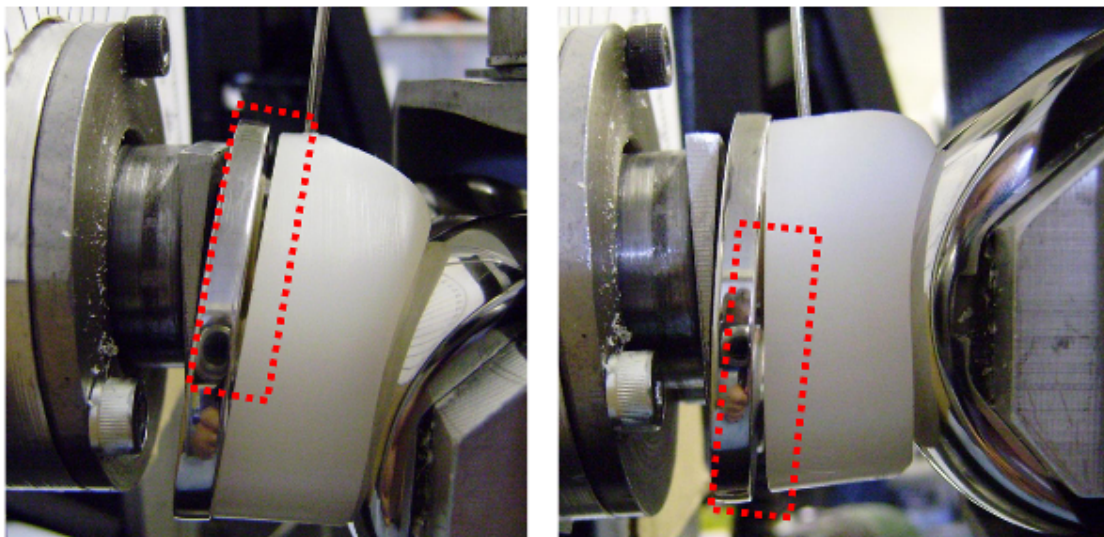
Figure 5.24   Mobile bearing "rocking" during AP testing, the red dashed boxes indicate where the UHMWPE bearing has separated from the polished CoCr tibial tray. Left: anterior translation of the tibia. Right: posterior translation of the tibia

The stability increased with increasing axial compressive joint force. This makes sense as there will be an increase in friction between the femoral and tibial components as the normal force is increased. However, it was interesting to note that not only did the gradient of the stability curve increase, the overall distance over which the device remained stable also increased. It was a concern that plastic deformation of the edge of the tibial bearing would occur under increased loading and the stability would actually decrease, but this did not appear to be the case in these tests, which may be because the limit finding test was always stopped as soon as the force-displacement (or torque-rotation) curve started to plateau, or because the axial loads used and the number of cycles conducted were low enough not to deform the plastic. Another observation was that the shear force reached at the stability limits was often different in the cyclic tests than in the limit-finding tests. This may be due to the fact that different velocities were used for these tests: in the limit finding tests, the tibial component was moved at 10 mm/minute; in the cyclic tests the velocity was 50 mm/minute, in line with the methods in the literature.

It was also shown that the TKR designs tested were stable in ML translation. This is the first published report of ML translational stability, which did not vary greatly between the similar devices tested, or the loading conditions. Although ML stability appears to have limited clinical importance, there is a lack of evidence regarding the implications of ML slope of the joint line during TKR implantation. Some TKR designs may be less stable in the ML directions than the congruent spherical geometries tested here, leading to stress concentrations on the edges or central spines of the bearings.

The three medial-sphere type devices were also assessed in IE rotation. The reduced stability in flexion reflected the transition from a congruent fit of the articular surfaces in extension, becoming progressively less congruent as the knee flexed. This may be a general finding that will also occur in implants with a smaller femoral condylar radius posteriorly than distally. The results confirmed that the medial pivot worked as intended, with rotation being more apparent when the joint load was at the 60:40 M:L distribution, freeing the lateral compartment. With the rotation occurring about the centre of the medial condyle, the centre of the tibial tray underwent a secondary coupled translation of approximately ± 5 mm. It may be useful to more precisely measure these secondary motions, which may have implications for how the implant "feels" to the patient. These results were also compared to those in the literature (Figure 5.25). It is interesting to note how constrained the MRK and Genesis II devices are at full extension.
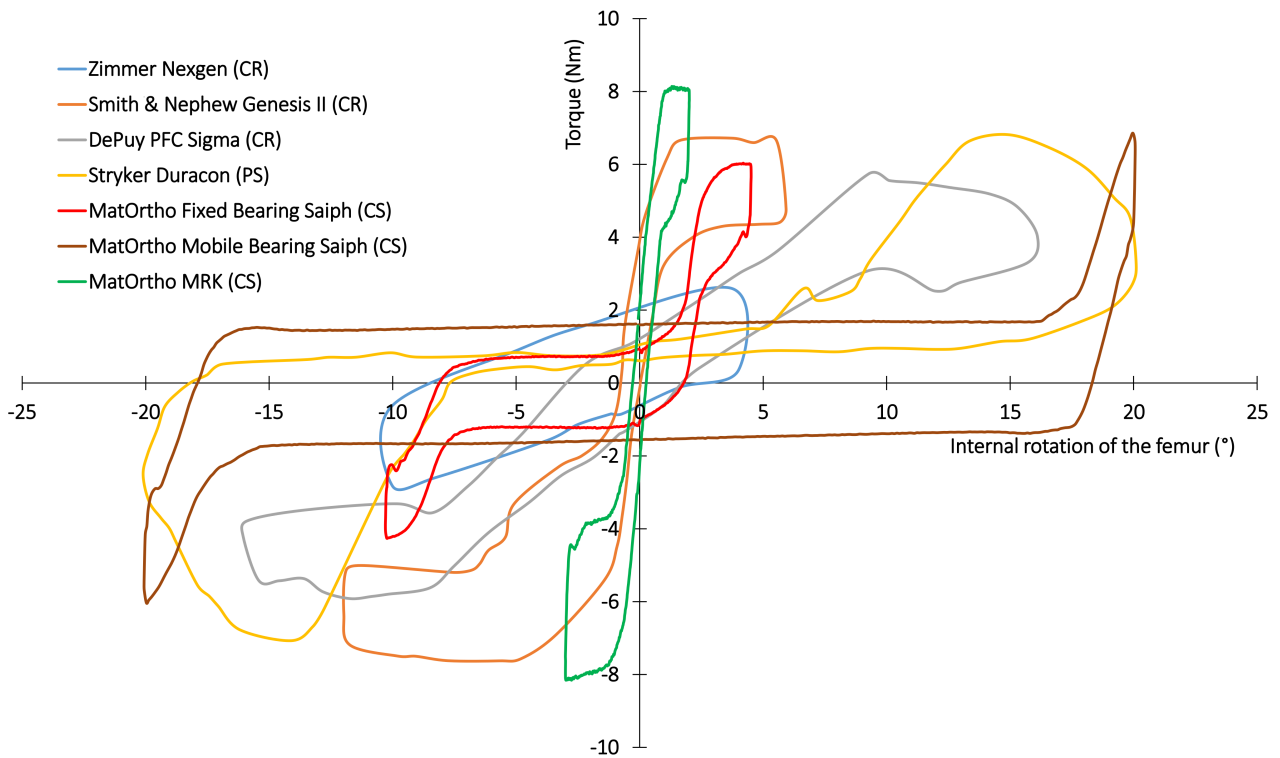
Figure 5.25   IE stability of 7 different TKRs. The devices were tested at 0° flexion, 710 N axial load and 50:50 M:L loading. The Nexgen, Genesis II and PFC Sigma data are reproduced from Haider and Walker (2005). The Duracon data are reproduced from Moran *et al.* (2008). The Stryker Duracon was rotated to ±20° despite it clearly reaching instability at around 15° rotation. All the other devices were stopped before subluxation. The mobile bearing Saiph reached 20° rotation in both directions and remained stable.

97

5.6 Comparison to the stability of human knees

If these results are compared to data from normal knees (Daniel *et al.*, 1985; Edixhoven *et al.*, 1987; Fukubayashi *et al.*, 1982; Markolf *et al.*, 1984; Shino *et al.*, 1987) the MRK tended to be over constrained in the anterior drawer direction, whereas the Triathlon's stability in that direction appeared to match quite closely the behaviour of normal knees (Figures 5.26 & 5.27). In the posterior direction, however, the Triathlon was much less stable that the human knees and the other TKRs, which makes sense at it is a CR device and the other TKRs (the Saiph and the MRK) are CS implants. Of course, it is not only the cruciate ligaments that contribute to anteroposterior translational stability in the human knee, but also the collateral ligaments and muscles surrounding the knee joint, so these implant-only test results should be considered with that in mind.
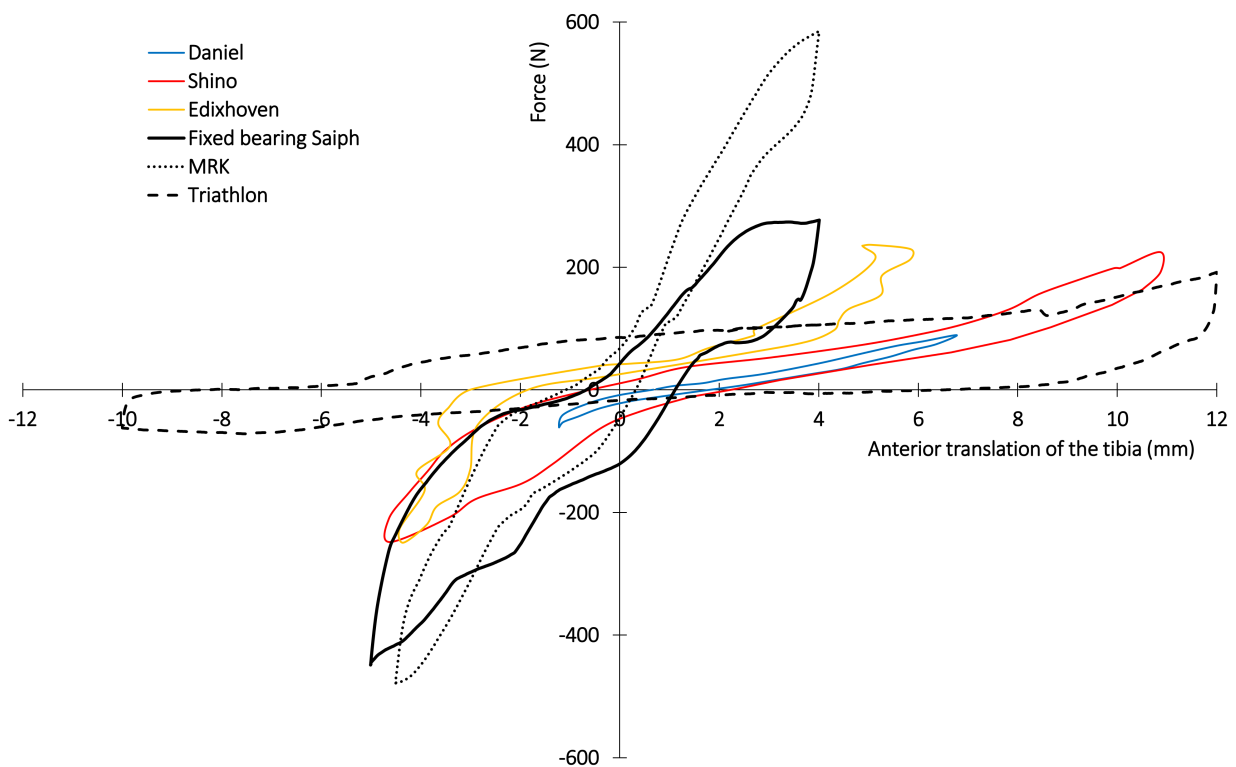
Figure 5.26 TKR and human knee stability at or near full extension. The human knee data are reproduced from Daniel *et al.* (1985), Shino *et al.* (1987), and Edixhoven *et al.* (1987).
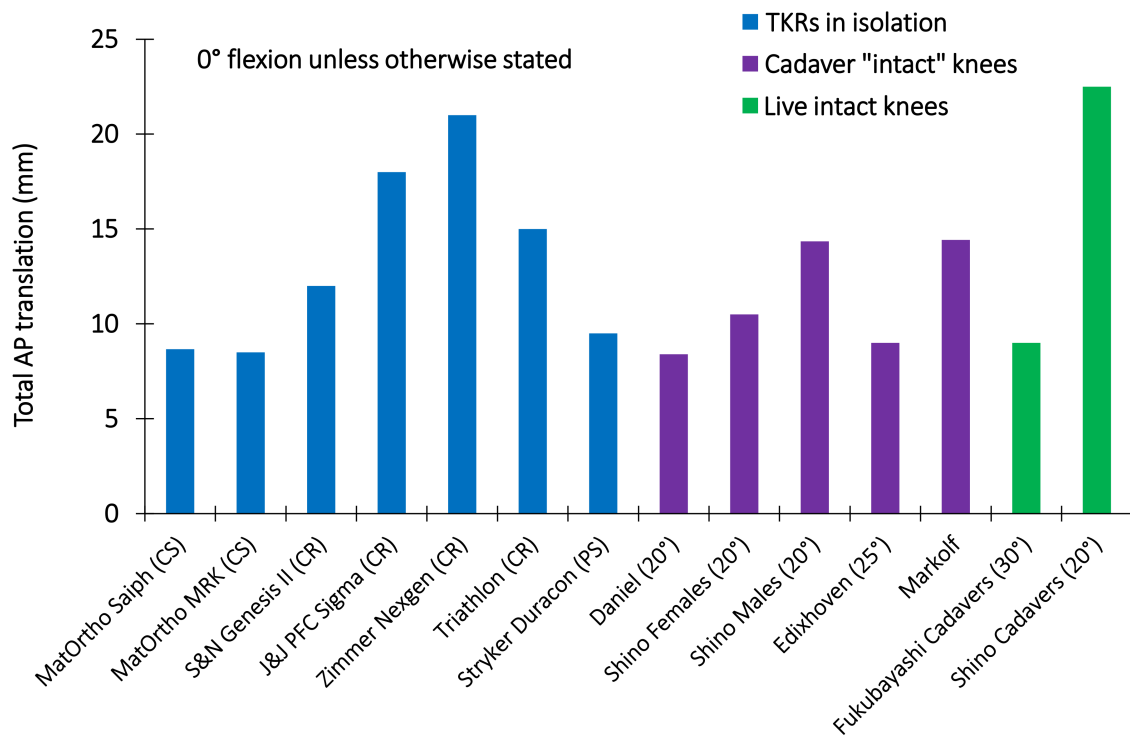
Figure 5.27   Total AP laxity of a range of TKRs and real human knees. The Nexgen, Genesis II and PFC Sigma data are reproduced from Haider and Walker (2005). The Duracon data are reproduced from Moran *et al.* (2008). The human knee data are reproduced from Daniel *et al.* (1985), Edixhoven *et al.* (1987), Fukubayashi *et al.* (1982), Markolf *et al.* (1984), and Shino *et al.* (1987).

5.7 Recommendations

Following this series of tests and interpretation of the results, the following recommendations are made with regards to the future of this ASTM test procedure:

— The axial load required by ASTM for these standard tests should be increased to that which is physiological, in the region of 2 kN (Heim *et al.*, 1996), to match the peak loading experienced during normal walking gait, rather than the 710 N that is currently stipulated.

— The test protocol defined by F1223 should stipulate the M:L loading distribution and perhaps include additional tests with variations of this loading included. It has been shown to vary between patients and activities (Varadarajan *et al.*, 2008; Mundermann *et al.*, 2008; Zhao *et al.*, 2007) and the AP stability and associated secondary motions have been shown to be very sensitive to this distribution, particularly with a less-congruent device such as the Stryker Triathlon.

— The secondary motions observed during all three types of stability tests should be measured and recorded as these can provide more information about the device's stability characteristics.

5.8 Conclusions, limitations & further work

A series of bench-top tests was conducted using specially constructed test rigs in order to measure the stability of three different designs of TKR. Also investigated were the effects of changing the medial-lateral loading distribution and the magnitude of the axial load on the constraint measurements. To gain a better understanding of the inherent stability characteristics of a TKR, constraint tests must be carried out at a range of flexion angles, loading distributions and compressive loads; secondary coupled motions should be reported.

The ASTM standard testing has been made mandatory for all new TKRs in order for the device to be CE marked. Every manufacturer therefore has these stability data on file. Unfortunately, there is almost no data made publicly available by them, in published peer-reviewed journal articles. Therefore this is a lost opportunity to learn about the effect of the stability characteristics on patient outcome. Ideally, the results from these tests could be used by surgeons alongside patient specific variables, such as the condition of the PCL and collateral ligaments, in selecting the most appropriate device for each patient. Whether or not this is possible in practice is debatable, and

even if it were, it does not seem to be ideal for surgeons to be using lots of different devices routinely as each are quite different in terms of instrumentation and operative technique and each time a new device is introduced into practice there is a learning curve to overcome. In addition, the condition of the ligaments might be difficult to properly assess prior to the operation by which time it would be too late because the implant needs to be chosen before the arthrotomy is made (and therefore before knowing the condition of the soft tissues).

Stability results such as these may also be viewed with potential implant loosening in mind; inherent stability of a device suggests that the implant has a greater ability to transfer shear forces or torques (in translational and rotational modes, respectively) to the underlying bone, and this may have implications for the efficacy of the fixation of the device. It is difficult to scrutinise this theory any further from large datasets such as the joint registries, because although they contain failure mechanisms for all primary TKRs that need revising, and revision rates for individual TKR designs, they do not combine the two.

Despite these kind of bench-top tests being relatively quick and cheap to perform and producing easy to interpret data, there are obvious limitations with this simplistic approach to pre-clinical testing. First, the test simulates a very specific motion of the tibial component relative to the femur, which is unlikely to occur in everyday life. Secondly, although the lack of soft tissues and other constraints that are present in a real knee make this test very repeatable in terms of assessing the device's performance, it is debatable whether the function of the implant can really be separated from its working environment. For a more physiological demonstration of the function of TKRs, they must be implanted into cadaver knees and tested. However, in this case it is likely that the variation between the stability of native knees will be larger than the differences between prosthesis designs. Another limitation was that movement of the PMMA cement used to secure the implants into position prior to testing was not measured; any such movements, though likely to be very small, would have affected the results somewhat. Stability rigs such as those described in this chapter, could be adapted to allow cadaver knees to be tested in them, before and after TKR implantation. More sophisticated rigs, such as those described in the next chapters, can also be used to describe TKR function in a more realistic manner. The constraint test described here should continue to be used as a "common sense" check for new designs of implant, but it is the author's opinion, based on the findings presented here, that functional inferences from stability testing results should be avoided.

CHAPTER 6

SOFT TISSUE STRAINS & KINEMATICS IN GUIDED-MOTION TOTAL KNEE REPLACEMENT

Some of the work in this chapter has been presented in a peer-reviewed journal article:

Halewood C, Risebury M, Thomas NP, Amis AA. Kinematic behaviour and soft tissue management in guided motion total knee replacement. *Knee Surgery, Sports Traumatology, Arthroscopy 2014;22(12):3074-82.*

6.1 Overview

This chapter describes work done to assess the kinematics and soft tissue behaviour in knees with 3 different TKRs implanted. There is some concern that so-called "guided-motion" TKRs, designed to replicate normal knee kinematics via the geometry of the femoral and tibial components, can cause anterolateral knee pain due to over-stretching of the soft tissues in that region. It was hypothesised that, with one particular device (Journey, Smith & Nephew, Memphis, TN, USA), excessive tibial internal rotation and femoral roll-back during flexion were to blame for the pain in some patients. Therefore the objectives of this piece of work were to: 1) measure the soft-tissue elongations in cadaver knees in the intact and implanted states and 2) measure the kinematic behaviour of another set of knees with the same devices inserted.

6.2 Introduction

Despite many refinements since the first TKRs of the 1970s, most existing TKR designs exhibit unnatural knee kinematics and up to 20% of patients are left dissatisfied (Becker *et al.*, 2011; Bourne *et al.*, 2010) even if not in pain, and many more have abnormal gait patterns, typically with less knee flexion during the swing phase of gait and reduced quadriceps function (McClelland *et al.*, 2007). This dissatisfaction after TKR has been partly attributed to "paradoxical" anterior femoral

motion and a lack of tibial rotation during flexion, even with posterior cruciate ligament-substituting (PS) designs (Bellemans *et al.*, 2005). Guided-motion TKRs have been developed in an effort to more closely replicate normal knee kinematics and help to reduce dissatisfaction rates amongst TKR patients. These devices substitute for the lack of menisci and cruciate ligaments with more-conforming tibiofemoral articular geometry, a more anatomical femoral shape and with cam-post mechanisms (Luyckx *et al.*, 2010; Duren *et al.*, 2012). The Journey is an example of such an implant: it has an asymmetrical femoral component, aimed at maintaining the natural obliquity of the joint line in the coronal plane; concave medial and convex lateral compartments on the tibial bearing; and anterior and posterior cams. It is described as "bi-cruciate stabilised" (BCS; Figure 6.1). It has been used clinically since 2004, and has been shown to generate tibial anterior translation and internal rotation during knee flexion in vivo (Victor and Bellemans, 2006; Victor *et al.*, 2010). However, there has been a higher incidence of patients reporting anterolateral knee pain and other "adverse events" with the Journey implant than with other TKR designs, leading to further surgery in some cases (Luyckx *et al.*, 2010; Schimmel *et al.*, 2012). This pain has been attributed to excessive internal rotation of the tibia with increasing flexion, causing stretching of the ITB (Luyckx *et al.*, 2010).
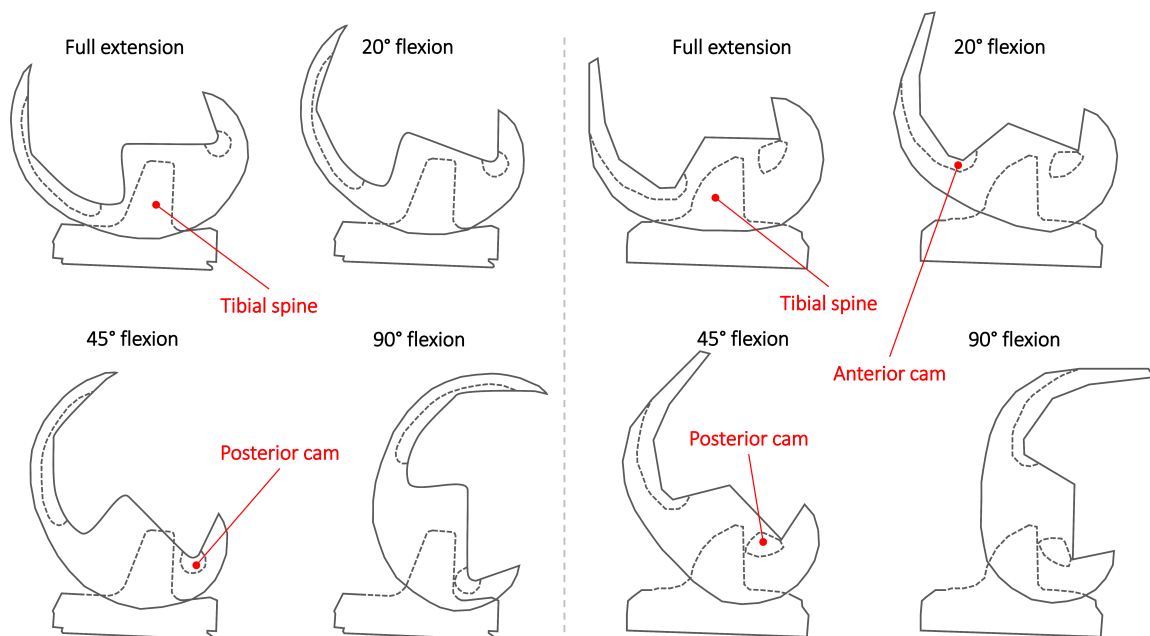
Figure 6.1   Comparison of the Genesis II and Journey II: cross sectional views showing the tibial post and cam mechanisms at various angles of flexion. Left: Genesis II. Right: Journey II. The anterior cam of the Journey II is designed to substitute for the resected ACL, though it does not appear that it would function in this manner beyond around 30° of knee flexion.

The manufacturer responded with several design changes to try to reduce this excessive internal rotation and other soft tissue strains which may have been causing pain, and have released a new device, the "Journey II" (Figure 6.2). Three design changes were made to the UHMWPE tibial bearing: its post was moved anteriorly and increased in height to move the tibia into a more posterior position and to reduce the chance of dislocation resulting from the cam "jumping" over the post; in the lateral compartment, the posterior slope was increased to encourage posterior movement of the femoral component (which seems odd given the theory of over internal rotation of the tibia being a cause of pain). In the medial compartment, the posterior lip was moved anteriorly in an effort to constrain the medial condyle (presumably with the medial-pivot theory of knee motion in mind). The femoral component design changes consisted of: a reduced mediolateral width to prevent overhang; the mid-flexion thickness of the medial femoral condyle was reduced, as was the thickness of the lateral anterior flange, in order to reduce tension in the lateral retinaculum and the ITB, and the posterior cam was moved superiorly and reduced in size, in order to lessen its tendency to force the tibia anteriorly in knee flexion. However, the anterior cam was moved anteriorly slightly which would allow the tibia to translate further anteriorly near extension. The design changes seem, in combination, to represent a "softening" of the guided-motion philosophy from the original Journey design.

Therefore, the cadaveric laboratory study described here was designed to measure the kinematic behaviour and soft tissue elongations in knees implanted with the Journey, the Journey II and the more conventionally designed PS Genesis II (also a Smith & Nephew device) and to compare the three implants with each other and with the intact knee state. With the clinical history and aims of the design changes in mind, it was hypothesised that the Journey would cause greater elongation of the ITB than the other designs and that the Journey II would cause less anterior translation of the tibia than the earlier design in the flexed knee, suggesting a potential reduction in the incidence of anterolateral knee pain clinically in patients with a guided-motion TKR. It was also hypothesised that the guided-motion Journey devices would give more physiological kinematics during knee flexion/extension than the conventional Genesis II device.

Figure 6.2   Comparison of the Journey and Journey II designs. Green = Journey. Orange = Journey II. A: higher, more anterior tibial spine and greater slope on the lateral compartment. B: bigger box, anterior cam moved anteriorly and posterior cam moved superiorly. C: narrower ML width. D: smaller anterior flange and narrower condyles.

6.3 Materials & Methods

6.3.1 Cadaver specimens

Eighteen fresh-frozen left-sided cadaveric knees (12 female, 6 male; median age 71.5 years; range 46 to 91 years) from consented donations were obtained from the International Institute for the Advancement of Medicine (Jessup, Pennsylvania, USA). Nine knees were used for the kinematic study and 9 for the soft tissue study. The same Consultant Orthopaedic Surgeon (Mr Michael Risebury, Basingstoke) performed all the cadaver surgery, with the assistance of the author.

The first stage of the preparation of the cadaver specimens was common to both experiments: they were stored at -25° C before testing, and then thawed. The femur and tibia were cut so that approximately 200 mm remained either side of the joint line. Preparation and testing of the intact knee were carried out on one day, the knee was then kept in a refrigerator at 4° C overnight and the implantations and testing were completed on the following day. Knees were prevented from drying out during testing using water spray.

6.3.2 Testing rigs

Two separate rigs were used for the soft tissue length change measurements and the kinematics testing. A "knee extension" rig, with separate loading for the heads of the quadriceps muscles, was used for the length change measurements, following the methods used by previous investigators (Ghosh *et al.*, 2009; Ghosh *et al.*, 2010; Stephen *et al.*, 2012; Kittl *et al.*, 2014). A "knee flexion" rig, with a single centralised quadriceps load, applied through the patella, was used for the kinematics testing. This rig allows controlled forces and moments to be applied to the knee without restricting any of the degrees of freedom of the joint throughout flexion-extension. This rig was improved from the version used in previous experiments (Bull *et al.*, 2008; Kondo *et al.*, 2011).

6.3.3 Implants and instrumentation

The 3 devices (Journey, Journey II and Genesis II; Figure 6.3) were especially manufactured with the same fixation geometry, so that they could each fit onto the same bone cuts and the order of testing could be varied (Tables 6.1 & 6.2). Standard instrumentation was used, with a femur-first approach and an intramedullary alignment technique for the tibia due to the lack of foot and ankle; all surgery was performed by the same consultant orthopaedic surgeon.
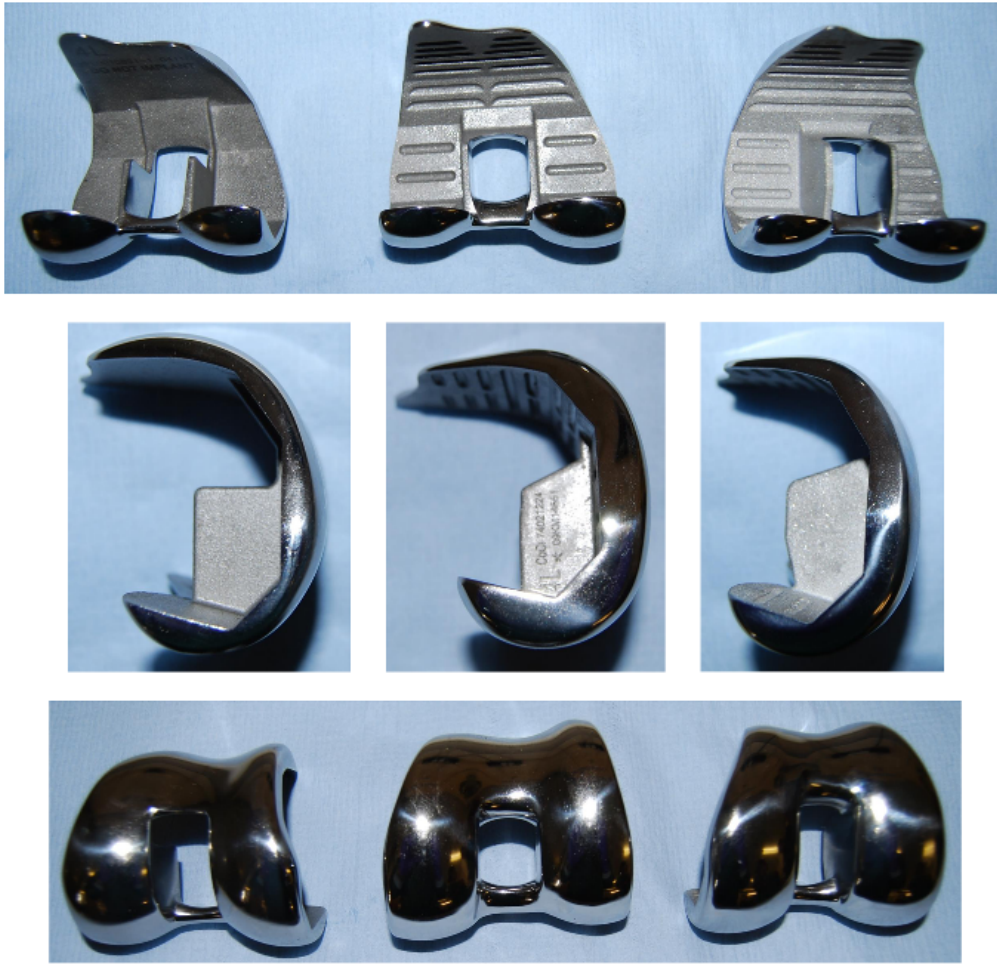
Figure 6.3   Comparison of the Genesis II (Left), Journey (Centre) and Journey II (Right) designs.

Table 6.1   Testing matrix for soft tissue elongation measurement study with details of the implant sizes used for the experiments.

Knee	Stage 1	1st TKR	2nd TKR	3rd TKR	Femur size	Tibia size	Poly thickness (mm)
CH11	Intact	Journey	Journey II	Genesis II	5	4	11
CH13	Intact	Journey II	Journey	Genesis II	5	4	10
CH15	Intact	Genesis II	Journey	Journey II	6	5	9
CH21	Intact	Journey	Genesis II	Journey II	5	5	11
CH22	Intact	Genesis II	Journey II	Journey	5	4	9
CH23	Intact	Journey II	Genesis II	Journey	7	6	10
CH27	Intact	Journey II	Genesis II	Journey	7	6	9
CH29	Intact	Journey	Journey II	Genesis II	8	7	9
CH30	Intact	Genesis II	Journey	Journey II	6	5	9

Table 6.2 **Testing matrix for kinematics study with details of the implant sizes used for the experiments.**

Knee	Stage 1	1st TKR	2nd TKR	3rd TKR	Femur size	Tibia size	Poly thickness (mm)
CH24	Intact	Journey	Journey II	Genesis II	4	4	13
CH26	Intact	Journey	Journey II	Genesis II	5	5	9
CH35	Intact	Genesis II	Journey II	Journey	6	5	8
CH36	Intact	Journey	Genesis II	Journey II	4	4	10
CH39	Intact	Journey II	Genesis II	Journey	6	6	11
CH41	Intact	Genesis II	Journey	Journey II	4	3	9
CH42	Intact	Genesis II	Journey	Journey II	6	6	10
CH43	Intact	Journey II	Genesis II	Journey	8	7	9
CH44	Intact	Journey II	Journey	Genesis II	5	4	9

6.3.4 Soft tissue length change measurements

The cadaver knee specimens were prepared prior to testing. The skin and subcutaneous fat were removed, taking care not to damage the medial or lateral retinacula. The vastus intermedius was detached from the femur, and the quadriceps muscle was separated into 6 components: rectus femoris (RF), vastus intermedius (VI), vastus lateralis longus (VLL), vastus lateralis obliquus (VLO), vastus medialis longus (VML), and vastus medialis obliquus (VMO). Strips of fabric were securely stitched to the proximal end of each head of the quadriceps and the iliotibial band (ITB) to provide an anchor for the application of the muscle loads. The RF and VI muscles were grouped together to form a central muscle group. Small eyelets were fixed into the bone at 6 locations: Gerdy's tubercle; the lateral side of the patella; the medial side of the patella; the medial femoral epicondyle; the tibial attachment of the superficial medial collateral ligament (MCL), and the ITB attachment at the linea aspera (Figure 6.4). An eyelet was also stitched into the ITB directly posterior from the lateral patellar eyelet. By connecting pairs of eyelets with monofilament nylon suture, the distances between these pairs and therefore length changes for five soft tissue structures could be measured (Figure 6.5):

1. The superficial ITB to Gerdy's tubercle ("superficial ITB");

2. The deep ITB to Gerdy's tubercle ("deep ITB");

3. The lateral retinaculum;

4. The medial patellofemoral ligament (MPFL) ;

5. The MCL.

Ligament length changes between the pairs of eyelets were measured by attaching the monofilament sutures to linear variable displacement transducers (LVDT) and recorded using the Orbit software plug in (Solartron Metrology, Bognor Regis, United Kingdom) in Excel (Microsoft, Seattle, WA, USA) running on a PC. The LVDTs were confirmed to be accurate to within ± 0.01 mm by direct measurement using a micrometer. In the cases where both ends of a soft tissue structure were mobile relative to the fixed femur (superficial ITB and the lateral retinaculum), two LVDTs were used for length change measurements; and the difference between their readings represented the relative motions of the eyelets, arising from tissue length changes (Figure 6.6).

MEDIAL   LATERAL

Ⓐ MCL attachment on tibia
Ⓑ Medial epicondyle
Ⓒ MPFL attachment on patella
Ⓓ Lateral patella
Ⓔ Gerdy's tubercle
Ⓕ ITB (eyelet placed in the soft tissues)
Ⓖ Linea aspera
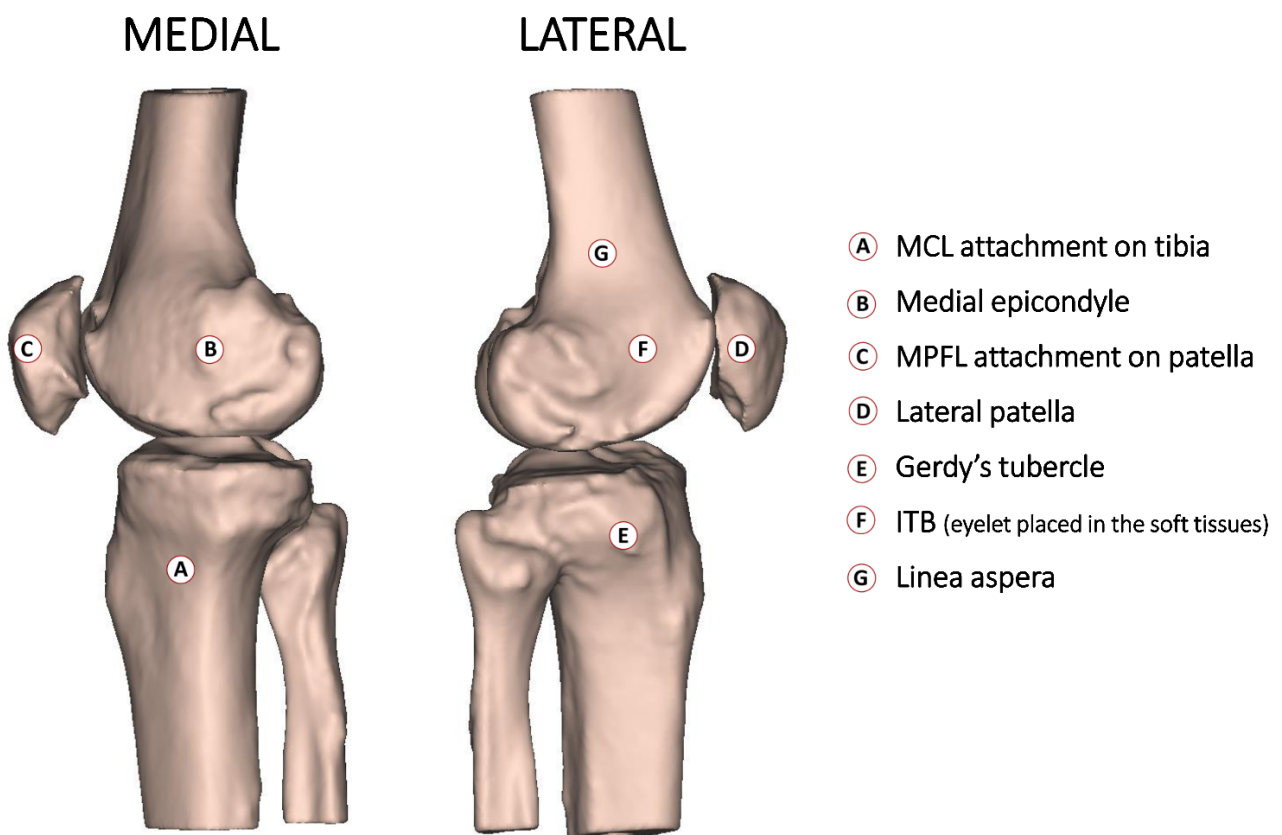
Figure 6.4   A diagram showing the location of the eyelets that were used for the ligament length changes with the LVDTs.
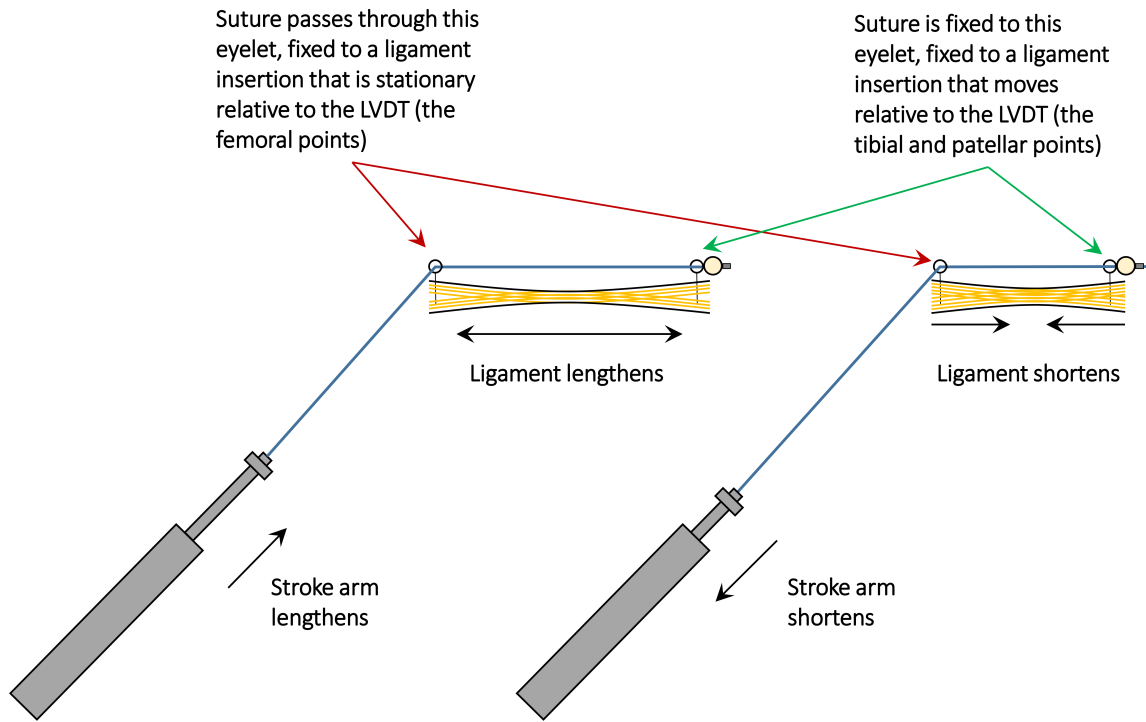
Figure 6.5   A schematic showing how LVDTs were used to measure ligament length changes during knee flexion. By fixing the end of the suture to the eyelet that is *mobile* relative to the LVDT but allowing it to pass smoothly through the eyelet *fixed* relative the LVDT, stretching and shortening of the ligaments resulted in the stroke arm of the LVDT moving out or in of the solenoid core, resulting in mm length change measurements outputted in Excel.
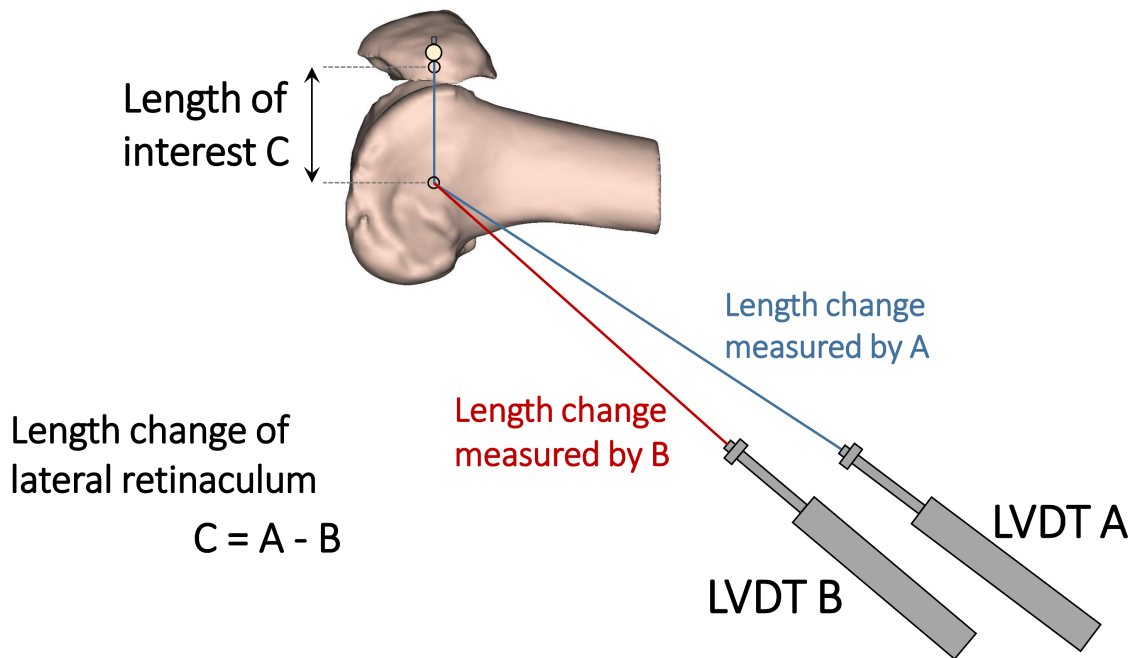
Figure 6.6   A schematic showing the technique for measuring the length change of the lateral retinaculum, where both insertion points are mobile relative to the LVDT. By using 2 LVDTs and taking the difference between their measurements, the length changes of the lateral structures could be measured.

An intramedullary (IM) rod was then cemented into the femur using PMMA. The TKR approach was then made with an oscillating saw, using a midline trans-patellar technique in order to avoid damaging the soft tissue structures on the medial side of the knee that would occur with a standard medial parapatellar approach (Figure 6.7). Two fixation holes were pre-drilled mediolaterally through the patella prior to sawing the patella into 2 pieces so that it could be fixed back together into the correct position. A previous study has shown that this procedure does not affect the native knee kinematics (Merican *et al.*, 2009), but it was done prior to testing the intact knee state for consistency. The patella was reunited immediately so the intact knee could be tested.

The knee was mounted into the test rig and fixed using the femoral rod, with the anterior aspect uppermost (Figure 6.8). A rod was then inserted into the distal tibial IM canal. A total load of 175 N was applied to the quadriceps and 30 N to the ITB (Bull *et al.*, 1999) via a hanging weight and pulley system. The total quadriceps load was reduced from physiological levels to avoid rupturing the cadaveric muscles but the tensions were proportional to their mean physiological cross-sectional areas and were applied in their physiological directions in relation to the femoral axis (Farahmand *et al.*, 1998) (Figure 6.9). The femur was fixed relative to the rig and knee flexion was imposed by hand, moving the tibia by way of its IM rod. By imposing this posterior force onto the IM rod at some distance (approximately 300 mm) from the flexion/extension axis, secondary rotations (internal/external and varus/valgus) were not inhibited. Before recording data, 10 loaded knee conditioning cycles were performed to reduce soft tissue hysteresis.

Measurements were taken every 10° from 0° to 120° knee flexion and were repeated three times and then a mean was taken. Once the intact measurements had been taken, the patella was reopened and the TKR implantation was performed. Standard mechanical alignment was used, making the distal femoral cut perpendicular to the mechanical axis of the femur and placing the tibial tray approximately perpendicular to the long axis of the tibia, while matching flexion and extension gaps so the knee was balanced. Because there was no proximal femur on the specimens, the location of the femoral head and therefore the mechanical axis of the femur had to estimated. Due to the lack of a foot and ankle, intramedullary guides were used for the tibial preparation. Journey instrumentation was used and only one set of bone cuts was required, because the implants had been especially made with the same internal geometries.

The test regime was then repeated with the knee in 3 further states: (1) Genesis II; (2) Journey and (3) Journey II. This order was varied systematically across the 9 specimens (Table 6.1, Figure 6.7).
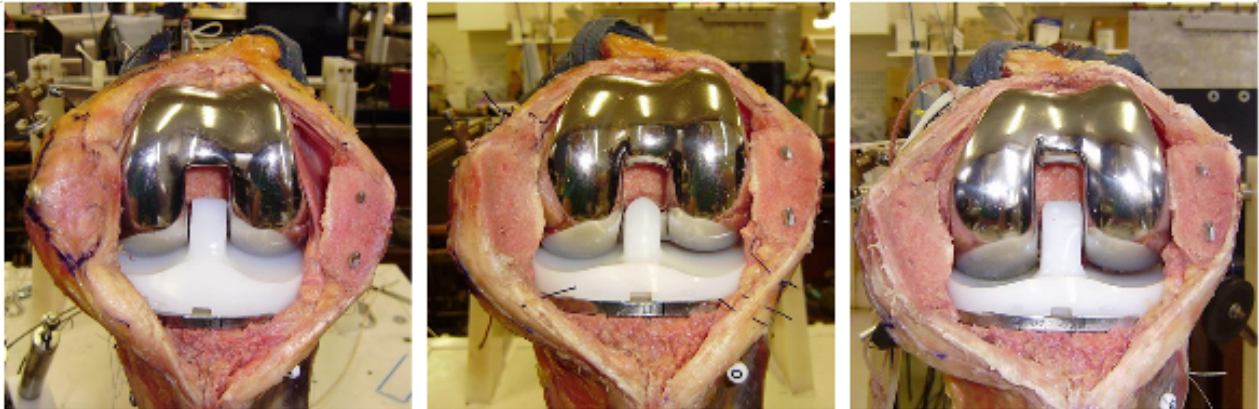
Figure 6.7   The implanted knee in the knee extension rig, showing the trans-patellar approach. From left to right: Genesis II, Journey, Journey II TKRs.

Figure 6.8   A cadaver knee mounted in the knee extension rig.

0° lateral
0° anterior
61 N (35%)

14° lateral
0° anterior
58 N (33%)

VLL

RF+IV

VML

15° medial
0° anterior
24 N (14%)

35° lateral
33° posterior
16 N (9%)

VLO

VMO

47° medial
44° posterior
16 N (9%)

ITB

0° lateral
6° posterior
30 N
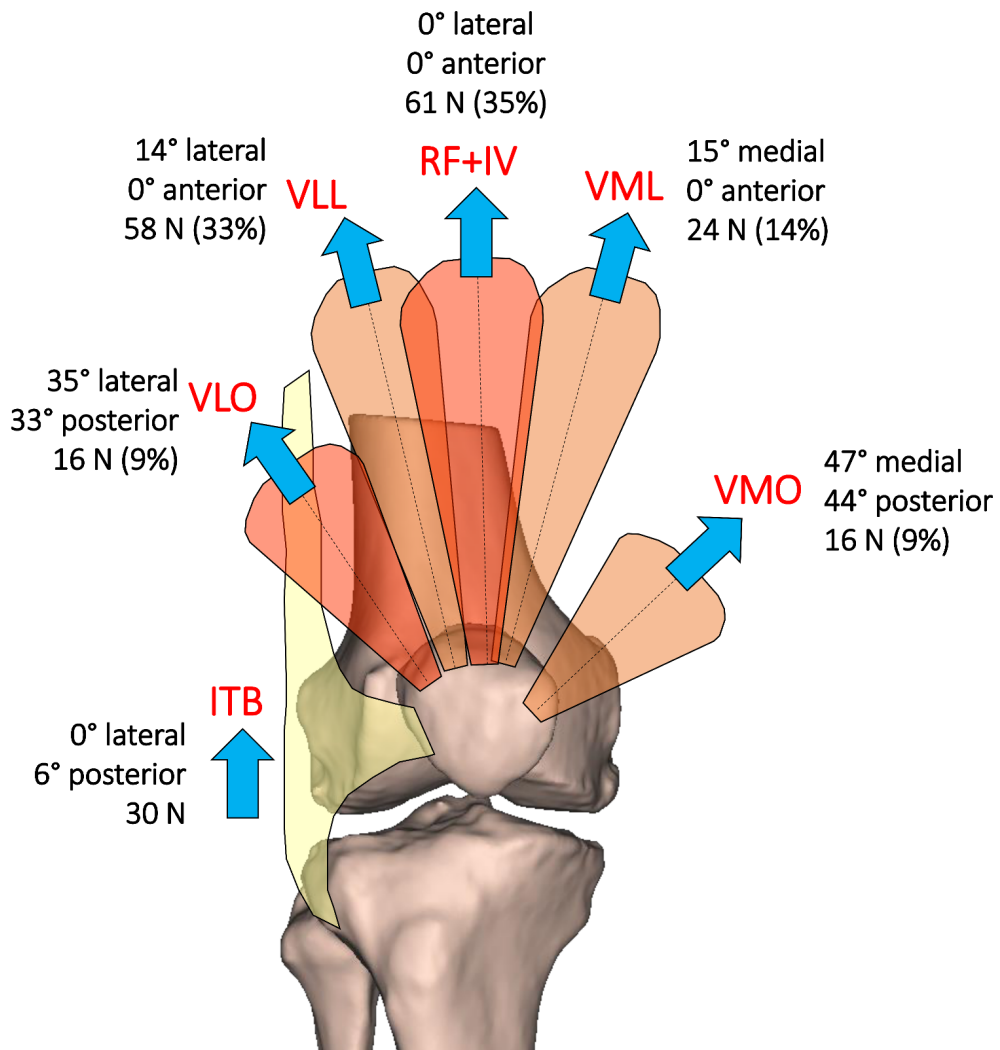
Figure 6.9   Load distribution across the quadriceps muscles. The muscles shown are: RF - rectus femoris, VI - vastus intermedius, VLL - vastus lateralis longus, VLO - vastus lateralis obliquus, VML - vastus medialis longus, and VMO - vastus medialis obliquus. Plus the ITB - iliotibial band.

6.3.5 Kinematics testing

A steel IM rod was cemented into the femur using PMMA, and the distal end of the tibia was cemented into a small bone pot with a rod screwed and welded to the centre of the base of the pot so that it was co-axial with the pot and the tibia within it. Care was taken to align both rods to the anatomical axes of the bones. A standard medial parapatellar incision was made and then sutured closed prior to testing the intact knee. The femoral rod was clamped into a rig that allowed manual passive knee flexion-extension by moving the femur, with the flexion-extension axis of the knee approximately matched to that of the rig, with the tibia hanging vertically and unconstrained except for flexion (Figure 6.10). The knee was positioned in the rig such that the femoral mechanical-anatomical (FMA) angle was approximately 6° with the tibia hanging vertically, thus achieving a close to horizontal epicondylar axis and minimising unnatural varus-valgus motion during the flexion-extension cycles. A steel pin (5 mm in diameter) was drilled medio-laterally through the proximal tibia and two semi-circular hoops were mounted onto this pin. A disc, 200 mm in diameter, was secured on the tibial rod. Weights could then be connected via pulleys and strings to apply drawer forces, rotational torques or varus or valgus moments, without inhibiting any natural coupled tibial motion (Bull *et al.*, 2008). Another pin was drilled medio-laterally through the patella and connected to a pneumatic cylinder via a semi-circular hoop in order to simulate a 400 N quadriceps tension applied parallel to the femur and the femoral anatomic axis in the sagittal and coronal planes, respectively (Figure 6.11).
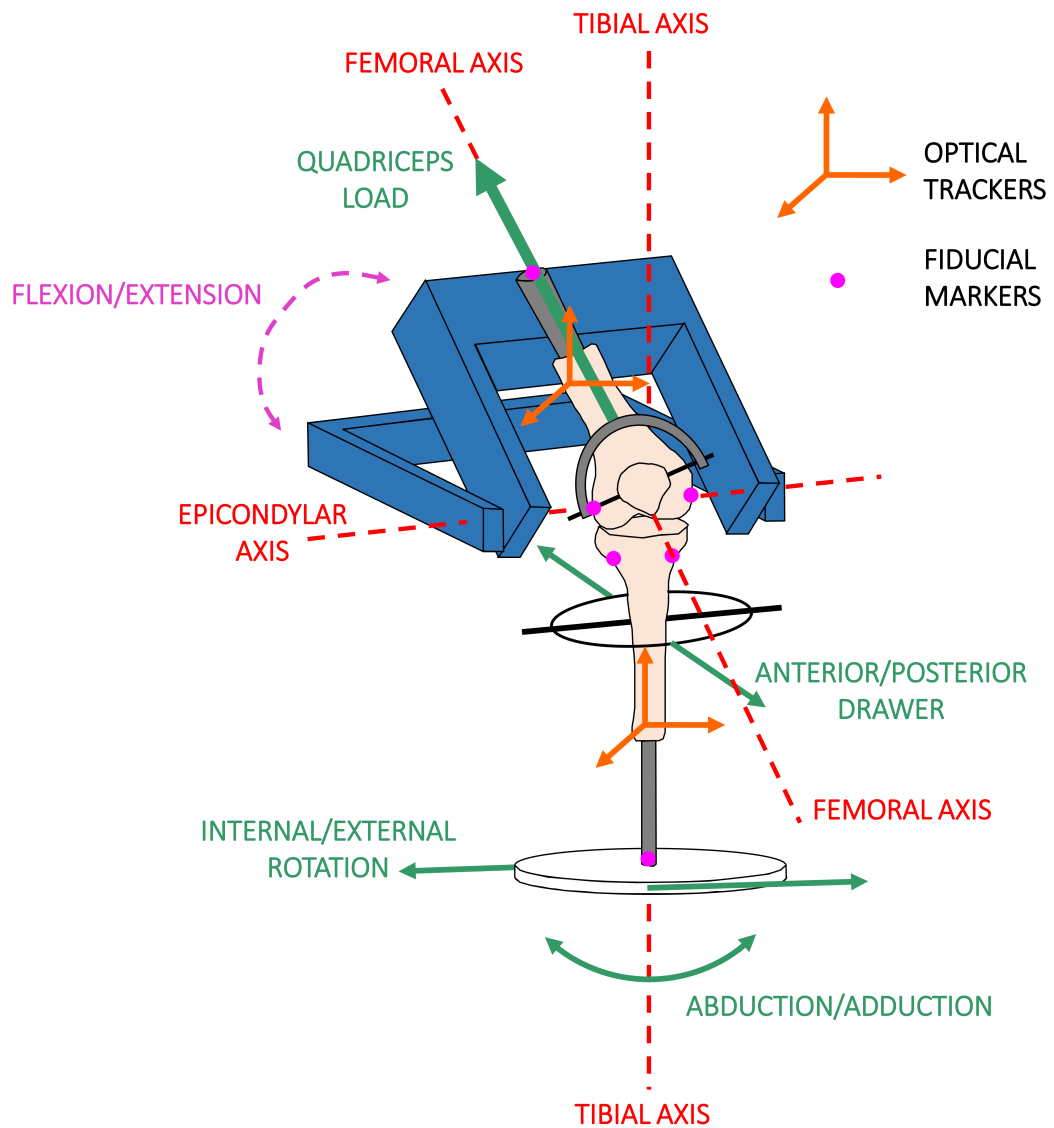
Figure 6.10   Schematic of the knee flexion rig.
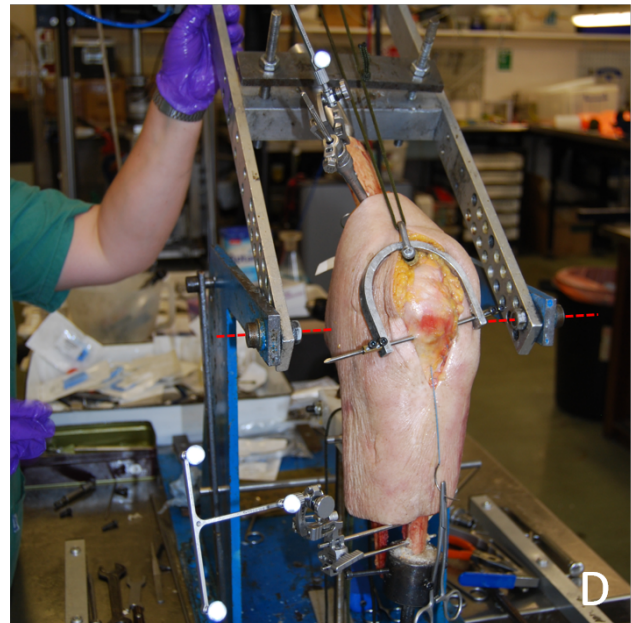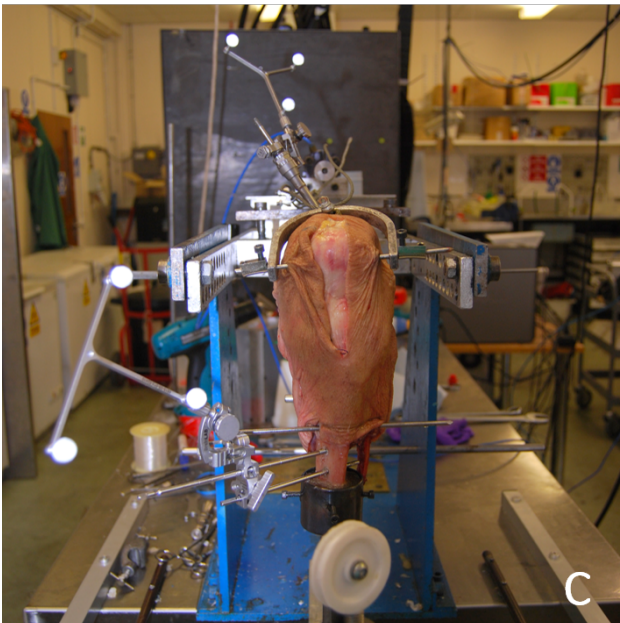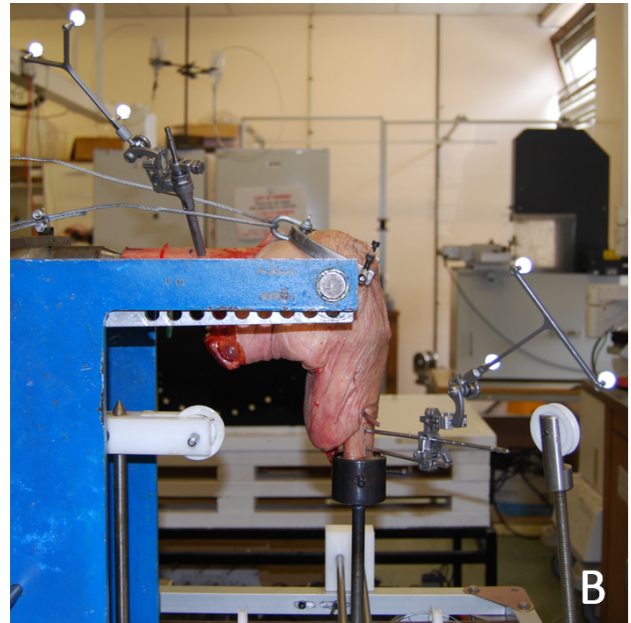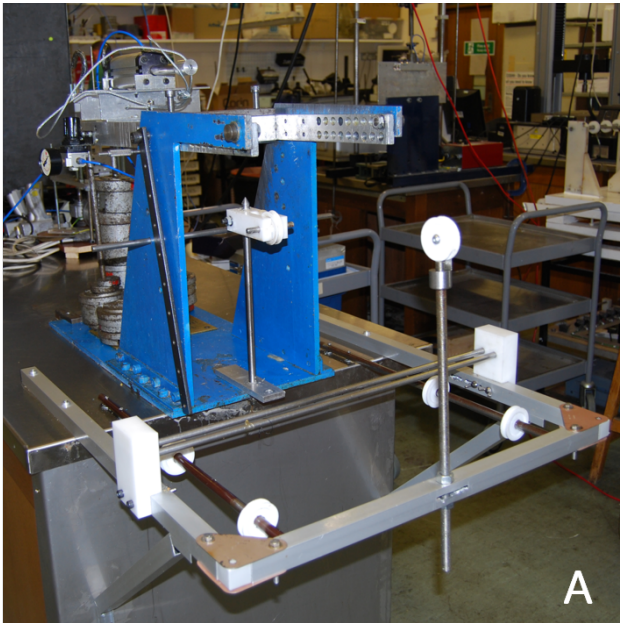
Figure 6.11   The knee flexion rig. A: The rig without a knee mounted in it. B: A side (medial) view of a cadaver knee in the rig with optical trackers fixed in place. C: an anterior view of the same knee. D: a cadaver knee being brought towards full extension in the rig.

The intact knee was tested with only the 400 N simulated quadriceps force and then with the following loads applied in conjunction with the quadriceps: (1) 135 N tibial anterior drawer force; (2) 135 N tibial posterior drawer force; (3) 7.5 Nm tibial internal rotation torque; (4) 7.5 Nm tibial external rotation torque; (5) 7.5 Nm valgus moment and (6) 7.5 Nm varus moment. In each loading condition, the knee was moved manually over 3 cycles of knee flexion-extension between 0° and 110°. When the intact measurements were complete, the incision was opened and the TKR implantation made, in the same way as described in Section 6.3.4. The test regime was then repeated with the knee in 3 further states: (1) Genesis II; (2) Journey and (3) Journey II. This order was varied across the 9 specimens (Table 6.2). The forces and torques were 50% greater than in previous work (Cuomo *et al.*, 2007; Kondo *et al.*, 2011; Miyatake *et al.*, 2011) in order to amplify any differences in the envelopes of laxity between the knee states. The movement of the knee with the forces and torques are used to define envelopes of laxity in the 3 directions (Figure 6.12).

The kinematics of the tibiofemoral joint were measured using a Polaris optical tracking system (NDI, Waterloo, Ontario, Canada) with passive BrainLab reflective markers (BrainLab, Feldkirchen, Germany). The trackers were mounted using bi-cortical screws onto the tibia and femur, positioned so that both could be "seen" by the Polaris camera for the whole range of 0-110° knee flexion. The design of these trackers allowed them to be unclipped from their bony attachments and then repositioned exactly, allowing them to be safely removed in between testing (while the TKR implantations were being made, for example). Coordinate systems for the bones were constructed by digitising landmarks using an optical stylus. Small incisions were made at the epicondyles and at the medial and lateral edges of the tibial plateau and small pozi-head self-tapping wood screws inserted into the cortical bone at each location. The tip of the stylus fitted exactly into the head of the screw, so the bones could be re-digitised precisely if required. The ends of the femoral and tibial rods were also digitised to complete the coordinate systems. These digitised points were fixed relative to their respective optical tracker, so from the tracker data, the movements of the digitised points could be calculated. The kinematic data were processed with Visual3D (C-Motion Inc, Germantown, Maryland, USA; Figure 6.13).
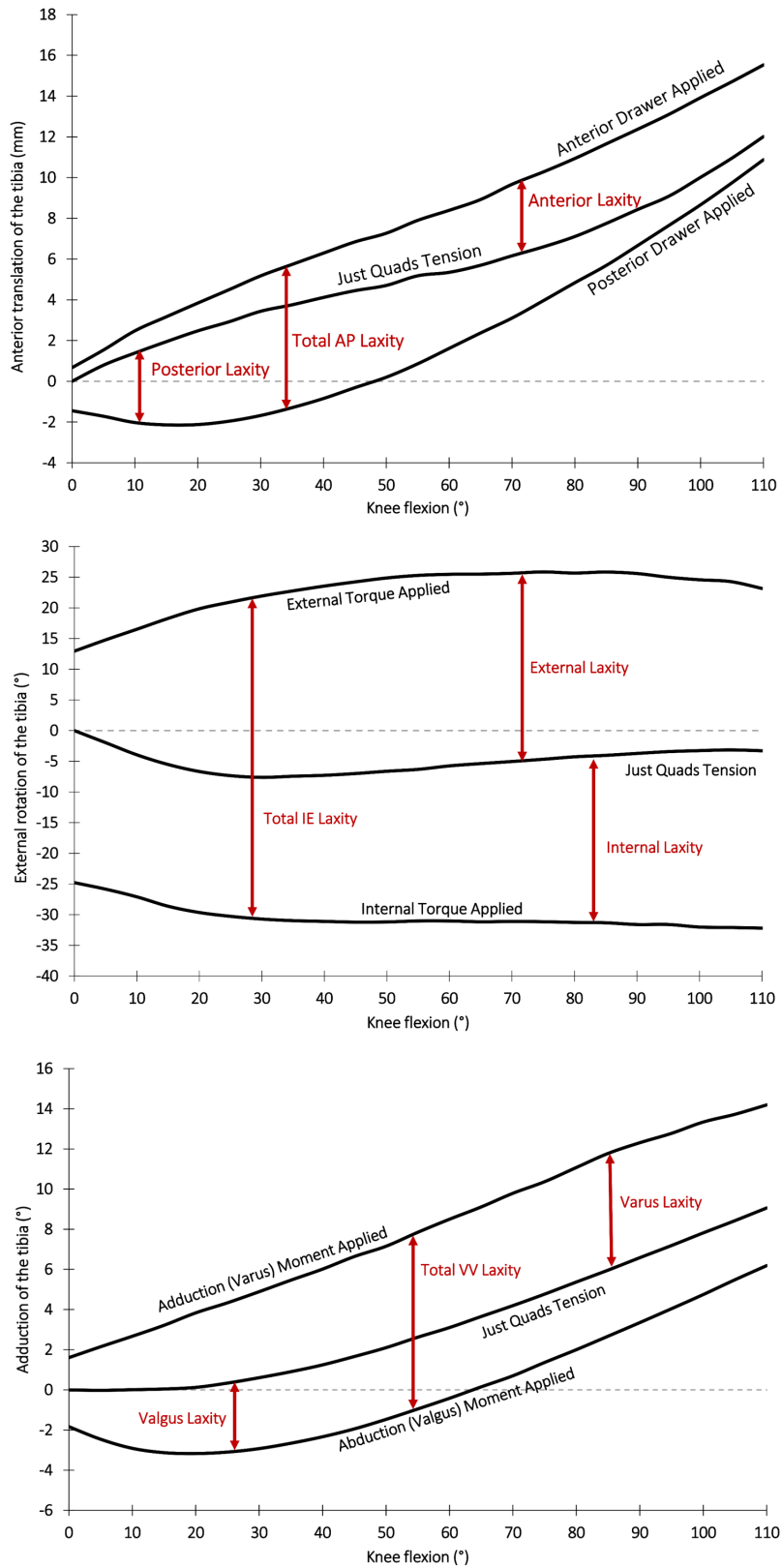
Figure 6.12   Laxity explanation
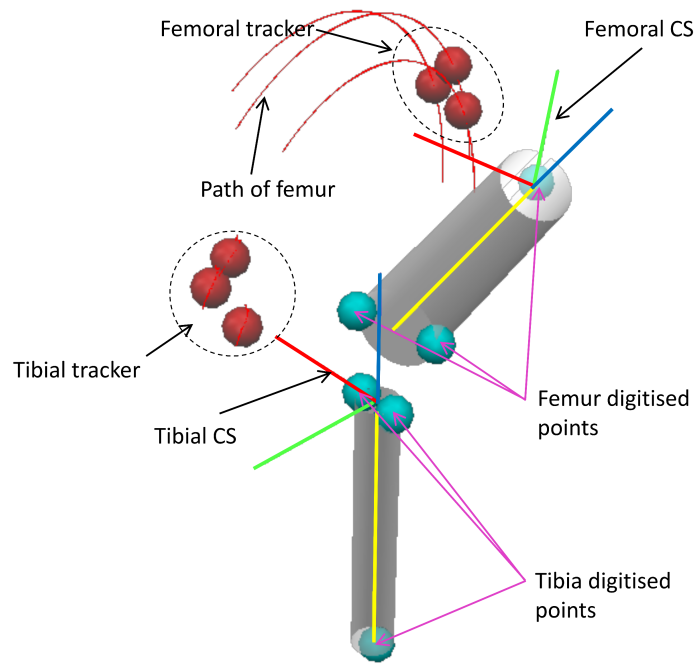
Figure 6.13   Visual 3D data processing model.

Zero-degree knee flexion (full extension) was defined as the angle when the intramedullary rods were parallel in the sagittal plane. All movements were calculated as tibial relative to femoral: anterior-posterior translation was defined as the perpendicular distance of the midpoint of the femoral epicondylar axis from the tibial coronal reference plane; internal-external rotation was defined as the angle between the lines joining the medial and lateral points of the femur and the medial and lateral points of the tibia in the transverse plane: varus-valgus rotation was defined as the angle between the same two lines, in the coronal plane.

6.4 Statistical analysis

To compare the intact knee to the implanted knee, two-way repeated-measures analyses of variance (ANOVA) were used to analyse the data. If significant differences were found, pairwise comparisons with a Bonferroni correction were then used. The primary variables were the four states of the knee (intact and three TKRs) and knee flexion; the dependent variables were the length changes of the soft tissue structures in the first experiment, and the kinematics in each degree of freedom examined in the second experiment: anterior-posterior translation, internal-external rotation, and varus-valgus

rotation. Significance was set at P<0.05, and analysis was performed using SPSS 22 (IBM SPSS Statistics, Armonk, NY, USA). One-way repeated-measures ANOVAs were used to examine the effect of flexion angle on the behaviour of the intact knee state from 0° to 90° flexion. From previous experiments, 8 specimens would provide adequate power; this was increased to 9 to allow all 3 devices to be tested first, second and third an equal number of times.

6.5 Results

6.5.1 Soft tissue length changes

The length of the soft tissues in the intact knee at 0° flexion was taken to be 0 mm and all the other measurements were relative to this. This results section presents mean values for the variables measured; these data can be seen in more detail (with plots for each specimen) in Appendix A.

6.5.1.1 The intact knee

Some variation in soft tissue behaviour was observed in the intact knees, however some trends and some significant differences were observed. The superficial fibres of the ITB slackened by 6.7±4.7 mm from full extension to 120° flexion ($P = 0.003$), while the deep fibres tightened during flexion by 11.5±9.0 mm ($P = 0.005$; Figure 6.14). The lateral retinaculum also tightened as the knee flexed from 0° to 90° flexion, by 6.0±7.2 mm ($P = 0.036$; Figure 6.14). The MPFL slackened by 8 mm during the first 50° of flexion ($P = 0.003$) and then tightened ($P = 0.016$), while the MCL remained almost isometric, only slackening slightly between 10° and 50° flexion (Figure 6.14) and then going back to its original length ($P = 0.982$).

6.5.1.2 The implanted knee

Overall, the length changes in the soft tissues around all three TKRs showed similar behaviour to each other, and to the intact knee. No significant differences were found when comparing TKRs to each other and to the intact knee state in the ANOVAs ($P > 0.05$), except for the MPFL measurements ($P = 0.037$). In the pairwise comparisons, significant differences were found between the intact knee and the Genesis II for MPFL length changes between 90° and 120° flexion, with the MPFL shortening more with the Genesis II. There was a trend for the MCL to be shorter in flexion past 50° post-TKR than in the intact knee but this was not found to be a significant difference (Figure 6.15). On the lateral side of the knee, there was a trend for the deep ITB to be longer in flexion past 50° with the Journey than with the Journey II, Genesis II or the intact knee (relative elongation *> 2 mm* from 70° to
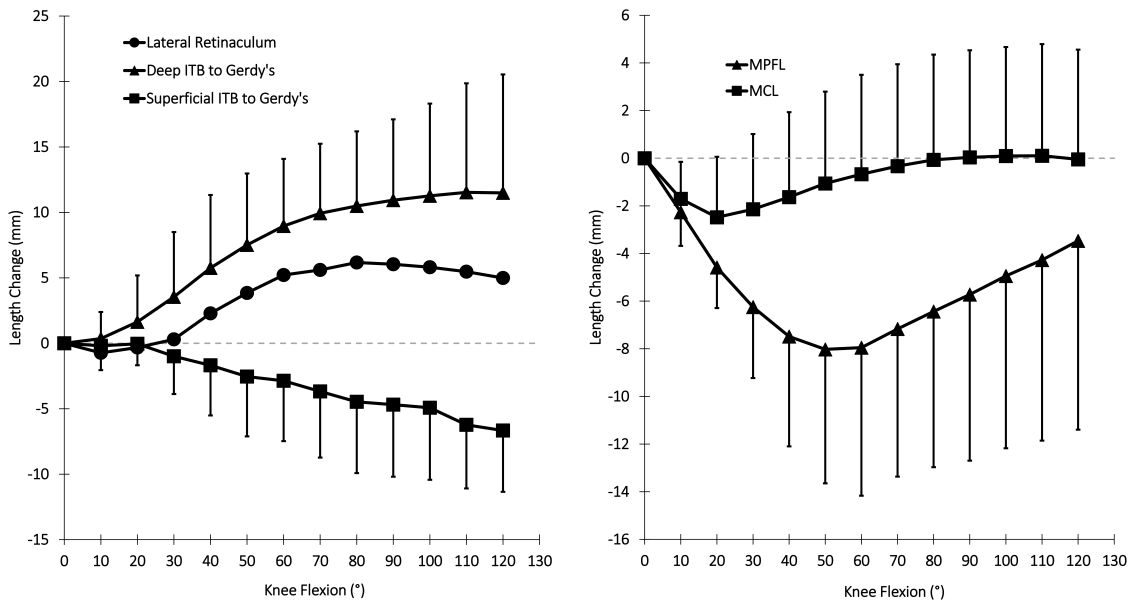
Figure 6.14 Soft tissue length changes in the intact knee during flexion. Mean values ± 1 standard deviation (*n=9*).

100° knee flexion; Figure 6.17), but this was not found to be significant. No significant differences were found for the length changes of the superficial ITB for the three TKRs compared to the intact knee. No significant differences were found in the lateral retinaculum behaviour (Figure 6.16).

When paired t-tests were run at individual flexion angles between pairs of implants, some significant differences were found for the MCL. The MCL was longer with the Journey implanted than with the Journey II implanted above 30° flexion, but was then shorter than in the natural knee with all three TKRs (Figure 6.15). No significant differences were found between the two Journey TKRs for the other soft tissues.
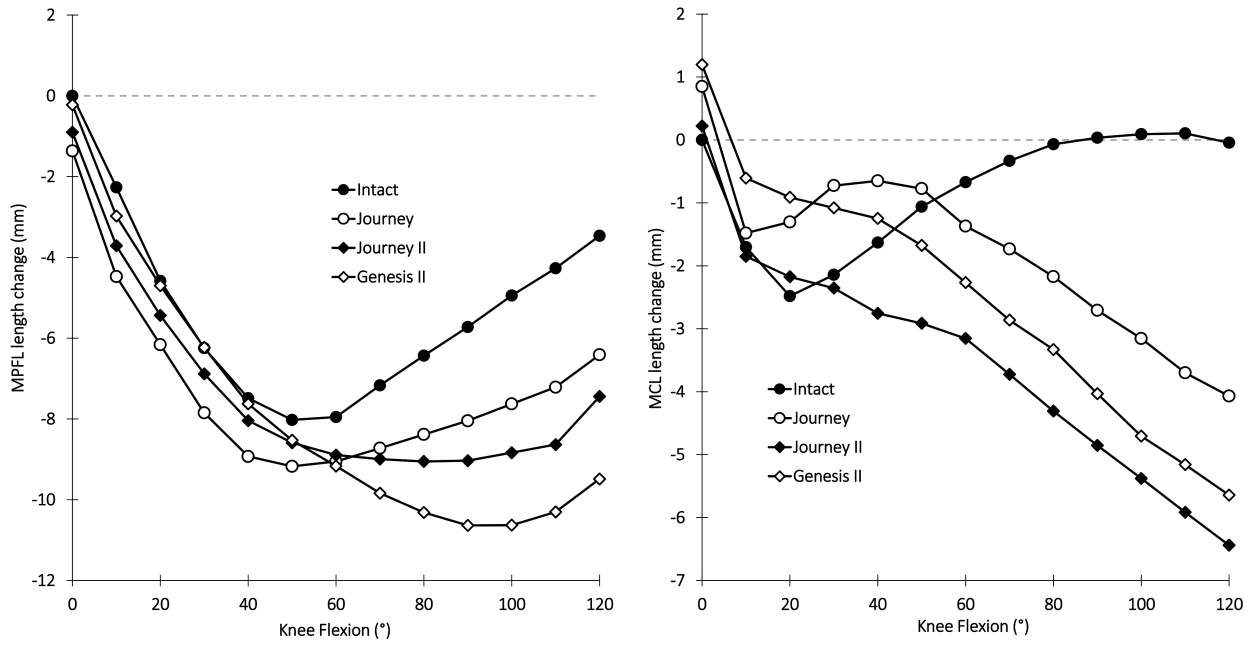
Figure 6.15   Medial soft tissue length changes in the intact and replaced knee. Mean values (*n=9*).
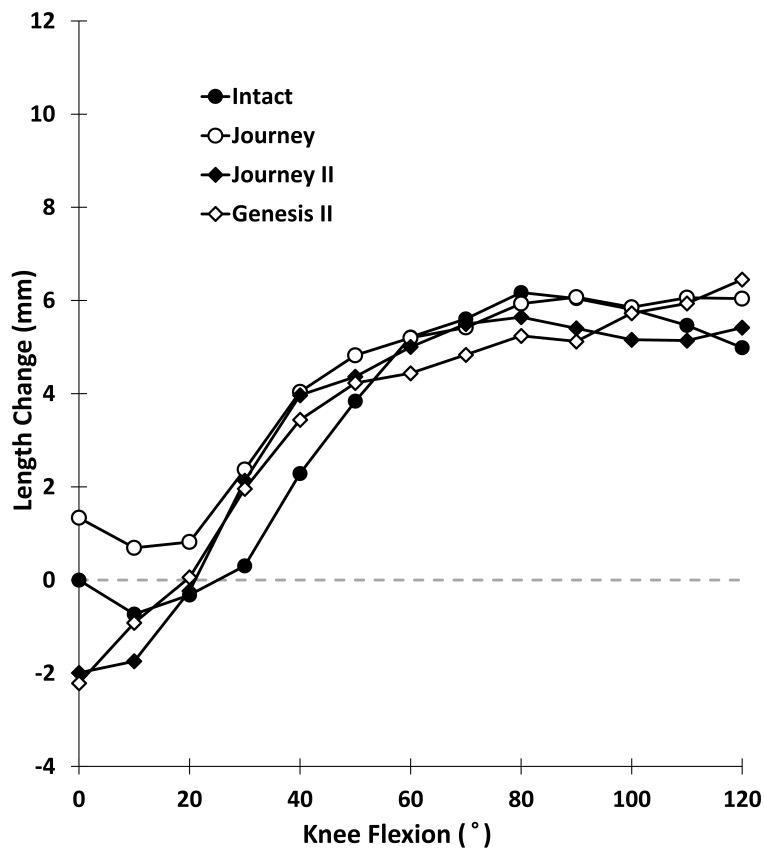
Figure 6.16   Lateral retinaculum length changes in the intact and replaced knee. Mean values (*n=9*).
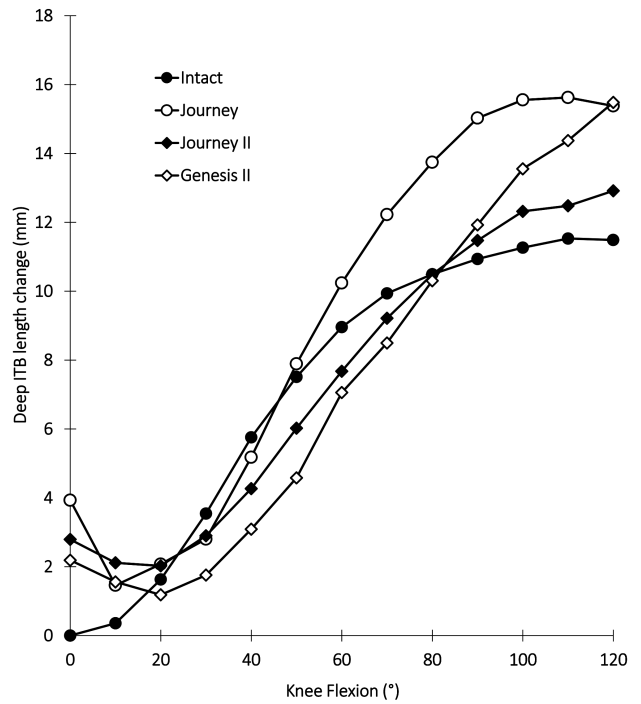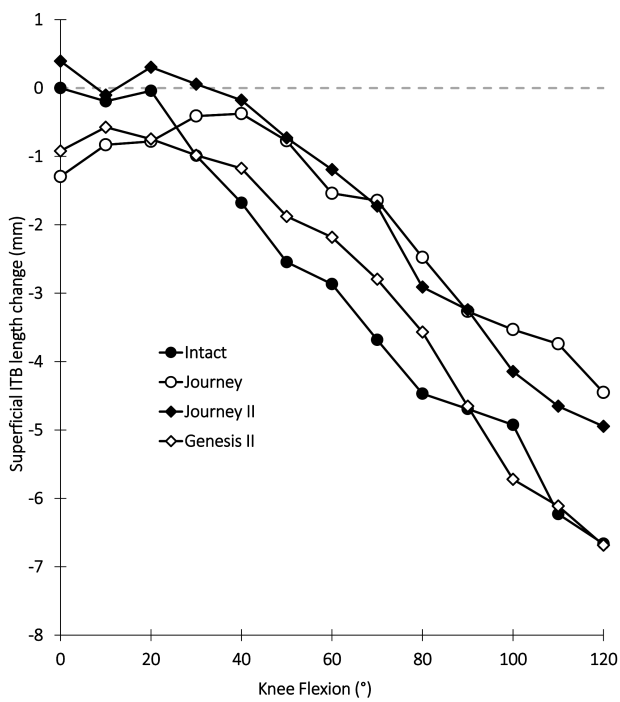
Figure 6.17   Lateral soft tissue length changes in the intact and replaced knee. Mean values (*n=9*).

6.5.2 Kinematics

The position of the intact knee at full extension (0° flexion) was taken to be 0 mm translation and 0° rotation. All other measurements were normalised to this. The motions described are always tibial motion relative to the femur. This results section presents mean values for the variables measured; these data can be seen in more detail (with plots for each specimen) in Appendix A.

6.5.2.1 The intact knee

There was little variation in intact knee behaviour across the 9 specimens, particularly in the neutral loading condition for AP translation (Figure 6.18). AP motion in the intact knee was fairly consistent across all nine specimens (Figure 6.20). As the intact knee extended from 30° with just quadriceps loading, the tibia rotated externally by 7° $\pm$3° (range 4° to 11°); the screw-home mechanism ($P < 0.0001$; Figure 6.19). Between 30° and 110° flexion the tibia rotated very little with respect to the femur. With the internal torque applied, the tibia internally rotated 25° in full extension and continued to rotate until 40° flexion when it stabilised. With the external moment applied, the tibia externally rotated from the neutral position by 12° and rotated further until plateauing at around 60° flexion. The maximum total IE laxity occurred at 75° flexion (57° difference between the position of the knee under the internal and external torques; Figure 6.20).
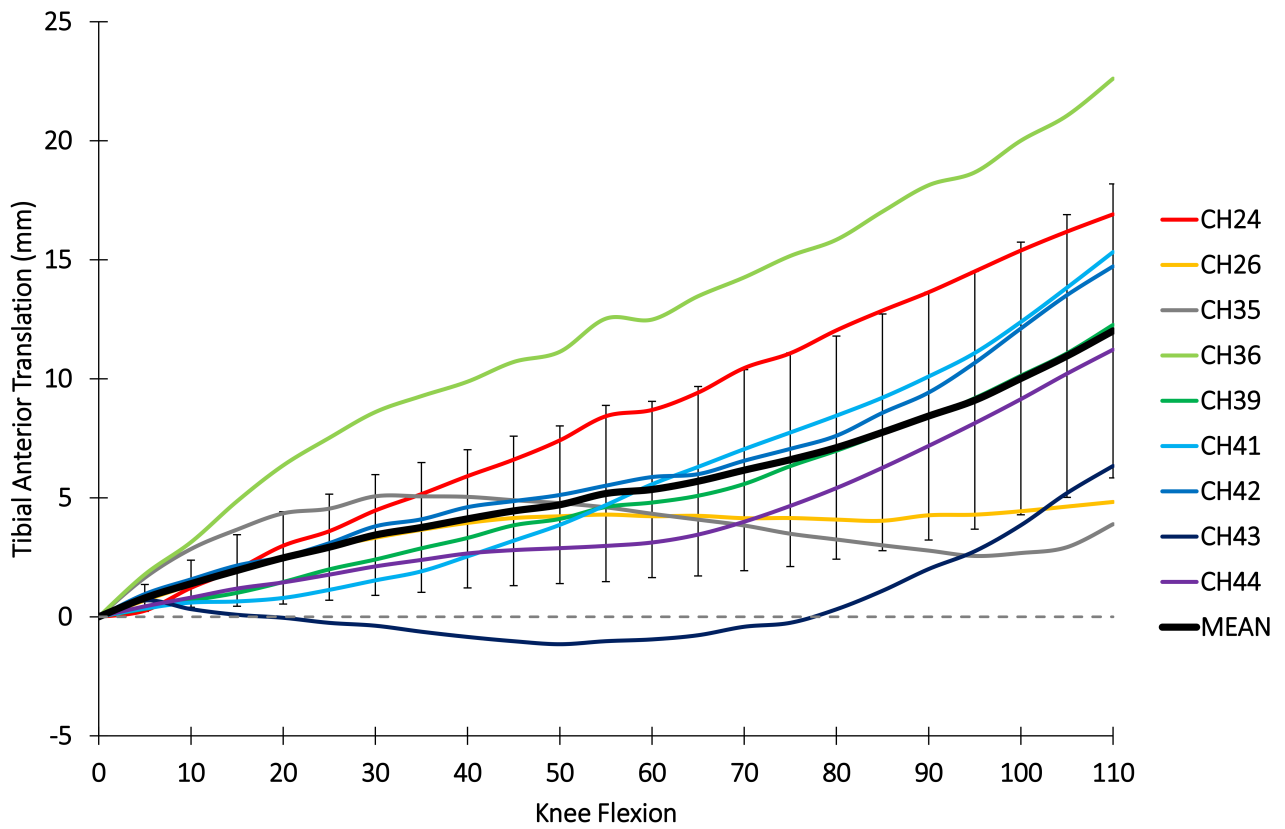
Figure 6.18 Anterior translation of the tibia during flexion for the intact knees. The error bars on the mean value are ±1 standard deviation (*n=9*).
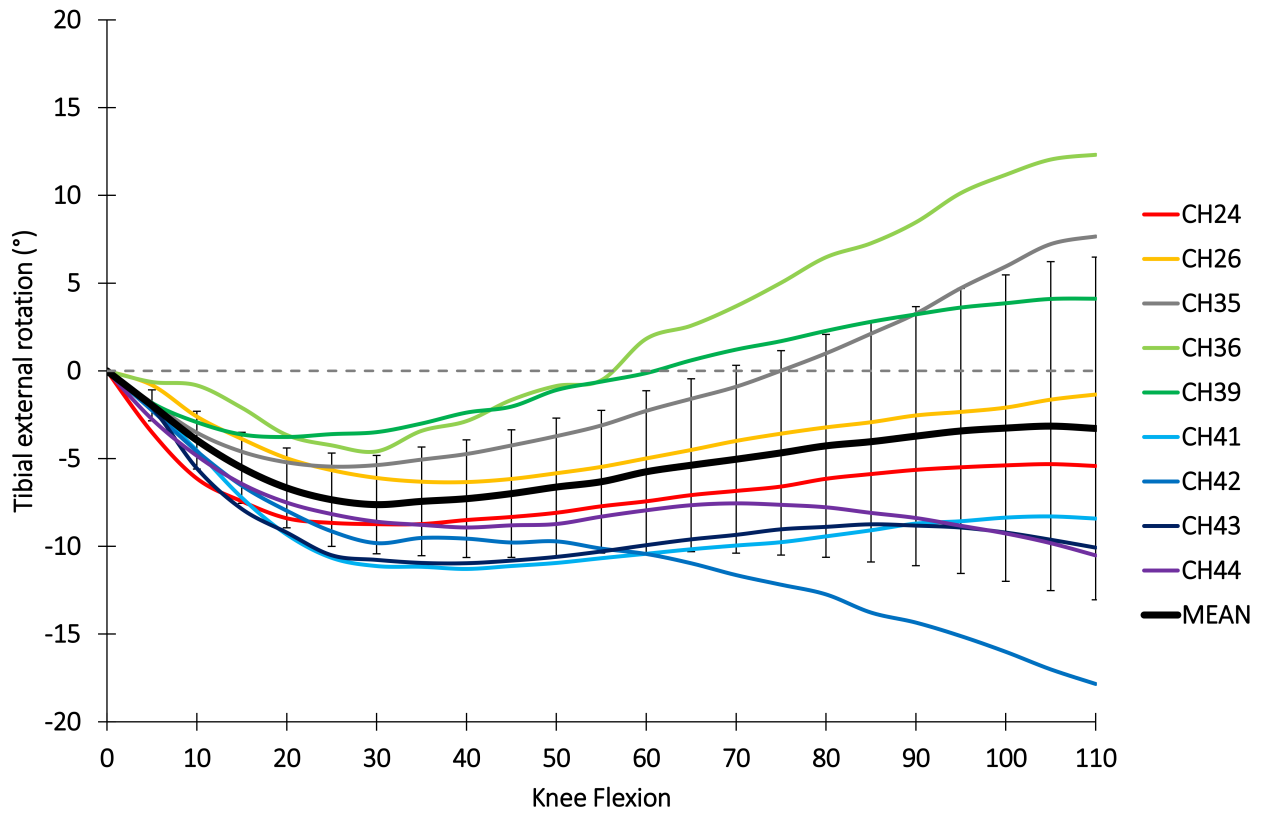
Figure 6.19   Internal rotation of the tibia during flexion for the intact knees. The error bars on the mean value are ± 1 standard deviation (*n=9*).
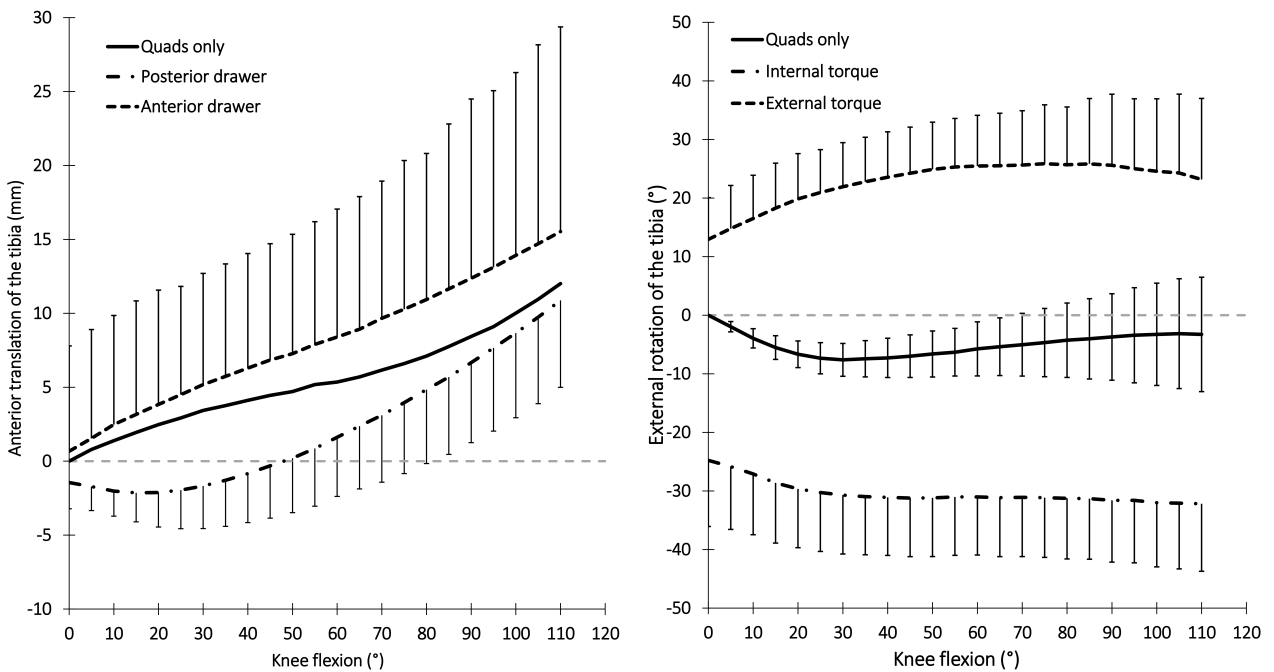
Figure 6.20   Intact knee kinematics. On the left, the AP translational behaviour; on the right, the internal and external rotation. (*n=9*).

6.5.2.2 The implanted knee

The screw-home behaviour observed in the intact knees was absent after TKR, and at full extension the replaced knees remained at a mean of 6 to 7° internally rotated for all 3 devices (Figure 6.21), although this difference between the TKRs and the intact knee was not found to be significant. In the mid-range of flexion (30° to 80°), the TKR knees tended to be more externally rotated than the intact case but again, this was not found to be significant. The rotational laxity envelopes for the three TKRs were very similar to each other and to the intact knee state (*P > 0.05*; Figure 6.21); but it must be noted that the internal and external torques had to be halved from those used in the intact cases due to excessive rotational laxity post TKR.

The TKRs did not cause a significant change in the neutral path of AP motion of the tibia for any flexion angle when compared to the native knee motion, although the Genesis II had a tendency to start at full extension in a more anterior position than the native knee and was in a significantly more anterior position than the other TKRs at full extension and 5° of flexion (*P < 0.022*; Figure 6.22). The Journey TKR was found to be in a more anterior position than both the Genesis II and Journey II in deeper flexion (75-105° for the Genesis II, *P < 0.043*; and 85-110° for the Journey II, *P < 0.021*).
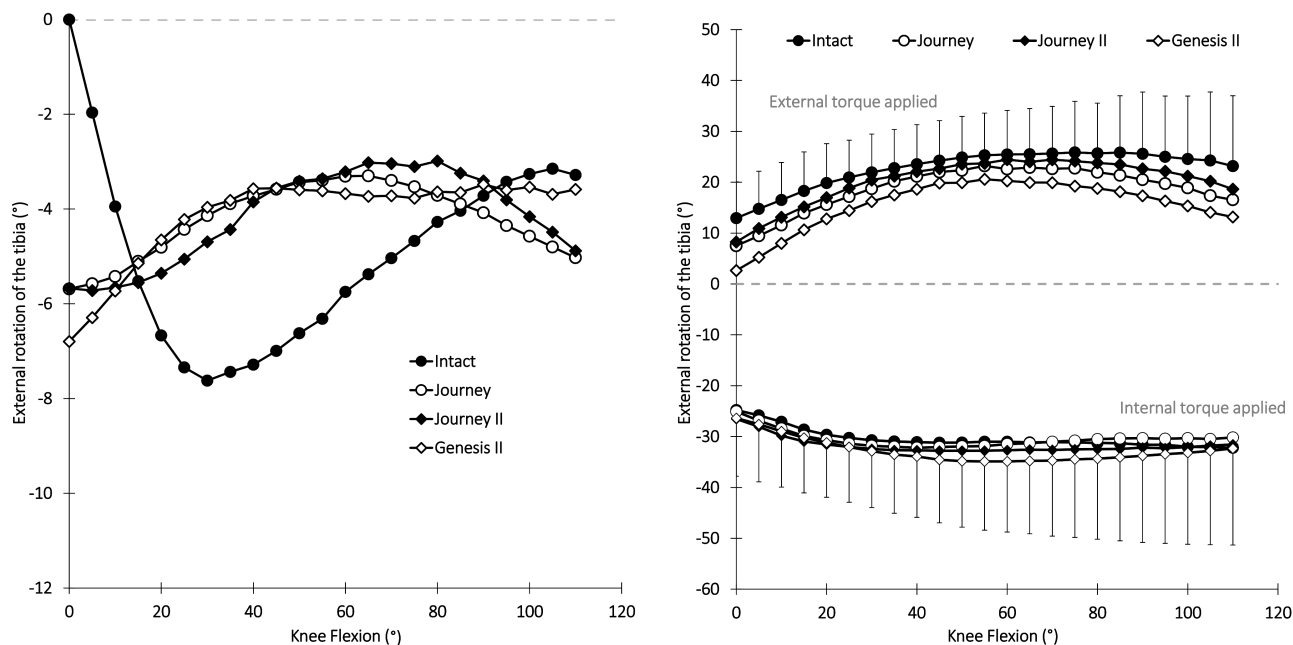
Figure 6.21   Rotational behaviour of the knee. On the left, external rotation of the tibia during neutral loading; on the right, the external and internal limts of laxity under applied torques (*n=9*).
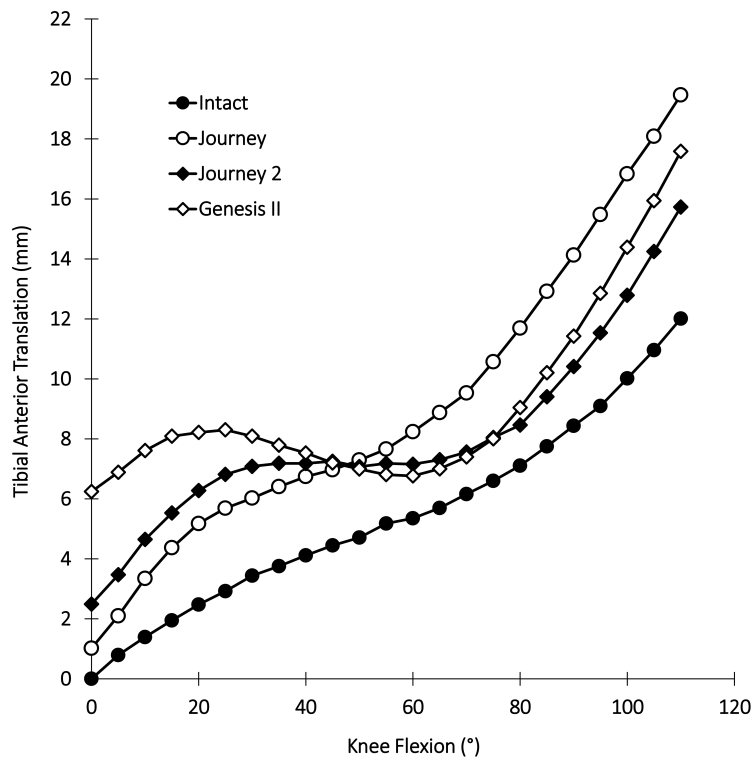
Figure 6.22   Neutral path of AP motion for the 4 knee states. (*n=9*).

The 135 N anterior drawer force produced significantly greater tibial anterior translation (i.e. the anterior laxity was greater) for all three TKRs than in the intact knee (Figure 6.23). In the pairwise comparisons, significant differences from intact were found for the Journey between 10° and 35° flexion (*P < 0.031*); the Journey II between 20° and 80° (*P < 0.044*) and the Genesis II between 5° and 85° flexion (*P < 0.015*). The envelopes of total AP laxity of the Journey II and the Genesis II were larger than in the intact knee (*P = 0.004* and *P = 0.006*, respectively; Figure 6.24) but that of the Journey TKR was not found to be significantly different (*P = 0.072*). When considered in more detail in the pairwise comparisons, the Journey II was found to have significantly greater AP laxity than the intact knee from 0 to 70° flexion and the Genesis II between 10 and 70° flexion. The Genesis II device was found to have significantly more AP laxity than the Journey TKR (*P = 0.013*); no other significant differences were found between the other devices. Significant differences of tibial posterior translation laxity among the intact knee and the three TKRs were not found. Variability across the 9 specimens appeared to increase from intact to Journey to Journey II to Genesis II, despite the order of the TKR implantations being varied (Figure 6.24).
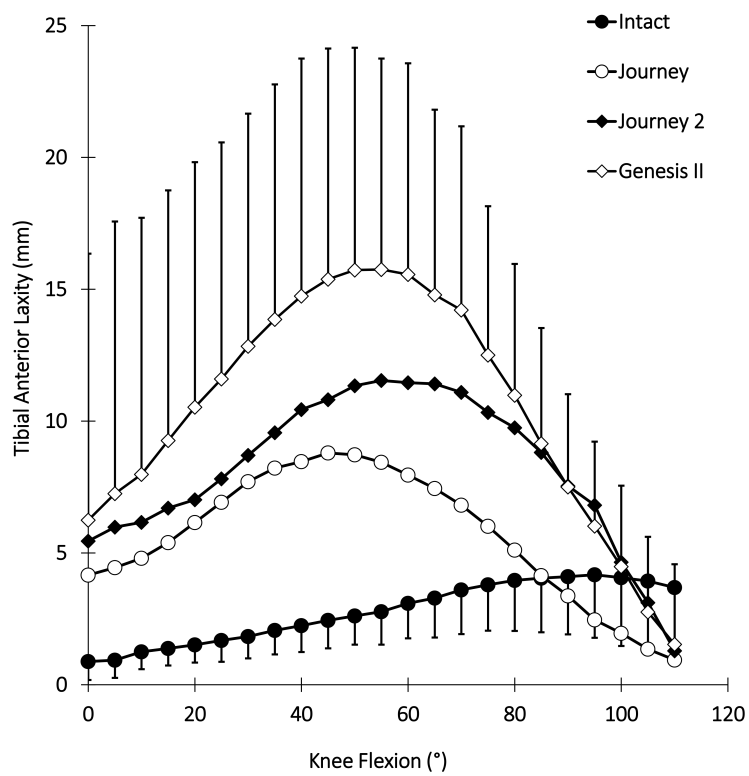
Figure 6.23   Anterior laxity for the 4 knee states, calculated as the difference between the anterior positions under the 135 N anterior drawer force and the neutral position at each angle of flexion. (*n=9*).
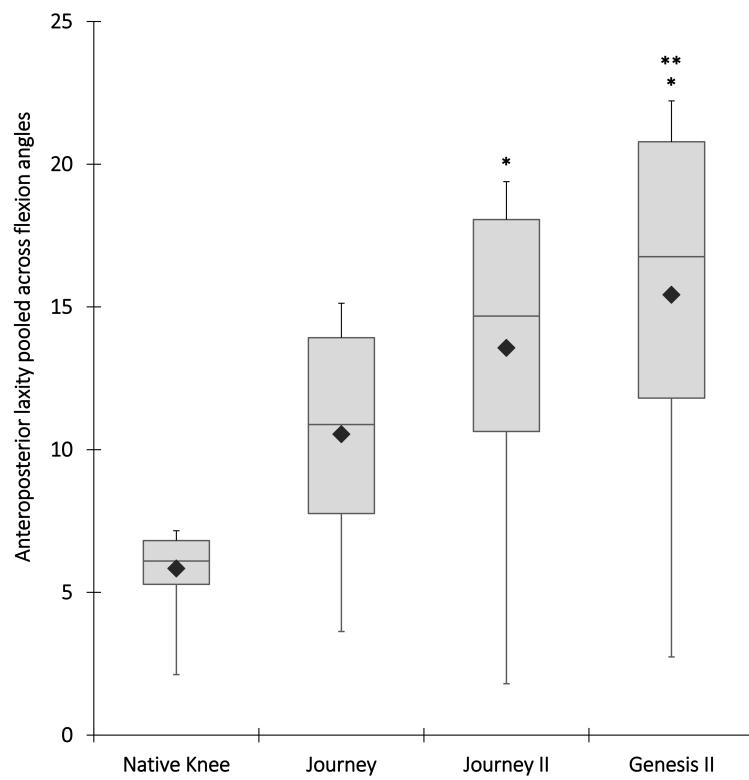
Figure 6.24   AP laxity pooled across all flexion angles. * = significantly greater than intact. ** = significantly greater than Journey TKR. (*n=9*).

The implanted knees followed a similar path of abduction/adduction motion to the intact knee state with all three prosthesis designs, but were abducted by approximately 2°, in the neutral loading case (Figure 6.25). There was a trend for the TKR knees to be more lax with the valgus moment applied, suggesting a loose MCL. In contrast, the TKRs had less laxity than the intact knee with the varus moment applied in deep flexion (3° to 4° difference between 90° and 110° flexion) consistent with an overtight LCL. However, neither of these results was found to be significant.
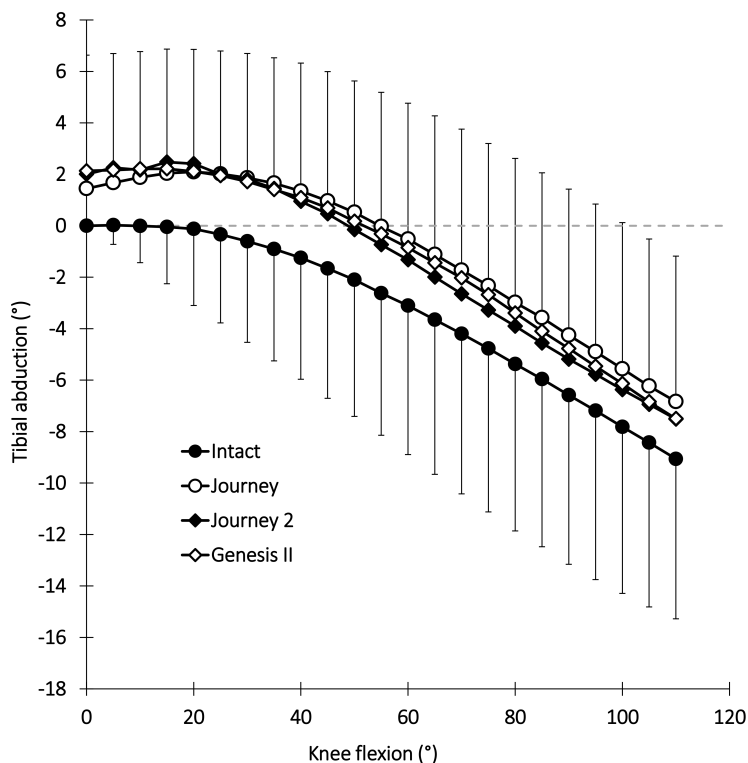
Figure 6.25   Abduction of the tibia during flexion, mean values ±1 standard deviation. (*n=9*).

6.6 Discussion

The most important finding of this study was that the three designs of TKR – two guided-motion TKRs and the third a conventional PS design – led to similar patterns of kinematics and of soft tissue length changes across the arc of knee flexion-extension in response to the specific testing conditions used. An improvement in kinematics was not found with the Journey II design when compared to the original Journey prosthesis and no statistically significant differences were found to support the tissue elongation hypothesis.

There were, however, tendencies that were observable in the data which agreed with the initial

hypotheses:

- There was slightly more elongation of the ITB with the Journey TKR at some angles of flexion, which also agreed with some in silico results produced by Smith & Nephew (Smith & Nephew, 2012);

- There was less tibial anterior translation in the flexed knee with the Journey II than with the Journey;

- The Genesis II deviated further from natural knee kinematics than the guided-motion prostheses.

The results from the soft-tissue study do not indicate an excessive stretching of any of the soft tissue constructs for the Journey compared to the intact knee state or to the Journey II or Genesis II TKRs. The measurements were highly variable across the nine tested specimens – in both the intact and implanted states – and so significant differences were not found overall or at any angle of flexion. This may match with the soft tissue pain being reported by only a small minority of patients. The behaviour of the lateral retinaculum and MPFL in the native knee in this study were in agreement with previous similar work (Ghosh *et al.*, 2009; Stephen *et al.*, 2012), as is the absence of any change in lateral retinaculum length after Genesis II TKR (Ghosh *et al.*, 2009). However, Ghosh *et al.* (2009), did see a stretching of the MPFL after Genesis II TKR (Ghosh *et al.*, 2009), which was the opposite finding to that observed in this work. It is possible that this is related to the patella button component which was used by Ghosh *et al.* (2009) but was not implanted in this study. The small length changes of the MCL, and the relative slackening with knee flexion after all three TKR designs in this study, have been reported in previous studies of the Genesis II TKR (Duren *et al.*, 2012; Ghosh *et al.*, 2009). The ITB did have a tendency to be more stretched with the Journey than the Journey II and the Genesis II in mid-flexion, in agreement with the initial hypothesis and LifeMOD/KneeSIM simulations produced by the manufacturer (Smith & Nephew, 2012). Reasons for the variation across the different specimens could include: differing anatomy, size and geometry of the intact knee; variations in surgical technique; and the approximate sizing used in TKR surgery (having to size up or down as required when an exact fit is not available), as well as the fact that there is a discrepancy in the size ranges in the two knee systems (Journey and Genesis; Figure 6.26). Care was taken to place the length-change sutures in the same anatomical positions for each knee specimen, but slight differences may have occurred, contributing to the variations observed.
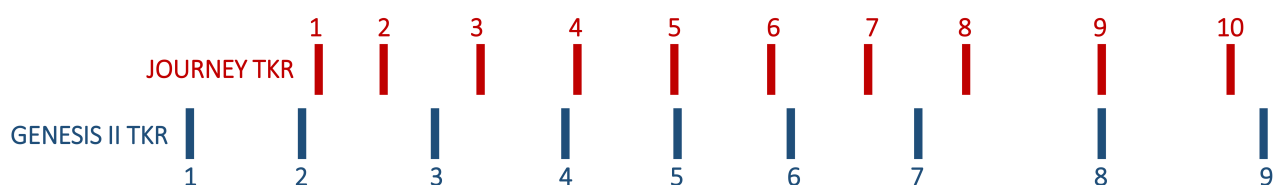
Figure 6.26   Size ranges of the Journey and Genesis II TKRs and how they relate to one another (adapted from data provided by the manufacturer).

The kinematics study showed that, on average, the tibiofemoral motions (under neutral loading) for the three prostheses were similar to the intact knee and to each other, although the screw-home mechanism observed in the intact knee was absent after all three TKRs, despite the asymmetrical design of the condyles of the guided-motion Journey devices which is intended to position the femoral component in internal rotation in full extension. It has been suggested that the tightening of the ACL in the intact knee near extension causes the screw-home mechanism, so the motion is lost in conventional ACL-excising TKR procedures (Hallen and Lindahl, 1966). This lack, or reversal, of the screw-home mechanism post-TKR has been observed previously (Bull *et al.*, 2008; Merican and Amis, 2009). The Genesis II allowed the tibia to translate anteriorly more than the guided-motion prostheses, and the Journey caused the tibia to be more anterior than with the other prostheses above 75° knee flexion, which would contribute to increased lateral femoral rollback, as had been hypothesised. The largest differences between the natural knee and the TKRs were that the prostheses all allowed greater tibial anterior translation (drawer) laxity and internal-external rotation laxity than in the natural knee. This is likely due to the conformity between the femoral and tibial components and the cam-post mechanism not adequately replacing the natural articular geometry or the action of the cruciate ligaments. Even with guided-motion TKRs, designed to produce more physiological knee motion via their geometry and cam-posts, knee kinematics have been shown to be strongly related to muscle activity (Catani *et al.*, 2009), with the absence of the cruciate ligaments being compensated for via the muscles of the leg. In this experiment, where the only muscle activity was a constant centralised 400 N load on the patella for the both the native and the replaced knee, the differences between the two cases were emphasised, with normal knee motion not being restored. In addition, it does not appear that the cam-post acts across the whole range of knee flexion in either the Journey or Journey II knees. It is true that the ACL is more functional at lower angles of flexion during normal walking, but under anterior loads, such as the ones used here, it carries substantial load over all flexion angles (Sakane *et al.*, 1997) and so its absence does affect

134

the stability of the knee in this scenario.

All three prosthesis designs led to replaced knees which had much greater laxity than the intact knee when internal and external rotation torques were applied. Similarly, with an anterior drawer force applied, the replaced knees all had greater laxity than the intact knee from extension through the mid-range of flexion. In addition to the constraint inherent in the prostheses, this may also reflect the preference of the surgeon during implantation. The replaced knee behaviour was more variable than for the intact knee, but there was little difference in variability among the three devices. The Journey II design was more constrained than the Genesis II device with the anterior drawer applied, but behaved very similarly to the Journey implant. All the replaced knees were abducted approximately 2° more than the native knee, which has also been observed previously (Merican and Amis, 2009). Variability across specimens did appear to increase with the Journey II and Genesis II compared to the Journey, despite the order in which they were implanted being varied across the 9 specimens (each TKR design was implanted 1st, 2nd and 3rd 3 times each). It is possible that certain TKRs were more sensitive to the inevitable soft tissue changes that would occur during the experiment and it does appear that the AP laxity of the Genesis II TKR was more affected by being the 2nd or 3rd implanted device, compared to the other TKRs (Table 6.3). A much bigger study would be required to quantify the effect, if any, that the implantation order had to the overall results.

Table 6.3   Mean total AP laxity (pooled across all flexion angles) depending on order of TKR implantation.

TKR	Mean total AP laxity (mm) when implanted:		
	1st	2nd	3rd
Journey	8.9	11.8	11.0
Journey II	15.5	14.0	11.2
Genesis II	8.9	17.3	20.1

Luyckx *et al.* (2010) suggested that the pain reported by some Journey TKR patients was due to excessive posterior movement of the lateral femoral condyle, in turn leading to greater internal rotation of the tibia and an eccentric loading of the iliotibial band (ITB), causing "ITB syndrome" (a common complaint amongst runners, often called "runners knee"). Out of 1070 patients included in that study, 77 (7.2%) reported anterolateral knee pain post TKR. However, 55 of those were successfully treated with a short dose of oral NSAIDS or a steroid injection. Only 2% of the original

cohort (22 patients) had anterolateral pain that persisted after those drug treatments. Those patients required surgical intervention (an ITB release) in order to relieve the pain which was attributed to their TKR. The same number of patients in the same study had to have their TKR revised, so the anterolateral pain problem was not an insignificant problem in that cohort of patients, but was definitely not seen in the vast majority of those patients.

Results from a cadaver study by Victor *et al.* (2009) also suggest that, overall, there was excessive internal rotation of the tibia with the Journey compared to the intact knee, but that study found no pairwise differences between native and replaced knees at individual flexion angles. Although the work presented here did not find significant differences in tibial rotation between the replaced and intact knees due to variation across the specimens, 4 out of 9 specimens had a more internally rotated tibia after TKR for the whole range of flexion; this was true for both guided-motion devices. This internal rotation occurred simultaneously with larger tibial anterior translation after the Journey TKR beyond 75° flexion, adding to the tendency to cause soft tissue elongation.

6.7 Strengths and limitations

The findings of this study must be considered along with the limitations of this type of in vitro experiments. First, the lack of loading to the hamstrings and the constant load applied to the quadriceps, across the range of flexion angles, in both types of rig, is not truly physiological. The loading was also limited due to the condition of cadaveric muscles – in order to prevent the muscles from tearing mid-substance or from their tendonous insertions, full physiological loading could not be used. The experiments simulated an open-chain knee extension cycle against resistance, in which the axial compressive joint force was imposed by the quadriceps/patellar tendon tension acting across the knee, without any ground reaction force or other external forces. This type of movement, even over the arc from full extension to 110° flexion, does not reproduce the full array of knee motions during activities of daily living, when different muscle forces and therefore knee kinematics will most likely occur. Another limitation comes from the use of the largely "normal" cadaveric knees, which lacked severe signs of degenerative osteoarthritis on the articular cartilage, as well as the soft tissue changes that may occur alongside the disease, which is unrepresentative of the patients that would be treated with this type of device.

Muscle co-contractions were not simulated as they would have increased the complexity of both experiments and, given that the main concern was that the Journey caused excessive rollback with knee flexion, the inclusion of hamstrings tension would tend to give a negative result. The use of more "normal" knees than the average TKR patient is unrealistic of the clinical situation, but it is still relevant to compare TKR function to normal (as opposed to osteoarthritic) knee behaviour, and they avoid the confounding variability of pathological changes. Strengths of the study include: the use of custom-made components which could all be fitted onto the same bone cuts, thus ensuring consistent joint line positions, and enabling the order in which the TKRs were tested to be varied; the use of a repeated-measures protocol which should have eliminated the inevitable effects of between-specimen variability; and the ability to apply forces and torques accurately, and then to measure the resulting tissue length changes and kinematics accurately. In addition, the implants could be swapped over in situ, without moving the specimen out of the testing rig.

6.8 Conclusions & further work

When three designs of TKR were compared in vitro, the guided-motion designs did not lead to knee kinematics and soft tissue length change patterns which differed significantly from those of a conventional PS type of TKR. However, the earlier guided-motion design (Journey) did lead to significantly greater femoral posterior roll-back in knee flexion than in the intact knee, while the conventional PS-TKR (Genesis II) allowed greater tibial anterior drawer laxity than in the normal knee.

Guided-motion TKRs seek to reproduce normal knee kinematics by determining the path of tibiofemoral motion via cam and post mechanisms and, in the case of the Journey devices, a concave medial and convex lateral compartment on the tibial component, so it is a possibility that the few painful ones are associated with this joint slope in the coronal plane, which might not match the native anatomy. During development, these guided-motion knees are designed and tested using idealised models of knee motion and soft tissue constraints, using in silico simulators such as LifeMOD/KneeSIM. The results produced by this type of simulation may not be replicated either in vitro or in vivo when compounded with anatomical and surgical variability.

The clinical relevance of this study is that it shows how the variability of behaviour of the surrounding soft tissues in "real" knees may not always fit with predetermined ideas of how a TKR should move or the simulations of how it moves in a computational model, even in a controlled laboratory experiment, such as those performed here. It is also possible that the relatively small proportion of patients who had anterolateral soft tissue pain after implantation of the Journey device, had knees which were behaving beyond the range of kinematics seen in the small number of knees in this experiment. There are currently three clinical trials in progress, seeking to confirm the safety, efficacy and success rate of the Journey II device and to establish the rate of incidence of anterolateral pain. None of the trials has been designed with a control group of, for example, patients with a clinically proven TKR that does not cause this pain.

If further work were undertaken to examine the soft tissue strains after TKR, a further step should be included in the experimental procedure whereby the cadaver knees are CT-scanned with their implants in-situ, allowing measurements to be made of the positions of the tibial and femoral components. This would allow the soft tissue behaviour to be linked more directly with the implantation technique; it has been shown that, for example, a femoral component placed in over internal or external rotation, leads to altered soft tissue behaviour (Ghosh *et al.*, 2010). Being able to quantify the implant positioning with respect to the planned positioning (as defined by the surgical instrumentation) would allow component mis-positioning to either be eliminated or included as a variable. As well as the previously mentioned hamstrings force, an enhancement for both aspects of this study would be the incorporation of a ground-reaction force into the rig designs. This would not only make a more physiologically relevant testing rig but also add the ability to simulate ADLs other than just a squatting motion to the study: walking gait, chair rises and step climbing, for example. This would enable a more complete assessment of the kinematics and the soft tissue behaviour of the replaced knees to be made.

CHAPTER 7

DEVELOPMENT & ASSESSMENT OF A BICRUCIATE RETAINING TOTAL KNEE REPLACEMENT

Some of the work in this chapter has been presented in a peer-reviewed journal article:

Halewood C, Traynor A, Bellemans J, Victor J, Amis AA. Anteroposterior Laxity After Bicruciate-Retaining Total Knee Arthroplasty Is Closer to the Native Knee Than ACL-Resecting TKA: A Biomechanical Cadaver Study. *The Journal of Arthroplasty 2015;30(12):2315-9.*

7.1 Overview

This chapter describes work done to develop and test a total knee replacement (TKR) that retains both cruciate ligaments, with the aim of improving knee kinematics when compared to conventional TKRs and, as a result, improving patient function and satisfaction. The project started with a concept of having an integrated artificial anterior cruciate ligament (ACL), built into the tibial component of the TKR. Due to intellectual property (IP) constraints this aspect was abandoned before the experimental aspect of the project could begin and the focus changed to the retention of the intact ACL. Three different designs of bicruciate retaining (BCR) TKR were tested using cadaveric specimens in the laboratory and a finite element analysis (FEA) was conducted to aid the design development between phases (Appendix C).

7.2 Introduction

The ACL and PCL are known to control knee stability and tibiofemoral kinematics. The removal of the ACL for a CR prosthesis, or both ACL and PCL for a PS prosthesis, could be partially responsible for the loss of joint function that some TKR patients experience. The combined cruciate ligament function may not be adequately mimicked by conventional TKRs, causing instability and an unnatural feeling in the replaced knee which can result in reduced patient confidence, mobility and function

and an increase in related dissatisfaction. There is some in vivo evidence to suggest that there is a satisfaction and function gap between UKR and TKR patients (Noticewala *et al.*, 2012; Wiik *et al.*, 2013), and that, kinematically, a UKR performs more like the normal knee than a TKR (Patil *et al.*, 2005). Various studies have also suggested that a bi-cruciate retaining (BCR) TKR (one that keeps both the PCL and ACL) can improve replaced knee motion and patient satisfaction compared to conventional TKRs (Stiehl *et al.*, 2000; Cloutier *et al.*, 1999; Pritchett, 2011). However, the devices discussed in those studies (the Biopro and the Hermes 2C) have not often been used clinically beyond the realms of their surgeon-inventors and so large scale data on patient satisfaction following BCR TKR (like that presented for TKRs in the HES data) is not available. In addition, mechanical evaluation of any kind of BCR TKR has only been reported once in the literature (Victor *et al.*, 2009). However, all the major manufacturers have some IP related to BCR TKR surgery (Figure 7.1) and a new device, the Vanguard XP, developed by Biomet (Warsaw, IN, USA), has been given 510(k) approval by the FDA and is being used in clinical trials in the USA and Denmark (DeClaire, 2013; Lombardi, 2015).
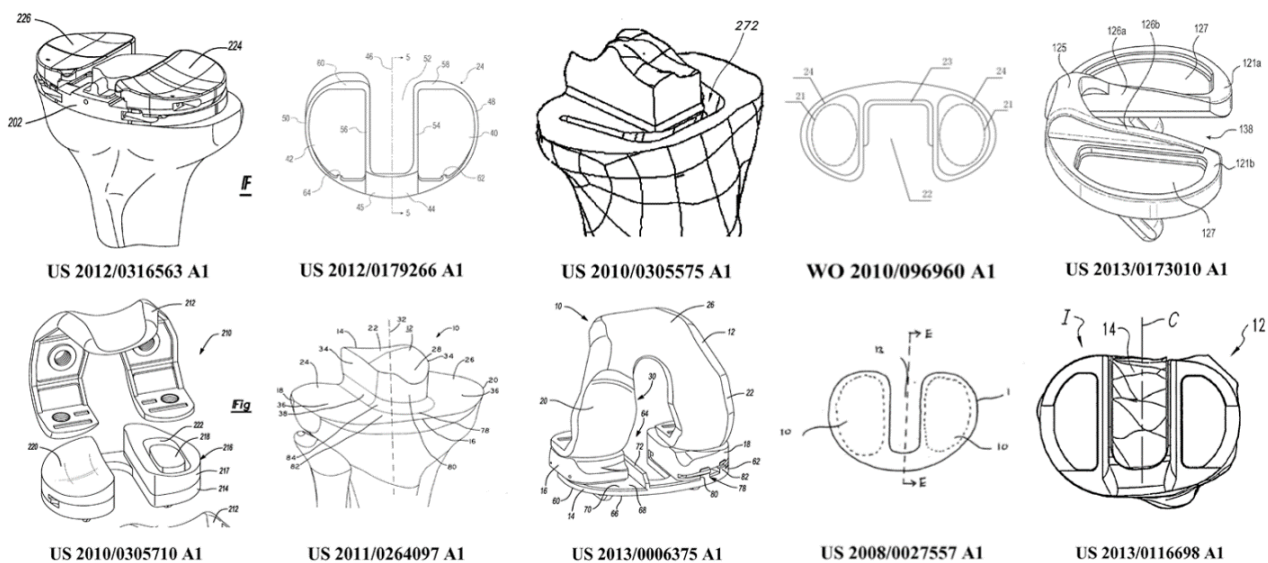
Figure 7.1 The bicruciate retaining TKR intellectual property landscape. These are a selection of images from patents pending assignment relating to bicruciate retaining total knee replacements. Beneath each image is the patent number.

7.3 Objectives

The aim of this study was to assess the surgical feasibility and the mechanical performance of a BCR TKR which preserves the ACL in cases where the integrity of the ligament has not been compromised by disease. Three cadaver studies were performed with different prototype designs and instrumentation to compare the kinematics and laxity of knees in 3 states: 1) intact; 2) BCR TKR; and 3) conventional CR TKR with resected ACL. Design modifications were made to the implant and instrumentation in between each round of cadaver testing. It was hypothesised that the kinematics with the BCR TKR would be closer to those of the intact knee that the conventional CR TKR, particularly in the anteroposterior direction. In addition to the cadaveric testing work, an FEA was undertaken to help guide the design process of the implant (Appendix C).

7.4 Materials and methods

7.4.1 Cadaveric experiments

The kinematic testing was split into three phases (Table 7.1). In total, 20 fresh-frozen cadaver knee specimens (11 male, 9 female; mean age 76 years; median age 79 years; range 51-96 years) from consented donations were obtained from the International Institute for the Advancement of Medicine (Jessup, Pennsylvania, USA) and ethical permission for the study was granted by the National Research Ethics Service. The same rig and testing method as described in the kinematic testing section of Chapter 6 were used for this study. During Phases 1 and 2, two Belgian surgeons carried out the cadaveric implantations (Steven Claes and Thomas Luyckx). For Phase 3, a British consultant orthopaedic surgeon carried out the implantations (Mr Charles Willis-Owen, London). First, the intact knee was prepared and tested between 0° and 110° of flexion, using different loading configurations to give envelopes of laxity in the AP, IE and VV directions (using loads and moments of 135 N, 7.5 Nm and 5 Nm, respectively). When the intact measurements were complete, the test regime was then repeated with the knee in 2 further states: BCR TKR and CR TKR.

Three separate phases of cadaveric experiments were conducted to compare the kinematic characteristics of a conventional CR TKR with 3 versions of a bi-cruciate retaining (BCR) TKR. All 3 of the BCR TKR designs and the CR TKR used the same cobalt-chrome alloy femoral component (Unity Knee™, Corin Group, Cirencester, UK), but had different tibial trays and UHMWPE bearings

(Table 7.1). All the surgery was carried out by experienced orthopaedic surgeons. The kinematics data were processed using Visual3D (C-Motion, MD, USA) and Excel (Microsoft, WA, USA). The intact knee at full extension was taken to be at 0° rotation and 0 mm translation in all directions; all other measurements were normalised to this point. Rotations and translations refer to tibial motion relative to the femur.

Table 7.1   Design details for the 3 phases of BCR TKR testing

Phase	Femur	Tibia	UHMWPE bearing(s)	No. Knees
1	Unity Knee™	Single piece horseshoe	Single piece, semi-constrained	8
2	Unity Knee™	Modified single piece horseshoe	Two pieces, semi-constrained	4
3	Unity Knee™	Dual Trays	Two pieces, minimally-constrained	8

7.4.1.1 Phase 1 testing details

The first cadaver study used a prototype BCR TKR with a horseshoe shaped, symmetrical tibial tray (Figure 7.2) and generic instrumentation using 8 cadaver knees. The surgery was carried out femur-first, using conventional cutting guides for the Unity Knee™. UKR instrumentation was then used for the tibial preparation. The medial and lateral vertical and horizontal sagittal cuts around the cruciate ligament attachment sites were made first, leaving a "strip" of bone in the centre of the tibial plateau (Figure 7.3). Due to the design of the tibial component, a third vertical cut, in the transverse plane, and a small horizontal cut in the coronal plane were then made at the front of the boney strip, leaving a tibial "island" around which the tibial component could fit. To avoid the need for cementation, the tibial component had 4 sharp spikes on its underside, which were pressed into the bone to get a fixation which was secure under the small loads imposed in this experiment. The single piece UHMWPE bearing was then snapped into place (Figure 7.4). This bearing surface was based on the Unity Knee™ device and had some AP conformity built into it.

POSTERIOR VIEW

PERSPECTIVE VIEW
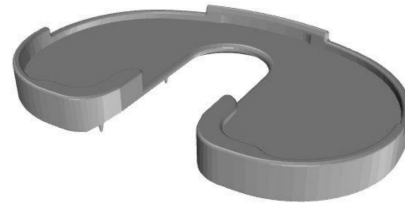
TOP VIEW
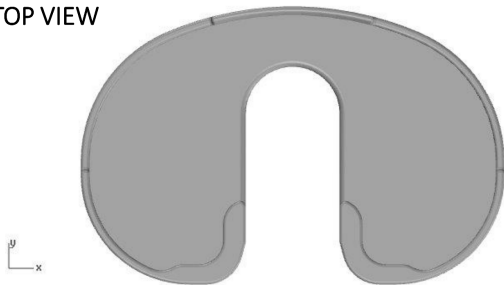
MEDIAL VIEW
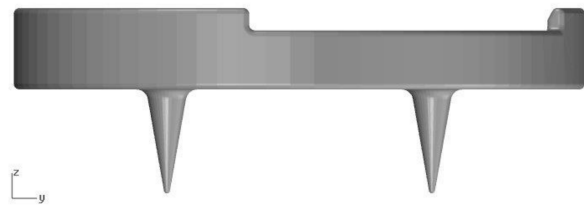
Figure 7.2   Phase 1 tibial component
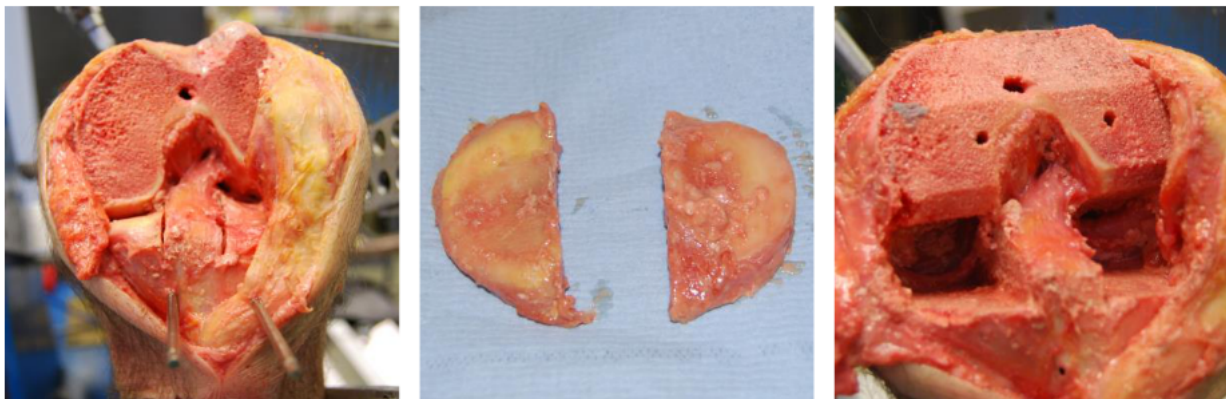
Figure 7.3   Phase 1 tibial saw cuts. Left: the two vertical sagittal cuts either side of the ACL attachment. Centre: the removed portions of the tibial plateau. Right: the prepared tibiofemoral joint awaiting implantation
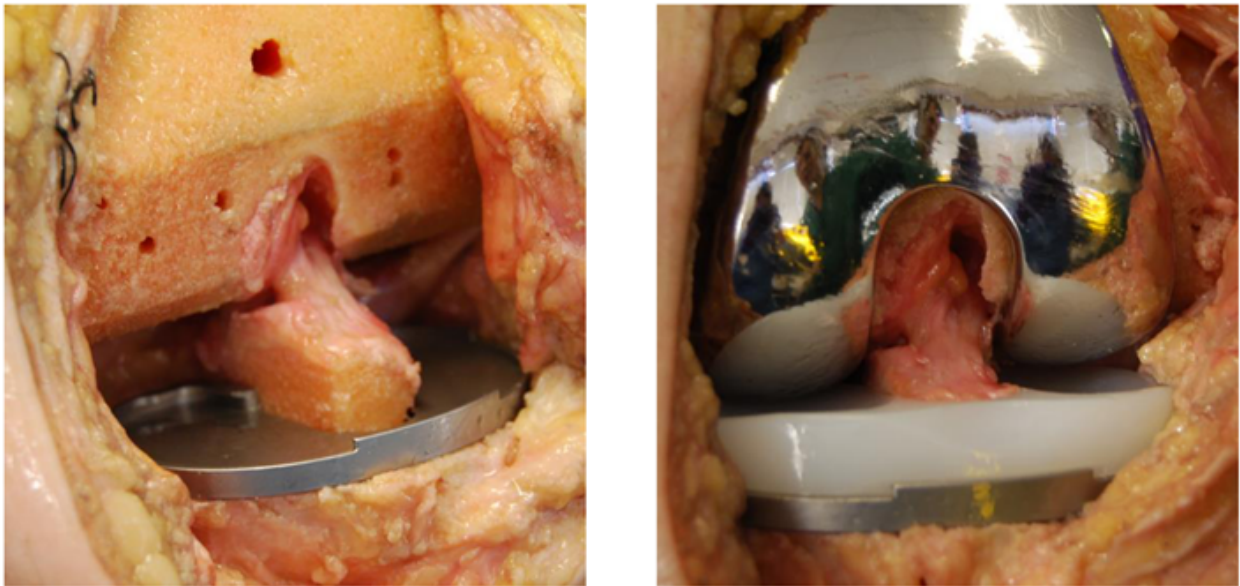
Figure 7.4   Phase 1 BCR TKR. Left: the tibial tray in-situ. Right: the completed TKR in place in a knee, ready for testing

7.4.1.2 Phase 2 testing details

Due to problems with the original horseshoe shaped tibial component (see Section 7.5), an updated tibial tray with some design improvements was tested using a further 4 knees. The tibial component was still horseshoe shaped, but had a much thinner, raised front section ("bridge": Figure 7.5) so that the final two tibial cuts in the transverse and coronal planes could be avoided, leaving more of the ACL attachment site intact (Figure 7.6). The baseplate had left and right versions, with a larger medial compartment to more closely replicate the intact knee anatomy. In addition, the plate had counter-sunk holes in its base to allow screw fixation of the device so that it could be slipped easily into position without requiring subluxation of the tibiofemoral joint. The medial cuts were made first, using UKR instruments and the lateral cuts were then based on these, to ensure that the implant could fit around the remaining bone. The bearing surface had two UHMWPE bearings, placed onto the metal tibial tray either side of the remaining tibial eminence. These bearings had a small amount of constraint built in at the anterior and posterior edges.

144

POSTERIOR VIEW

PERSPECTIVE VIEW

TOP VIEW

MEDIAL VIEW
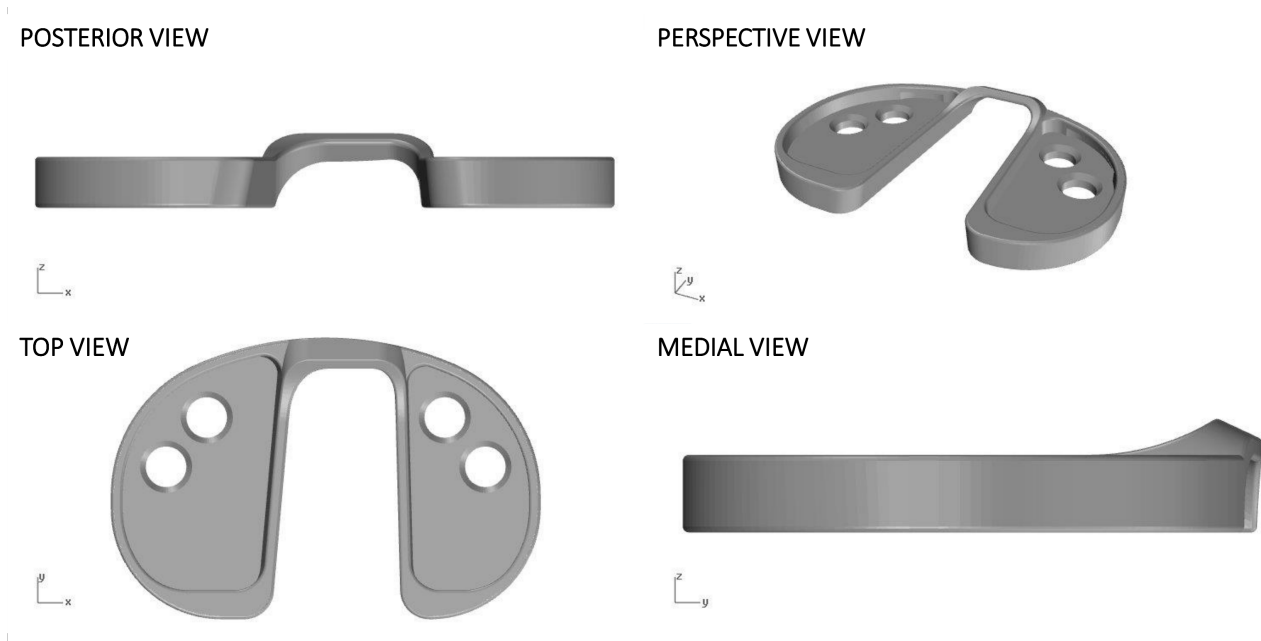
Figure 7.5   Phase 2 tibial component
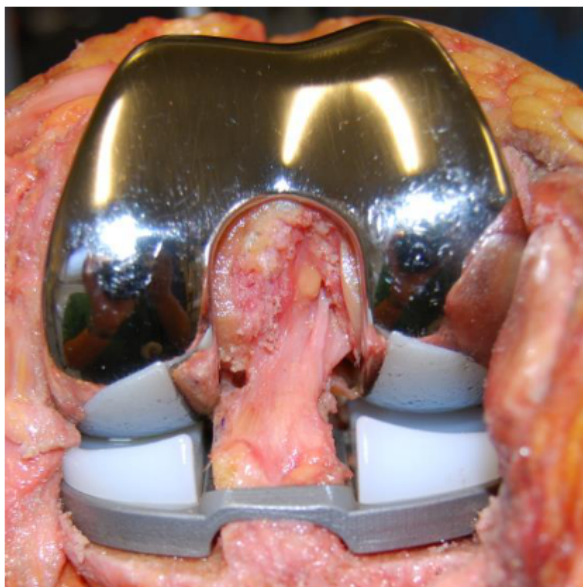
Figure 7.6   Phase 2 BCR TKR. Left: the completed BCR TKR in place in a knee. Right: the tibial tray with counter-sunk screw holes for fixation to the tibial plateau

7.4.1.3 Phase 3 testing details

Although some improvements were seen with the surgical technique and the kinematic results in Phase 2, mechanical and IP issues meant that another design change was required. A 3rd iteration of the device was tested in the laboratory using 8 cadaver knees. In this phase, the tibial component consisted of 2 parts, akin to using 2 fixed-bearing unicondylar tibial baseplates (Figure 7.7). One of the difficulties with implanting two UKRs into the same knee is getting the cuts correct so that the knee is well balanced and the joint line is as intended (in both the coronal and sagittal planes). To try to overcome this, 3D-printed cutting guides were used for the tibial preparation in this phase (Figure 7.8).

POSTERIOR VIEW   PERSPECTIVE VIEW

TOP VIEW   MEDIAL VIEW
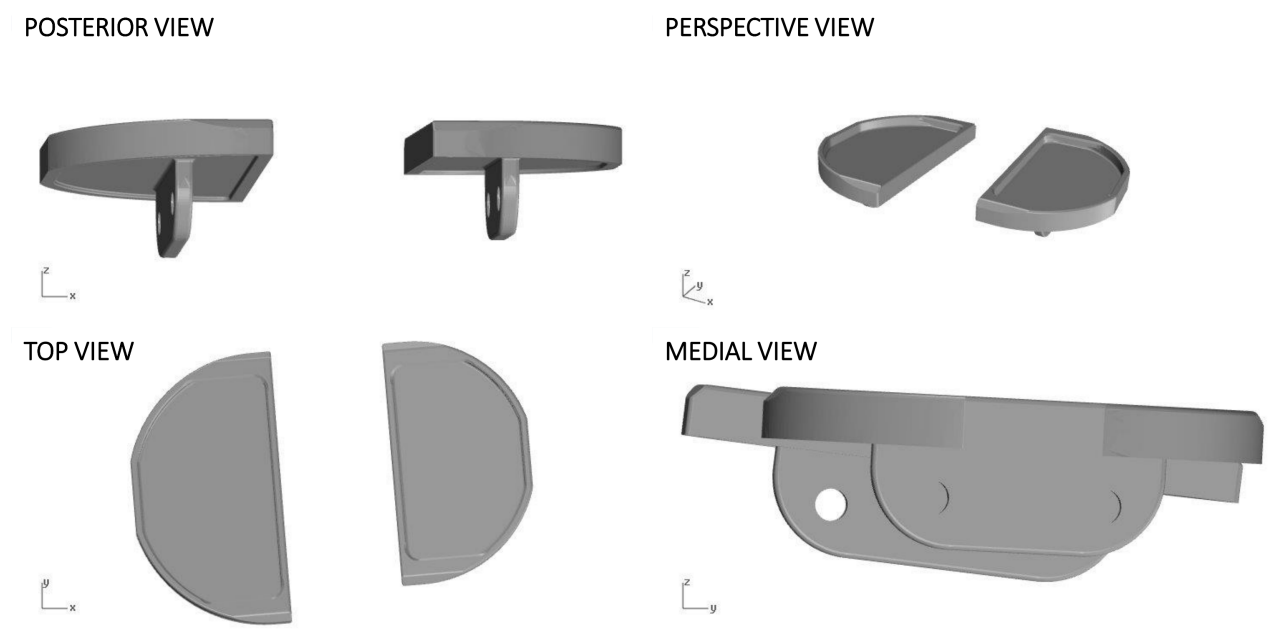
Figure 7.7   Phase 3 tibial components.   The implants shown here are positioned as they were in one of the implanted knees, with different posterior slopes medially and laterally. This was an intended feature, with the slopes matched to that of the native anatomy of the specimen, and one of the key advantages of using separate medial and lateral baseplates.
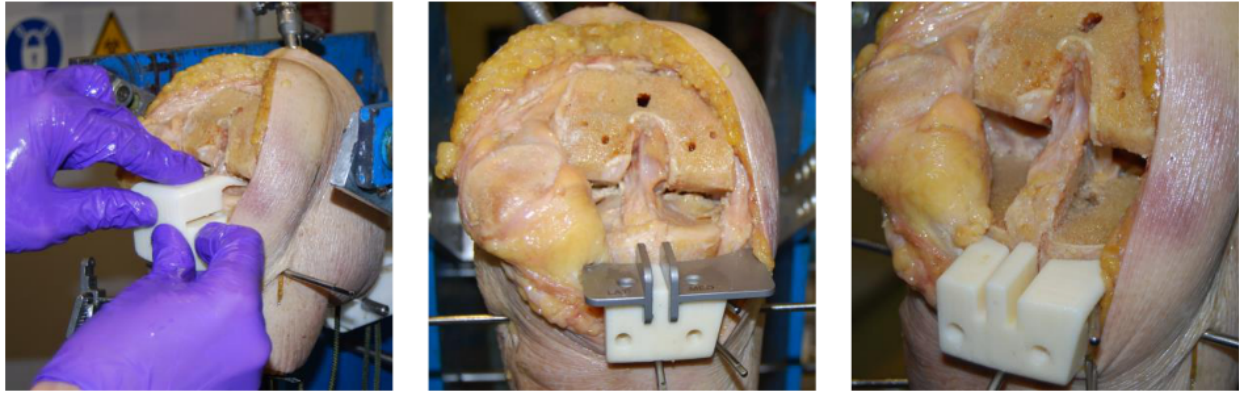
Figure 7.8 Preparation of the tibia for Phase 3. Left: positioning the 3D printed cutting guides onto the tibia. Centre: the cutting guides in place on the tibia, ready for the saw cuts to be made. Right: the prepared tibial plateau.

CT scans were taken of each of the cadaver specimens and the guides were designed using Mimics and Solidworks and manufactured by Corin, with design input from the author. With two separate medial and lateral components, there was no restriction in terms of where the bony cuts could go. If a knee had particularly large ACL and PCL attachment areas, then the lateral cuts could be lateralised and a smaller tibial component used on that side. If the lateral compartment was looser in flexion and extension than the medial compartment (as is the case in knees with a tight medial collateral ligament), a thicker lateral UHMWPE component could be used (Table 7.2). There was much more flexibility in the surgery with this device than in the previous phases. The UHMWPE bearings were completely flat in this Phase, as it was postulated that conformity between the femoral and tibial components in Phase 1 may have contributed to some of the avulsion problems observed in that experimental work.

Table 7.2 TKR sizes used for Phase 3. The lateral UHMWPE bearing was consistently thicker than its medial counterpart

Reference	Age	Side	Medial size	Medial UHMWPE bearing thickness	Lateral size	Lateral UHMWPE bearing thickness	Femur size
CH54	51	Left	3	7	4	9	4
CH62	68	Left	5	5	6	6	6
CH63	63	Left	5	5	6	11	7
CH65	83	Right	3	7	2	7	4
CH66	96	Right	4	5	3	7	6
CH67	51	Right	4	5	3	5	5
CH68	71	Right	2	7	3	13	6
CH69	68	Right	4	7	5	8	7
Mean	68.9	n/a	3.8	6.0	4.0	8.3	5.6

7.4.2 Conversion to CR TKR

In all three Phases of the experiment, once the testing was complete with the BCR TKRs, the tibial components were removed from the knee. The ACL was resected, allowing the tibia to sublux anteriorly and then the bone block was removed, using a TKR tibial cutting guide. This process was somewhat of an approximation as the sulcus of the medial compartment, usually used to align the tibial cutting guide in TKR surgery, was absent, but it was possible to check the rotational alignment of the tibial cut in the coronal plane using the extra-medullary guide. The conversion did lead to a thicker UHMWPE bearing being used than would usually be aimed for in primary TKR surgery (mean thickness of the UHMWPE bearing was 12 mm $\pm$ 1.7 mm; Table 7.3).

Table 7.3 CR TKR sizes used for Phase 3

Reference	Age	Side	CR Femur size	CR Tibia size	CR UHMWPE bearing+tray thickness
CH54	51	Left	4	4	14
CH62	68	Left	6	5	11
CH63	63	Left	7	5	14
CH65	83	Right	4	4	10
CH66	96	Right	6	5	14
CH67	51	Right	5	4	10
CH68	71	Right	6	5	12
CH69	68	Right	7	7	12
Mean	68.9	n/a	5.6	4.9	12.1

7.4.3 Statistical Analysis

A series of two-within-subject-factor repeated measures analysis of variance (ANOVA) were run in SPSS (Version 21.0, IBM Corp., NY, USA) to compare the 6 DoF kinematic characteristics of the 2 TKRs to each other and to the intact knee. If an overall significant difference was found in the inital ANOVA, pairwise comparisons with a Bonferonni correction were made at each flexion angle. Significance was set at *P=0.05*. A power calculation based on a 3 mm mean change in anteroposterior translation between the intact knee and a CR TKR in a prior study determined that a sample size of 8 was required to detect a significant change in translation with 80% power and 95% confidence.

7.5 Results

7.5.1 Phase 1

A BCR TKR was implanted into 8 left-sided cadaver knees in the laboratory, using a mixture of TKR and UKR instrumentation. It was difficult in some cases to insert the tibial component, with its backside spikes, into the tibiofemoral joint due to the presence of the ACL, which meant that the tibia did not sublux anteriorly or downwards as it would do in conventional TKR surgery. It was not always possible to get the rotational alignment of the tibial component correct (in the transverse plane) due to the anatomy of the cruciate ligament attachments. Correct ligament balancing of the joint was also more challenging than in a standard TKR procedure, again due to the presence of the ACL. The knees were almost always too tight in extension, requiring the femur to be proximalised. In cases where the knee was too tight in flexion *and* extension (and the thinnest bearing was already being used), the tibial cuts were distalised slightly.

Despite these efforts, the femoral component, in the slightly conforming UHMWPE bearing, had a tendency to act like a cam, causing increased forces in the ACL and, in turn, avulsion fractures of the remaining tibial spine at its anterior most aspect. Partial or complete fracture of the bone beneath the ACL attachment took place in 6 out of 9 knees (Figure 7.9). The avulsions usually occurred when the anterior drawer force was applied to the knee when it was at or near full extension. Attempts were made to prevent the bone block from avulsing, using bone screws and sutures (Figure 7.10), but a full set of results (for all 8 knees) was only collected between 20° and 80° knee flexion.

Despite the avulsion fractures, there was a clear trend for the total anteroposterior laxity in the BCR TKR to be closer to the intact knee than in the CR TKR, although this measure was not found to be significantly greater in the BCR TKR than in the intact knee in the overall ANOVA and no difference was found between the BCR TKR and the CR TKR (Figure 7.11; $P = 0.025$). This may have been partly due to large standard errors in the data, caused by variation between specimens which was in turn caused by the avulsion fracture problems.

Figure 7.9   Avulsion fractures during Phase 1, examples from 3 different knees
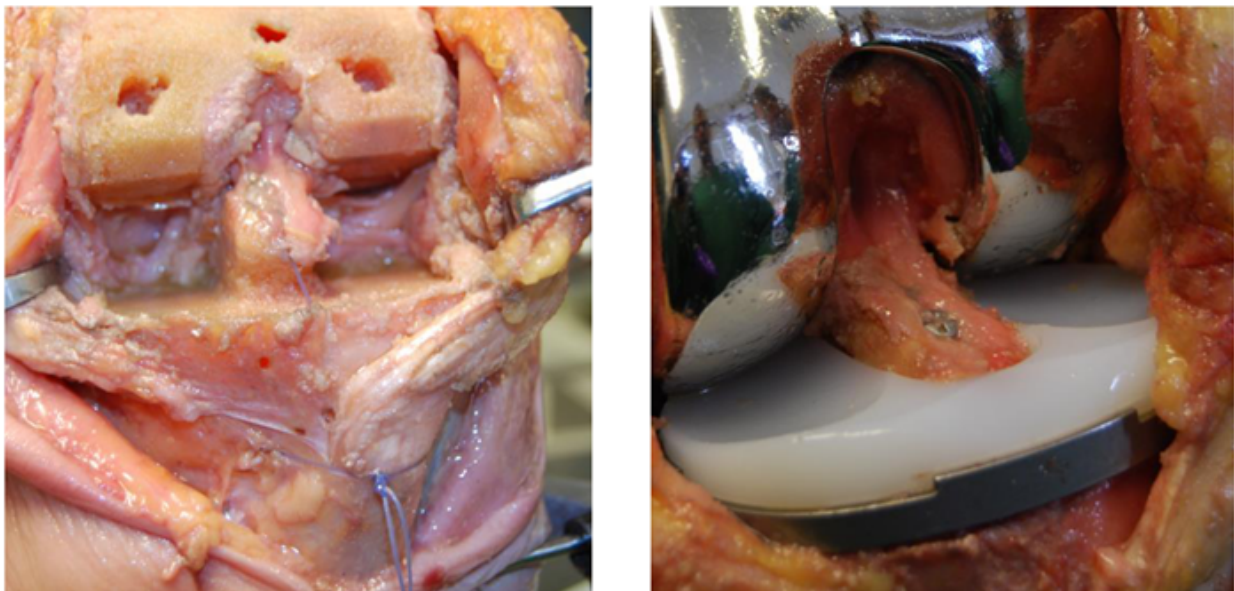
Figure 7.10   Attempts to repair the avulsion fractures in Phase 1. Left: this bone block was secured using surgical sutures. Right: a bone screw was inserted into this bone block to try to prevent it from avulsing as the knee extended
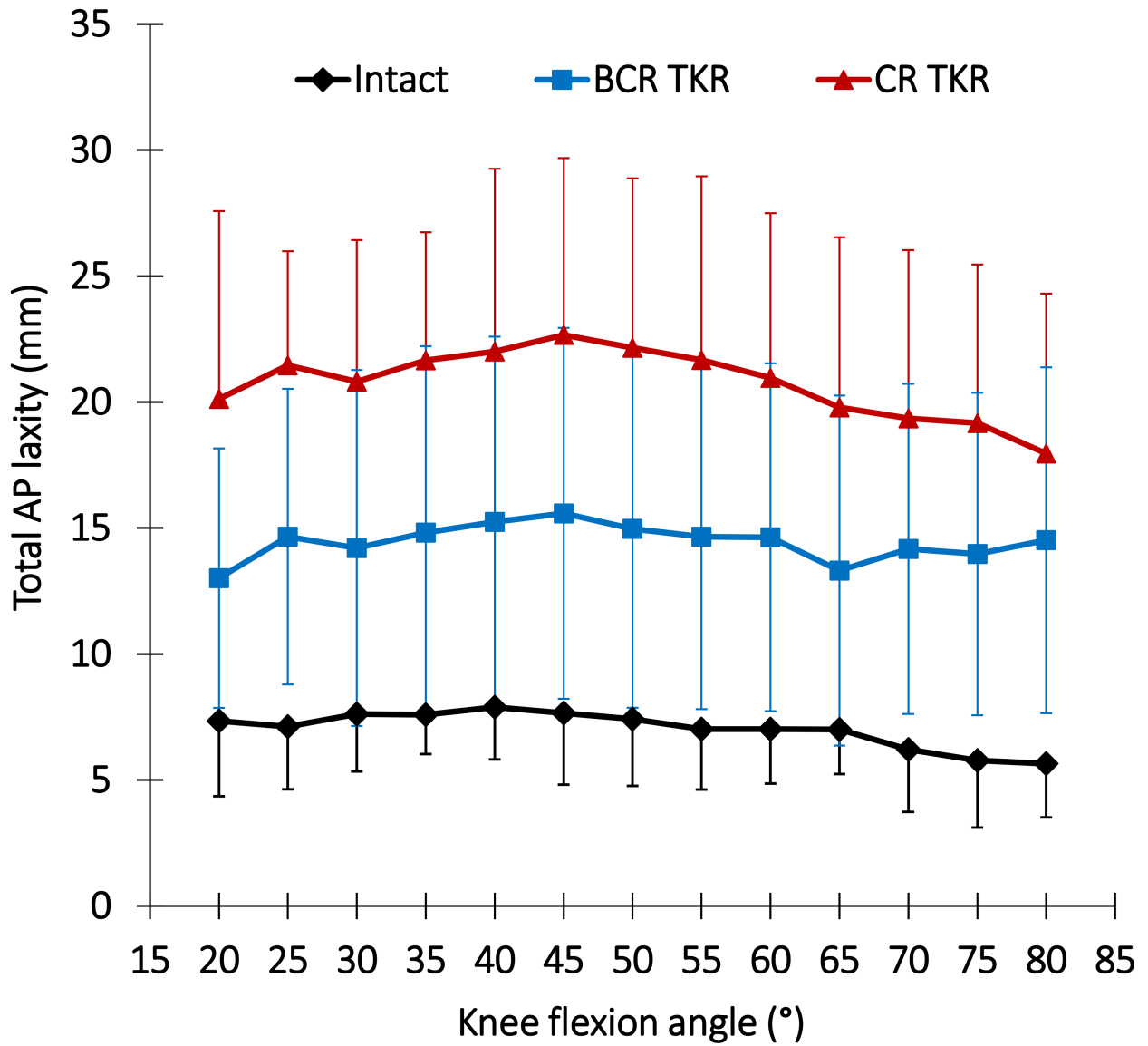
Figure 7.11   Total AP laxity in response to 135 N of anterior and posterior drawer force, Phase 1. Mean of 8 knees, error bars are 1 standard deviation

7.5.2 Phase 2

In this small study of 4 cadaver knees using the updated horseshoe tibial tray, 1 avulsion fracture occurred during kinematic testing. This represented an improvement on the levels observed in Phase 1, but was not a complete elimination of the problem. Removing the requirement for the cuts at the anterior most aspect of the tibia (to create the "island") obviously added strength to the remaining bone which was not there in Phase 1. But because the tibial baseplate was still one piece, with the lateral component attached to the medial side, a compromise often had to be made when making the sagittal cuts in order to retain as much of the cruciate ligament attachments as possible while, at the same time, preventing overhang of the baseplate in some cases and achieving the maximum possible amount of coverage of both compartments in other situations. Even with a range of sizes available, it was very clear that this compromise would always have to be made, and would have bigger implications than the under- or over-sizing of the tibial component that takes place routinely in conventional TKR surgery. In addition to these concerns, it also became apparent that the baseplate design used for this phase of testing would not pass the ASTM F1800 pre-clinical fatigue testing requirement for tibial baseplates (ASTM, 2012a), due top excessive bending stresses in the anterior "bridge". There was also a new IP conflict with another manufacturer's device.

7.5.3 Phase 3

The surgical feasibility of simultaneously implanting separate tibial trays either side of the ACL and PCL attachments using patient specific 3D-printed cutting guides was proven in this phase. No avulsion fractures were observed during testing with the BCR TKR in 8 cadaver knees.

7.5.3.1 Anteroposterior translations

The neutral path of AP motion in the intact knee consisted of a mean anterior translation of 4 mm in the first 60° of knee flexion and then a further 8 mm between 60° and 110° knee flexion. The BCR TKR started in a 4 mm more posterior position than the intact tibia ($P = 0.025$) but by 65° flexion had moved back to a similar position as the intact knee and no overall significant difference was found between the two in the overall ANOVA (Figure 7.12). The CR TKR translated less across the whole range of knee flexion than either the intact knee or the BCR TKR but was in a much more anterior position at full extension than either of them ($P < 0.02$).

Anterior laxity (that is, the difference in translation between the anterior drawer testing state and the neutral path of AP motion; see Figure 6.12 in Section 6.3.5 for an explanation of the laxity calculations) tended to be consistent across the whole range of knee flexion for the intact knee and the BCR TKR (2.9 mm $\pm$ 0.7 mm and 6.3 mm $\pm$ 1.0 mm, respectively; Figure 7.13). The CR TKR tended to exhibit greater anterior laxity beyond 35° than in early knee flexion and was found to have significantly more anterior laxity than the intact knee overall (10.1 mm $\pm$ 2.0 mm; $P = 0.006$). No significant differences in anterior laxity were found between the intact knee and the BCR TKR or between the BCR TKR and the CR TKR.

Total anteroposterior laxity was found to be significantly greater in the CR TKR than both the intact knee and the BCR TKR ($P = 0.006$, $P = 0.039$, respectively; Figures 7.14 & 7.15)
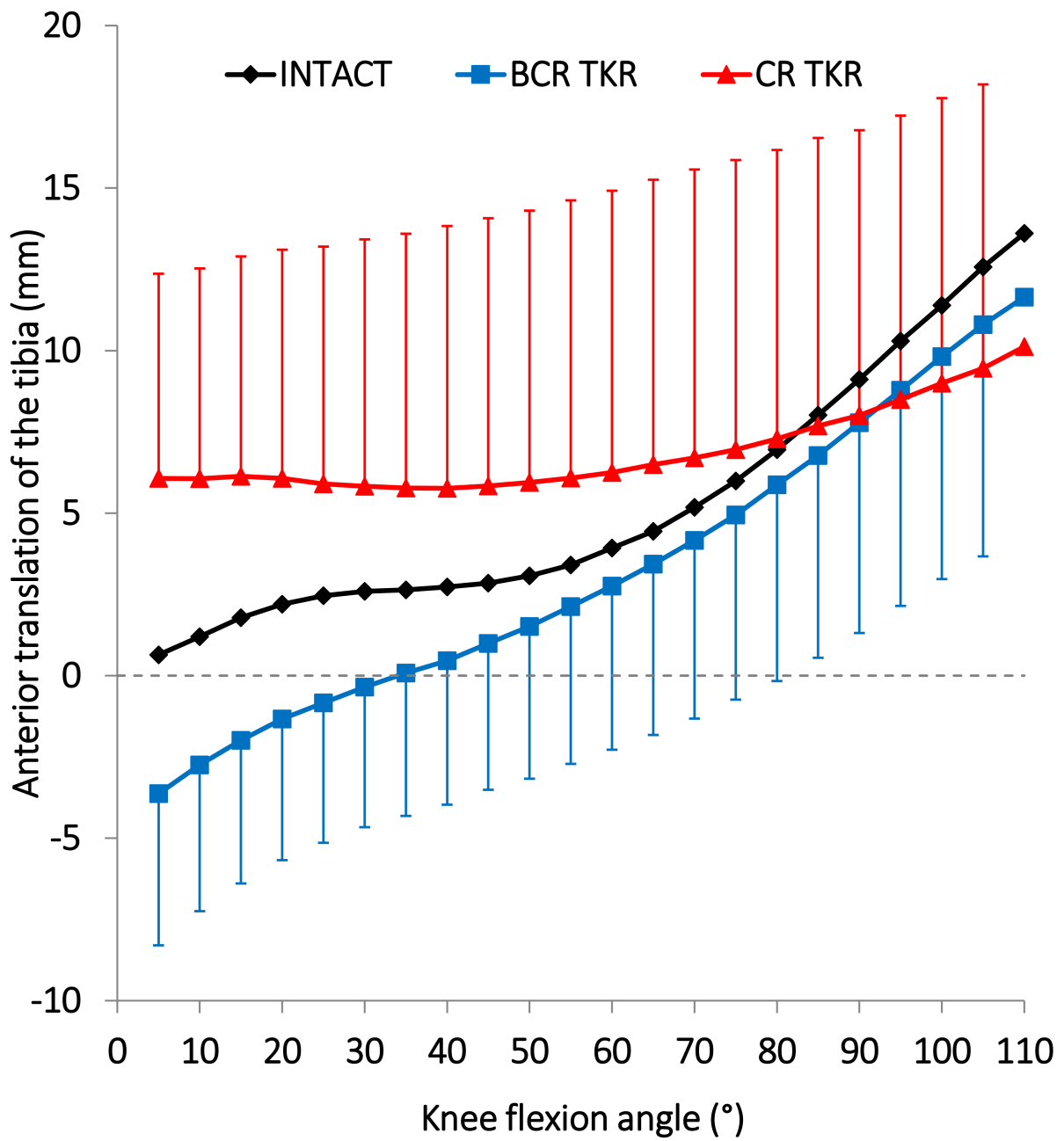
Figure 7.12   AP translation in neutral loading, Phase 3. Mean of 8 knees, error bars are 1 standard deviation
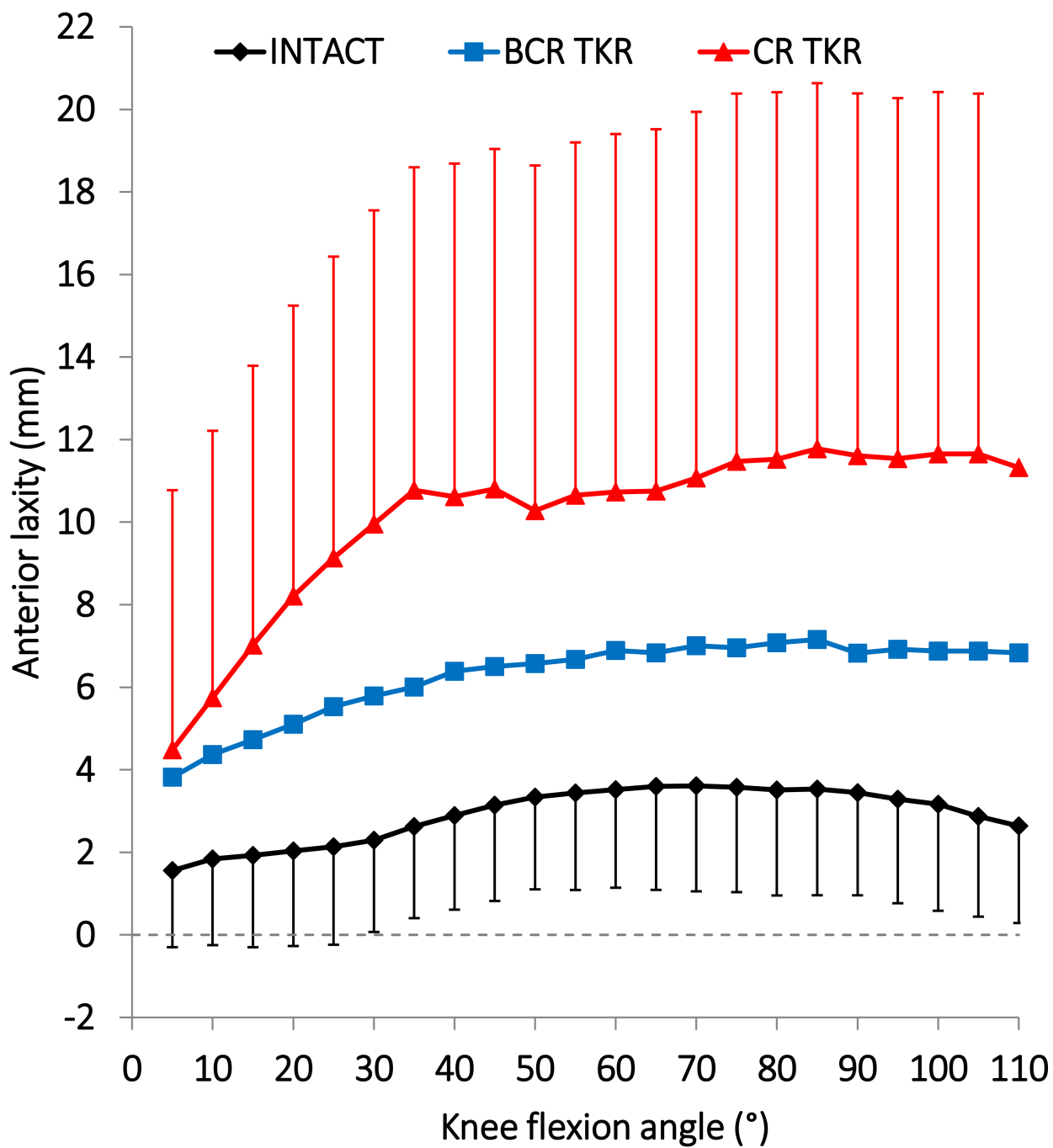
Figure 7.13   Anterior laxity, Phase 3. Mean of 8 knees, error bars are 1 standard deviation
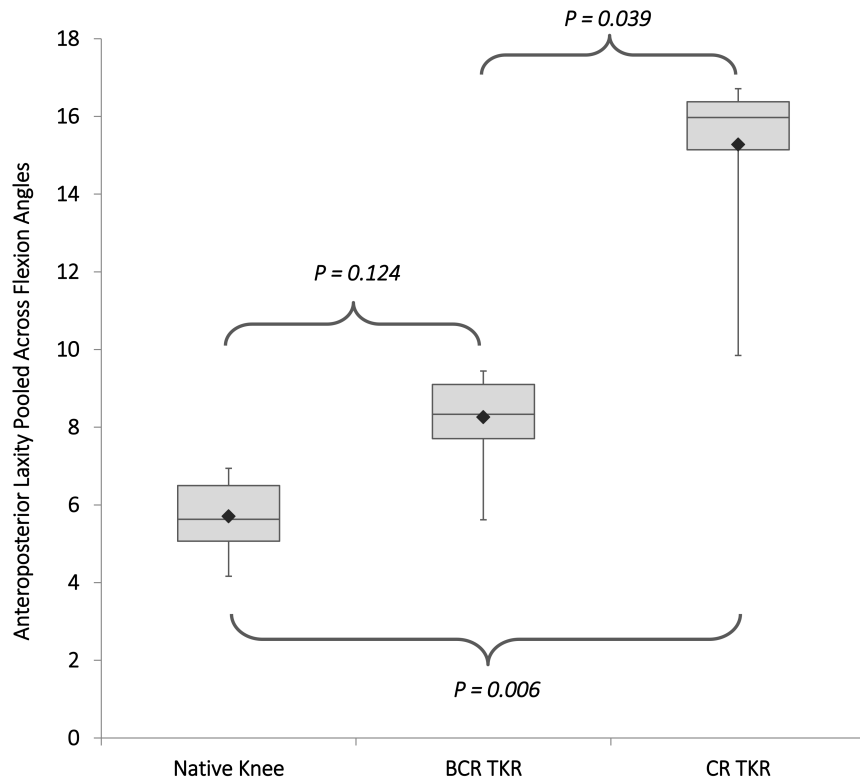
Figure 7.14   A box whisker plot showing total AP laxity pooled over all flexion angles for the 3 knee states in Phase 3. *n=8*
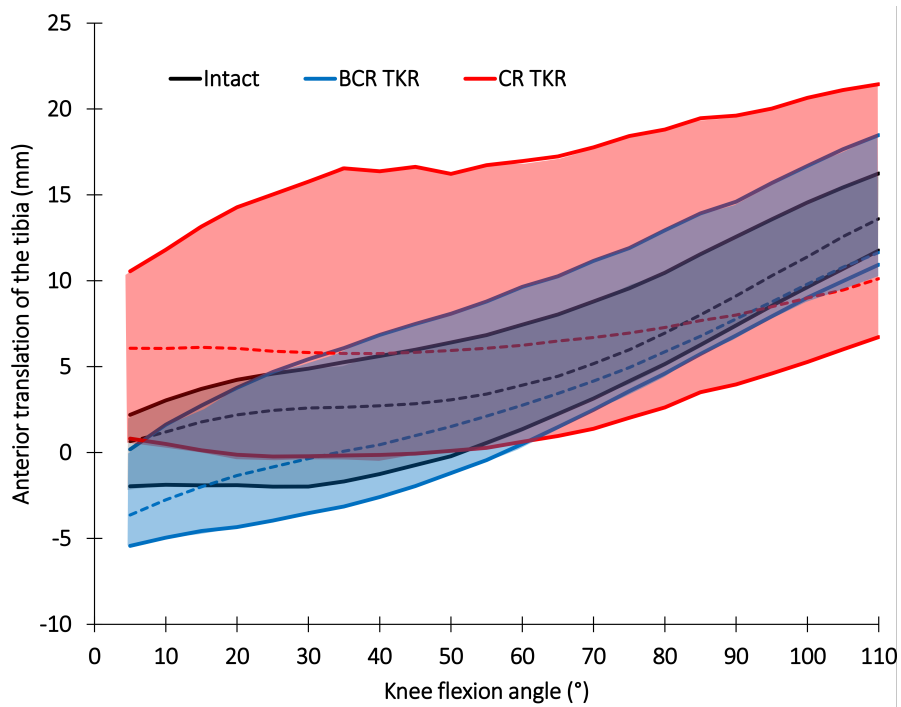
Figure 7.15   Envelopes of laxity, Phase 3. Mean of 8 knees. Dotted lines are AP translation during the neutral loading case. The shaded regions are between the anterior and posterior drawer cases, for each knee state.

7.5.3.2 Rotations

The intact knee exhibited the "screw home" mechanism as the knee extended from 30° flexion, rotating externally by around 5° ($P = 0.001$). Neither the BCR TKR or the CR TKR displayed this behaviour (Figure 7.16), instead tending to rotate continuously internally as the knee flexed. However, total IE laxity was not found to be significantly different between implants or the intact knee. All three knee states behaved similarly in varus/valgus, although the CR TKR tended to have lower total VV laxity than the intact knee or the BCR TKR, but this was not found to be significantly different (Figure 7.16). More graphs are presented in Appendix A.
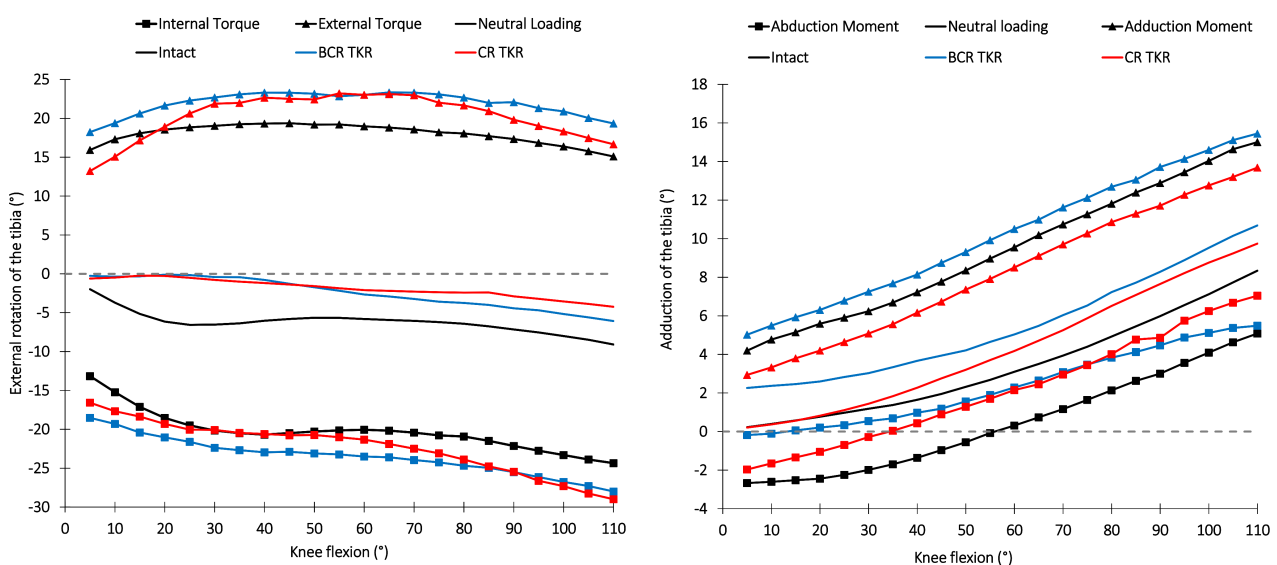
Figure 7.16   Knee rotations, Phase 3. Left: internal/external rotations. Right: varus/valgus rotations.

7.6 Discussion

The concept of a bi-cruciate retaining TKR was shown to be a valid and surgically feasible approach to reducing anteroposterior laxity in the replaced knee compared to a conventional CR TKR, in the pre-clinical setting. However, during the initial phase of experiments, the BCR TKR design frequently caused the remaining bony eminence on the tibia to avulse near knee extension. It is likely that this was due to: a) increased ACL forces caused by the insertion of the implant and the cam-like action of the femoral component on the tibial bearing surfaces, combined with b) the bony resections undermining the strength of the bone beneath the ACL attachment site.

The BCR TKR tibial component design was updated twice following Phase 1, and the avulsion fracture problem was eliminated in Phase 3 when a dual-tibial design was tested in a series of 8 cadaver tests in the laboratory. As well as eradicating the avulsion fracture problem, the dual-tibia design made the surgery a less technically challenging and much more repeatable process. Most importantly, the Phase 3 BCR TKR demonstrated anterior and anteroposterior laxity and a neutral path of translation closer to the normal knee than the conventional CR TKR, which was significantly different to the intact knee. Internal/external and valgus/varus rotational laxity did not differ significantly between devices or the intact knee, although external rotation of the tibia as the knee approached extension (the screw-home mechanism), observed in the intact knees, was eradicated by both the BCR and CR TKRs.

The motivation behind this study was that although survivorship of TKRs is excellent, patient dissatisfaction with TKRs is commonplace and PRO statistics appear to be skewed by good levels of pain relief, with post-operative functional improvement lagging behind. Improvements to PROMs are being made and the OKS has recently been supplemented with an "activity and participation" score to try to better understand patients' functional satisfaction after TKR surgery and reduce the influence of pain reduction on postoperative OKS (Dawson *et al.*, 2014). Pain relief is the primary aim of arthroplasty but abnormal knee kinematics relating to the TKR cause functional dissatisfaction and patient reported instability problems, at high socio-economic cost. The resection of the ACL during conventional TKR surgery may be to blame for some of the biomechanical inadequacies that patients experience.

BCR TKR as a possible solution to these abnormal knee kinematics after replacement is not a new concept but it is one that has not been extensively tested or widely used clinically, making it difficult to conclude whether the design does improve TKR patient function and satisfaction levels; although it does appear that patients prefer this type of device (Pritchett, 2011). Lack of surgeon enthusiasm for this type of TKR might be attributed to the perceived technical difficulty of the procedure. However, Jenny and Jenny (1998) found no significant difference in mean operative time between a BCR TKR and a conventional CR device. Another cause of apprehension relating to this type of device is associated to the lack of integrity of the ACL in OA patients. Although there is evidence to suggest that the ACL appears intact in patients indicated for TKR surgery between about 60% and 80% of the time (Lombardi, 2015; Johnson *et al.*, 2013; Lee *et al.*, 2005), there is a question of

whether it is really still functioning and there is some histological evidence that would suggest that it is only "normal" in around a quarter of patients requiring a total knee replacement (Cushner *et al.*, 2003). In situations where the ACL is deficient, it is possible that a ligament reconstruction could be incorporated with this device (Pandit *et al.*, 2006), although adding yet another layer of complexity to this procedure may not be feasible or sensible. Another potential problem that has been raised regarding BCR TKR is that, because tibiofemoral motion is controlled by the combination of the geometry of the bony articulations and the actions of the cruciate ligaments and the menisci (Wilson *et al.*, 2000), knee joint motion cannot be replicated solely via retention of the ACL, particularly because the lateral compartment slope in the sagittal plane is different to that of the medial one (Hofheinz, 2015). With the dual tibial components in Phase 3, this difference in slope could be and was accommodated, with the tibial cuts planned to match the native joint line as closely as possible.

The difference in anterior-posterior laxity between the intact and "conventional" TKR knees that was found in this study has been observed in other, similar studies (Stoddard *et al.*, 2013; Halewood *et al.*, 2014; Casino *et al.*, 2009). Lack of the screw-home mechanism in the replaced knee has also been noted in other studies examining total knee arthroplasty (Bull *et al.*, 2008; Merican and Amis, 2009); the fact that it was also eliminated in a TKR that retains the ACL perhaps confirms that this movement occurs due to a combination of factors, including the menisci and the conforming nature of the joint articulation, and not just the action of the ACL.

Victor *et al.* (2009) conducted in vitro experiments using a BCR TKR and an Oxford type knee rig. Details of the TKR design or surgical technique were not given. That study found significant differences in AP and IE motion of the femur in the BCR TKR compared to the native knee, but the authors did not examine stability of the knee joint. In a clinical study examining the Vanguard XP BCR TKR (Biomet, Warsaw, IN, USA), surgery time and intra-operative complications were assessed (Lombardi, 2015). The 6 surgeon inventors treated 383 patients in two batches (119 in the first and the remaining 258 in the second). In the first round of surgery, 10% of patients' "bone island" avulsed during surgery and the mean operative time was 82.7 minutes. After an unspecified change in operative technique, the rate of fracture fell to 2% and the operation time to 77.5 minutes. It will be interesting to observe the results of the clinical trial for this device (ClinicalTrials, 2014) and see whether the avulsion fracture is a problem after surgery and whether knee stability is improved compared to a CR TKR (the Vanguard) and if patient satisfaction is improved. The implant requires

a large resection at the anterior aspect of the ACL bone block and the slope of both compartments is matched to that of the medial side (Figure 7.17) and early clinical results suggest that reoperation rates are higher with this device than a conventional TKR (Christensen *et al.*, 2016).
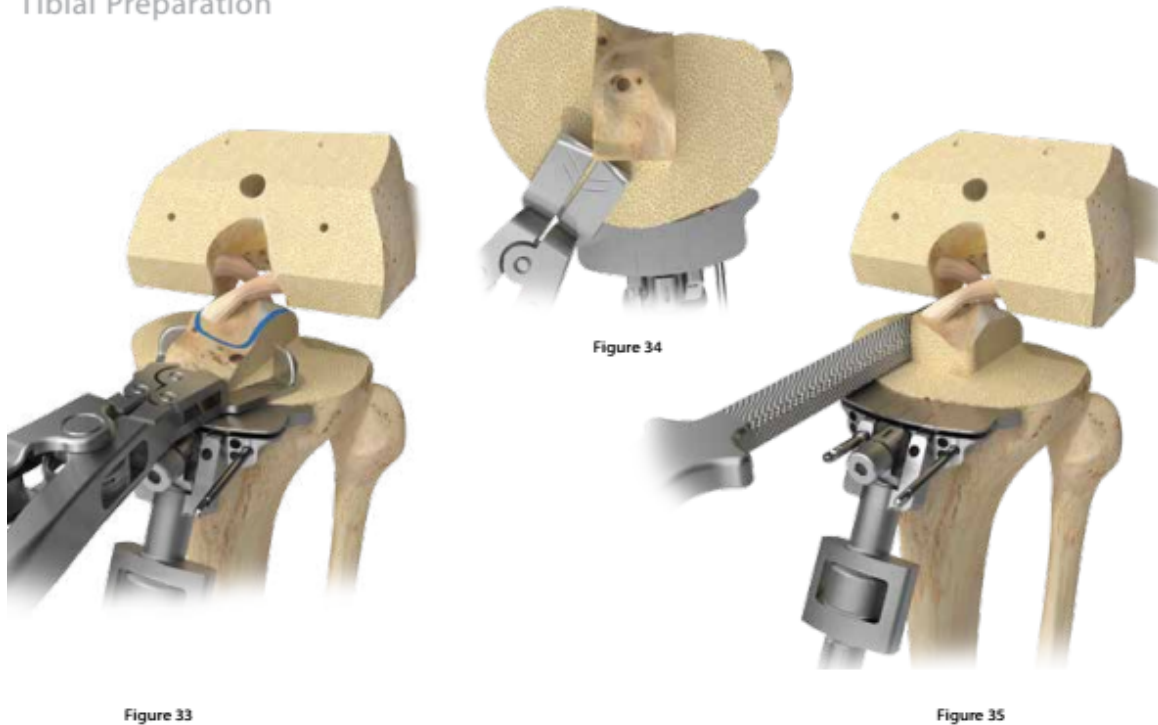
Figure 7.17   Preparation of the tibia for the Vanguard XP knee. Taken from page 23 of the surgical technique (Biomet, 2015)

7.7 Limitations

As with all cadaveric experiments, the results of this study must be considered alongside its limitations. These include the lack of hamstrings loading and the fact that the load used to simulate the quadriceps muscles acted only in one direction and remained constant over the arc of flexion. This loading was reduced from physiological to avoid patella fracture in the cadaver specimens. Open-chain knee flexion from 0° to 110° does not represent a full range of activities of daily living, which may produce different knee kinematics. In addition, none of the cadaver specimens showed signs of severe OA as would be expected in real TKR patients. However, comparing TKR kinematics to "normal" knees (as opposed to OA knees) is still relevant and avoids the problem of further specimen variability due to pathological changes. It was obviously not possible to vary the order in which the TKRs were tested; the BCR TKR always had to be tested prior to the CR TKR. This may

have had some effect on the results due to changes in the material properties of the collateral ligaments and other soft tissues over time and periods of testing. In order mitigate against these effects, each knee was prepared and tested in similar environmental conditions and the experiments were conducted as expediently as was possible.

Strengths of this study include: the repeated measures protocol design, which should have helped to eliminate the inevitable effects of inter-specimen variability; the ability to apply forces and torques accurately via the weights and rig design; the accurate measurement of the knee kinematics with 3D optical tracking; and the bespoke cutting guides for the tibial components in Phase 3, which should have ensured that the sagittal and transverse cuts were made as was intended across all the specimens.

7.8 Conclusions & further work

This study demonstrated that BCR TKR could represent an addition to the orthopaedic surgeon's armamentarium, bridging the gap between UKR and TKR, for the younger, more highly functioning patient with bi- or tri-compartmental OA and an intact and functioning ACL. It has been suggested that this procedure might suit around 15% of prospective TKR patients (Hofheinz, 2015). It appears to be surgically feasible and could improve post-operative knee laxity and kinematics, which could in turn close the functional gap between TKR patients and healthy patients, as described by Figure 3.8. Retaining the healthy ACL is desirable over mimicking its function via a cam/post and articular surface conformity, as is the case in BCS TKRs, which may not reproduce normal levels of knee laxity. The work described here demonstrated that care must be taken to preserve as much of the ACL attachment and the bone beneath it as possible, in order to avoid avulsion fractures of the tibial eminence. This study examined an early prototype of a BCR TKR and its design needs refining. Work to support further development of this device should concentrate on the simulation of more activities of the knee, using a more dynamic style knee rig, with more physiologically relevant muscle loads in a closed-chain setting. This set-up could also use Tekscan pressure sensitive film or a device such as a dual-part OrthoSensor (OrthoSensor, FL, USA) to check that the knee is correctly balanced. A clinical trial would be necessary to determine whether any biomechanical improvement due to the retention of the ACL actually translates into increased levels of patient satisfaction.

CHAPTER 8

CONCLUSIONS & FUTURE WORK

8.1 Summary

The main aim of the research described in this thesis was to investigate the performance of various types of TKR using different pre-clinical assessment methods in the laboratory, in order to enhance our understanding of TKR performance, and inform better testing methods and improved devices. Three distinct but related studies were carried out in the laboratory, using bespoke testing rigs, cadaveric specimens and 3D optical tracking equipment. A small FE study was also carried out. The work investigated several areas of research which had not been addressed previously, including: 1) the effect of altering loading distribution and magnitude on the stability characteristics of TKRs; 2) the mediolateral stability characteristics of TKRs; 3) the 6 DoF biomechanics of guided-motion TKRs; 4) the effects on the soft tissues of guided-motion TKRs and 5) research led development of a bicruciate retaining TKR.

8.2 Main contributions to knowledge

Each study produced many results from which to draw conclusions about device performance and also testing methods. This section highlights the most important findings resulting from this research.

TKR AP and IE stability is sensitive to design but may not help in device selection

The fairly simple and relatively low-cost testing methods using isolated implants were shown to be useful in terms of distinguishing between device designs. AP and IE stability characteristics varied according to the different design features, for example, the highly congruent medial-pivot type TKRs were very constrained in the AP directions, particularity around full extension, as was expected from their design features. IE stability was also sensitive to device design, although only the medial-pivot knees were tested. ML stability varied very little between devices.

As a requirement of the CE marking process, the ASTM standard testing method is a useful common-sense safety check of new devices, but can the results be used for better implant selection, as the standard claims? If there was a database of all these constraint measurements taken from TKRs then, in theory, a surgeon could pick one more suited to his or her patient. In reality, there is no such database and, even if there was, it is not proven that the results would allow such a selection to be made. Certain implants would appear more stable than others so, one could argue, those would be more suited to patients with weaker soft tissues and/or muscles surrounding the knee joint (due to old age, OA or other pathologies). But whether a less stable implant would necessarily be appropriate for patients with stronger muscles and other soft tissues in good condition is debatable. There is no follow-through yet established; does the measured implant stability (as opposed to that predicted by the design) relate to the stability of an implanted knee at all? This is not yet known, even in-vitro.

For uncomplicated primary TKR surgery, most surgeons pick the device that will best suit most of their patients and the design that their surgeon-teachers used. Maybe it is not surprising that the PFC Sigma knee, which has consistently been the most used device in primary TKR over the last 10 years, lies in the mid range of the constraint values measured during these stability tests (Figure 5.22); perhaps it presents a reliable option.

Mobile bearing TKRs rotate less than predicted

During the AP stability tests, the secondary, "coupled" rotation of the tibial component was measured. It was surprising to note that the mobile bearing version of the Saiph TKR rotated less during the AP stability tests than its fixed bearing counterpart. On closer inspection, it became clear that this was due to the bearing "rocking" on the tibial baseplate near its limits of stability, rather than rotating around the post of the polished metal tray.

Current stability assessment methods are not comprehensive enough

The results from the stability work presented in this thesis suggest that the current standard (the latest version was published in 2014 but has changed only trivially from the 2008 version followed during this study) is not comprehensive enough to adequately describe the stability characteristics of TKRs. It specifies only one axial load (710 N) and does not specify the M:L loading distribution to be used or that it is reported. Stability was shown to be sensitive to both of these variables in Chapter 5 and it is the author's recommendation that this standard test method be expanded to include more

physiologically realistic loading (twice body weight, for example) and that the loading distributions are specified to include 50:50 and 60:40 at least. Furthermore, the standard does not recommend that secondary rotations and translations are recorded. In fact, it does not state that all the degrees of freedom should be left unconstrained unless the device is asymmetrical in either the sagittal or coronal planes, despite the authors of the standard stating, in another publication:

> *"The results showed that for such testing to be meaningful, degrees of freedom other than those being tested must be free. If not, anomalous results would be obtained."* (Haider and Walker, 2005)

The rationale in the standard for "locking" the degrees of freedom other than that being tested, is that if the device is perfectly symmetrical there will be no secondary motions. However, this assumes perfect manufacturing tolerances and perfectly mounted devices in the test set up (and therefore in the clinical setting). So it seems sensible to leave all the constraints free even if the coupled motions are not evaluated, to ensure that the constraint values that are recorded are not influenced in any way by restricting the other degrees of freedom.

The author also recommends that any coupled motions that occur are recorded, particularly if M:L loading distributions other than 50:50 are used, as the secondary motions appear extremely sensitive to the loading distribution, even in the more symmetrical designs (Figure 5.16). It is not clear exactly what these secondary movements represent, but they are likely to be linked to how the device feels inside the patient and are an important consideration.

Guided-motion knees do not necessarily replicate normal knee motion

Guided-motion TKRs could be considered as a hybrid of the functional and anatomical TKR design philosophies. Although such knees are designed so that the bony anatomy of the tibiofemoral joint is more closely represented by the shape of the device (the Journey II, for instance, has a medial femoral condyle thicker than the lateral one, a slightly convex lateral tibial compartment, a larger medial tibial compartment and mismatched medial and lateral tibial slopes), the concept of guided-motion aims to control the rotations and translations of the tibiofemoral joint, rather than allowing the remaining soft tissues to take on that burden, as would be the case in a true anatomic knee. The guided-motion TKRs in Chapter 6 (the Journey and its successor the Journey II) were designed to restore normal knee motion, with an "enhanced" post-cam mechanism providing anteroposterior stability and a "built-in" screw-home mechanism. The manufacturer's claim was that normal knee motion would be

restored with the Journey but this was not confirmed by the cadaveric experiments conducted as part of this work, or by the LifeMOD/KneeSim kinematic data produced by the manufacturer (Figure 8.1). In the cadaveric experiments, the screw-home mechanism was not present in either device and the AP laxity was found to be significantly greater in the Journey II than in the intact knee and there was a trend for the Journey to be greater also. However, compared to the older, conventional TKR (Genesis II), both Journey TKRs were slightly closer to normal in terms of kinematics.
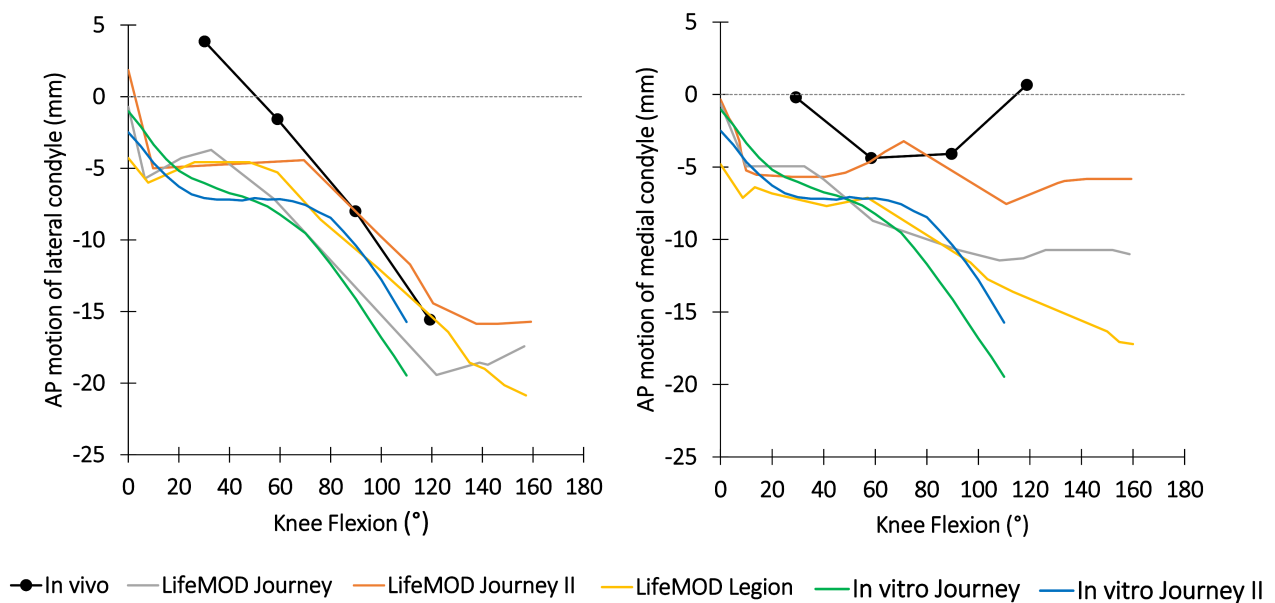
Figure 8.1   Journey and Journey II TKR kinematics compared to normal knees, modelled by LifeMOD/KneeSim and measured for this thesis in vitro. The kinematics are also compared to a non-guided-motion knee, the Legion. The normal knee data are from a fluoroscopic study conducted by Komistek *et al.* (2003). The LifeMOD/KneeSim data are taken from Smith & Nephew (2012).

Small design changes may have no impact on knee function

In the work described in Chapter 6, 2 very similar TKR designs were tested in comparison to one another (as well as to the intact knee state and a third, different device). The Journey II BCS TKR is a modified version of the Journey BCS TKR, which the manufacturer was concerned was causing patients anterolateral knee pain, due to over rotation during flexion and stretching of the soft tissues in that region of the knee.   Incremental changes were made to try to improve the device: the increased box depth and post height to prevent dislocations makes sense, although dislocations were not being studied in this piece of work. The other changes, described in detail in Chapter 6, appear to amount to a slightly less-guided guided-motion knee, which resulted in some small deviations in the cadaveric experiments, but few significant differences in performance between the 2 Journey devices. It is possible that such small design changes are within the tolerances of the

166

implant positioning during surgery (Heyse and Tibesku, 2015) and the other measurement errors associated with this type of work and that a much larger group, possibly a clinical trial, would need to be studied to observe discernible differences in patient function with the modified design. Better differentiation between devices might also have been elucidate through simulation of different ADLs.

Bicruciate retaining total knees may leave the ACL attachment vulnerable to avulsion

In the final study in this thesis, described in Chapter 7, the development and testing of a bicruciate retaining (BCR) TKR was conducted. During the first 2 phases of the development project, avulsion fractures of the ACL bone block (the bone underneath the ACL attachment on the tibial plateau) were a consistent problem. This is something that has since been reported in the literature as being an issue in the clinical setting (Lombardi, 2015), so it was not only as a result of using cadaveric knees whose bone quality was unknown. Not all TKR patients will be suitable for BCR TKR surgery (in Hofheinz (2015), Lombardi estimates that 15% of his patients are suitable candidates) and it may be that bone density should be one of the criteria for selection, as well as the more obvious requirement that the ACL is functional. However, this strategy would only help to prevent the symptom, rather than treating the cause of the issue. The experimental and computational work done in this study showed that the risk of avulsion reduced with the medialisation of the medial vertical sagittal saw cut, using flat, unconforming UHMWPE inserts on the tibial components and by not requiring the front of the bone block to be removed to accommodate the tibial tray. By having separate medial and lateral tibial trays, in a hybrid bi-UKR/TKR, correct implant positioning could be achieved without sacrificing good bone coverage or compromising the ACL attachment. It was also clear that this implant configuration, which demanded accurate positioning of the 2 tibial trays in relation to each other, was relatively straightforward to achieve when using PSI.

Bicruciate retaining total knees may improve knee stability in the anteroposterior direction

Despite the avulsion fractures seen in Phase 1 of the BCR TKR study, a reduction in total AP laxity was observable in the BCR TKR compared to the conventional CR TKR. In Phase 3, with the dual tibial components, AP laxity was significantly less in the BCR TKR than in the CR TKR and was not found to be significantly different to the intact knee. These results are promising, but further work needs to be done on the development of the device if the kinematics of the normal knee are to be more closely matched (replicating the screw-home mechanism, for example). The femoral component in this study was from a CR TKR implant and it may be that with a more

"shape-matching" femoral component, together with the minimally-constrained UHMWPE tibial trays and the presence of both cruciate ligaments, that normal knee biomechanics could be more closely met.

A combination of pre-clinical tests is required for proper characterisation of new designs

It seems clear from the work in this thesis that a range of assessments is required to properly characterise the performance of new designs of TKR. The isolated implant stability tests, mandatory for CE marking, provide some important information about TKR motion, but these studies demonstrate that new designs can be more completely characterised through cadaveric testing in the laboratory. It is the author's opinion that more evidence of superiority (rather than proof of equivalence to an existing device) should be required prior to new devices being used in the clinical setting.

8.3 Overall conclusions

This thesis describes three studies of TKR performance in the pre-clinical setting. The work in Chapter 5 led to a series of recommendations regarding the standard testing requirements for new TKRs. An in-depth study examining how small design changes might affect guided-motion TKR performance using in vitro testing methods is described in Chapter 6. Finally, in the first study of its kind, a comprehensive development and testing project was conducted, producing a bicruciate retaining TKR which demonstrated significant improvements in anteroposterior laxity over a conventional device (Chapter 7).

8.4 Future work

The pre-clinical testing methods utilised in this research can be improved. More physiologically relevant muscle loading, including the hamstrings, should be included in any updated version of the knee testing rigs, along with a ground reaction force so that there is the option to make the exercises closed-chain. Simulation of additional ADLs would also be desirable, rather than just examining pure flexion and extension. These requirements point to the development of a dynamic knee rig which can simulate walking gait and chair rising, such as those discussed in Chapter 4. In future studies using such a rig, pre- and post-intervention CT scans of the cadaver specimens should be undertaken routinely to allow the use of patient specific cutting guides, to try to minimise

implantation errors as far as is possible, and to monitor implant positioning and the effect it might have on performance.

The TKR technology landscape is a very mature one and further design developments should be mindful of the dangers of "tinkering" with what is a successful procedure. If genuine improvements are to be made in terms of patient function (and therefore satisfaction), it is the author's opinion that a more holistic view of the design and assessment process (for the device, the instrumentation and the implantation method) be taken by the manufacturers, the researchers and the surgeons alike. The final chapter of this thesis discusses this in more detail.

CHAPTER 9

FUTURE CONCEPTS IN TKR DESIGN & PRE-CLINICAL ASSESSMENT

9.1 Introduction

The total knee replacement literature is vast; in the quest for better total knee replacements there has been huge number of design tweaks, implantation strategies and follow-up studies carried out over the course of the last 4 decades or so, covering many of the TKRs in current clinical use. The results from pre-clinical and clinical studies are published on a daily basis; there were well over 1000 MEDLINE indexed journal articles about TKRs published in 2015, with over half of them focused on biomechanics, function or patient outcome. But some patients remain unhappy with their device. This chapter explores the future for the design and assessment of TKRs, informed by the work done in this thesis and the evidence in the literature, with improved patient outcome as the end goal.

Peter Walker recently published an article discussing total knee replacements and their future (2015). He wrote:

> *"There is no single process available today which will actually synthesize a design given the criteria, or from some other starting point. However, systematically asking questions can definitely produce a better result.*

> 1. *Is it better to replace all the bearing surfaces or be more focal?*
> 2. *Should as many ligaments as possible be preserved? How accurately do the original bearing surfaces need to be restored?*
> 3. *Should the kinematics be controlled by soft tissues and muscles, or by the implant's condylar surfaces and guiding surfaces?*
> 4. *How can the most durable fixation be achieved?*
> 5. *And how accurately do the components need to be inserted?*

It is not inconceivable that a design generation software could be formulated so that, given the answer to such questions, and an appropriate starting point, the best possible total knee could be designed. The end result however might look similar to an anatomical knee!"

The 5 questions posed above have been asked again and again over the last 40 years of TKR development and are still essentially unanswered; Walker suggests that by answering them systematically, TKR design could be optimised – but is it really so straight forward? It is not clear whether the solutions to all of these issues would be mutually cooperative.

The questions posed by Walker do, however, cover the unresolved problems of TKR, so it seems appropriate to consider them one by one. The first is a question about partial versus total knee replacement; this choice is not just about what option might be better in a functional sense but will also depend on how early the patient is seen by a surgeon and therefore the extent of the OA the patient presents with, as well as the condition of the cruciate ligaments. Surgeon preference will also play a role in the decision, together with the fact that single compartment OA is still an indication for TKR surgery in most hospitals. So, even if partial or more focal replacements produce superior biomechanics in the replaced knee, it may not always be possible for every patient to be prescribed one; a total replacement will sometimes be necessary.

Questions 2 and 3 refer to the debate over functional versus anatomic TKRs or, perhaps, in modern terms, guided-motion versus bicruciate retaining. Both the Journey II (guided-motion) and the Vanguard XP (BCR) are in various clinical trials. The Journey II is being assessed for rate of ITB friction pain in one trial (ClinicalTrials, 2015c) and equivalence of ROM and survivorship to those reported in the literature in another (ClinicalTrials, 2015a). The Vanguard XP is being compared to its CR equivalent in 2 trials. In the first, the primary outcome measure is the percentage of patients who report their knee feeling "normal" (ClinicalTrials, 2015b). In the second, the migration of the knee components, knee function, satisfaction and complication rates are being assessed (ClinicalTrials, 2014). It is a shame that the guided-motion TKR is not being compared to a more conventional TKR design, but it will be interesting to see the results from the BCR v CR TKR trial and whether ACL retention can improve patient outcome. It would also be interesting to try to compare the BCR TKR to a guided-motion or medial-pivot device, so which one is "better" might be discovered. It is of course most likely that one type of TKR is not best for all patients; more work

regarding patient choice and device selection is needed.

Question 4 relates to implant survival (rather than patient function and satisfaction) and refers to the fact that loosening is still the number one cause of knee implant revision after infection, and implant fixation continues to be the subject of a great deal of research, in an effort to try to develop the most durable fixation. The congruency of the UHMWPE bearing in TKRs is known to influence the stresses that are imposed onto the underlying implant-bone interface, so the answers to questions 2 and 3 must be considered alongside the loosening problem.

Walker's final query could be viewed as one relating to patient specific instrumentation, computer assisted navigation and alignment strategies in TKR surgery. Evaluating the effects of implantation accuracy and alignment on performance is very hard, not least because during everyday surgery, the method of implantation is not recorded, nor is the exact position of the implants and how that relates to the planned position. If these things were evaluated, potential links between accuracy of implantation and NJR survivorship data and the HES PROM scores could be investigated.

If any of these questions posed are to be answered, it seems that investment of further time and money in the development of better TKR surgery must continue. Implant manufacturers and surgeons want better outcomes for their TKR patients. The 20% or so of patients who are not satisfied with their device is viewed by many as unacceptably high. But outcome after TKR surgery is obviously multi-factorial; improvements rely on more than just implant design changes. Hopefully the introduction of new operative techniques and technologies such as patient specific instrumentation and kinematic alignment, as well as new devices, reflect the drive to eliminate functional problems in that percentage.

It is possible that one of the problems with new to market TKRs is that they tend to be approved for use via comparison to predicates and there is no requirement for the device to perform better than the current gold standard, it just has to be as good as something else that is already being used successfully clinically. If it is substantially different to anything else on the market, a clinical trial must be performed to prove safety and efficacy, which is a lengthy and costly process. This leads to "me too" devices which jump regulatory hurdles fairly easily but present no real improvements *and* require surgeons to learn new techniques. It has been demonstrated that patients have not been benefiting from the introduction of these new devices (Anand *et al.*, 2011). This author believes that

there needs to be a more integrated, strategic approach to developing new TKRs, encompassing everything from the design of the actual implant to the PROM scores of the patients, if function is to be improved and dissatisfaction rates are to be reduced.

9.2 Design and assessment strategy

Implant manufacturers and surgeon inventors should consider all the factors in the TKR process, how they interact with each other and what implications they have for design, assessment and patient outcome (Figure 9.1). This is a topic too large to be properly explored within this piece of work, but some ideas, informed by the studies conducted for this thesis, are presented in the following paragraphs, starting at the top of the cycle, with the patient requirements.
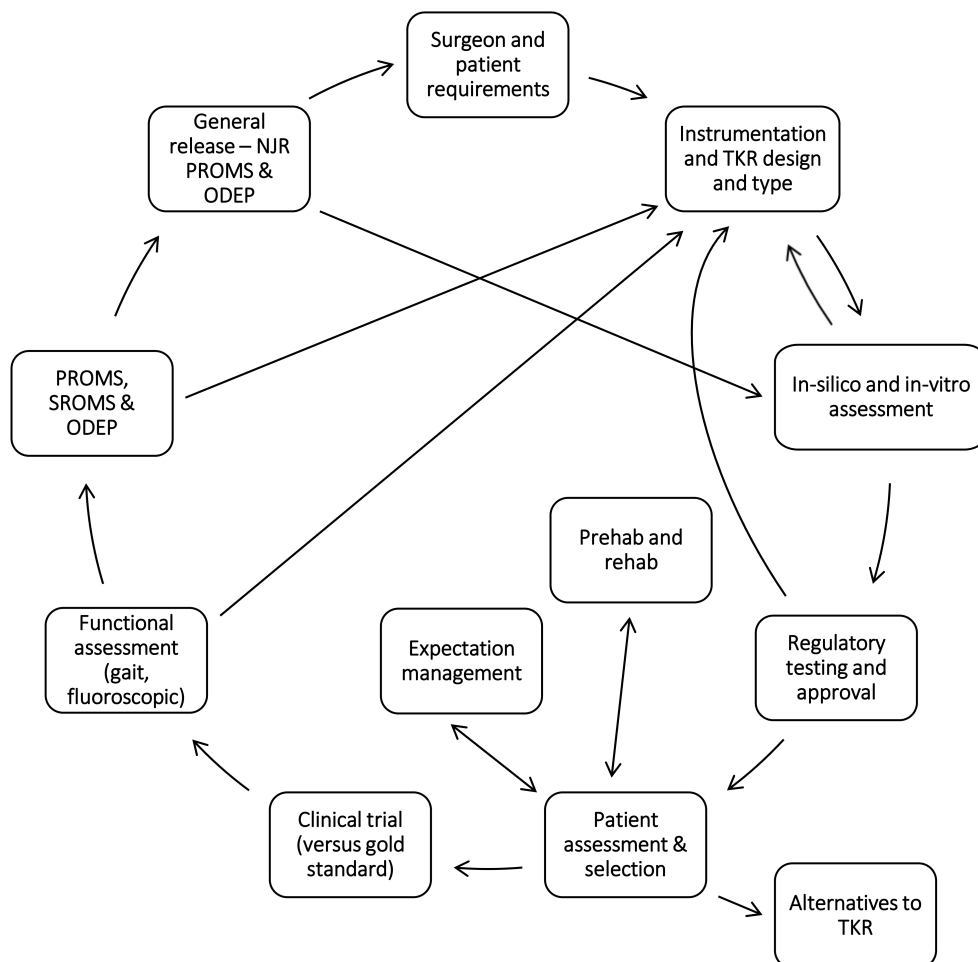

Figure 9.1   Design and assessment strategy for TKRs

9.2.1 Patient requirements

Patients who are not satisfied or feel neutral about their device constitute around 20% of all primary TKR patients; so the user requirement for a new device is a TKR that feels more normal and which will allow higher levels of patient function, in order to increase satisfaction rates. There are many reasons why a patient might not be happy with their TKR and many causes of those reasons. In the long-term, pain-free category of primary TKR patient, there are several often-cited reasons for dissatisfaction: limited range of motion; instability/giving way; feels funny/not as good as expected; clunking/catching. All of these experiences lead to below par function and can prevent patients from working, socialising or achieving their activity goals.

9.2.2 Implant design

Can changes in implant design solve the kinematic, functional problems outlined above?

The clinical trials currently under way for the Journey II guided-motion device and the Vanguard XP bicruciate retaining TKR are of great interest; it is not yet clear whether these modern TKRs bring higher levels of satisfaction to patients, although it has been suggested that BCR TKRs are preferred to conventional CR TKRs by patients (Pritchett, 2011). There have been so many incremental design changes over the course of TKR development – it is possible that a more disruptive development is required if real improvements are to be seen. In such a mature market as TKR technology, is there any development that would truly represent an advancing intervention?

Materials selection

Highly-crosslinked UHMWPE, Oxinium and ceramic femoral components, high-flexion and gender specific knees have all been touted as the game-changer in TKR design and technology, but there is no evidence in the literature that supports the suggestion that patients are more satisfied with any of these devices. Though there is no doubt that improvements in UHMWPE manufacturing have reduced the risk of wear and associated failure.

Given the compliant nature of articular cartilage and the menisci in the knee joint, it makes logical sense that compliant bearings, made from something like polycarbonate urethane (PCU) or other compliant polymer could be preferential to the relatively non-compliant UHMWPE that is universally used in replaced knees. The idea of soft or "cushion" tibial bearings has been suggested (Auger *et al.*, 1995a; Auger *et al.*, 1995b; Flannery *et al.*, 2010a; Flannery *et al.*, 2010b) and these pilot

studies showed promising results, with low friction and low wear in knee simulators and no cases of delamination or separation of the bearing from the baseplate. However, the concept does not appear to have been pursued any further. The second iteration of a PCU meniscal implant, the "NuSurface" (Active Implants, Israel) is currently in clinical trials and results from that are eagerly anticipated, to see whether or not PCU can cope in the demanding environment of the human knee joint.

Ligament retention

BCR TKRs might bring improved function to a certain cohort of TKR patient; but this is hardly disruptive technology – the very first total knee replacements retained both cruciate ligaments. However, with improved implant design that does not compromise the ACL attachment site, and technology such as PSI and instrumented trials such as the OrthoSensor (OrthoSensor, FL, USA) to aid with ligament balancing in the ACL sufficient knee, the concept of BCR TKR could be brought into the modern era of TKR surgery and potentially benefit those patients suitable for the procedure.

It seems unlikely that there will be a "silver bullet" implant that will reduce patient dissatisfaction after TKR surgery down to zero; people are inherently variable and one design of device will not be right for everybody. There are bespoke implants, made by Conformis (Bedford, MA, USA), where each device is individually designed for each patient, so that good implant-bone fit is achieved without having to resect away more healthy bone and cartilage than is necessary. This type of device will cost more to healthcare providers and insurance companies but it is possible that a tailor-made device could represent an improvement in patient outcome compared to off-the-shelf implants. The data are not yet helpful – only 7 Conformis knees were implanted in England & Wales in 2013, and none were recorded as having been used in 2014 (NJR, 2014b; NJR, 2015).

9.2.3 Implantation methods

Instrumentation is always being improved upon by manufacturers, in an attempt to make the TKR implantation process more repeatable and more accurate. Computer assisted surgery (CAS), minimally invasive surgery (MIS), patient specific instrumentation (PSI) and kinematic alignment have all been promoted as great advances in terms of implanting the devices. There is a wealth of information in the literature relating to the inaccuracies of the implantation process; the actual saw cuts and implant positions often do not correlate with the plan. It is possible that more sophisticated implantation techniques, such as CAS and PSI, might help to eliminate some of those differences

and improve postoperative outcomes, although it is not even clear that the mismatch between the plan and the reality is a cause of TKR dissatisfaction.

It might also be the case that well-planned and designed PSI have the potential to eliminate some of the learning curve that more junior surgeons must tackle when they first start using a TKR system, but the publications that assess the accuracy of these devices tend to use consultant surgeons who are extremely familiar with the generic instrumentation, which potentially biases the results in those studies.

Alignment strategies

Different alignment strategies, such as "kinematic alignment" are also being considered. Kinematic alignment, unlike the conventional gap-balancing technique used for mechanically aligned total knee replacements, aligns the distal and posterior cuts on the femur to be parallel to the flexion axis of the femur and matches the thickness of bone cuts to the thickness of the femoral component. The tibial component saw cut is then aligned so that it is parallel to the distal femoral cut, rather than aiming to be approximately perpendicular to the long axis of the tibia. The leading exponent of this technique, Stephen Howell, explains that using this method the natural joint line obliquity is maintained and trapezoidal shaped gaps are avoided. But, with the concept of kinematic alignment comes the question of whether a specifically designed TKR is required to match the surgical technique – the majority of TKR designs today use the transepicondylar axis as a reference and it has been suggested that although the kinematics after kinematic alignment are improved, PFJ contact stresses may be elevated (Ishikawa *et al.*, 2015), raising the question of whether a kinematic alignment specific device is required to ensure longevity as well as superior function.

The concept of "constitutional varus" has become a popular topic in the TKR literature in recent years; it has been suggested that if a patient is in varus prior to TKR surgery, they should be left in varus, rather than trying to correct the varus angle to 0-3°. However, it has recently been suggested that although satisfaction rates are improved when using this strategy, survivorship might be reduced with varus alignment (Liu *et al.*, 2015).

More work needs to be done to establish whether these relatively new methods of TKR implantation will prove to be beneficial to patients, improving satisfaction but not compromising on survival rates.

9.2.4 Pre-clinical assessment

In vitro

Implant manufacturers routinely commission pre-clinical assessment in the laboratory, above and beyond that which is required for pre-market approval of a new device. However, improvements could be made to these pre-clinical testing regimens. Knee kinematics should ideally be measured not only during a squatting exercise (which is infrequent in most people's everyday lives) but also during a walking gait, chair rising and possibly stair climbing/descending. Implant positioning and bone cuts should be measured using CT imaging, so potential misalignment of the device can be evaluated. Manufacturers should be obliged to report the results of these experiments in more detail, rather than referring to "data on file".

In silico

Computational simulations can be extremely powerful, if validated by well-designed in vitro work. Because loading conditions can be controlled accurately, computer models can be ideal for comparing small design changes between devices, without the vagaries of cadaveric specimens. Results from such idealised knee loading conditions must, however, be treated with some caution as there will be no patient with those ideal conditions and there is a need for more in vitro data to validate them, especially with respect to weight bearing function. Developments in probabilistic methods and population based modelling may be able to help account for patient and surgical variability, improving the predictions made by FE models.

9.2.5 The patient

Patient assessment and selection

It is possible that the "right" implant for each patient is already in existence, but that the right device is not always used for the appropriate patient. This would require a reorganisation of the current healthcare system, with patients being sent to centres that specialise in the type of TKR that they require. Even then there is no guarantee that the patient selection process would be good enough to improve satisfaction, or that the pre-clinical evaluation of the device would be good enough to accurately make those predictions. In addition, the correct type of post-operative rehabilitation is also very important considerations for successful knee replacement surgery.

Expectation management

It may be that one of the most efficient ways to improve satisfaction after TKR is via better patient education by the surgeon; expectation management has been shown to significantly affect patient outcome. The PPI presented in Appendix B highlights the lack of information that is given to TKR patients – none of those questioned as part of this work knew that they wouldn't be able to kneel down after the operation. This may seem to be a small detail but it is indicative of the lack of patient education that is routine. That expectation management might be the key to getting rid of the 20% is a depressing thought for those striving to make a TKR "forgotten" in more than the current 50% of patients, but it has been done for THR patients without this lowering of expectations (Behrend *et al.*, 2012; Eymard *et al.*, 2015).

9.2.6 Post-operative information

There is so much valuable data in the joint registries, schemes like ODEP and Hospital Episode Statistics. If these data looking at survivorship and PROMs could coordinate better with the design and pre-clinical assessment of the implant, there could be a discernible route from design to clinical outcome. For instance, the OKS is used pre and post-operation for a majority of TKR patients in England; these operations are also recorded in the NJR, with implant details. The two databases could be linked, providing PROM information relating to device type and design. With such large numbers, this would be much more powerful information than the current survivorship data (which does not appear to be very good at discerning between devices) to help steer future innovation.

9.2.7 Alternatives to TKRs

In all patients, where possible, realignment and repair should come before replacement. Combining procedures such as high tibial osteotomy and meniscal replacement (with either an allograft or an artificial implant) could prevent OA progression and the need for whole joint arthroplasty. These concomitant reconstructions are happening already, but very little is known about how the procedures interact with each other or what the long term patient outcomes are. More research should be conducted into how to carry out these concomitant procedures. If replacement is necessary, then more conservative partial replacements should be tried before TKR. Currently, isolated compartment (medial, lateral or PFJ) OA is an indication for a TKR in most hospitals, even though healthy bone and cartilage would be removed in the other compartments in the process. It has been suggested that medial unicompartmental knee replacement could be used in 25-48% of

knee arthroplasty patient candidates (Willis-Owen *et al.*, 2009; Shakespeare and Jeffcote, 2003) but currently these partial procedures make up only 9% of primary knee replacements in England, Wales and Northern Ireland. It may that more surgeon training for these techniques, often reported as being more complex than that used for TKR surgery, is required to encourage greater uptake.

9.3 Discussion

Total knee replacement surgery is hugely successful, relieving pain and improving function to hundreds of thousands of people worldwide on an annual basis. Because of the nature of a TKR, where the knee is replaced by metal and plastic, some proprioception and function is lost, and it is perhaps likely that there will always be a certain proportion of patients who will be unhappy with a TKR, no matter how many design improvements are made. One of the big difficulties is the multi-factorial nature of the unhappy TKR patient and trying to understand the cause of their dissatisfaction. Development of new devices has been the strategy for some implant companies but there seem to be many other, better value, ways in which satisfaction rates could be improved without designing new implants: comprehensive non-clinical testing to better characterise how the device functions, better patient selection, careful expectation management, partial replacements when the OA is more focal, and improved TKR surgical techniques and technology so that, at the very least, every device is implanted in the way that is intended.

REFERENCES

Adib, N., Davies, K., Grahame, R., Woo, P., and Murray, K. (2005). Joint hypermobility syndrome in childhood. A not so benign multisystem disorder? *Rheumatology* 44 (6), 744–750.

Amis, A. (2013). Biomechanics of high tibial osteotomy. English. *Knee Surgery, Sports Traumatology, Arthroscopy* 21 (1), 197–205.

Anand, R., Graves, S. E., Steiger, R. N. de, Davidson, D. C., Ryan, P., Miller, L. N., and Cashman, K. (2011). What is the benefit of introducing new hip and knee prostheses? *The Journal of Bone & Joint Surgery* 93 (Supplement 3), 51–54.

Andrews, S., Shrive, N., and Ronsky, J. (2011). The shocking truth about meniscus. *Journal of Biomechanics* 44 (16), 2737–2740.

Andriacchi, T. P., Galante, J. O., and Fermier, R. W. (1982). The influence of total knee-replacement design on walking and stair-climbing. *The Journal of Bone & Joint Surgery, American Volume* 64 (9), 1328–35.

Anglin, C., Brimacombe, J. M., Wilson, D. R., Masri, B. A., Greidanus, N. V., Tonetti, J., and Hodgson, A. J. (2008). Intraoperative vs. weightbearing patellar kinematics in total knee arthroplasty: A cadaveric study. *Clinical Biomechanics* 23 (1), 60–70.

AOANJRR (2014). Australia Orthopaedic Association National Joint Replacement Registry Annual Report.

Arno, S., Hadley, S., Campbell, K. A., Bell, C. P., Hall, M., Beltran, L. S., Recht, M. P., Sherman, O. H., and Walker, P. S. (2013). The Effect of Arthroscopic Partial Medial Meniscectomy on Tibiofemoral Stability. *The American Journal of Sports Medicine* 41 (1), 73–79.

ASTM (2008). Standard Test Method for Determination of Total Knee Replacement Constraint.

ASTM (2010). Standard Specification for Wrought Zirconium 2.5Niobium Alloy for Surgical Implant Applications (UNS R60901).

ASTM (2012a). Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements. Legal Rule or Regulation.

ASTM (2012b). Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

ASTM (2012c). Standard Specification for Total Knee Prosthesis.

Athwal, K. K., Hunt, N. C., Davies, A. J., Deehan, D. J., and Amis, A. A. (2014). Clinical biomechanics of instability related to total knee arthroplasty. *Clinical Biomechanics* 29 (2), 119–128.

Auger, D., Dowson, D., and Fisher, J. (1995a). Cushion form bearings for total knee joint replacement Part 1: design, friction and lubrication. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine* 209 (2), 73–81.

Auger, D., Dowson, D., and Fisher, J. (1995b). Cushion form bearings for total knee joint replacement Part 2: wear and durability. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine* 209 (2), 83–91.

Baker, P., Rushton, S., Jameson, S., Reed, M., Gregg, P., and Deehan, D. (2013). Patient satisfaction with total knee replacement cannot be predicted from pre-operative variables alone. *Bone Joint J* 95 (10), 1359–1365.

Baldwin, M. A., Clary, C. W., Fitzpatrick, C. K., Deacy, J. S., Maletsky, L. P., and Rullkoetter, P. J. (2012). Dynamic finite element knee simulation for evaluation of knee replacement mechanics. *Journal of biomechanics* 45 (3), 474–483.

Banks, S. (2014). Healthy Knee Motions and Implications for Arthroplasty Design. *Inernational Society for Technology in Arthroplasty Annual Congress*. Kyoto, Japan.

Barnes, C. L., Blaha, J. D., DeBoer, D., Stemniski, P., Obert, R., and Carroll, M. (2012). Assessment of a medial pivot total knee arthroplasty design in a cadaveric knee extension test model. *The Journal of arthroplasty* 27 (8), 1460–1468. e1.

Becker, R., Daring, C., Denecke, A., and Brosz, M. (2011). Expectation, satisfaction and clinical outcome of patients after total knee arthroplasty. *Knee Surgery, Sports Traumatology, Arthroscopy* 19 (9), 1433–1441.

Behrend, H., Giesinger, K., Giesinger, J. M., and Kuster, M. S. (2012). The "forgotten joint" as the ultimate goal in joint arthroplasty: validation of a new patient-reported outcome measure. *The Journal of arthroplasty* 27 (3), 430–436. e1.

Bellemans, J., Vandenneucker, H., and Vanlauwe, J. (2005). Total knee replacement. *Current Orthopaedics* 19 (6), 446–452.

Bellemans, J., Colyn, W., Vandenneucker, H., and Victor, J. (2012). The Chitranjan Ranawat Award: is neutral mechanical alignment normal for all patients?: the concept of constitutional varus. *Clinical Orthopaedics and Related Research* 470 (1), 45–53.

Beverland, D. (2010). Patient satisfaction following TKA: Bless them all! *Orthopedics* 33 (9), 657.

Biomet (2013). E1 Antioxidant Infused Technology.

Biomet (2015). Vanguard XP Total Knee System: Surgical Technique.

Bland-Sutton, J. (1897). Ligaments. Their Nature and Morphology. 2nd. London: H.K. Lewis.

Bohnsack, M., Hurschler, C., Demirtas, T., Rühmann, O., Stukenborg-Colsman, C., and Wirth, C.-J. (2005). Infrapatellar fat pad pressure and volume changes of the anterior compartment during knee motion: possible clinical consequences to the anterior knee pain syndrome. *Knee Surgery, Sports Traumatology, Arthroscopy* 13 (2), 135–141.

Bollen, S. (2000). Epidemiology of knee injuries: diagnosis and triage. *British Journal of Sports Medicine* 34 (3), 227–228.

Bourne, R., Goodfellow, J., and O'Connor, J. (1978). A functional analysis of various knee arthroplasties. *Trans Orthop Res Soc* 24, 160.

Bourne, R. B., Chesworth, B. M., Davis, A. M., Mahomed, N. N., and Charron, K. D. J. (2010). Patient Satisfaction after Total Knee Arthroplasty: Who is Satisfied and Who is Not? *Clinical Orthopaedics and Related Research* 468 (1), 57–63.

Brander, V., Gondek, S., Martin, E., and Stulberg, S. D. (2007). Pain and Depression Influence Outcome 5 Years after Knee Replacement Surgery. *Clinical Orthopaedics and Related Research* 464, 21–26.

Bull, A. M., Andersen, H. N., Basso, O., Targett, J., and Amis, A. A. (1999). Incidence and mechanism of the pivot shift. An in vitro study. *Clinical Orthopaedics and Related Research* 363 (363), 219–31.

Bull, A. M., Kessler, O., Alam, M., and Amis, A. A. (2008). Changes in knee kinematics reflect the articular geometry after arthroplasty. *Clinical Orthopaedics and Related Research* 466 (10), 2491–9.

Burleigh, A., Chanalaris, A., Gardiner, M. D., Driscoll, C., Boruc, O., Saklatvala, J., and Vincent, T. L. (2012). Joint immobilization prevents murine osteoarthritis and reveals the highly mechanosensitive nature of protease expression in vivo. *Arthritis & Rheumatism* 64 (7), 2278–2288.

Casino, D., Zaffagnini, S., Martelli, S., Lopomo, N., Bignozzi, S., Iacono, F., Russo, A., and Marcacci, M. (2009). Intraoperative evaluation of total knee replacement: kinematic assessment with a navigation system. *Knee Surgery, Sports Traumatology, Arthroscopy* 17 (4), 369–373.

Catani, F., Ensini, A., Belvedere, C., Feliciangeli, A., Benedetti, M. G., Leardini, A., and Giannini, S. (2009). In vivo kinematics and kinetics of a bi-cruciate substituting total knee arthroplasty: A combined fluoroscopic and gait analysis study. *Journal of Orthopaedic Research* 27 (12), 1569–1575.

Christensen, J. C., Brothers, J., Stoddard, G. J., Anderson, M. B., Pelt, C. E., Gililland, J. M., and Peters, C. L. (2016). Higher Frequency of Reoperation With a New Bicruciate-retaining Total Knee Arthroplasty. *Clinical Orthopaedics and Related Research*, 1–8.

Claes, S., Hermie, L., Verdonk, R., Bellemans, J., and Verdonk, P. (2012). Is osteoarthritis an inevitable consequence of anterior cruciate ligament reconstruction? A meta-analysis. *Knee Surgery, Sports Traumatology, Arthroscopy* 21 (9), 1967–76.

Clary, C. W., Fitzpatrick, C. K., Maletsky, L. P., and Rullkoetter, P. J. (2013). The influence of total knee arthroplasty geometry on mid-flexion stability: An experimental and finite element study. *Journal of Biomechanics* 46 (7), 1351–1357.

ClinicalTrials (2014). Comparison of Vanguard XP and Vanguard CR Total Knee Arthroplasties. A Trial Evaluating Early Component Migration by RSA and Patient Reported Outcome. Web Page. URL: `http://www.clinicaltrials.gov/ct2/show/NCT01966848`.

ClinicalTrials (2015a). JOURNEY II CR Total Knee System. Web Page. URL: `http://www.clinicaltrials.gov/ct2/show/NCT02440672`.

ClinicalTrials (2015b). Randomized Controlled Clinical Outcomes of the Vanguard XP Bicruciate Knee System. Web Page. URL: `http://www.clinicaltrials.gov/ct2/show/NCT02175576`.

ClinicalTrials (2015c). Safety and Efficacy of the Journey II BCS Total Knee System (NIMBLE). Web Page. URL: `http://www.clinicaltrials.gov/ct2/show/NCT01705067`.

Cloutier, J. M., Sabouret, P., and Deghrar, A. (1999). Total knee arthroplasty with retention of both cruciate ligaments. A nine to eleven-year follow-up study. *The Journal of Bone & Joint Surgery, American Volume* 81 (5), 697–702.

Coles, L., Gheduzzi, S., and Miles, A. (2014). In vitro method for assessing the biomechanics of the patellofemoral joint following total knee arthroplasty. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine* 228 (12), 1217–1226.

Cuomo, P., Rama, K. R. B. S., Bull, A. M. J., and Amis, A. A. (2007). The Effects of Different Tensioning Strategies on Knee Laxity and Graft Tension After Double-Bundle Anterior Cruciate Ligament Reconstruction. *The American Journal of Sports Medicine* 35 (12), 2083–2090.

Cushner, F. D., La Rosa, D. F., Vigorita, V. J., Scuderi, G. R., Scott, W. N., and Insall, J. N. (2003). A quantitative histologic comparison: ACL degeneration in the osteoarthritic knee. *The Journal of arthroplasty* 18 (6), 687–692.

Dakin, H., Gray, A., Fitzpatrick, R., Maclennan, G., Murray, D., and null (2012). Rationing of total knee replacement: a cost-effectiveness analysis on a large trial data set. *BMJ open* 2 (1).

Daniel, D., Malcom, L., Losse, G., Stone, M., Sachs, R., and Burks, R. (1985). Instrumented measurement of anterior laxity of the knee. *The Journal of Bone & Joint Surgery, American Volume* 67, 720–726.

Dawson, J., Beard, D. J., McKibbin, H., Harris, K., Jenkinson, C., and Price, A. J. (2014). Development of a patient-reported outcome measure of activity and participation (the OKS-APQ) to supplement the Oxford knee score. *The Bone & Joint Journal* 96-B (3), 332–338.

Dawson, J., Fitzpatrick, R., Murray, D., and Carr, A. (1998). Questionnaire on the perceptions of patients about total knee replacement. *The Journal of Bone & Joint Surgery, British Volume* 80-B (1), 63–69.

DeClaire, J. H. (2013). Bicruciate TKA: Science and Development. Conference Paper.

Delincé, P. and Ghafil, D. (2012). Anterior cruciate ligament tears: conservative or surgical treatment? A critical review of the literature. *Knee Surgery, Sports Traumatology, Arthroscopy* 20 (1) (1), 48–61.

Dennis, D. A. (2004). Evaluation of painful total knee arthroplasty. *The Journal of arthroplasty* 19 (4), 35–40.

DePuy (2010). Attune 510 K Document K101433.

DesJardins, J., Banks, S., Benson, L., Pace, T., and LaBerge, M. (2007). A direct comparison of patient and force-controlled simulator total knee replacement kinematics. *Journal of Biomechanics* 40, 9.

D'Lima, D., Trice, M., Urquhart, A., and Colwell Jr., C. (2000). Comparison Between the Kinematics of Fixed and Rotating Bearing Knee Prostheses. *Clinical Orthopaedics and Related Research* (380), 151–157.

Dossett, H. G., Swartz, G. J., Estrada, N. A., LeFevre, G. W., and Kwasman, B. G. (2012). Kinematically versus mechanically aligned total knee arthroplasty. *Orthopedics* 35 (2), e160–e169.

Duren, B. van, Pandit, H., Tilley, S., Price, M., Gill, H., Murray, D., and Thomas, N. (2012). How Effective is the "Guided Motion" of Modern Total Knee Replacements? *The Journal of Bone & Joint Surgery, British Volume* 94-B (SUPP XXIX), 102.

Edixhoven, P., Huiskes, R., and De Graaf, R. (1987). Anteroposterior Drawer Measurements in the Knee Using an Instrumented Test Device. *Clinical Orthopaedics and Related Research* 247, 232–242.

Edwards, A., Bull, A. M., and Amis, A. A. (2007a). The attachments of the anteromedial and posterolateral fibre bundles of the anterior cruciate ligament. *Knee Surgery, Sports Traumatology, Arthroscopy* 15 (12), 1414–1421.

Edwards, A., Bull, A. M., and Amis, A. A. (2007b). The attachments of the fiber bundles of the posterior cruciate ligament: an anatomic study. *Arthroscopy: The Journal of Arthroscopic & Related Surgery* 23 (3), 284–290.

Elson, D. and Brenkel, I. (2007). A conservative approach is feasible in unexplained pain after knee replacement A SELECTED COHORT STUDY. *Journal of Bone & Joint Surgery, British Volume* 89 (8), 1042–1045.

Englund, M., Roos, E. M., and Lohmander, L. S. (2003). Impact of type of meniscal tear on radiographic and symptomatic knee osteoarthritis: A sixteen-year followup of meniscectomy with matched controls. *Arthritis & Rheumatism* 48 (8), 2178–2187.

Essner, A., Herrera, L., Yau, S., Wang, A., Dumbleton, J., and Manley, M. (2005). Sequentially crosslinked and annealed UHMWPE knee wear debris. *Orthop Res Soc, Washington DC* 71.

Eymard, F., Charles-Nelson, A., Katsahian, S., Chevalier, X., and Bercovy, M. (2015). "Forgotten knee" after total knee replacement: A pragmatic study from a single-centre cohort. *Joint Bone Spine* 82 (3), 177–181.

Farahmand, F., Senavongse, W., and Amis, A. A. (1998). Quantitative study of the quadriceps muscles and trochlear groove geometry related to instability of the patellofemoral joint. *Journal of Orthopaedic Research* 16 (1), 136–43.

Flannery, M., Flanagan, S., Jones, E., and Birkinshaw, C. (2010a). Compliant layer knee bearings: part I: friction and lubrication. *Wear* 269 (5), 325–330.

Flannery, M., Jones, E., and Birkinshaw, C. (2010b). Compliant layer knee bearings. Part II: Preliminary wear assessment. *Wear* 269 (5), 331–338.

Freeman, M., Sculco, T., and Todd, R. (1977). Replacement of the severely damaged arthritic knee by the ICLH (Freeman-Swanson) arthroplasty. *Journal of Bone & Joint Surgery, British Volume* 59 (1), 64–71.

Freeman, M., Swanson, S., and Todd, R. (1973). Total replacement of the knee using the Freeman-Swanson knee prosthesis. *Clinical orthopaedics and related research* 94, 153–170.

Freeman, M. A. R. and Swanson, S. A. V. (1975). Knee joint prosthesis. US Patent 3924277.

Fukubayashi, T., Torzilli, P., Sherman, M., and Warren, R. (1982). An in vitro Biomechanical Evaluation of Anterior Posterior Motion of the Knee. *The Journal of Bone & Joint Surgery, American Volume* 64-A (2), 258–264.

Gage, B. E., McIlvain, N. M., Collins, C. L., Fields, S. K., and Dawn Comstock, R. (2012). Epidemiology of 6.6 million knee injuries presenting to United States emergency departments from 1999 through 2008. *Academic emergency medicine* 19 (4) (4), 378–385.

Ghosh, K. M., Merican, A. M., Iranpour, F., Deehan, D. J., and Amis, A. A. (2010). The effect of femoral component rotation on the extensor retinaculum of the knee. *Journal of Orthopaedic Research* 28 (9), 1136–41.

Ghosh, K. M., Merican, A. M., Iranpour-Boroujeni, F., Deehan, D. J., and Amis, A. A. (2009). Length change patterns of the extensor retinaculum and the effect of total knee replacement. *Journal of Orthopaedic Research* 27 (7), 865–70.

Gianotti, S. M., Marshall, S. W., Hume, P. A., and Bunt, L. (2009). Incidence of anterior cruciate ligament injury and other knee ligament injuries: a national population-based study. *Journal of Science and Medicine in Sport* 12 (6), 622–627.

Gluck, T. (1891). Referat über die durch das moderne chirurgische Experiment. *Arch. klin. Chit* 41, 186.

Glyn-Jones, S., Palmer, A. J. R., Agricola, R., Price, A. J., Vincent, T. L., Weinans, H., and Carr, A. J. (2015). Osteoarthritis. *The Lancet* Seminar.

Goodfellow, J., O'Connor, J., and Murray, D. (2010). A critique of revision rate as an outcome measure. *The Journal of Bone & Joint Surgery, British Volume* 92 (12), 1628–1631.

Gray, H. (2008). Gray's Anatomy. The Anatomical Basis of Clinical Practice. Edited by S. Standring. Fortieth Edition. Edinburgh: Churchill Livingstone.

Gu, Y., Roth, J. D., Howell, S. M., and Hull, M. L. (2014). How Frequently Do Four Methods for Mechanically Aligning a Total Knee Arthroplasty Cause Collateral Ligament Imbalance and Change Alignment from Normal in White Patients? *The Journal of Bone & Joint Surgery* 96 (12), e101.

Guess, T. M. and Maletsky, L. P. (2005). Computational Modeling of a Dynamic Knee Simulator for Reproduction of Knee Loading. *Journal of Biomechanical Engineering* 127 (7), 1216.

Gunston, F. H. (1971). Polycentric knee arthroplasty prosthetic simulation of normal knee movement. *Journal of Bone & Joint Surgery, British Volume* 53 (2), 272–277.

Gupte, C. M., Bull, A. M., Thomas, R. D., and Amis, A. A. (2003). The meniscofemoral ligaments: secondary restraints to the posterior drawer. Analysis of anteroposterior and rotary laxity in the intact and posterior-cruciate-deficient knee. *The Journal of Bone & Joint Surgery, British Volume* 85 (5), 765–73.

Haider, H., Walker, P. S., DesJardins, J., and Blunn, G. (2006). Effects of Patient and Surgical Alignment Variables on Kinematics in TKR Simulation Under Force-Control. *Journal of ASTM International* 3 (10), 3–16.

Haider, H. and Walker, P. (2005). Measurements of constraint of total knee replacement. *Journal of Biomechanics* 38, 341–348.

Halewood, C. and Amis, A. A. (2015). Clinically relevant biomechanics of the knee capsule and ligaments. *Knee Surgery, Sports Traumatology, Arthroscopy* 23 (10), 2789–2796.

Halewood, C., Risebury, M., Thomas, N., and Amis, A. (2014). Kinematic behaviour and soft tissue management in guided motion total knee replacement. *Knee Surgery, Sports Traumatology, Arthroscopy*, 1–9.

Hallen, L. G. and Lindahl, O. (1966). The Screw-Home Movement in the Knee-Joint. *Acta Orthopaedica Scandinavica* 37 (1), 97–106.

Hara, T., Horii, E., An, K.-N., Cooney, W. P., Linscheid, R. L., and Chao, E. Y. (1992). Force distribution across wrist joint: application of pressure-sensitive conductive rubber. *The Journal of hand surgery* 17 (2), 339–347.

Harris, I. A., Harris, A. M., Naylor, J. M., Adie, S., Mittal, R., and Dao, A. T. (2013a). Discordance Between Patient and Surgeon Satisfaction After Total Joint Arthroplasty. *The Journal of Arthroplasty* 28 (5), 722–727.

Harris, K., Dawson, J., Doll, H., Field, R. E., Murray, D. W., Fitzpatrick, R., Jenkinson, C., Price, A. J., and Beard, D. J. (2013b). Can pain and function be distinguished in the Oxford Knee Score in a

meaningful way? An exploratory and confirmatory factor analysis. *Quality of Life Research* 22 (9), 2561–2568.

Harris, M. L., Morberg, P., Bruce, W. J. M., and Walsh, W. R. (1999). An improved method for measuring tibiofemoral contact areas in total knee arthroplasty: a comparison of K-scan sensor and Fuji film. *Journal of Biomechanics* 32 (9), 951–958.

Heever, D. van den, Scheffer, C., Erasmus, P., and Dillon, E. (2012). In vitro measurement of tibiofemoral kinematics after patient-specific unicompartmental knee replacement.

Heim, C. S., Postak, P. D., and Greenwald, A. S. (1996). Stability Characteristics of Posterior Stabilized Total Knee Systems. Cleveland.

Heim, C. S., Postak, P. D., Plaxton, N. A., and Greenwald, A. S. (2001). Classification of Mobile-Bearing Knee Designs: Mobility and Constraint. *The Journal of Bone & Joint Surgery, American Volume* 83 (2), S32–37.

Herrera, L., Sweetgall, J., Essner, A., and Wang, A. (2008). Evaluation of sequentially crosslinked and annealed wear debris. *World Biomater Cong, Amsterdam* 583.

Heyse, T. J. and Tibesku, C. O. (2015). Improved tibial component rotation in TKA using patient-specific instrumentation. *Archives of orthopaedic and trauma surgery* 135 (5), 697–701.

Hill, P. F., Vedi, V., Williams, A., Iwaki, H., Pinskerova, V., and Freeman, M. A. R. (2000). Tibiofemoral movement 2: the loaded and unloaded living knee studied by MRI. *The Journal of Bone & Joint Surgery, British Volume* 82-B (8), 1196–1198.

Hofheinz, E. (2015). Lombardi Takes on Ranawat Over Bi-Cruciate Retaining Total Knees. Edited by R. Young. URL: `http://ryortho.com/2015/03/lombardi-takes-on-ranawat-over-bi-cruciate-retaining-total-knees/`.

Hoshino, Y. and Tashman, S. (2012). Internal tibial rotation during in vivo, dynamic activity induces greater sliding of tibio-femoral joint contact on the medial compartment. *Knee Surgery, Sports Traumatology, Arthroscopy* 20 (7), 1268–1275.

Howell, S. M., Papadopoulos, S., Kuznik, K. T., and Hull, M. L. (2013). Accurate alignment and high function after kinematically aligned TKA performed with generic instruments. *Knee Surgery, Sports Traumatology, Arthroscopy* 21 (10), 2271–2280.

HSCIC (2013). Provisional Monthly Patient Reported Outcome Measures (PROMs) in England - April 2011 to March 2012, Pre- and post-operative data.

Hui, C., Salmon, L. J., Kok, A., Williams, H. A., Hockers, N., Tempel, W. M. van der, Chana, R., and Pinczewski, L. A. (2011). Long-term survival of high tibial osteotomy for medial compartment osteoarthritis of the knee. *The American journal of sports medicine* 39 (1), 64–70.

Hunt, N. C., Ghosh, K. M., Blain, A. P., Rushton, S. P., Longstaff, L. M., and Deehan, D. J. (2015). No statistically significant kinematic difference found between a cruciate-retaining and posterior-stabilised Triathlon knee arthroplasty: a laboratory study involving eight cadavers examining soft-tissue laxity. *Bone & Joint Journal* 97-B (5), 642–648.

Hunt, N. C., Ghosh, K. M., Blain, A. P., Athwal, K. K., Rushton, S. P., Amis, A. A., Longstaff, L. M., and Deehan, D. J. (2014). How does laxity after single radius total knee arthroplasty compare with the native knee? *Journal of Orthopaedic Research*.

Insall, J. N., Dorr, L. D., Scott, R. D., and Scott, W. N. (1989). Rationale of the Knee Society clinical rating system. *Clinical Orthopaedics and Related Research* 248 (11), 13–14.

Isberg, J., Faxén, E., Laxdal, G., Eriksson, B., Kärrholm, J., and Karlsson, J. (2011). Will early reconstruction prevent abnormal kinematics after ACL injury? Two-year follow-up using dynamic radiostereometry in 14 patients operated with hamstring autografts. *Knee Surgery, Sports Traumatology, Arthroscopy* 19 (10), 1634–1642.

Ishikawa, M., Kuriyama, S., Ito, H., Furu, M., Nakamura, S., and Matsuda, S. (2015). Kinematic alignment produces near-normal knee motion but increases contact stress after total knee arthroplasty: A case study on a single implant design. *The Knee* Available online 13 April 2015.

ISO (2009). ISO 14243. Implants for surgery. Wear of total knee-joint prostheses.

Iwaki, H., Pinskerova, V., and Freeman, M. A. R. (2000). Tibiofemoral movement 1: the shapes and relative movements of the femur and tibia in the unloaded cadaver knee. *The Journal of Bone & Joint Surgery, British Volume* 82-B (8), 1189–1195.

Jacobson, A. F., Myerscough, R. P., DeLambo, K., Fleming, E., Huddleston, A. M., Bright, N., and Varley, J. D. (2008). Patients' perspectives on total knee replacement. *AJN The American Journal of Nursing* 108 (5), 54–63.

Jenny, J. Y. and Jenny, G. (1998). Preservation of anterior cruciate ligament in total knee arthroplasty. *Archives of Orthopaedic and Trauma Surgery* 118 (3), 145–148.

Johnson, A., Howell, S., Costa, C., and Mont, M. (2013). The ACL in the Arthritic Knee: How Often Is It Present and Can Preoperative Tests Predict Its Presence? *Clinical Orthopaedics and Related Research* 471 (1), 181–188.

Kakarlapudi, T. K. and Bickerstaff, D. R. (2000). Knee instability: isolated and complex. *British Journal of Sports Medicine* 34 (5), 395–400.

Kettelkamp, D. B. and Leach, R. B. (1973). Total Knee Replacement: Perspective. *Clinical orthopaedics and related research* 94, 2–3.

Kim, T. K., Kwon, S. K., Kang, Y. G., Chang, C. B., and Seong, S. C. (2010). Functional disabilities and satisfaction after total knee arthroplasty in female Asian patients. *The Journal of arthroplasty* 25 (3), 458–464.

Kittl, C., Halewood, C., Stephen, J. M., Gupte, C. M., Weiler, A., Williams, A., and Amis, A. A. (2014). Length Change Patterns in the Lateral Extra-articular Structures of the Knee and Related Reconstructions. *The American Journal of Sports Medicine* 43 (2), 354–62.

Klein, R., Serpe, L., Kester, M., Edidin, A., Fishkin, Z., Mahoney, O., and Schmalzried, T. (2003). Rotational Constraint in Posterior-Stabilized Total Knee Prostheses. *Clinical Orthopaedics and Related Research* 410, 82–89.

Komistek, R. D., Dennis, D. A., and Mahfouz, M. (2003). In vivo fluoroscopic analysis of the normal human knee. *Clinical orthopaedics and related research* 410, 69–81.

Kondo, E., Merican, A. M., Yasuda, K., and Amis, A. A. (2011). Biomechanical Comparison of Anatomic Double-Bundle, Anatomic Single-Bundle, and Nonanatomic Single-Bundle Anterior Cruciate Ligament Reconstructions. *The American Journal of Sports Medicine* 39 (2), 279–288.

Koo, S. and Andriacchi, T. P. (2008). The knee joint center of rotation is predominantly on the lateral side during normal walking. *Journal of Biomechanics* 41 (6), 1269–1273.

Kozanek, M., Hosseini, A., Liu, F., Velde, S. K. V. de, Gill, T. J., Rubash, H. E., and Li, G. (2009). Tibiofemoral kinematics and condylar motion during the stance phase of gait. *Journal of Biomechanics* 42 (12), 1877–1884.

Kuster, M. S., Bitschnau, B., and Votruba, T. (2004). Influence of collateral ligament laxity on patient satisfaction after total knee arthroplasty: a comparative bilateral study. *Archives of Orthopaedic and Trauma Surgery* 124 (6), 415–7.

Kuster, M. S., Wood, G. A., Stachowiak, G. W., and Gächter, A. (1997). Joint load considerations in total knee replacement. *Journal of Bone & Joint Surgery, British Volume* 79 (1), 109–113.

Lee, G.-C., Cushner, F. D., Vigoritta, V., Scuderi, G. R., Insall, J. N., and Scott, W. N. (2005). Evaluation of the Anterior Cruciate Ligament Integrity and Degenerative Arthritic Patterns in Patients Undergoing Total Knee Arthroplasty. *The Journal of Arthroplasty* 20 (1), 59–65.

Little, C. B., Barai, A., Burkhardt, D., Smith, S. M., Fosang, A. J., Werb, Z., Shah, M., and Thompson, E. W. (2009). Matrix metalloproteinase 13-deficient mice are resistant to osteoarthritic cartilage erosion but not chondrocyte hypertrophy or osteophyte development. *Arthritis & Rheumatism* 60 (12), 3723–3733.

Liu, H.-x., Shang, P., Ying, X.-Z., and Zhang, Y. (2015). Shorter survival rate in varus-aligned knees after total knee arthroplasty. English. *Knee Surgery, Sports Traumatology, Arthroscopy*, 1–9.

Lohmander, L. S., Englund, P. M., Dahl, L. L., and Roos, E. M. (2007). The Long-term Consequence of Anterior Cruciate Ligament and Meniscus Injuries: Osteoarthritis. *The American Journal of Sports Medicine* 35 (10), 1756–1769.

Lombardi, A. (2015). The Bi-Cruciate Retaining TKA: A Thing of Beauty Is a Joy Forever - Affirms. *Current Concepts in Joint Replacement (CCJR) Winter 2014*. Orlando, Florida.

Luyckx, L., Luyckx, T., Bellemans, J., and Victor, J. (2010). Iliotibial band traction syndrome in guided motion TKA. A new clinical entity after TKA. *Acta Orthopaedica Belgica* 76, 507–12.

Machotka, Z., Scarborough, I., Duncan, W., Kumar, S., and Perraton, L. (2010). Anterior cruciate ligament repair with LARS (ligament advanced reinforcement system): a systematic review. *BMC Sports Science, Medicine and Rehabilitation* 2 (1), 29.

Maffulli, N., Longo, U. G., Campi, S., and Denaro, V. (2010). Meniscal tears. *Open access journal of sports medicine* 1, 45.

Mancuso, C. A., Sculco, T. P., and Salvati, E. A. (2003). Patients with poor preoperative functional status have high expectations of total hip arthroplasty. *The Journal of Arthroplasty* 18 (7), 872–8.

Markolf, K., Kochan, A., and Amstutz, H. (1984). Measurement of Knee Stiffness and Laxity in Patients with Documented Absence of the Anterior Cruciate Ligament. *The Journal of Bone & Joint Surgery, American Volume* 66-A (2), 242–253.

Masouros, S. D., Bull, A. M. J., and Amis, A. A. (2010). Biomechanics of the Knee Joint. *Orthopaedics and Trauma* 24 (2), 84–91.

McClelland, J. A., Webster, K. E., and Feller, J. A. (2007). Gait analysis of patients following total knee replacement: A systematic review. *The Knee* 14 (4), 253–263.

McDermott, I., Sharifi, F., Bull, A., Gupte, C., Thomas, R., and Amis, A. (2004). An anatomical study of meniscal allograft sizing. *Knee surgery, sports traumatology, arthroscopy* 12 (2), 130–135.

McEwen, H., Barnett, P., Bell, C., Farrar, R., Auger, D., Stone, M., and Fisher, J. (2005). The influence of design, materials and kinematics on the in vitro wear of total knee replacements. *Journal of biomechanics* 38 (2), 357–365.

Merican, A. M. and Amis, A. A. (2009). Iliotibial band tension affects patellofemoral and tibiofemoral kinematics. *Journal of Biomechanics* 42 (10), 1539–46.

Merican, A. M., Ghosh, K. M., Deehan, D. J., and Amis, A. A. (2009). The transpatellar approach for the knee in the laboratory. *Journal of Orthopaedic Research* 27 (3), 330–4.

Miyatake, S., Kondo, E., Tsai, T. Y., Hirschmann, M. T., Halewood, C., Jakobsen, B. W., Yasuda, K., and Amis, A. A. (2011). Biomechanical Comparisons Between 4-Strand and Modified Larson 2-Strand Procedures for Reconstruction of the Posterolateral Corner of the Knee. *The American Journal of Sports Medicine* 39 (7), 1462–69.

Mont, M. A., Serna, F. K., Krackow, K. A., and Hungerford, D. S. (1996). Exploration of radiographically normal total knee replacements for unexplained pain. *Clinical Orthopaedics and Related Research* 331, 216–220.

Moran, M. F., Bhimji, S., Racanelli, J., and Piazza, S. J. (2008). Computational assessment of constraint in total knee replacement. *Journal of Biomechanics* 41 (9), 2013–2020.

Morrison, J. (1970). The mechanics of the knee joint in relation to normal walking. *Journal of Biomechanics* 3 (1), 51–61.

Moverley, R., Williams, D., Bardakos, N., and Field, R. (2014). Removal of the infrapatella fat pad during total knee arthroplasty: does it affect patient outcomes? *International Orthopaedics* 38 (12), 2483–2487.

Müller, W. (1983). The knee: form, function and ligament reconstruction. Berlin: Springer.

Mundermann, A., Dyrby, C., D'Lima, D., Colwell Jr., C., and Andriacchi, T. P. (2008). In Vivo Knee Loading Characteristics during Activities of Daily Living as Measured by an Instrumented Total Knee Replacement. *Journal of Orthopaedic Research* 26, 1167–1172.

Nakagawa, S., Kadoya, Y., Todo, S., Kobayashi, A., Sakamoto, H., Freeman, M., and Yamano, Y. (2000). Tibiofemoral movement 3: full flexion in the living knee studied by MRI. *Journal of Bone & Joint Surgery, British Volume* 82 (8), 1199–1200.

Ngai, V., Schwenke, T., and Wimmer, M. A. (2009). In-vivo kinematics of knee prostheses patients during level walking compared with the ISO force-controlled simulator standard. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine* 223 (7), 889–896.

NICE (2014). Clinical Guidelines. Osteoarthritis. Care and management in adults (CG177).

NJR (2014a). National Joint Registry, 11th Annual Report. Report.

NJR (2014b). Prostheses used in hip, ankle, elbow and shoulder replacement procedures in 2013. Report.

NJR (2015). Prostheses used in hip, ankle, elbow and shoulder replacement procedures in 2014. Report.

Noble, P. C., Conditt, M. A., Cook, K. F., and Mathis, K. B. (2006). The John Insall Award: Patient expectations affect satisfaction with total knee arthroplasty. *Clinical Orthopaedics and Related Research* 452, 35–43.

Noble, P. C., Gordon, M. J., Weiss, J. M., Reddix, R. N., Conditt, M. A., and Mathis, K. B. (2005). Does Total Knee Replacement Restore Normal Knee Function? *Clinical Orthopaedics and Related Research* 431, 157–165.

Noticewala, M. S., Geller, J. A., Lee, J. H., and Macaulay, W. (2012). Unicompartmental Knee Arthroplasty Relieves Pain and Improves Function More Than Total Knee Arthroplasty. *The Journal of Arthroplasty* 27 (8, Supplement), 99–105.

Nowakowski, A. M., Majewski, M., Muller-Gerbl, M., and Valderrabano, V. (2011). Development of a force-determining tensor to measure "physiologic knee ligament gaps" without bone resection using a total knee arthroplasty approach. *Journal of Orthopaedic Science* 16 (1), 56–63.

NZJR (2014). The New Zealand Joint Registry.

Oshea, R., Tech, K., Camisa, W., Leasure, J., Warmerdam, J. v., and McGann, W. (2014). Engagement Of PCL During Flexion With Custom TKR Implants. *Orthopaedic Research Society Annual Meeting*. New Orleans, LA, USA.

Pandit, H., Beard, D. J., Jenkins, C., Kimstra, Y., Thomas, N. P., Dodd, C. A. F., and Murray, D. W. (2006). Combined anterior cruciate reconstruction and Oxford unicompartmental knee arthroplasty. *Journal of Bone & Joint Surgery, British Volume* 88-B (7), 887–892.

Papannagari, R., Hines, G., Sprague, J., and Morrison, M. (2012). Long-term wear performance of an advanced bearing knee technology. *Journal of Bone & Joint Surgery, British Volume* 94 (SUPP XXV), 152–152.

Parikh, A., Morrison, M., and Jani, S. (2007). Wear testing of crosslinked and conventional UHMWPE against smooth and roughened femoral components. *Orthop Res Soc, San Diego, CA* 21.

Patil, S., Colwell Clifford W., J., Ezzet, K. A., and D'Lima, D. D. (2005). Can Normal Knee Kinematics Be Restored with Unicompartmental Knee Replacement? *The Journal of Bone & Joint Surgery, American Volume* 87 (2), 332–338.

Pianigiani, S., Chevalier, Y., Labey, L., Pascale, V., and Innocenti, B. (2012). Tibio-femoral kinematics in different total knee arthroplasty designs during a loaded squat: A numerical sensitivity study. *Journal of Biomechanics* 45 (13), 2315–2323.

Pritchett, J. W. (2004). Patient preferences in knee prostheses. *The Journal of Bone & Joint Surgery, British Volume* 86 (7), 979–82.

Pritchett, J. W. (2011). Patients prefer a bicruciate-retaining or the medial pivot total knee prosthesis. *The Journal of Arthroplasty* 26 (2), 224–8.

Ramappa, A. J., Apreleva, M., Harrold, F. R., Fitzgibbons, P. G., Wilson, D. R., and Gill, T. J. (2006). The Effects of Medialization and Anteromedialization of the Tibial Tubercle on Patellofemoral Mechanics and Kinematics. *The American Journal of Sports Medicine* 34 (5), 749–756.

Ramkumar, P. N., Harris, J. D., and Noble, P. C. (2015). Patient-reported outcome measures after total knee arthroplasty: a systematic review. *Bone and Joint Research* 4 (7), 120–127.

Ranawat, C. (2001). History of total knee replacement. *Journal of the Southern Orthopaedic Association* 11 (4), 218–226.

Robinson, J. R., Bull, A. M. J., Thomas, R. R. d., and Amis, A. A. (2006). The Role of the Medial Collateral Ligament and Posteromedial Capsule in Controlling Knee Laxity. *The American Journal of Sports Medicine* 34 (11), 1815–1823.

Robinson, R. P. (2005). The Early Innovators of Todays Resurfacing Condylar Knees. *The Journal of Arthroplasty* 20 (1, Suppl. 1), 2–26.

Rodríguez-Merchán, E. (2015). Revision Total Knee Arthroplasty: Surgical Technique in Dealing with Instability. English. *Total Knee Arthroplasty*. Edited by E. Rodríguez-Merchán and S. Oussedik. Springer International Publishing, 259–265.

Rudy, T. W., Livesay, G. A., Woo, S. L. Y., and Fu, F. H. (1996). A combined robotic/universal force sensor approach to determine in situ forces of knee ligaments. *Journal of Biomechanics* 29 (10), 1357–1360.

Rusly, R. J., Lee, J., Xie, X., Walker, K. J., Broome, B., Tanner, S. J., and DesJardins, J. D. (2014). Influence of Hamstrings Activation on Knee Mechanics Using a Novel Deep Knee Bending Simulator. *Orthopaedic Research Society Annual Meeting*. New Orleans, LA, USA.

Sakane, M., Fox, R. J., Glen, S. L.-Y. W., Livesay, A., Li, G., and Fu, F. H. (1997). In situ forces in the anterior cruciate ligament and its bundles in response to anterior tibial loads. *Journal of Orthopaedic Research* 15 (2), 285–293.

Schaerer, C., Mimnaugh, K., Popoola, O., and Seebeck, J. (2010). Wear of UHMWPE tibial inserts under simulated obese patient conditions. *Orthop Res Soc, New Orleans, LA* 2329.

Schimmel, J., Wyemnga, A., Defoort, K., and Van Hellemondt, G. (2012). Maximal Flexion After Total Knee Arthroplasty: A Randomized Controlled Trial Comparing the Journey to the Genesis II Prosthesis. *The Journal of Bone & Joint Surgery, British Volume* 94-B (SUPP XL), 163.

Schroer, W. C., Berend, K. R., Lombardi, A. V., Barnes, C. L., Bolognesi, M. P., Berend, M. E., Ritter, M. A., and Nunley, R. M. (2013). Why Are Total Knees Failing Today? Etiology of Total Knee Revision in 2010 and 2011. *The Journal of Arthroplasty* 28 (8, Supplement), 116–119.

Scott, C. E., Bugler, K. E., Clement, N. D., MacDonald, D., Howie, C. R., and Biant, L. C. (2012). Patient expectations of arthroplasty of the hip and knee. *The Journal of Bone & Joint Surgery, British Volume* 94 (7), 974–81.

Scott, W. N., **(ed.)** (2011). Insall & Scott Surgery of the Knee. Elsevier Health Sciences.

Shakespeare, D. and Jeffcote, B. (2003). Unicondylar arthroplasty of the knee – cheap at half the price? *The Knee* 10 (4), 357–361.

Sharkey, P. F., Lichstein, P. M., Shen, C., Tokarski, A. T., and Parvizi, J. (2014). Why Are Total Knee Arthroplasties Failing Today? Has Anything Changed After 10 Years? *The Journal of Arthroplasty*.

Sharkey, P. F. and Miller, A. J. (2011). Noise, numbness, and kneeling difficulties after total knee arthroplasty: is the outcome affected? *The Journal of arthroplasty* 26 (8), 1427–1431.

Shelburne, K. B., Torry, M. R., and Pandy, M. G. (2006). Contributions of muscles, ligaments, and the ground-reaction force to tibiofemoral joint loading during normal gait. *Journal of Orthopaedic Research* 24 (10), 1983–1990.

Shimmin, A., Martinez-Martos, S., Owens, J., Iorgulescu, A. D., and Banks, S. (2015). Fluoroscopic motion study confirming the stability of a medial pivot design total knee arthroplasty. *The Knee* 22 (6), 522–526.

Shino, K., Inoue, M., Horibe, S., Nakamura, H., and Ono, K. (1987). Measurement of the Anterior Instability of the Knee. *The Journal of Bone & Joint Surgery, British Volume* 69-B (4), 608–613.

SKAR (2013). Swedish Knee Arthroplasty Register Annual Report. Deptartment of Orthopedics, Skåne University Hospital, Lund.

Sloan, F. A., Ruiz Jr, D., and Platt, A. (2009). Changes in functional status among persons over age sixty-five undergoing total knee arthroplasty. *Medical care* 47 (7), 742–748.

Smith & Nephew (2012). The Evolution of Guided Motion Total Knee Arthroplasty: The JOURNEY II Bi-Cruciate Stabilized Knee System. *Bone & JointScience: Our Innovation in Focus* 3 (3), 1–8.

Smith & Nephew (2014). Designed for life: Implant technology with unmatched performance.

Steinbrück, A., Schroder, C., Woiczinski, M., Fottner, A., Muller, P. E., and Jansson, V. (2013). Patellofemoral contact patterns before and after total knee arthroplasty: an in vitro measurement. *BioMedical Engineering Online* 12 (58).

Stephen, J. M., Lumpaopong, P., Deehan, D. J., Kader, D., and Amis, A. A. (2012). The Medial Patellofemoral Ligament: Location of Femoral Attachment and Length Change Patterns Resulting From Anatomic and Nonanatomic Attachments. *The American Journal of Sports Medicine* 40, 1871–9.

Stiehl, J. B., Komistek, R. D., Cloutier, J. M., and Dennis, D. A. (2000). The cruciate ligaments in total knee arthroplasty: a kinematic analysis of 2 total knee arthroplasties. *The Journal of Arthroplasty* 15 (5), 545–50.

Stoddard, J. E., Deehan, D. J., Bull, A. M. J., McCaskie, A. W., and Amis, A. A. (2013). The kinematics and stability of single-radius versus multi-radius femoral components related to Mid-range instability after TKA. *Journal of Orthopaedic Research* 31 (1), 53–58.

Strickland, M., Arsene, C., Pal, S., Laz, P., and Taylor, M. (2010). A multi-platform comparison of efficient probabilistic methods in the prediction of total knee replacement mechanics. *Computer methods in biomechanics and biomedical engineering* 13 (6), 701–709.

Sugita, T. and Amis, A. A. (2001). Anatomic and Biomechanical Study of the Lateral Collateral and Popliteofibular Ligaments. *The American Journal of Sports Medicine* 29 (4), 466–472.

Talbot, S., Hooper, G., Stokes, A., and Zordan, R. (2010). Use of a new high-activity arthroplasty score to assess function of young patients with total hip or knee arthroplasty. *The Journal of arthroplasty* 25 (2), 268–273.

Taylor, W. R., Heller, M. O., Bergmann, G., and Duda, G. N. (2004). Tibio-femoral loading during human gait and stair climbing. *Journal of Orthopaedic Research* 22 (3), 625–632.

The EU (2007). Directive 2007/47/EC of the European Parliament and of the Council.

Tsoukas, D., Fotopoulos, V., Basdekis, G., and Makridis, K. G. (2015). No difference in osteoarthritis after surgical and non-surgical treatment of ACL-injured knees after ten years. English. *Knee Surgery, Sports Traumatology, Arthroscopy*, 1–7.

Tuncer, M., Cobb, J. P., Hansen, U. N., and Amis, A. A. (2013). Validation of multiple subject-specific finite element models of unicompartmental knee replacement. *Medical Engineering & Physics* 35 (10), 1457–64.

Van de Velde, S. K., Gill, T. J., and Li, G. (2009). Evaluation of Kinematics of Anterior Cruciate Ligament-Deficient Knees with Use of Advanced Imaging Techniques, Three-Dimensional Modeling Techniques, and Robotics. 91, 108–114.

Van Der Straeten, C., Doyen, B., Dutordoir, C., Goedertier, W., Pirard, S., and Victor, J. (2014). Short- and Medium Term Results of Artificial Meniscal Implant. *International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine Annual Congress*. Lyon, France.

Van Haver, A., De Roo, K., Claessens, T., De Beule, M., Verdonk, P., and De Baets, P. (2013). Pilot validation study on a quasi-static weight-bearing knee rig. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine* 227 (3), 229–233.

Van Opstal, N., Feyen, H., Luyckx, J. P., and Bellemans, J. (2014). Mean tensile strength of the PCL in TKA depends on the preservation of the tibial insertion site. *Knee Surgery, Sports Traumatology, Arthroscopy*, 1–6.

Varadarajan, K. M., Moynihan, A. L., D'Lima, D., Colwell, C. W., and Li, G. (2008). In vivo contact kinematics and contact forces of the knee after total knee arthroplasty during dynamic weight-bearing activities. *Journal of Biomechanics* 41 (10), 2159–2168.

Vedi, V., Spouse, E., Williams, A., Tennant, S. J., Hunt, D. M., and Gedroyc, W. M. W. (1999). Meniscal movement: an in-vivo study using dynamic MRI. *The Journal of Bone & Joint Surgery, British Volume* 81-B (1), 37–41.

Verdonk, P., Beaufils, P., Bellemans, J., Djian, P., Heinrichs, E.-L., Huysse, W., Laprell, H., Siebold, R., Verdonk, R., and Actifit Study Group, the (2012). Successful Treatment of Painful Irreparable Partial Meniscal Defects With a Polyurethane Scaffold. *The American Journal of Sports Medicine* 40 (4), 844–853.

Victor, J. and Bellemans, J. (2006). Physiologic kinematics as a concept for better flexion in TKA. *Clinical Orthopaedics and Related Research* 452, 53.

Victor, J., Mueller, J. K., Komistek, R. D., Sharma, A., Nadaud, M. C., and Bellemans, J. (2010). In vivo kinematics after a cruciate-substituting TKA. *Clinical Orthopaedics and Related Research* 468 (3), 807–814.

Victor, J. and Premanathan, A. (2013). Virtual 3D planning and patient specific surgical guides for osteotomies around the knee. *Bone Joint J* 95 (11 Supple A), 153–158.

Victor, J., Van Glabbeek, F., Vander Sloten, J., Parizel, P. M., Somville, J., and Bellemans, J. (2009). An Experimental Model for Kinematic Analysis of the Knee. *The Journal of Bone & Joint Surgery, American Volume* 91 (Supplement 6), 150–163.

Vos, T. *et al.* (2012). Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990 to 2010: a systematic analysis for the Global Burden of Disease Study 2010. *The Lancet* 380 (9859), 2163–2196.

Walker, P. S., Blunn, G. W., Broome, D. R., Perry, J., Watkins, A., Sathasivam, S., Dewar, M. E., and Paul, J. P. (1997). A knee simulating machine for performance evaluation of total knee replacements. *Journal of biomechanics* 30 (1), 83–89.

Walker, P. S., Heller, Y., Cleary, D. J., and Yildirim, G. (2011). Preclinical Evaluation Method for Total Knees Designed to Restore Normal Knee Mechanics. *The Journal of Arthroplasty* 26 (1), 152–160.

Walker, P. (2015). The design and pre-clinical evaluation of knee replacements for osteoarthritis. *Journal of biomechanics* 48 (5), 742–749.

White, B. F. and Carignan, F. J. (2012). Method and apparatus for joint motion simulation. WO 2012/068015 A2.

White, B. F., D'Lima, D., Drueding, A. C., Cox, J., Carignan, F. J., and Dean, S. (2006). A simulator study of TKR kinematics using modeled soft-tissue constraint: Virtual soft-tissue control for knee simulation. *Journal of Testing and Evaluation* 3 (8).

Wiik, A. V., Manning, V., Strachan, R. K., Amis, A. A., and Cobb, J. P. (2013). Unicompartmental Knee Arthroplasty Enables Near Normal Gait at Higher Speeds, Unlike Total Knee Arthroplasty. *The Journal of Arthroplasty* 28 (9, Supplement), 176–178.

Willis-Owen, C. A., Brust, K., Alsop, H., Miraldo, M., and Cobb, J. P. (2009). Unicondylar knee arthroplasty in the UK National Health Service: An analysis of candidacy, outcome and cost efficacy. *The Knee* 16, 473–478.

Wilson, D., Feikes, J., and O'Connor, J. (1998). Ligaments and articular contact guide passive knee flexion. *Journal of Biomechanics* 31 (12), 1127–1136.

Wilson, D., Feikes, J., Zavatsky, A., and O'connor, J. (2000). The components of passive knee movement are coupled to flexion angle. *Journal of Biomechanics* 33 (4), 465–473.

World Health Organization (1997). The World Health Report.

Wright, V. and Dowson, D. (1976). Lubrication and Cartilage. *Journal of Anatomy* 121 (1), 107–118.

Wünschel, M., Lo, J., Dilger, T., Wülker, N., and Müller, O. (2011). Influence of bi-and tri-compartmental knee arthroplasty on the kinematics of the knee joint. *BMC Musculoskeletal Disorders* 12 (1), 29.

Yamamoto, S. (1979). Total knee replacement with the Kodama-Yamamoto knee prosthesis. *Clinical orthopaedics and related research* 145, 60–67.

Yildirim, G., Walker, P. S., and Boyer, J. (2009). Total knees designed for normal kinematics evaluated in an up-and-down crouching machine. *Journal of Orthopaedic Research* 27 (8), 1022–1027.

Zavatsky, A. B. (1997). A kinematic-freedom analysis of a flexed-knee-stance testing rig. *Journal of Biomechanics* 30 (3), 277–280.

Zhao, D., Banks, S., D'Lima, D., Colwell Jr., C., and Fregyl, B. (2007). In vivo Medial and Lateral Tibial Loads During Dynamic and High Flexion Activities. *Journal of Orthopaedic Research* 25, 593–602.

APPENDIX A

ADDITIONAL DATA

A.1 Introduction

This appendix serves to provide additional data relating to Chapters 6 & 7. It presents graphs of kinematic knee data for individual knee specimens (rather than mean values) in the intact state and after the various TKR interventions that were carried out for this research.

A.2 Chapter 6 additional data

A.2.1 Soft tissue length changes

A.2.1.1 Intact knees
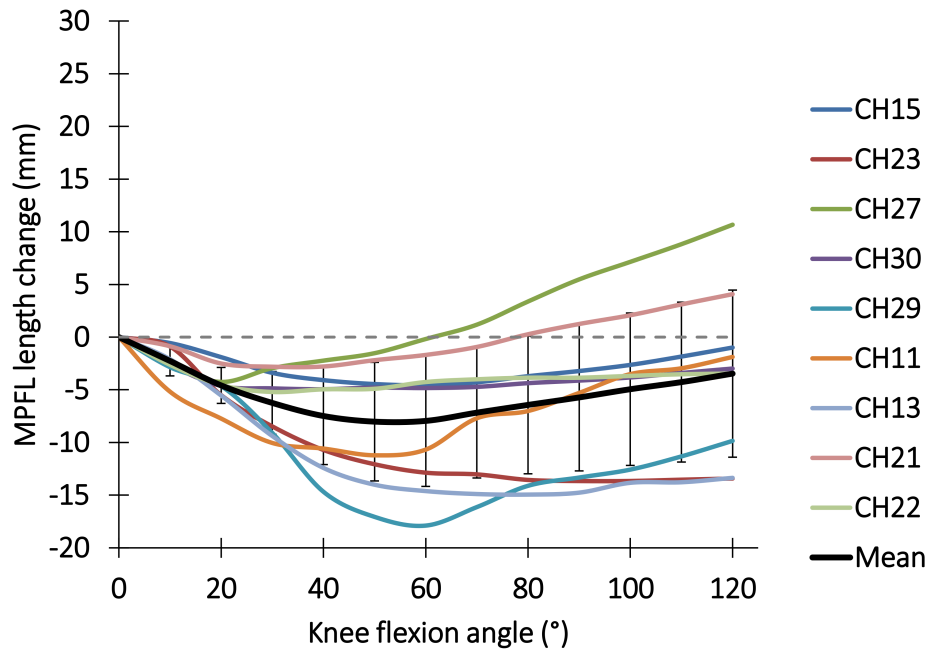
Figure A.1 MPFL length changes during knee flexion for 9 cadaver knees, plus a mean with standard deviation error bars shown.
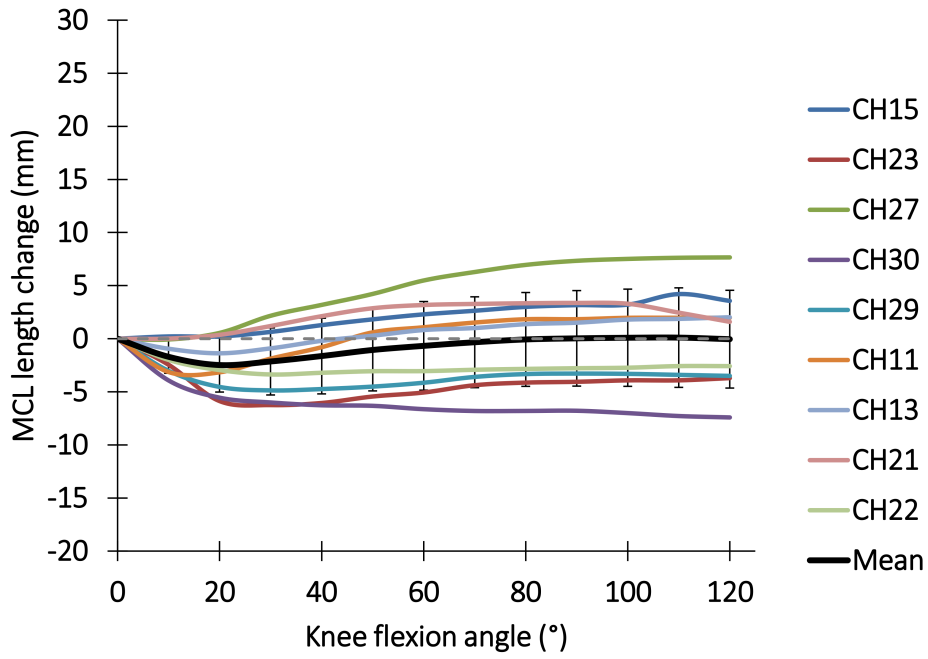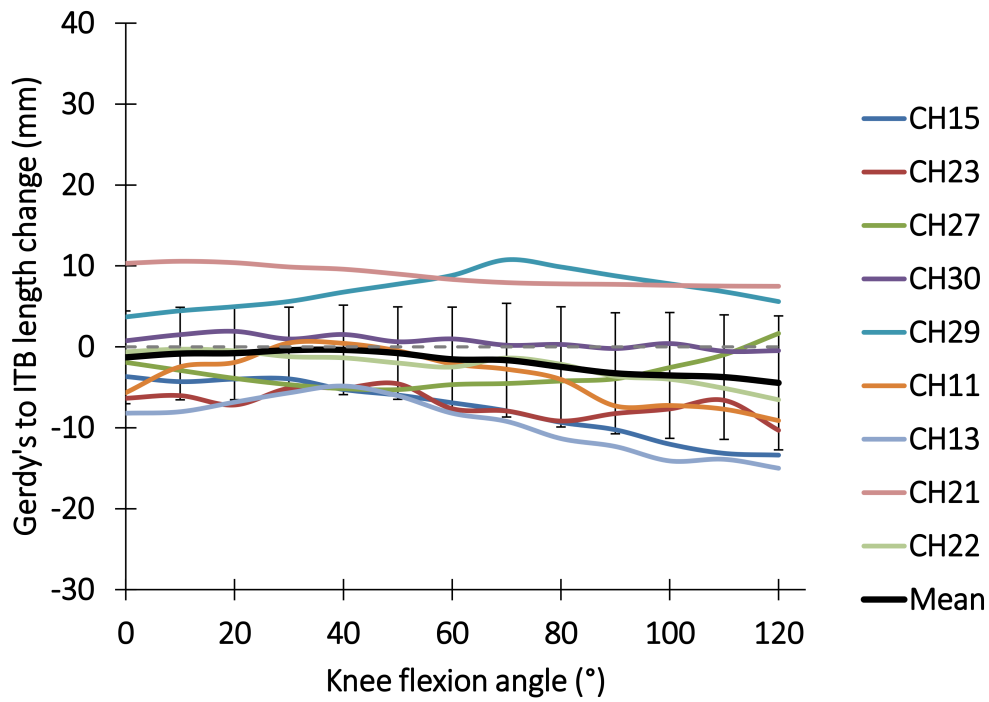
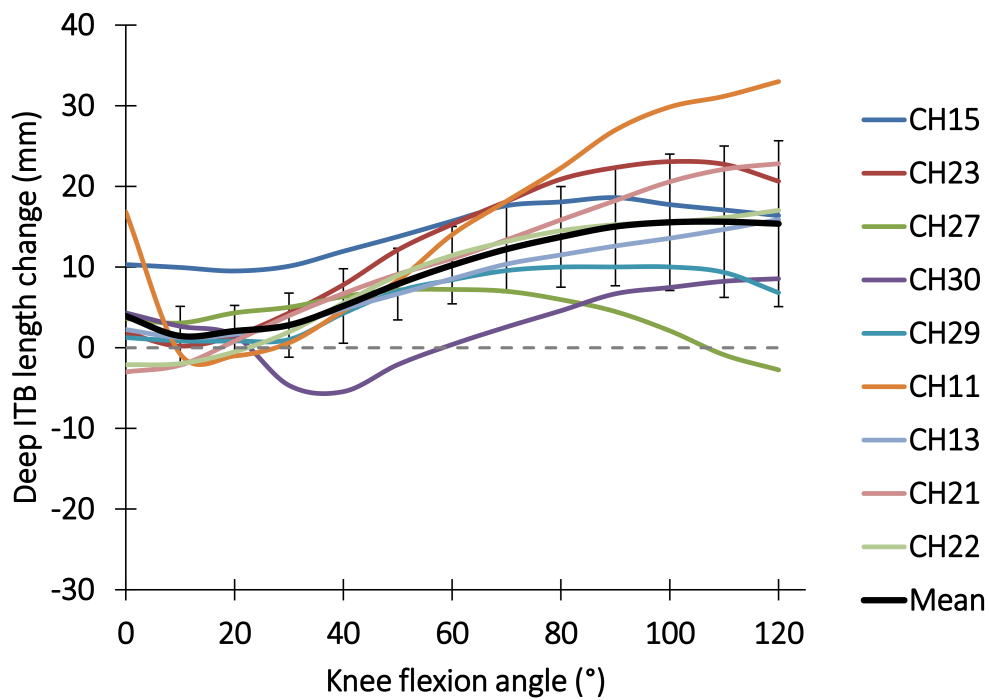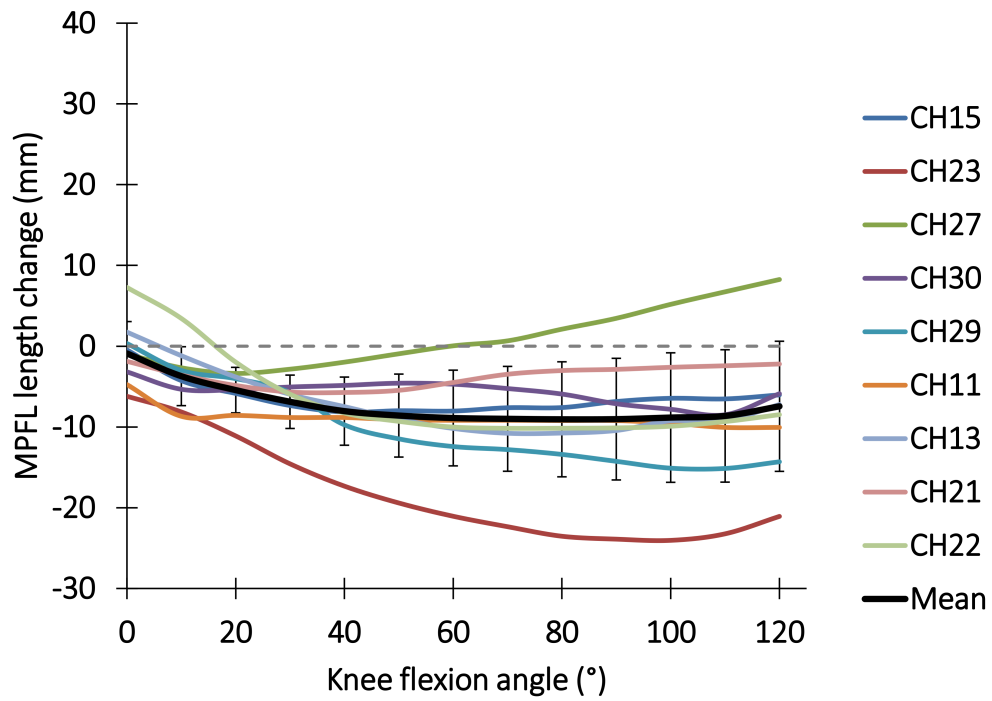**Figure A.2** MCL length changes during knee flexion for 9 cadaver knees, plus a mean with standard deviation error bars shown.
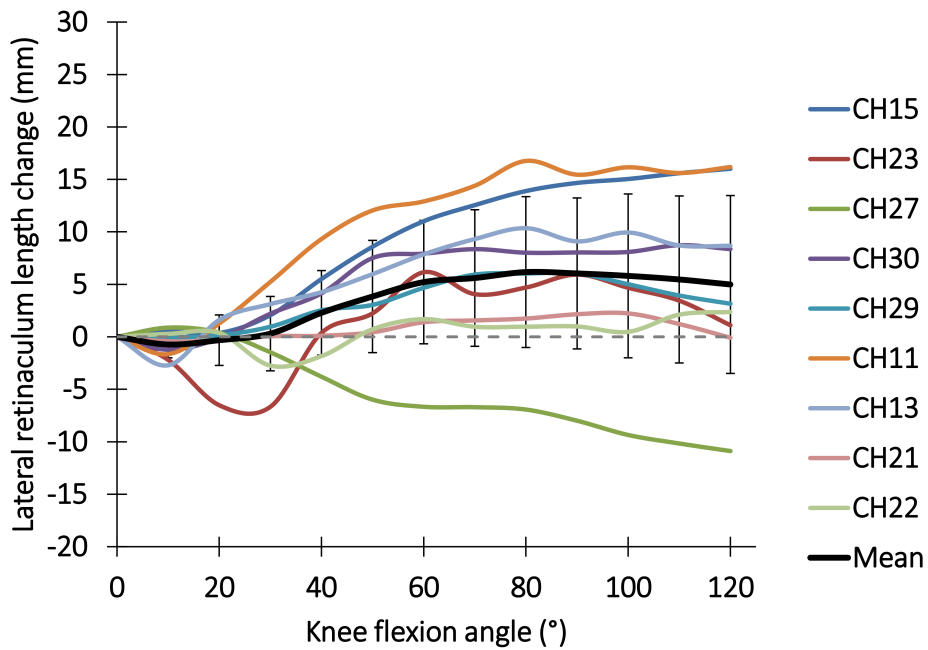
Figure A.3 Lateral retinaculum length changes during knee flexion for 9 cadaver knees, plus a mean with standard deviation error bars shown.
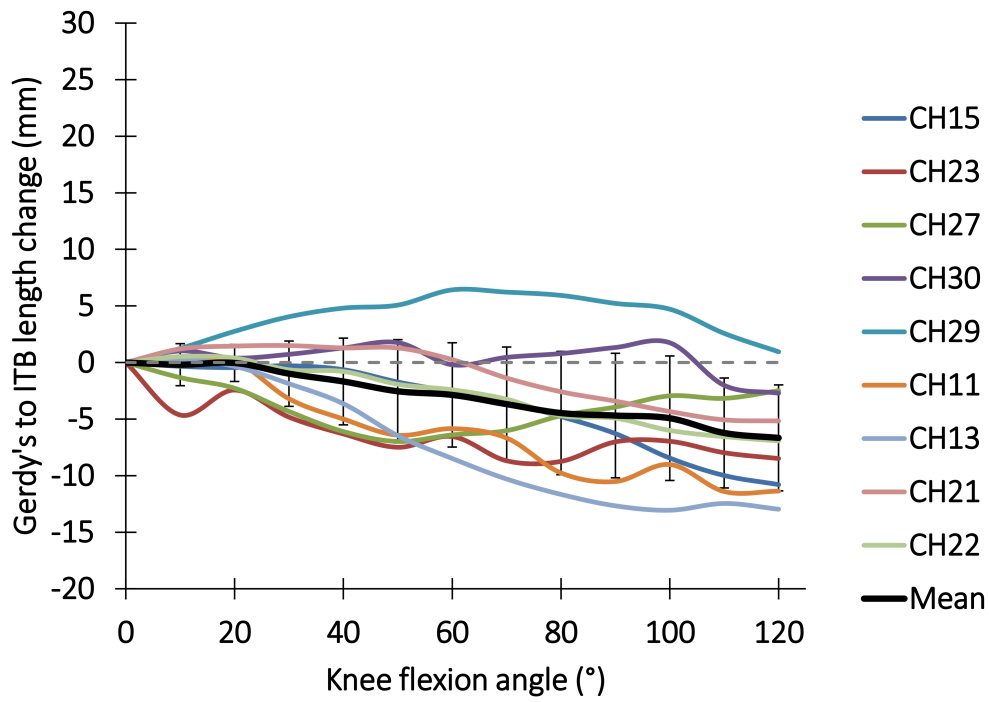
Figure A.4 Superficial ITB length changes during knee flexion for 9 cadaver knees, plus a mean with standard deviation error bars shown.
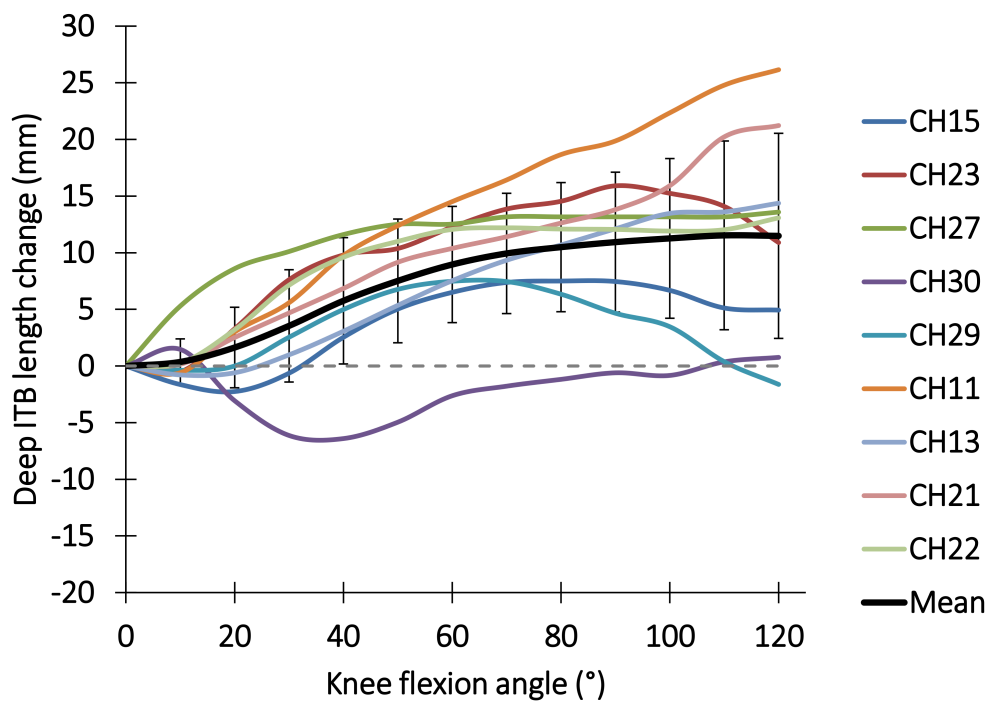
Figure A.5 Deep ITB length changes during knee flexion for 9 cadaver knees, plus a mean with standard deviation error bars shown.

A.2.1.2 Journey TKR knees
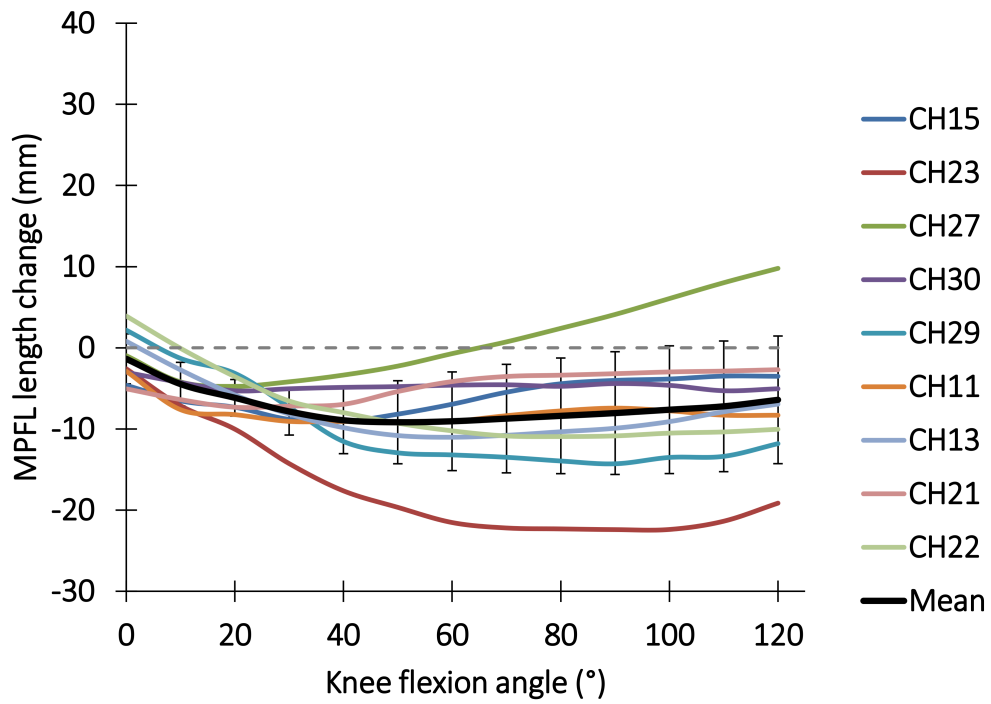
Figure A.6   MPFL length changes during knee flexion for 9 cadaver knees with the Journey TKR implanted, plus a mean with standard deviation error bars shown.
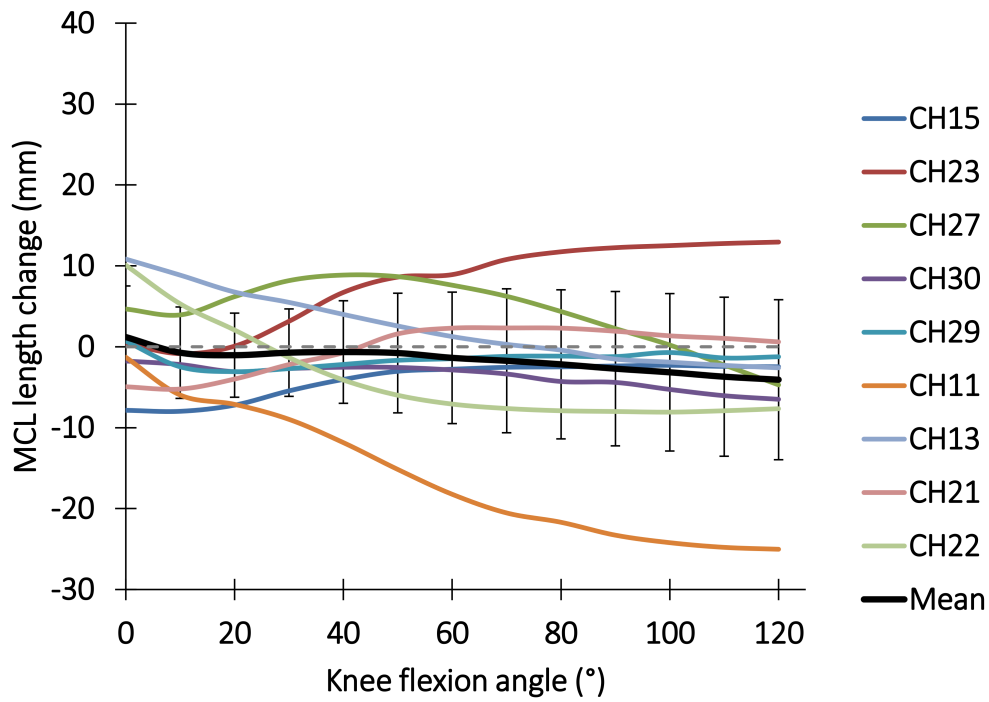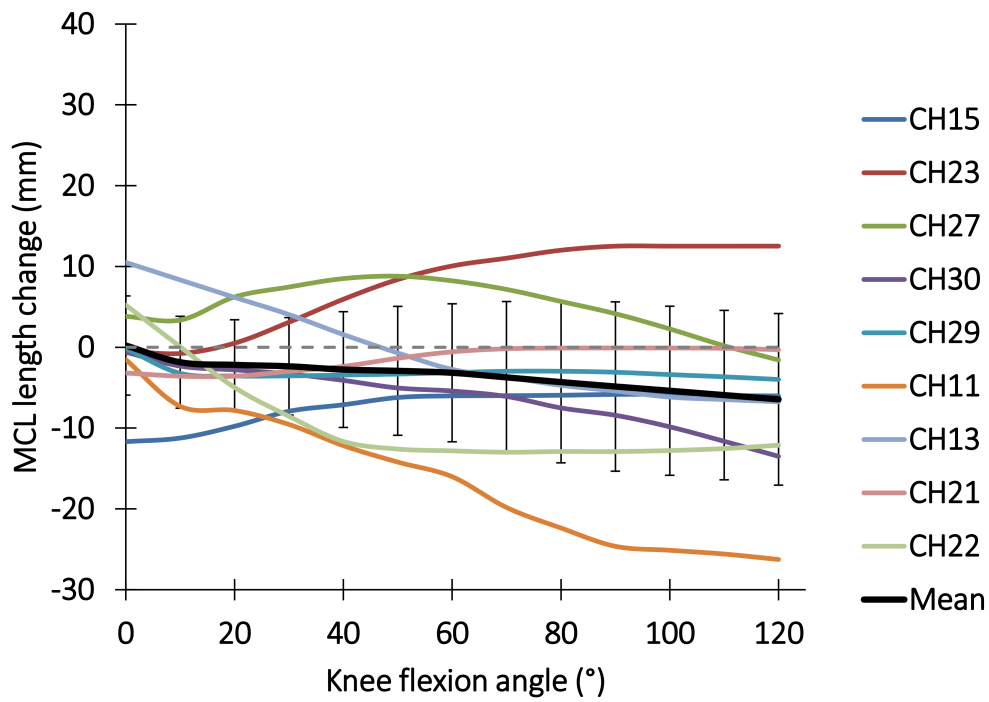
Figure A.7   MCL length changes during knee flexion for 9 cadaver knees with the Journey TKR implanted, plus a mean with standard deviation error bars shown.
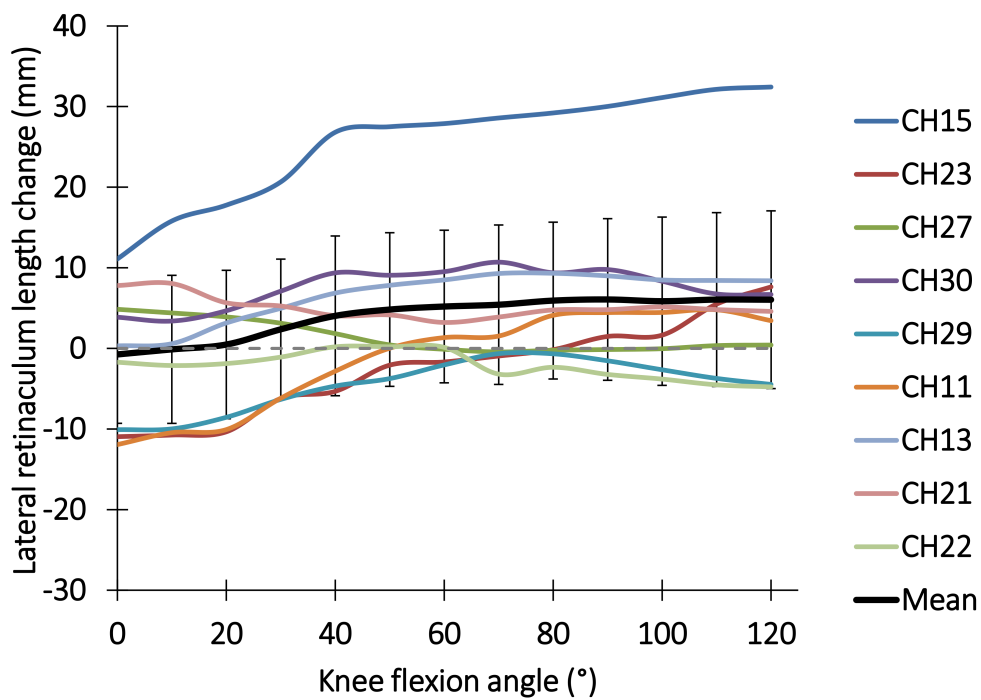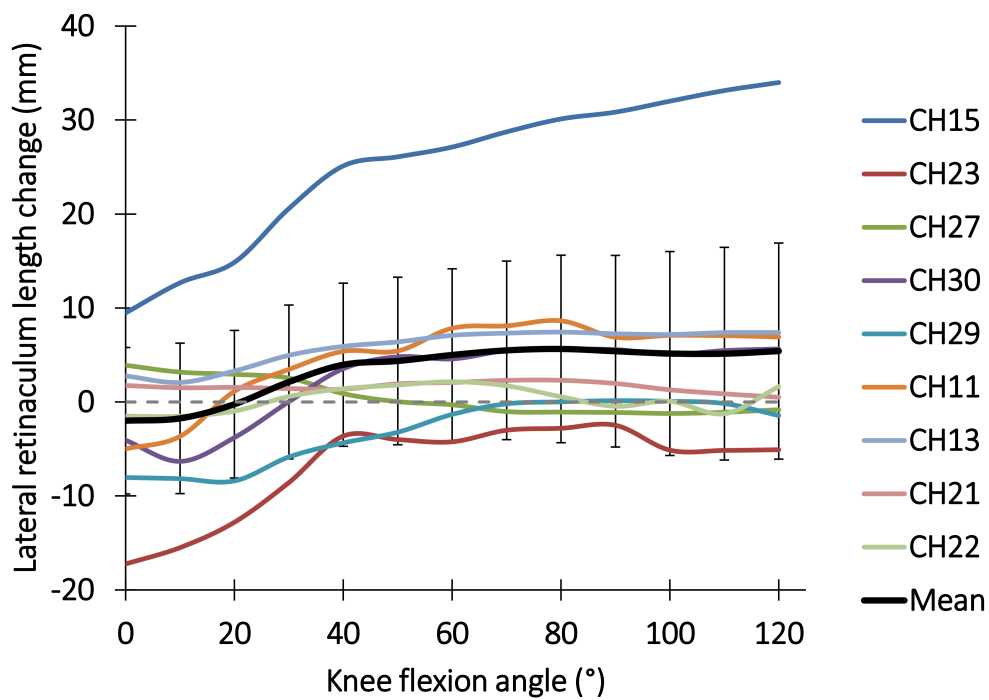

Figure A.8   Lateral retinaculum length changes during knee flexion for 9 cadaver knees with the Journey TKR implanted, plus a mean with standard deviation error bars shown.
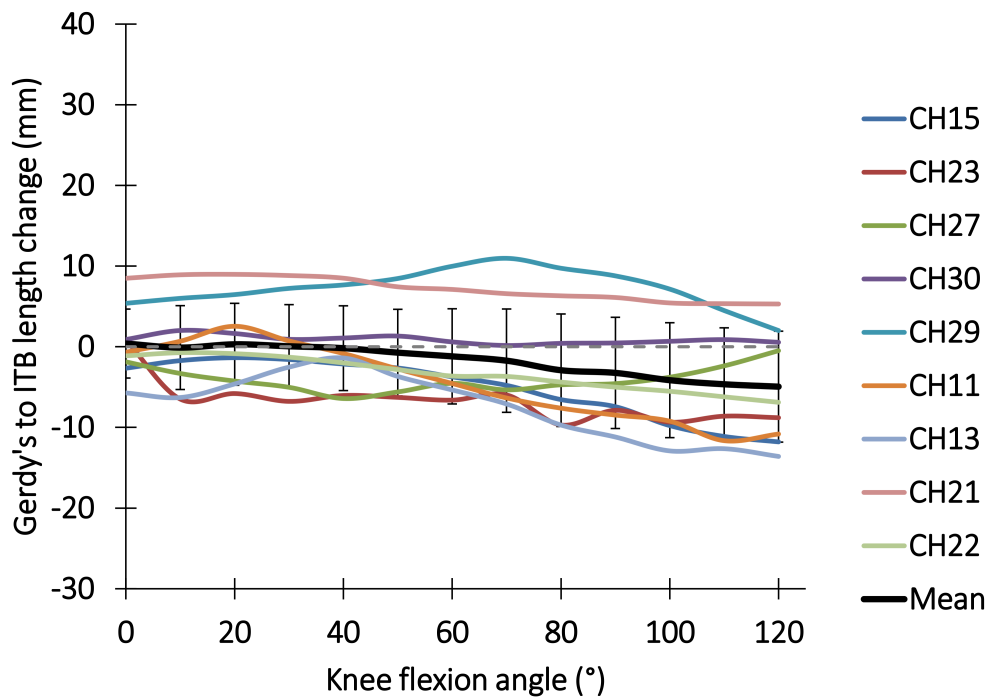
Figure A.9 Superficial ITB length changes during knee flexion for 9 cadaver knees with the Journey TKR implanted, plus a mean with standard deviation error bars shown.

Figure A.10 Deep ITB length changes during knee flexion for 9 cadaver knees with the Journey TKR implanted, plus a mean with standard deviation error bars shown.

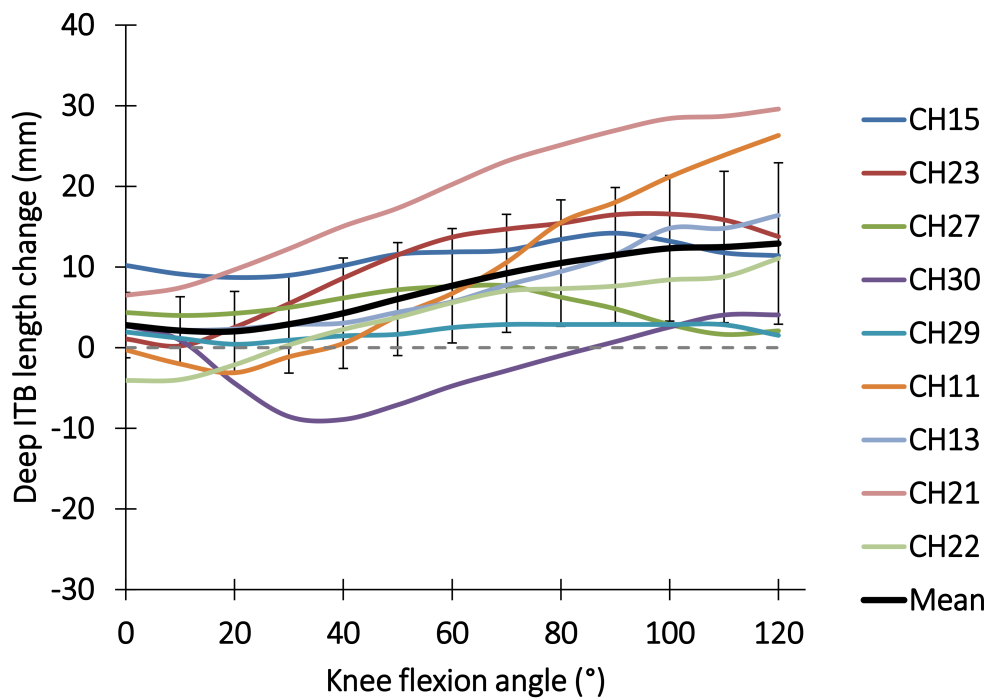## A.2.1.3 Journey II TKR knees

Figure A.11   MPFL length changes during knee flexion for 9 cadaver knees with the Journey II TKR implanted, plus a mean with standard deviation error bars shown.

Figure A.12   MCL length changes during knee flexion for 9 cadaver knees with the Journey II TKR implanted, plus a mean with standard deviation error bars shown.

Figure A.13   Lateral retinaculum length changes during knee flexion for 9 cadaver knees with the Journey II TKR implanted, plus a mean with standard deviation error bars shown.

Figure A.14 **Superficial ITB length changes during knee flexion for 9 cadaver knees with the Journey II TKR implanted, plus a mean with standard deviation error bars shown.**

Figure A.15 **Deep ITB length changes during knee flexion for 9 cadaver knees with the Journey II TKR implanted, plus a mean with standard deviation error bars shown.**

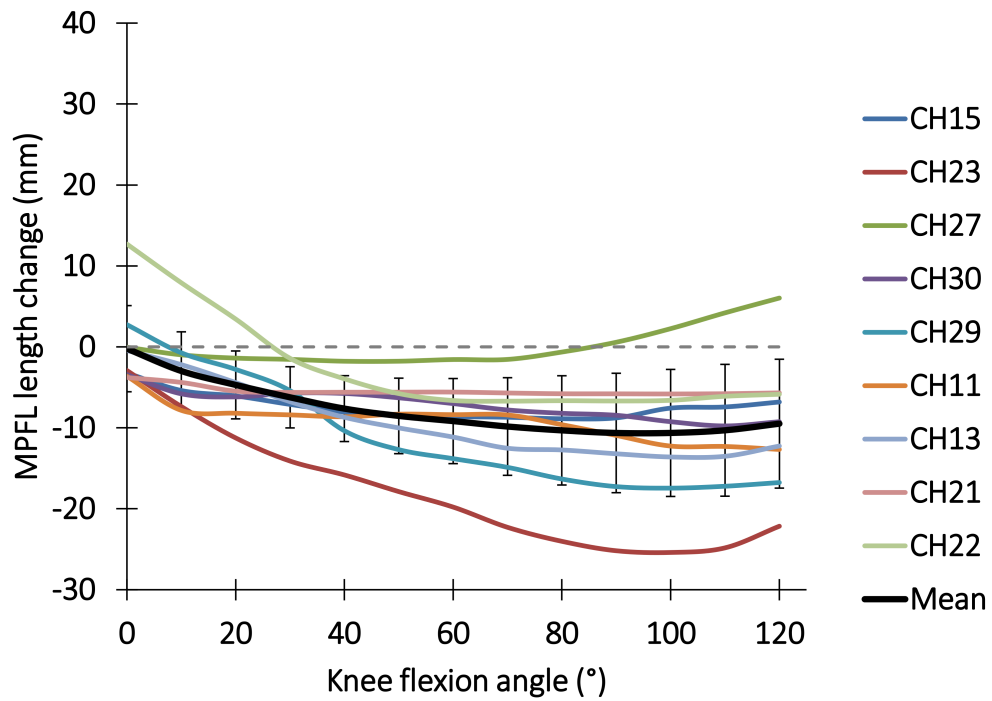## A.2.1.4 Genesis II TKR knees

Figure A.16   MPFL length changes during knee flexion for 9 cadaver knees with the Genesis II TKR implanted, plus a mean with standard deviation error bars shown.
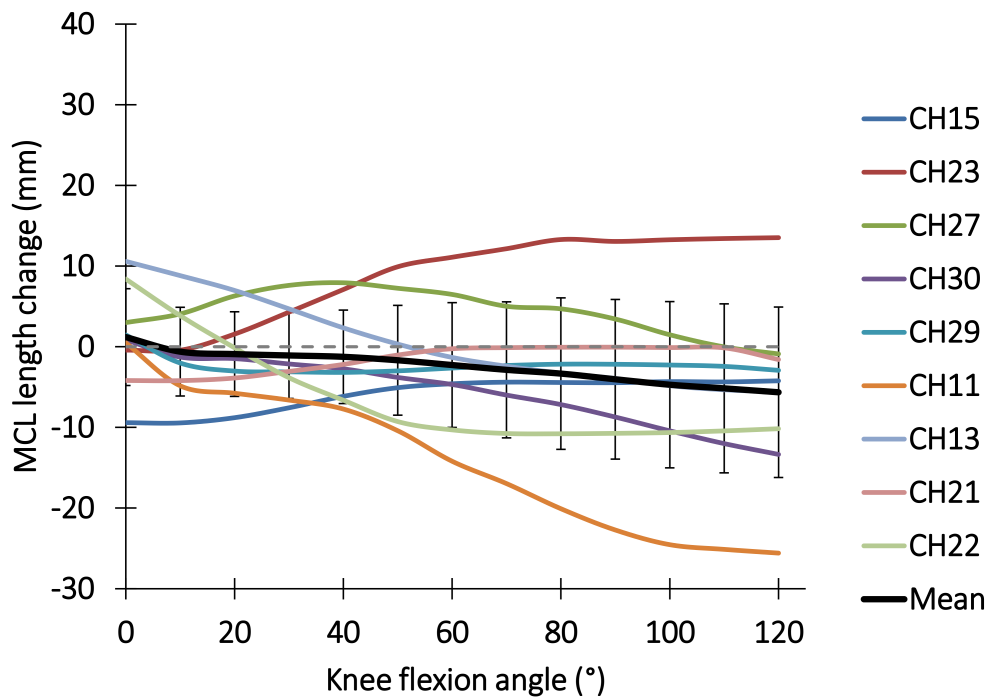
Figure A.17   MCL length changes during knee flexion for 9 cadaver knees with the Genesis II TKR implanted, plus a mean with standard deviation error bars shown.
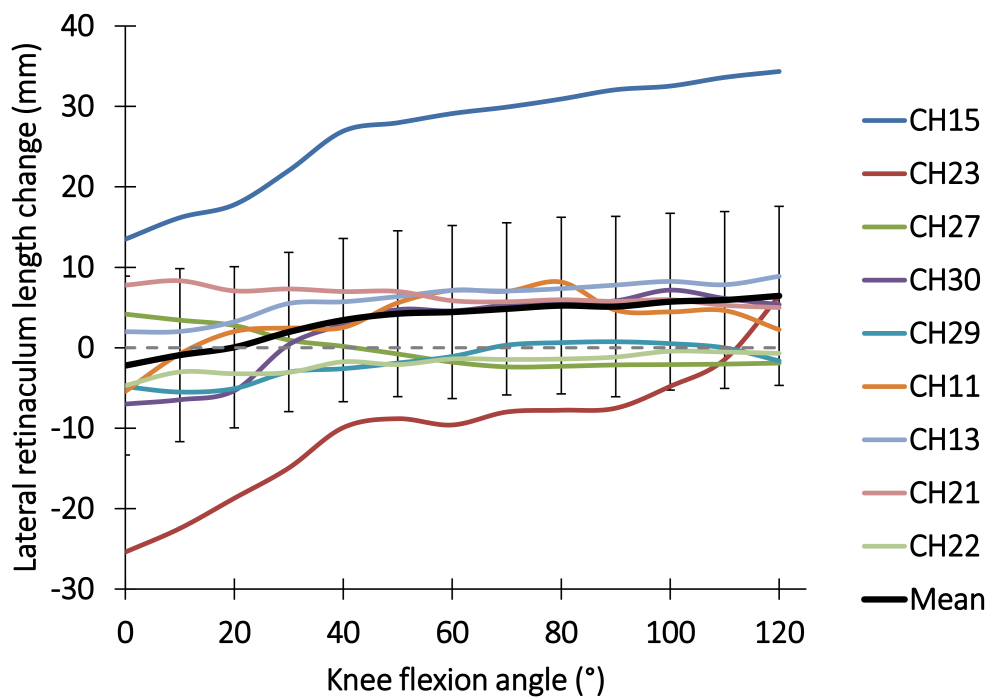

Figure A.18   Lateral retinaculum length changes during knee flexion for 9 cadaver knees with the Genesis II TKR implanted, plus a mean with standard deviation error bars shown.
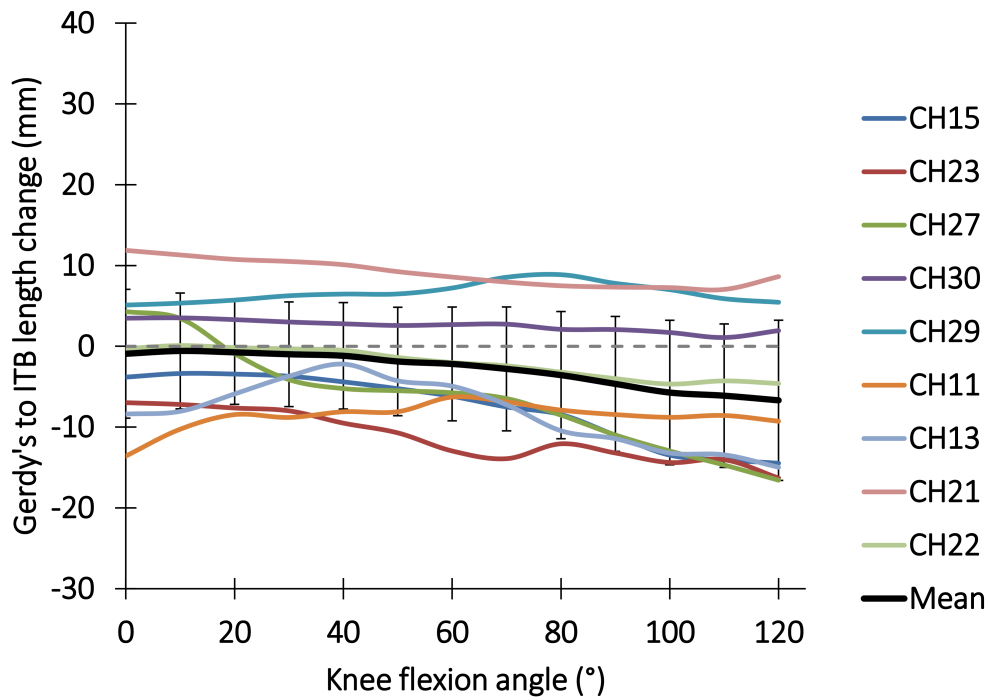
Figure A.19 Superficial ITB length changes during knee flexion for 9 cadaver knees with the Genesis II TKR implanted, plus a mean with standard deviation error bars shown.

Figure A.20   Deep ITB length changes during knee flexion for 9 cadaver knees with the Genesis II TKR implanted, plus a mean with standard deviation error bars shown.

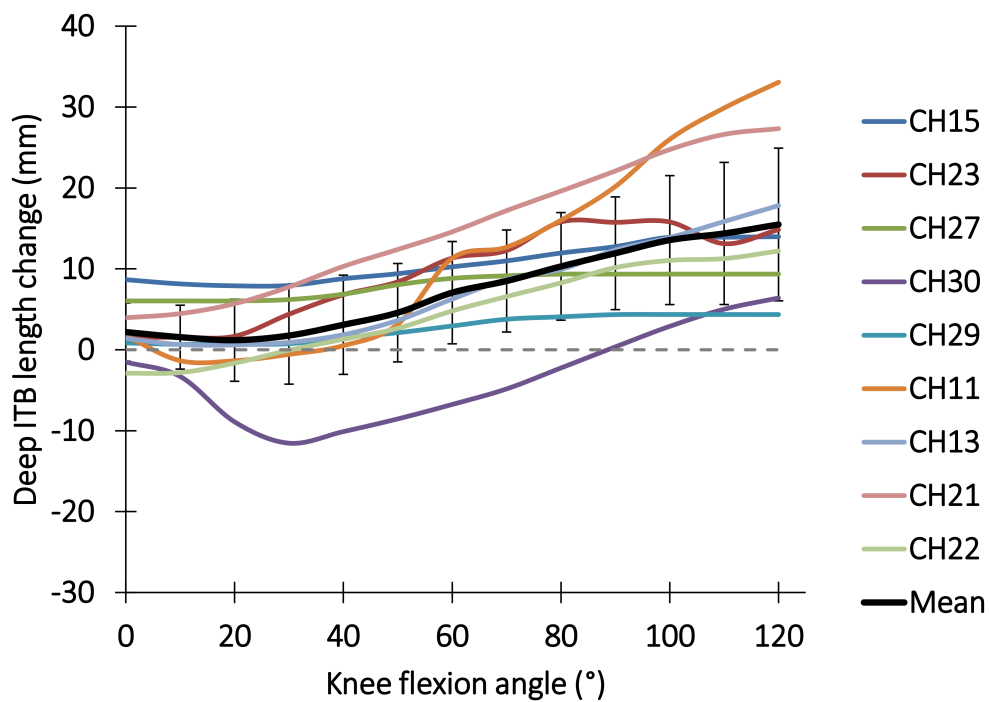## A.2.2 Kinematics

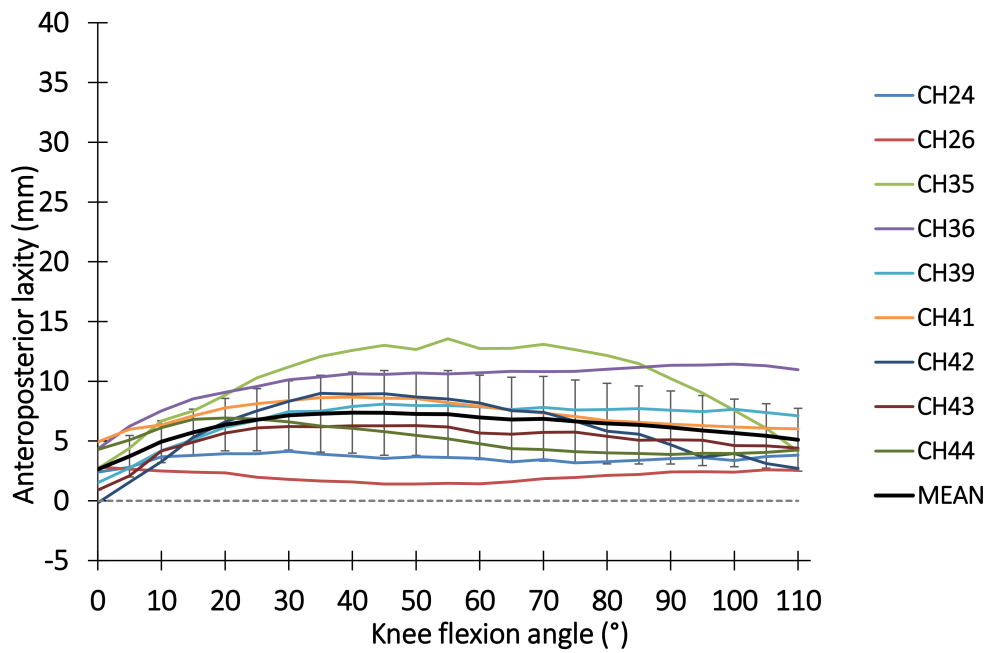### A.2.2.1 Total anteroposterior laxity

Figure A.21   Anteroposterior laxity during knee flexion for 9 cadaver knees, plus a mean with standard deviation error bars shown.
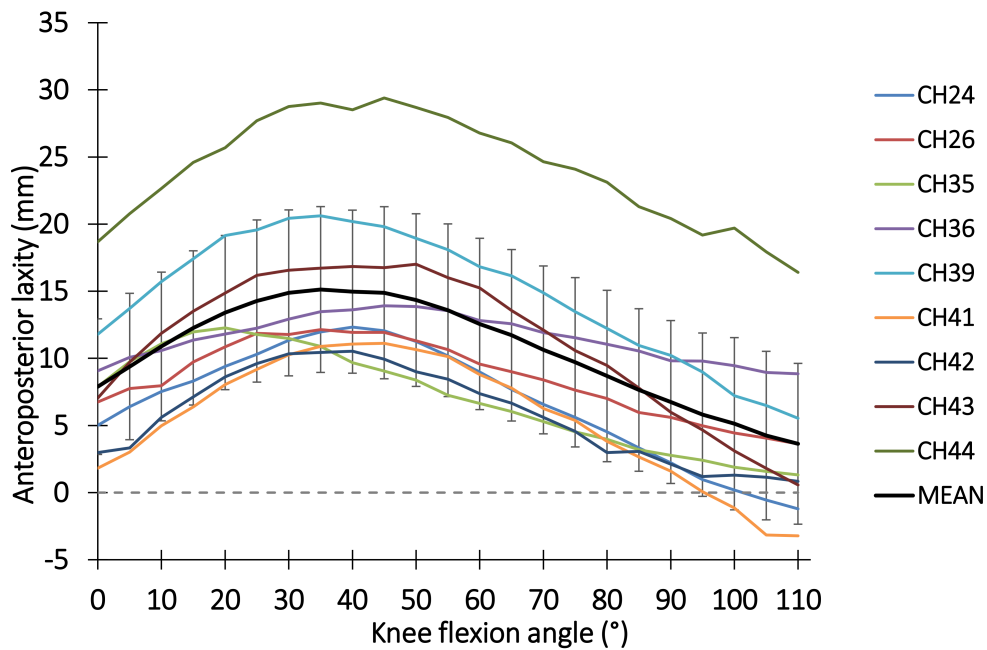

Figure A.22   Anteroposterior laxity during knee flexion for 9 cadaver knees with the Journey TKR implanted, plus a mean with standard deviation error bars shown.

Figure A.23   Anteroposterior laxity during knee flexion for 9 cadaver knees with the Journey II TKR implanted, plus a mean with standard deviation error bars shown.
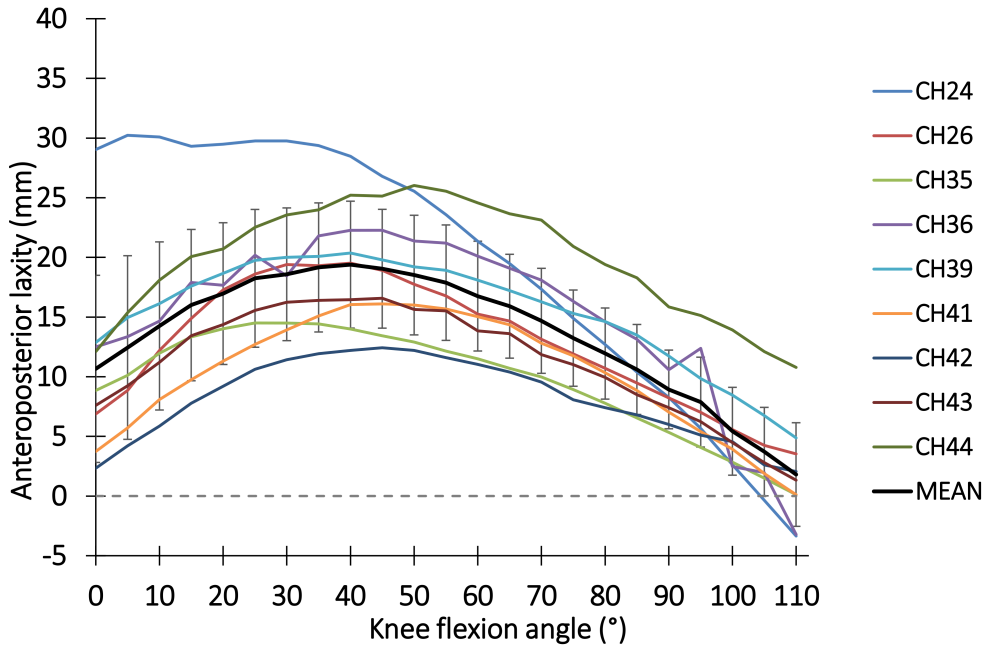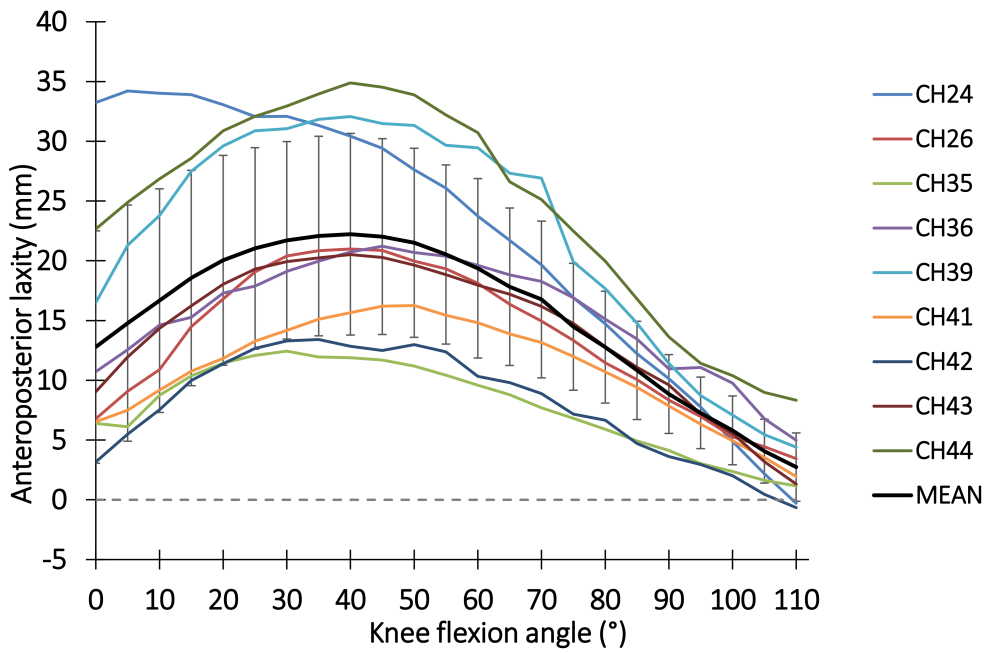

Figure A.24   Anteroposterior laxity during knee flexion for 9 cadaver knees with the Genesis II TKR implanted, plus a mean with standard deviation error bars shown.

A.3 Chapter 7 additional data
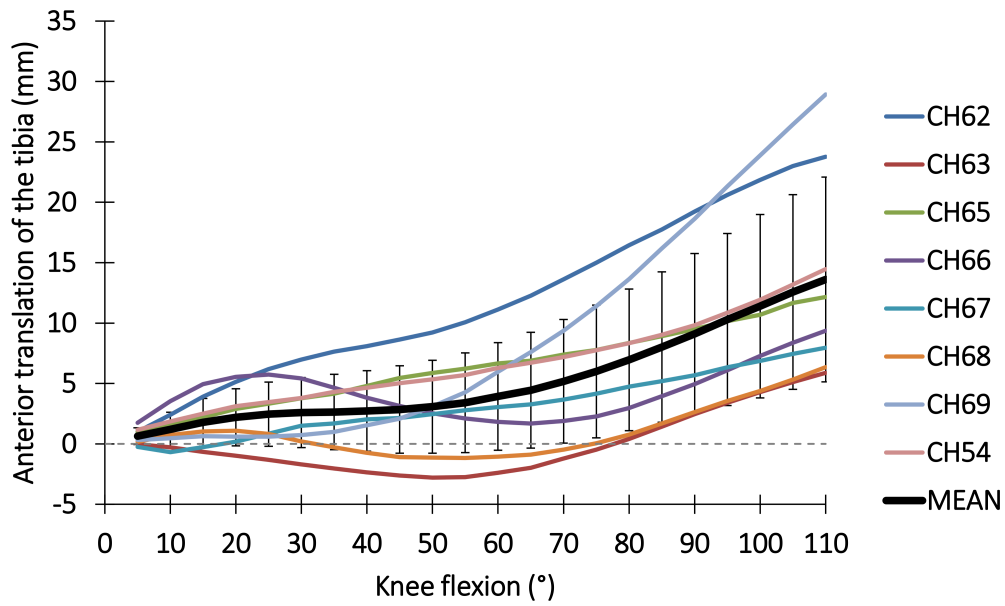
Figure A.25 Tibial anterior translation during knee flexion for 8 cadaver knees, plus a mean with standard deviation error bars shown.

Figure A.26   Tibial anterior translation during knee flexion for 8 cadaver knees with the BCR TKR implanted, plus a mean with standard deviation error bars shown.

Figure A.27   Tibial anterior translation during knee flexion for 8 cadaver knees with the Unity CR TKR implanted, plus a mean with standard deviation error bars shown.
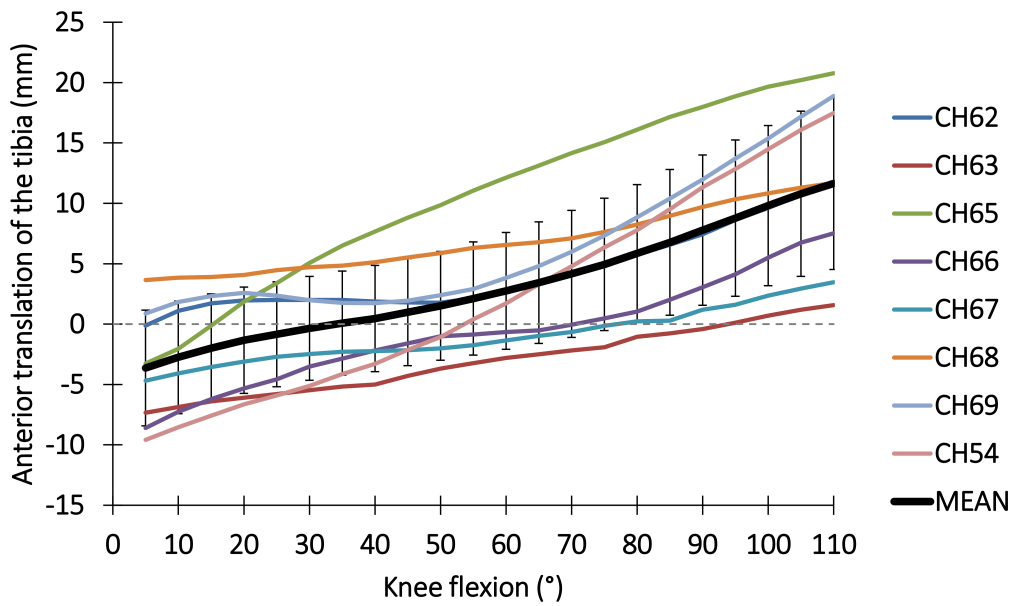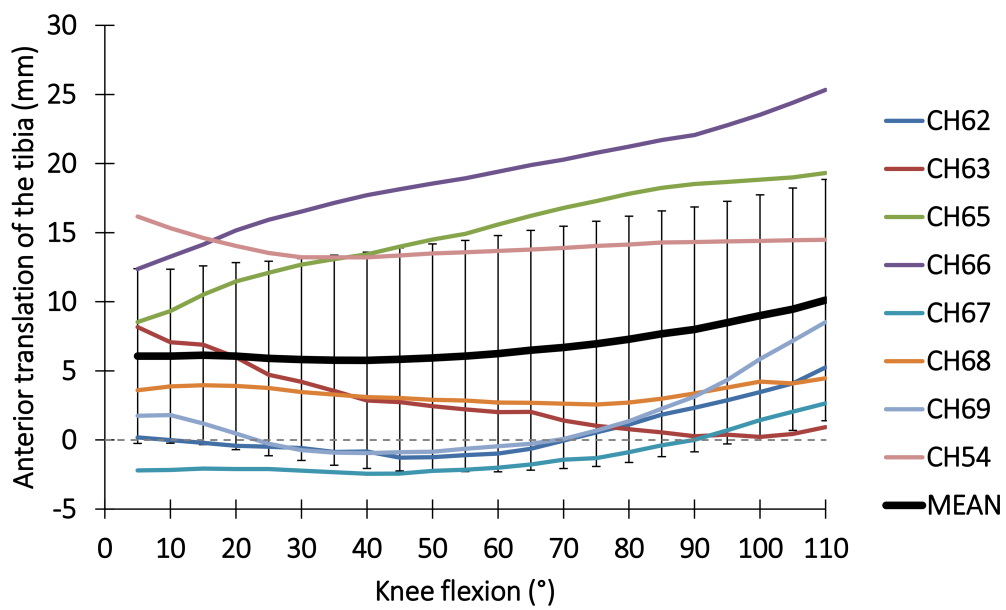
APPENDIX B

PATIENT REPORTED OUTCOMES AFTER TOTAL KNEE REPLACEMENT

B.1 Introduction

As part of the background to the project described in Chapter 7, a public and patient involvement (PPI) work package was completed. A key element of National Institue of Health Research (NIHR) funded projects is PPI and this Appendix describes the PPI activities that were completed for the BCR TKR project described in Chapter 7,. The project to develop a new type of TKR was focused on improving patient outcomes and quality of life following a major surgical event. Due to the increasingly large burden of primary and revision knee surgery there is a significant cost implication for the NHS and wider healthcare providers. Patient feedback and expectation for their replacement joint were the driving forces behind the project; both from published work and consultations with key opinion leader surgeons involved in the project. The aim of the PPI work package was to ensure that patient feedback influenced the development of the device throughout the project. Total knee replacement (TKR) implants are used to reduce pain and restore functionality to patients suffering from osteoarthritis. Historically, these devices have performed well, with revision of the device (surgical removal and replacement) being regarded as a failure. In its most recent Annual Report covering TKR procedures in 2012, the England and Wales National Joint Registry reports 9-year survivorship as 97% (NJR, 2013). But a much larger proportion of patients - up to 30% - report non-pain related dissatisfaction with some aspect of their life after TKR (Bourne *et al.*, 2010).

B.2 Objectives

The objectives of this work were to:

— Involve current and future TKR patients in the development process;

- Examine patient expectation and current satisfaction levels;

- Find out why non-painful dissatisfied TKR patients exist;

- Look at Patient Reported Outcome (PRO) measures for TKR surgery in the NHS.

B.3 Background to TKR dissatisfaction

When considering the reasons and solutions for post-operative dissatisfaction, it is important to distinguish between survivorship, surgeon satisfaction, post-operative pain and patient satisfaction. There are patients who experience pain after TKR which leads to dissatisfaction. But this pain can, for the most part, be explained and is linked most commonly to aseptic loosening, misalignment, polyethylene wear, infection, patellofemoral problems and instability (Dennis, 2004) and unexplained long-term pain after TKR surgery is very rare (Elson and Brenkel, 2007; Brander *et al.*, 2007; Mont *et al.*, 1996). While it is obviously important to address the causes of post-operative pain, it was the purpose of this work package to explore dissatisfaction with uncomplicated, pain free, TKR surgery. Understanding the cause and nature of this dissatisfaction is important in order to come up with solutions to it. Survival rates of TKRs are high but these statistics, while vital for identifying dangerous levels of implant failure, do not give an indication of who is actually happy with their device. It is a fairly crude measurement of success, because it only has a "yes/no" outcome (Goodfellow *et al.*, 2010). There are other conflicts which make it hard to assess TKR success:

- Patients with TKRs can score well on surgeon reported outcome (SRO) measures such as the Knee Society Score (Insall *et al.*, 1989) but still not be satisfied with their device (Harris *et al.*, 2013a). It is important that surgeons and implant designers are aware of this mismatch in satisfaction levels;

- Most PRO questionnaires are conducted soon after surgery (within 6 months) so any long term functional deficit that the patient might have with the device might not yet have been realised;

- Many patients do not complete the PRO questionnaires.

A review of some of the literature (Jacobson *et al.*, 2008; Kim *et al.*, 2010; Sharkey and Miller, 2011; Sloan *et al.*, 2009) suggests that post-operative dissatisfaction with TKR surgery, that is not directly related to the care received during the patient's stay in hospital, can be split into three broad categories: short term; long term pain; and long term function (Table B.1). It is the solving of the problems in the last category which is of most interest to implant designers.

Table B.1   Reasons for dissatisfaction with TKR surgery

Short term	Long term: pain	Long term: function
- More painful than expected	- Hurts during activity	- Feels funny
- More swelling that expected	- Hurts during activity	- "Clunking" sensation
- Recovery took longer than expected	- Hurts during the night	- Limited ROM
- Return to ADLs slow	- Hurts all the time	- Feels unstable
- Depression	- Infection	- Cannot do job any more
- Difficulty sleeping		- Activity goal not reached
		- "Not as good as expected"

B.4 Collection of PPI data

Recruitment for patient and public involvement through focus groups proved to be very challenging despite exploring several advertising avenues. As a result, pre- and post operative questionnaires were generated as an alternative method of gathering feedback on TKR surgery and experiences. The pre operative questionnaire (Section B.4.1) was based on a publication by Mancuso *et al.* (2003), while the post operative questionnaire (Section B.4.2) was based on publications by Bourne *et al.* (2010) and Scott *et al.* (2012). Both questionnaires were reviewed by the Clinical Research Manager at Corin. They were both published on the Imperial Biomechanics website and allowed completely anonymous online responses. The URL was disseminated via colleagues and social media outlets. 10 pre-operative and 23 post-operative questionnaires were completed. The feedback was analysed as and when the questionnaires were received. In addition to the questionnaires, a survey of the Oxford Knee Score (Dawson *et al.*, 1998) from the Hospital Episode Statistics (HES) Patient Reported Outcome Measures for 2011 to 2012 has also being completed (HSCIC, 2013) and is summarised later in this chapter.

B.4.1 Pre-operative questions

Question 1

How important are these expectations with regards to your total knee replacement?

Expectation	Very important	Somewhat important	A little important	I do not expect this	This does not apply to me
Relieve daytime pain in your knee	☐	☐	☐	☐	☐
Relieve pain that interferes with sleep	☐	☐	☐	☐	☐
Improve ability to walk	☐	☐	☐	☐	☐
Increase knee stability	☐	☐	☐	☐	☐
Increase knee mobility	☐	☐	☐	☐	☐
Improve ability to climb stairs	☐	☐	☐	☐	☐
Improve ability to go down stairs	☐	☐	☐	☐	☐
Improve ability to kneel	☐	☐	☐	☐	☐
Stop knee from catching or buckling	☐	☐	☐	☐	☐
Improve ability to get in or out of bed, a chair, a car or a bus	☐	☐	☐	☐	☐
Improve ability to perform activities of daily living around the home	☐	☐	☐	☐	☐
Improve ability to perform activities of daily living away from the home	☐	☐	☐	☐	☐
Improve psychological wellbeing	☐	☐	☐	☐	☐
Make knee straight	☐	☐	☐	☐	☐
Remove the need for a stick or frame	☐	☐	☐	☐	☐
Improve ability to exercise or take part in recreational sports	☐	☐	☐	☐	☐
Improve ability to participate in recreational or social activities	☐	☐	☐	☐	☐
Sexual activity	☐	☐	☐	☐	☐
Go back to paid work	☐	☐	☐	☐	☐
Improve ability to maintain general health	☐	☐	☐	☐	☐
Have confidence in knee	☐	☐	☐	☐	☐

Question 2

If you expect there to be pain relief after your knee replacement, which of these do you expect:

☐ Relieve some pain

☐ Relieve most pain

☐ Relieve all pain

Question 3

If you expect your ability to walk to be improved, over what distance do you expect it to be improved:

☐ Short distance (indoors, walk round the corner)

☐ Medium distance (go for a walk for less than a mile)

☐ Long distance (go for a walk for more than a mile)

Question 4

Have you had any advice from your surgeon about pain or function after the surgery?

Question 5

Do you have any concerns about how your knee will function after surgery?

Question 6

What is your employment status?

☐ Retired

☐ Working full time

☐ Working part time

☐ Student

☐ Unemployed, not looking for work

☐ Unemployed, looking for work

☐ Other:

Question 7

Which age bracket are you in?

☐ 18-30

☐ 31-45

☐ 46-60

☐ 61-75

☐ 76-90

☐ Over 90

B.4.2 Post-operative questions

Question 1

Overall, how satisfied are you with the results of your most recent knee replacement surgery?

☐ Very satisfied

☐ Satisfied

☐ Neutral

☐ Dissatisfied

☐ Very dissatisfied

Question 2

If you answered either ☐Neutral", ☐Dissatisfied" or ☐Very Dissatisfied" with your TKR, what aspect(s) of your knee or your hospital care are you dissatisfied with?

Question 3

How satisfied are you with your most recent knee replacement surgery for reducing your pain, when doing the following?

Activity	Very satisfied	Satisfied	Neutral	Dissatisfied	Very dissatisfied
Walking on a flat surface	☐	☐	☐	☐	☐
Going up stairs	☐	☐	☐	☐	☐
Going down stairs	☐	☐	☐	☐	☐
Sitting	☐	☐	☐	☐	☐
Lying down	☐	☐	☐	☐	☐
Standing	☐	☐	☐	☐	☐

Question 4

How satisfied are you with your most recent knee replacement surgery for improving your ability to perform the following functions?

Activity	Very satisfied	Satisfied	Neutral	Dissatisfied	Very dissatisfied
Getting in and out of a car	☐	☐	☐	☐	☐
Going up stairs	☐	☐	☐	☐	☐
Going down stairs	☐	☐	☐	☐	☐
Getting out of bed	☐	☐	☐	☐	☐
Lying in bed	☐	☐	☐	☐	☐
Performing light domestic duties	☐	☐	☐	☐	☐
Having sex	☐	☐	☐	☐	☐
Playing recreational sport	☐	☐	☐	☐	☐

Question 5

Is there anything you had been expecting to be able to do after your total knee replacement, that you COULDN'T do before the operation that you still CANNOT do?

Question 6

Is there anything you COULD do before the operation that you now CANNOT do?

Question 7

Is there anything you COULDN'T do before the operation that you now CAN do?

Question 8

Is there anything you wish you had discussed with your surgeon prior to your surgery?

Question 9

Were you warned about any of the following prior to surgery?

☐ Pain might not completely go

☐ There will be swelling which may last weeks or months

☐ You may have reduced flexion for several weeks or months

☐ Wasn't warned about any of these things

Question 10

Do you ever experience any of the following with your TKR?

☐ Clunking

☐ Clicking

☐ Stiffness

☐ Feeling of instability

☐ None of the above

Question 11

Have you had more than one total knee replacement?

☐ Yes

☐ No

Question 12

Do you have any other comments or remarks about your satisfaction and experiences with your total knee replacement?

Question 13

Would you have the surgery again (on your other knee) or recommend the surgery to a friend or family member?

☐ Yes

☐ No

Question 14

What is your employment status?

☐ Retired

☐ Working full time

☐ Working part time

☐ Student

☐ Unemployed, not looking for work

☐ Unemployed, looking for work

☐ Other:

Question 15

Which age bracket are you in?

☐ 18-30

☐ 31-45

☐ 46-60

☐ 61-75

☐ 76-90

☐ Over 90

Question 16

Do you have any idea what type of total knee replacement you were given?

B.5 Results

B.5.1 Pre-operative questionnaire – summary of results

– Improving walking ability is the most important expectation (100% said it was very important)

– 70% would like to do sport post TKR - 1 patient would like to ski again

– Confidence is also very important to 80%

– 8 out of 10 responders expect to be able to walk distances of over 1 mile post TKR

– Pre-op patients are concerned about going back to work - 60% of responders work at least part time

Functional aspirations were highlighted by this questionnaire. It is a very small sample size so far but it has confirmed that prospective TKR patients are looking for high functioning devices and will be disappointed if their TKR does not allow them to reach their functional goals.

B.5.2 Post-operative questionnaire – summary of results
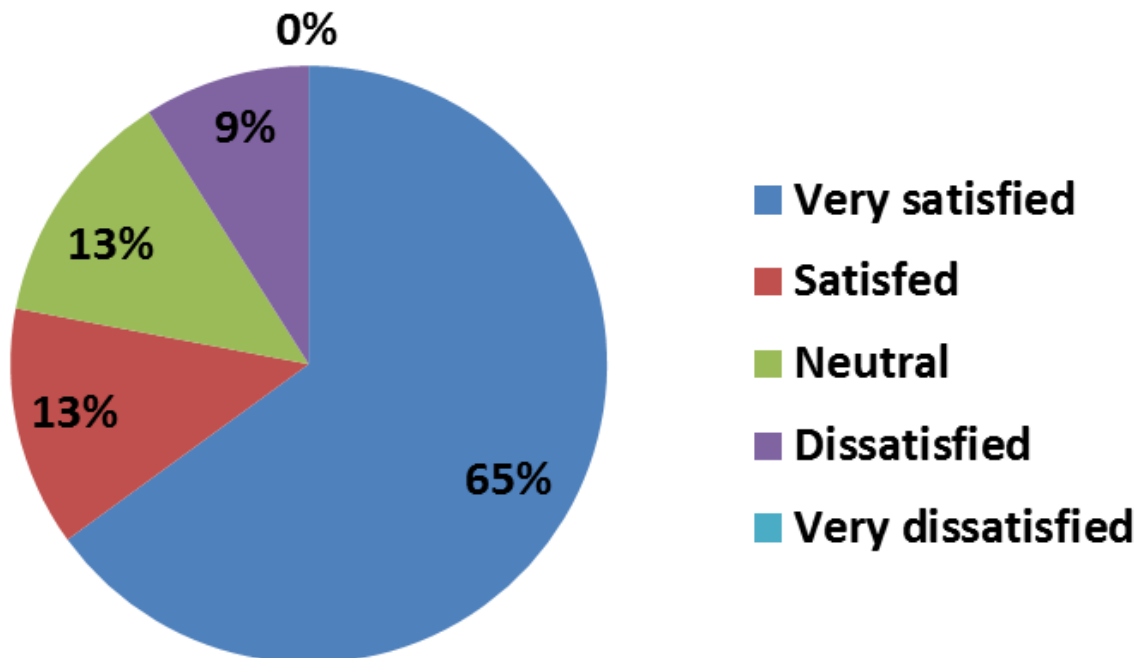
Figure B.1   Question 1.   Overall, how satisfied are you with the results of your most recent knee replacement surgery?

- 65% very satisfied BUT 22% either feel neutral about their TKR or are dissatisfied. This agrees with data in the literature.

- Stairs and manoeuvres like getting in and out of cars seem to pose most problems post TKR

- 35% of responders are neutral, dissatisfied or very dissatisfied about the amount of sport they can play post TKR

- Patients were generally warned about potential problems with their TKR but some seemed to have had very little dialogue with their surgeon prior to the procedure

- Stiffness affects nearly half the responders (43%)

- Going down stairs is a problem for 21% of patients

- 35% work part time or would like to

- Most responders were aged over 60 but 26% were between 31 and 60 years old

- Kneeling appears to be a big problem that was not directly queried by the survey. It came up repeatedly as something that respondents could do prior to surgery but could not do post-TKR and were not necessarily warned about this limitation.

B.6 HES OKS data

Because of the small amount of data collected via the questionnaires, the data collected by the HES and published by the Health & Social Care Information Centre (HSCIC) became a valuable resource of PRO data. All NHS TKR patients in England are asked to complete the Oxford Knee Score (OKS) (Dawson *et al.*, 1998) and EQ-5D questionnaire before and after their surgery (this is also done for other elective surgeries, namely hip replacement, varicose vein treatment and groin hernia surgery). OKS data for the period May 2011 to April 2012 were downloaded from the HSCIC website (HSCIC, 2013). There were data for 43,116 TKR patients. Incomplete data were removed (in some cases there were no post-operative PROMs scores), leaving 41,306 data points. Although some PROMs data is now published as part of the NJR Annual Report, the raw data was downloaded to enable a more thorough investigation of the pre- and post-operative PRO scores, particularly the OKS. The OKS has twelve questions which are a mixture of pain and function related questions. Each question

in the OKS is worth 0, 1, 2, 3 or 4 points, where 4 is the best score. The scores are added together to give a total score of between 0 (worst) and 48 (best) (Table B.2).

Table B.2   The Oxford Knee Score – scale and indications.

OKS	Indication
0-19	May indicate severe knee arthritis. It is highly likely that you may well require some form of surgical intervention, contact your family physician for a consult with an Orthopaedic Surgeon.
20-29	May indicate moderate to severe knee arthritis. See your family physician for an assessment and x-ray. Consider a consult with an Orthopaedic Surgeon.
30-39	May indicate mild to moderate knee arthritis. Consider seeing your family physician for an assessment and possible x-ray. You may benefit from non-surgical treatment, such as exercise, weight loss, and/or anti-inflammatory medication
40-48	May indicate satisfactory joint function. May not require any formal treatment.

For this research, the questions in the OKS were split into pain and function categories (Table B.3) to try to better understand post operative OKS improvement. It was hypothesised that overall improvement in the OKS after TKR surgery might be skewed by the pain related questions.

Table B.3   The Oxford Knee Score questions – split into pain and function categories.

No.	Question	Pain or function?
1	How would you describe the pain you usually have in your knee?	Pain
2	Have you had any trouble washing and drying yourself (all over) because of your knee?	Function
3	Have you had any trouble getting in and out of the car or using public transport because of your knee?	Function
4	For how long are you able to walk before the pain in your knee becomes severe?	Pain
5	After a meal (sat at a table) how painful has it been for you to stand up from the chair because of your knee?	Pain
6	Have you been limping when walking, because of your knee?	Pain
7	Could you kneel down and get up afterwards?	Function
8	Are you troubled by pain in your knee in bed at night?	Pain
9	How much has pain from your knee interfered with your work (including housework)?	Pain
10	Have you ever felt that your knee might suddenly □give way" or let you down?	Pain
11	Could you do household shopping on your own?	Function
12	Could you walk down a flight of stairs?	Function

This method of splitting the OKS has been shown to be statistically meaningful using exploratory factor analysis and confirmatory factor analysis (Harris *et al.*, 2013b). Two separate scores were therefore calculated:

1. "Function OKS" score consisting of questions 2, 3, 7, 11, 12 (total possible points = 20).

2. "Pain OKS" score consisting of questions 1, 4, 5, 6, 8, 9, 10 (total possible points = 28).

So that they can be directly compared to each other, these scores were then each standardised
to range from 0 (worst) to 100 (best) (rather than 0 to 48) by multiplying the "Function" score by
$\frac{100}{20}$ and the "Pain" score by $\frac{100}{28}$. The modified indication scores are given in Table B.4

Table B.4   The Oxford Knee Score questions – split into pain and function categories.

Total OKS	Pain OKS	Function OKS
0-19	0-39.58	0-39.58
20-29	41.67-60.42	41.67-60.42
30-39	62.5-81.25	62.5-81.25
40-48	83.33-100	83.33-100

The overall OKS data indicate a big improvement in outcome after TKR surgery, with the number
of patients in the 40-48 bracket increasing from 171 to 14,739 (Table B.5). However, over 10% of
patients (4,497) had OKS scores of 0-19 after surgery and there were 8% of patients whose OKS
worsened or stayed the same after the procedure (Table B.5).

Table B.5   Pre- and post-operative OKS for TKRs in England May 2011 - April 2012.

OKS	Pre-op	Post-op
0-19	23012	4497
20-29	14677	8120
30-39	3446	13950
40-48	171	14739
Total	41306	41306

The data was then split into the pain and function OKS subscores. When only pain is considered,
patient outcome is even better, with over 93% of patients showing an improvement. However, when
the function subscore is calculated, nearly 12% of patients worsened after their TKR implantation
and nearly 6% showed no difference (Table B.6).

Table B.6   Change in OKS.

Post Op	Overall	Pain	Function
Worsened	7%	5.1%	11.7%
Stayed the same	1%	1.8%	5.7%
Improved	92%	93.1%	82.6%

The information was then further split, using patient age and *pre-operative* Oxford knee scores as
categories (Figure B.2). It was hypothesised that this result might be exaggerated if only patients
with pre-operative OKS scores of below 30 (i.e. in the worst two indication bands) but there was

no evidence to support this. However, when the results were split into age categories, this functional deficit did appear to be worse in younger patients, with over 30% of patients between 40 and 50 years old recording a "Function OKS" that either worsened or stayed the same post-TKR (Figure B.2). For patients between 50 and 60 years old, this number was close to 25%.
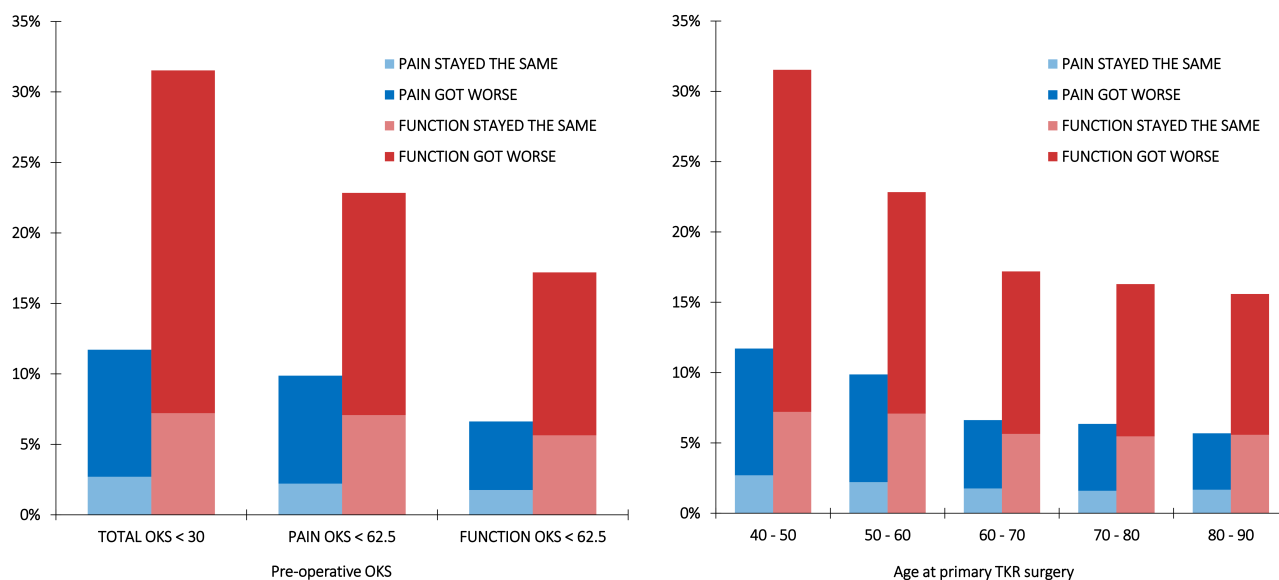
Figure B.2   Changes in OKS scores according to pre-operative OKS scores and ages of patient. These data just represent cases where OKS scores stayed the same or got worse, improvements are not shown

B.6.1 Summary

The OKS scores were split into "Pain OKS" and "Function OKS" to allow a more meaningful interpretation of the data. An improvement in "Pain OKS" was recorded in the vast majority of cases (93.1%), but the "Function OKS" showed a different story, with over 17% of patients recording a post-operative "Function OKS" that had worsened or stayed the same compared to the pre-operative score. The data also suggest that younger patients do not function as well post-TKR as their older counterparts.

The pain aspect of the OKS does appear to skew the results. If the OKS is split into pain and function subscores, post-operative success can be assessed more thoroughly. The primary objective of TKR is being achieved – almost all patients report an improvement in pain levels. But there is clearly a function problem which needs to be addressed.

B.7 Conclusions

A mixture of project-specific patient feedback and HES PROMs was analysed for this study. Responses from pre-operative patients suggest that while pain-relief is the number one priority for those waiting for a TKR procedure, post-operative function is also a major concern. The post-operative responses agreed with this and demonstrated certain functional deficiencies in post-operative TKR patients, with 21% of patients being unhappy about going downstairs with their TKR. Kneeling was also highlighted as being problematic. The PROMs data from England for 2011-2012 confirmed that improvement in function lags behind pain relief in TKR patients. Better

APPENDIX C

FINITE ELEMENT STUDY OF PROXIMAL TIBIAL STRAINS AFTER BCR TKR

C.1 Introduction

Although the Phase 2 design gave promising results in the cadaveric experiment, with fewer avulsion fractures occurring than with the Phase 1 design, more work was needed to optimise the shape and size of the tibial component and the saw cuts by considering the size and shape of the ACL and PCL attachment sites and by analysing the bone strains in the proximal tibia.

C.2 Method

First, 50 CT scans of knee injury patients were analysed: AP and ML distances were measured directly and, using relationships in the literature, the positions and sizes of the ACL and PCL attachment sites, the medial and lateral compartmental widths, and the width of the tibial spine were calculated (Edwards *et al.*, 2007a; Edwards *et al.*, 2007b; McDermott *et al.*, 2004) (Figure C.1). This information was fed into the design of the Phase 3 tibial components and the 3D printed cutting guides and the surgical technique (Figure C.2).

A Anterior tibial surface
B Apex of medial tibial spine
C Lateral border of medial tibial spine
D "Over the back" ridge
E Posterior tibial axis
F ML width
G AP depth
H Posterior tibial axis to over the back ridge
J Length of ACL attachment
K Centre of ACL to posterior tibial axis
L Over the back ridge to centre of ACL
M ACL width
N ACL centre to medial spine border
P ACL centre to medial edge of tibia
R Width of AL bundle of PCL
S Centre of AL bundle of PCL to posterior tibia axis
T Centre of AL bundle of PCL to medial tibial edge
U AP depth of lateral compartment
V Medial edge of ACL to medial edge of tibia
W Lateral edge of ACL attachement to lateral tibial border
X Medial tibial border to medial edge of PCL attachment
Y Lateral edge of PCL attachment to lateral tibial border

Figure C.1   Tibial plateau measurements. By direct measurement of F (ML width) and G (AP depth), the data in Edwards *et al.* (2007a), Edwards *et al.* (2007b), and McDermott *et al.* (2004) were used to calculate M, R, V, W, X, Y, for input into the design of Phase 3 implants and surgical technique
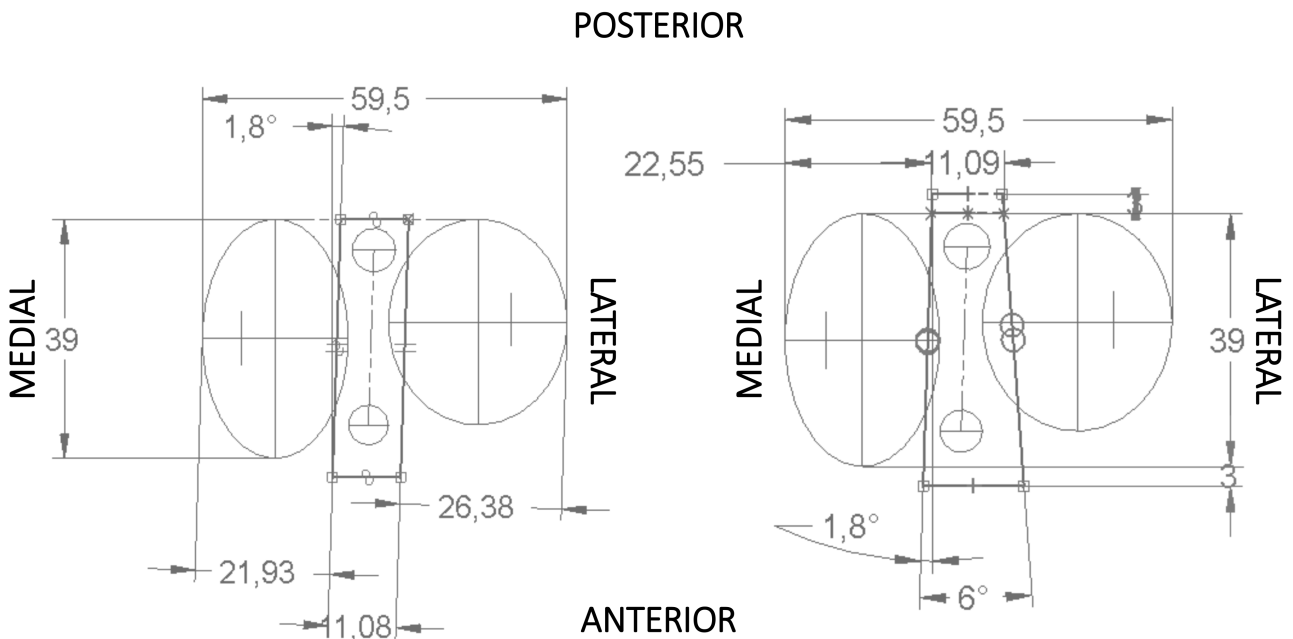
Figure C.2   Phase 3 tibial surgical technique for a left knee. Left: parallel cut preparation. Right: divergent cut preparation. All dimensions are in mm. This particular knee is equivalent to a size 1 Unity Knee™ TKR (the smallest available)

C.3 FE model

C.3.1 Segmentation

A small scale finite element study was then conducted to elucidate more information and further inform the design of the Phase 3 tibia. The Materialise Innovation software package (Mimics version 15.0 and 3-Matic version 7.01, Materials, Leuven, Belgium) was used to segment the bony geometry from a CT scan of an intact knee and then build a mesh Figure C.3, using previously validated criteria for element size and shape and material properties of bone (Tuncer *et al.*, 2013). Material property assignment was as follows:

$$\rho = 0.000504 \times grey\ value \qquad \text{(C.1)}$$

$$E = -817 + 9093\rho \qquad \text{(C.2)}$$

$$\nu = 0.3 \qquad \text{(C.3)}$$

Where ρ = bone density, E = Young's Modulus, ν = Poisson's Ratio and grey value refers to values in the CT data.
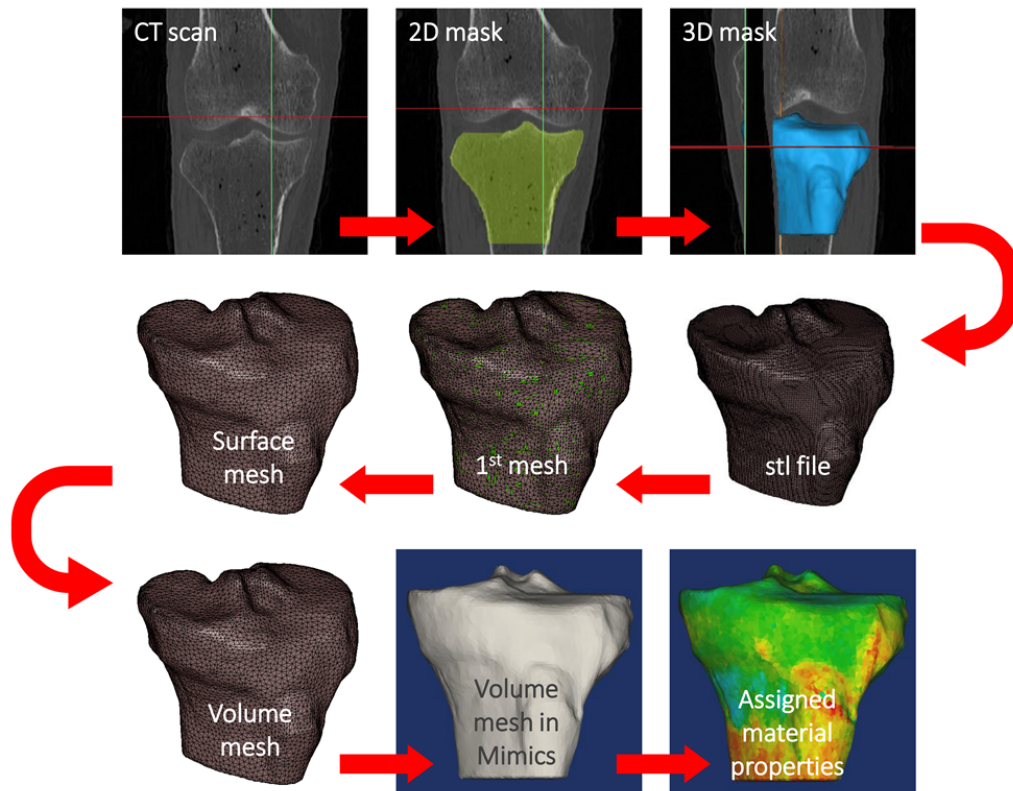
Figure C.3   FEA process

For baseline strains in the proximal tibia, a mesh of the intact knee was imported into Abaqus (Version 6.12, Dassault SystÃmes, VÃlizy-Villacoublay Cedex, France) and ACL and PT loads were simulated (Figure C.4).

C.3.2 in silico surgery

Once an FE model of the intact tibia had been created, the saw cuts had to be simulated so that the post-operative tibia could also be analysed. Three "cutters" were built using Solidworks (Version 12, Dassault SystÃmes, VÃlizy-Villacoublay Cedex, France) and then Rhino 3D (Version 5, Robert McNeel, Seattle, WA, USA) was used to perform Boolean operations on the mesh, as follows:

– Use CAD model of tibia trays to create a "cutter" in Solidworks, export cutter and tray as STL file;

– Import intact tibia surface mesh into Rhino;

– Import cutter and tray into Rhinoceros;

– Align tray and cutter correctly to tibial geometry and delete tray (Figure C.5);

– Perform Boolean function to make the simulated cuts;
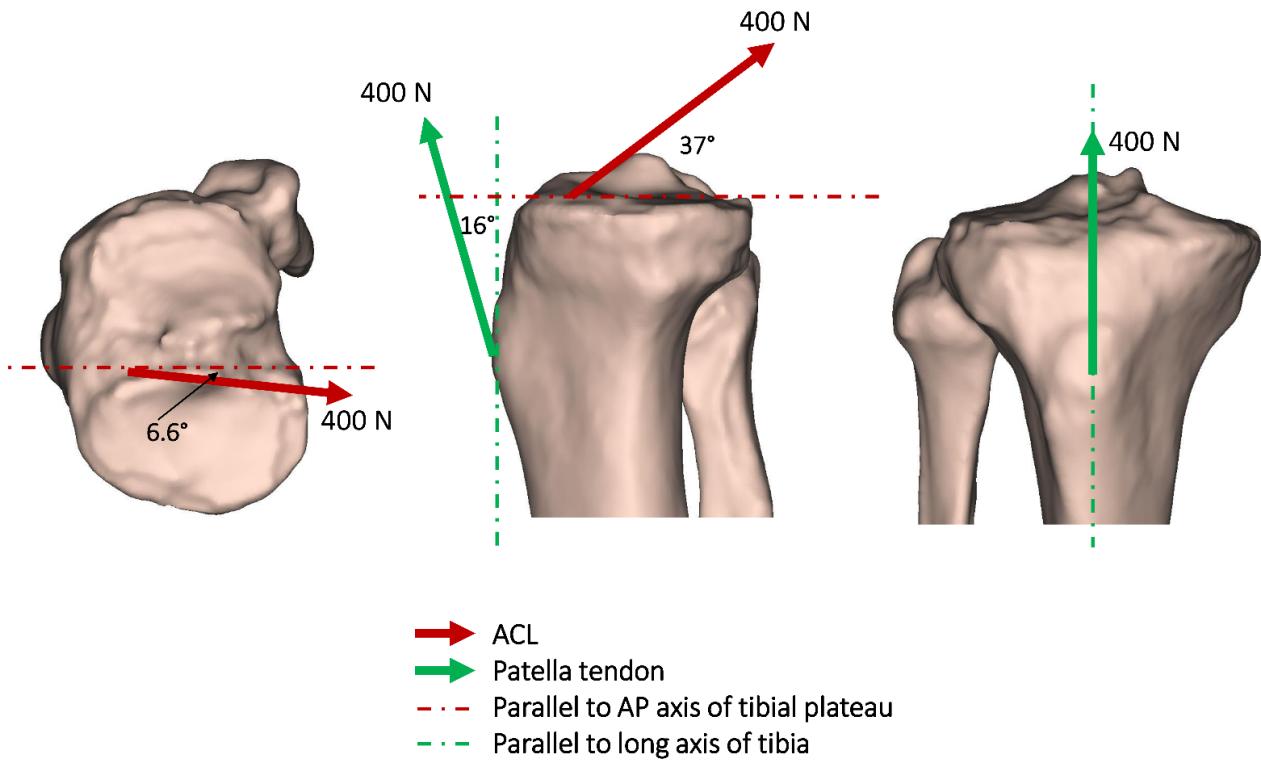
Figure C.4   Directions and magnitudes of the ACL and PT loads used in the FE model

– Export resulting mesh as STL file;

– Import back into 3-Matic and remesh, then create volume mesh using TET10 elements;

– Import back into Mimics and assign material properties;

– Export volume mesh and material information as an Abaqus input file.
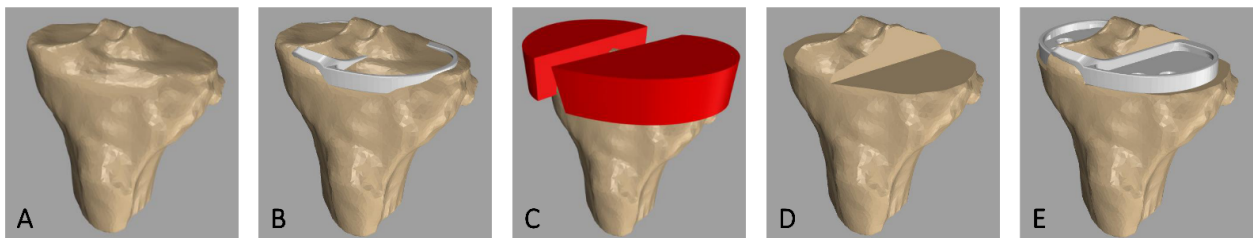
Figure C.5   In silico saw cuts for BCR TKR. A: intact tibia; B: implant positioning; C: cutters in place; D; prepared tibia; E: implant in place on the prepared tibial plateau.

Seven different models were created using this technique:

1. Intact tibia

2. Phase 1 tibia

3. Phase 2 tibia

237

4. Phase 2 tibia with a reduced width tibial spine (larger lateral compartment)

5. Phase 2 tibia with a radius at the intersection of the vertical and horizontal cuts

6. Phase 3 tibia with parallel vertical sagittal cuts

7. Phase 3 tibia with divergent vertical sagittal cuts

C.3.3 Validation of the FE model

All seven of the prepared tibiae were then evaluated in Abaqus, with the applied loads as described previously. The Phase 1 and 2 tibiae were modelled to cross-validate the FE model with the experimental observations. The model agreed with the experimental work, showing elevated tibial strains around the bone block where the vertical and horizontal cuts met, particularly around the anteromedial aspect of the bone island. The radius reduced the strains around the bone block somewhat, but the results of the models demonstrated that the proximal strains are most sensitive to a) the location of the medial, vertical sagittal cut (where it is in relation to the ACL attachment and b) the removal of the front portion of the bone block that was required by the Phase 1 design (Figures C.6 and C.7). The results from this FEA, combined with the other concerns about a horseshoe shaped monoblock component, confirmed that the dual tibial tray option would be the best option to proceed with for Phase 3 and would give the most amount of flexibility in terms of bone coverage, ligament preservation and rotational alignment.
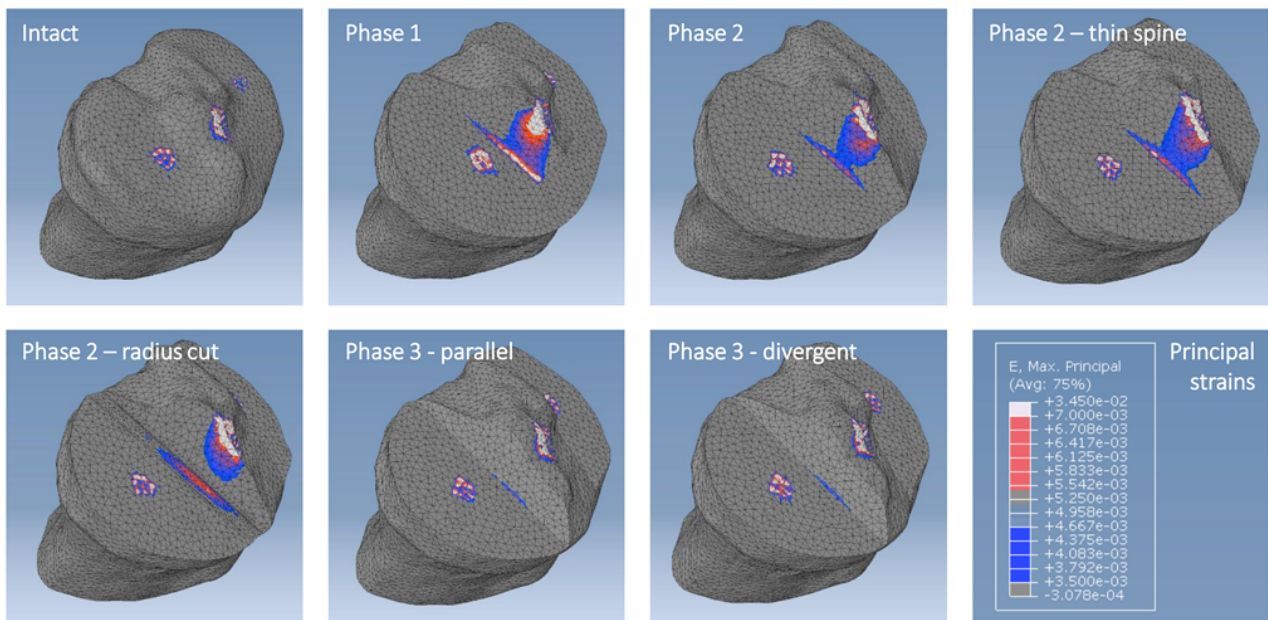
Figure C.6   FEA results
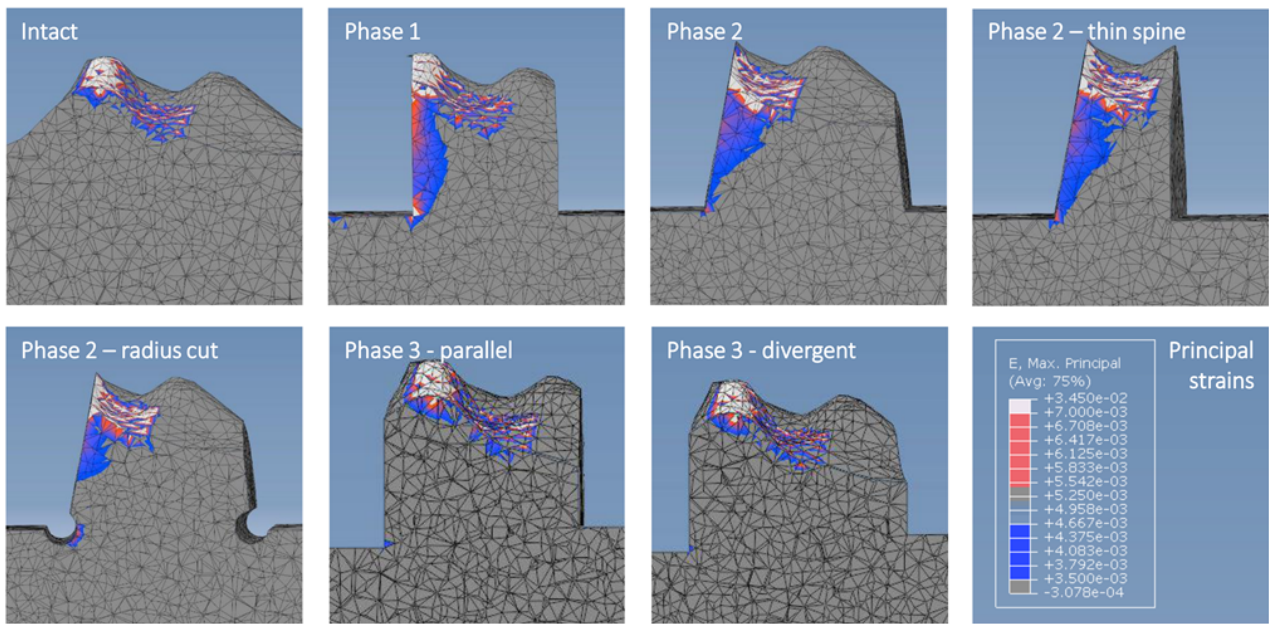
Figure C.7   FEA results, section through tibia

C.3.4 Phase 3 check for size

Once the dual implant design was chosen, it was important to check that the implants gave good bone coverage and fitted the tibia as intended. This was done in two ways. First, the fit with cadaver specimens in the laboratory was checked using a template of the implants (an example is shown in Figure C.8). Secondly, the fit using an FE model of the tibia and CAD model of the implants was checked. Once the cuts had been made in Rhino, the CAD models of the actual implants were imported and positioned on the bone (Figure C.9). The template shown in Figure C.8 was generated using the Unity Knee™ tibia plate profile as a basis. The ACL-PCL slot was positioned with reference to the medial aspect of the tibia and the posterior axis. The size was determined based on the ML dimension. Figure C.9 shows the bi-unicompartmental device; the cuts were positioned as before but the implant was now sized based on the AP dimension, resulting in a smaller sized device for the lateral compartment relative to the medial, giving greater bone coverage while also keeping the central bone "island" as strong as possible.
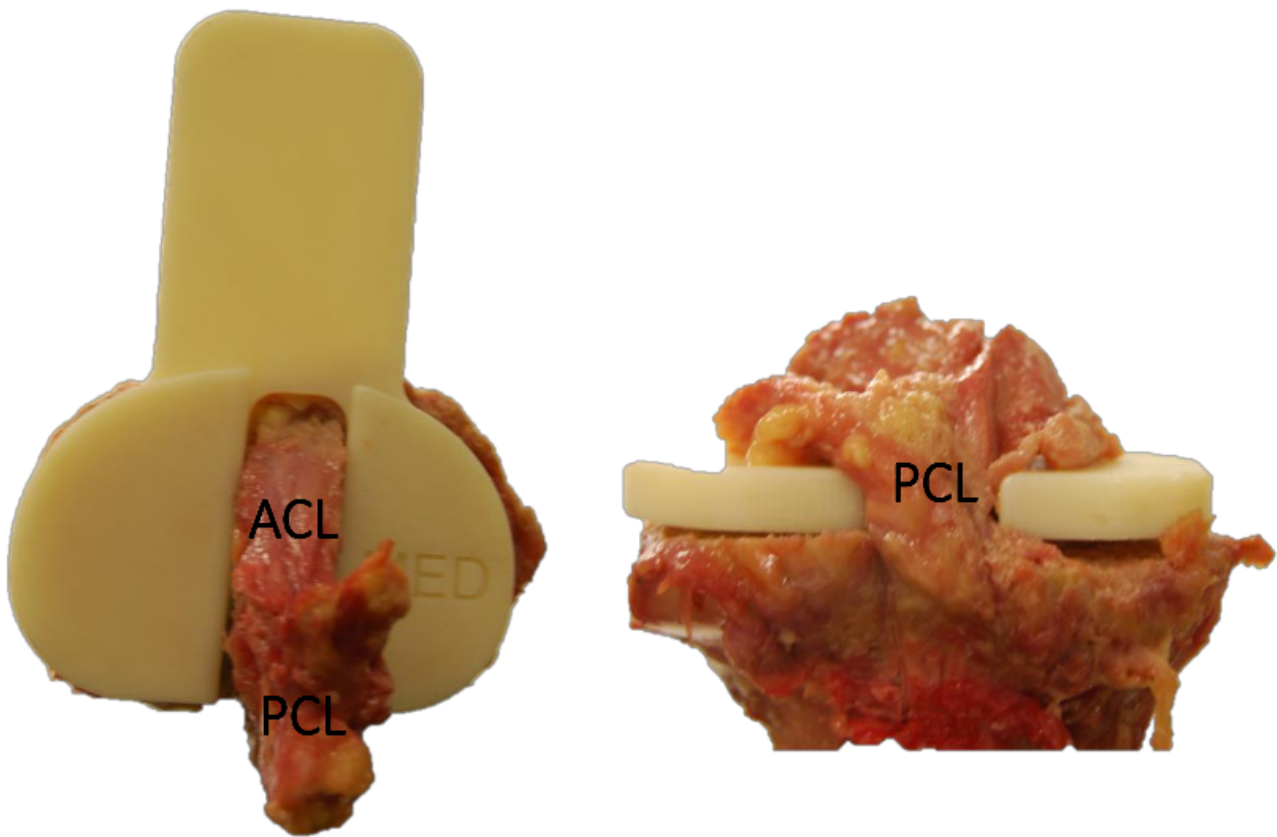
Figure C.8   The template used for size checking and positioning of the medial and lateral components for the BCR TKR with dual tibial trays.
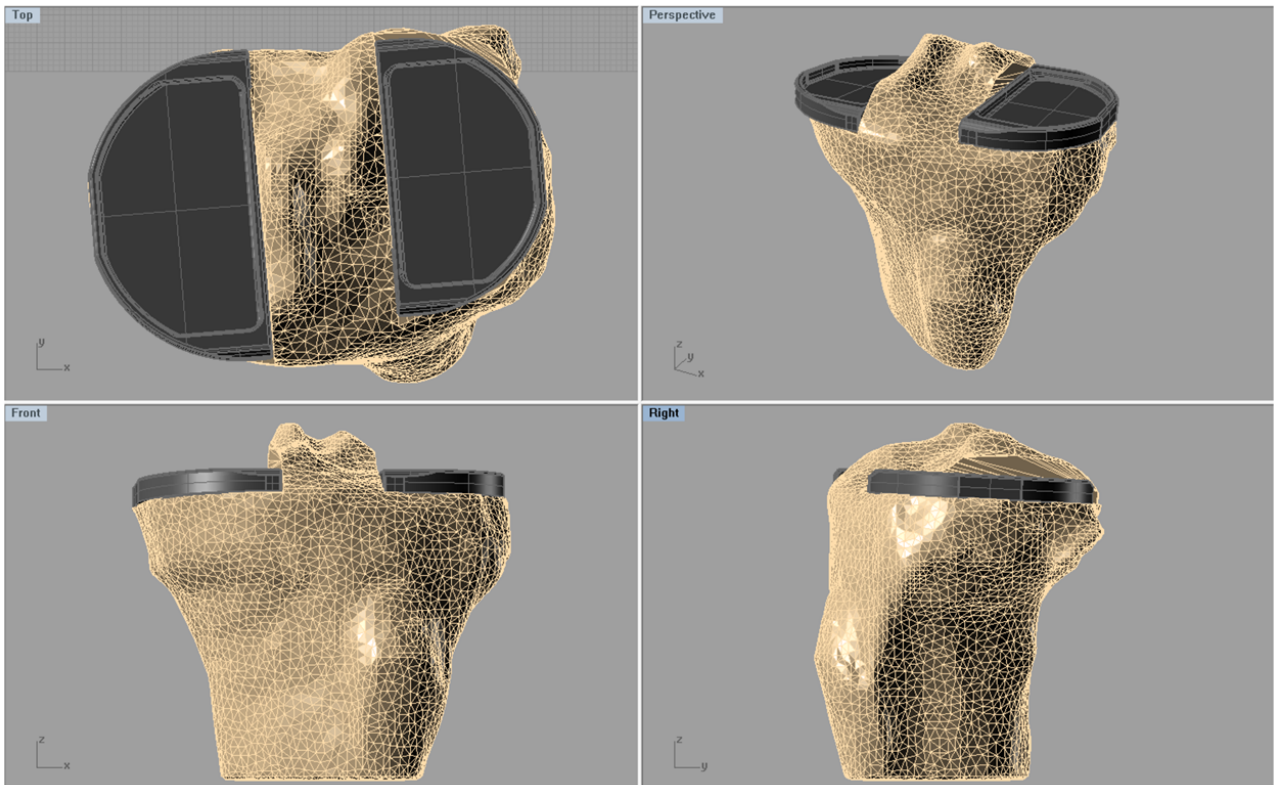
Figure C.9   In silico visualisation of the dual tibia BCR TKR

C.4 Conclusion

A small FE study was completed to assess the bone strains in the proximal tibia after saw cuts for three different designs of BCR TKR. The risk of the ACL bone block avulsing is very sensitive to the location of the medial vertical sagittal cut; as long as this is medial enough, and the front vertical cut is not required, the risk of an avulsion fracture is low. A dual tibial design gives the most flexibility in terms of implant alignment and bone coverage.

APPENDIX D

PUBLICATIONS

Some of the work in this thesis has been presented in peer-reviewed journals and via oral presentations at conferences.

Peer-Reviewed Journal Articles

– Halewood C, Traynor A, Bellemans J, Victor J, Amis AA. Anteroposterior laxity after bicruciate-retaining total knee arthroplasty is closer to the intact knee than ACL-resecting TKA: a biomechanical cadaver study. Journal of Arthroplasty, 30(12):2315-9, 2015

– Halewood C, Risebury M, Thomas, NP, Amis AA. Kinematic behaviour and soft tissue management in guided-motion total knee replacement. Knee Surgery Sports Traumatology Arthroscopy, 22(12); 3074-82, 2014.

Peer-Reviewed and Invited Oral Presentations at International Conferences (1st author)

– Halewood C, Amis AA. Basic Biomechanics of the Knee Joint. Ulm Biomechanics Symposium, 2015.

– Halewood C, Traynor A, Luyckx T, Claes S, Bellemans J, Victor J, Amis AA. Anteroposterior laxity after bicruciate-retaining TKR: a biomechanical study. Annual Congress, British Association for Surgery of the Knee, 2015.

– Halewood C, Luyckx T, Claes S, Collins, S, Lowry C, Amis AA. ACL Retaining Total Knee Arthroplasty can Improve Knee Stability. European Society of Biomechanics Annual Congress, 2013.

– Halewood C, Zakaria T, Amis AA. ASTM Assessment Methods for Total Knee Replacements. IMechE Knee Arthroplasty: From Early Intervention to Revision, 2009.

APPENDIX E

PERMISSIONS FOR THIRD PARTY COPYRIGHT WORKS

Table E.1   Summary of permission for third party copyright

Page Numbers	Type of work	Source of work	Copyright holder & year	Permission status
99-129	Text	KSSTA (2014)	© Springer-Verlag Berlin Heidelberg 2014	Granted
131-162	Text	Journal of Arthroplasty (2015)	© Elsevier 2015	Granted

The 2 License Agreements for the above permissions can be found on the following pages.

This is a License Agreement between Camilla Halewood ("You") and Springer ("Springer") provided by Copyright Clearance Center ("CCC"). The license consists of your order details, the terms and conditions provided by Springer, and the payment terms and conditions.

All payments must be made in full to CCC. For payment instructions, please see information listed at the bottom of this form.

License Number	3813621205102
License date	Feb 21, 2016
Licensed content publisher	Springer
Licensed content publication	Knee Surgery, Sports Traumatology, Arthroscopy
Licensed content title	Kinematic behaviour and soft tissue management in guided motion total knee replacement
Licensed content author	Camilla Halewood
Licensed content date	Jan 1, 2014
Volume number	22
Issue number	12
Type of Use	Book/Textbook
Requestor type	Publisher
Publisher	Imperial College
Portion	Excerpts
Format	Print and Electronic
Excerpt type	> 2000 words
Will you be translating?	No
Print run	1
Author of this Springer article	Yes and you are the sole author of the new work
Order reference number	None
Title of new book	TOTAL KNEE REPLACEMENTS: DESIGN AND PRE-CLINICAL TESTING METHODS
Publisher	Imperial College
Author of new book	Camilla Halewood
Expected publication date of new book	Apr 2016
Estimated size of new book (pages)	260
Total	0.00 GBP

Terms and Conditions

Introduction
The publisher for this copyrighted material is Springer. By clicking "accept" in connection with

completing this licensing transaction, you agree that the following terms and conditions apply to this transaction (along with the Billing and Payment terms and conditions established by Copyright Clearance Center, Inc. ("CCC"), at the time that you opened your Rightslink account and that are available at any time at http://myaccount.copyright.com).

Limited License

With reference to your request to reuse material on which Springer controls the copyright, permission is granted for the use indicated in your enquiry under the following conditions:

- Licenses are for one-time use only with a maximum distribution equal to the number stated in your request.

- Springer material represents original material which does not carry references to other sources. If the material in question appears with a credit to another source, this permission is not valid and authorization has to be obtained from the original copyright holder.

- This permission

• is non-exclusive

• is only valid if no personal rights, trademarks, or competitive products are infringed.

• explicitly excludes the right for derivatives.

- Springer does not supply original artwork or content.

- According to the format which you have selected, the following conditions apply accordingly:

• **Print and Electronic:** This License include use in electronic form provided it is password protected, on intranet, or CD-Rom/DVD or E-book/E-journal. It may not be republished in electronic open access.

• **Print:** This License excludes use in electronic form.

• **Electronic:** This License only pertains to use in electronic form provided it is password protected, on intranet, or CD-Rom/DVD or E-book/E-journal. It may not be republished in electronic open access.

For any electronic use not mentioned, please contact Springer at permissions.springer@spi-global.com.

- Although Springer controls the copyright to the material and is entitled to negotiate on rights, this license is only valid subject to courtesy information to the author (address is given in the article/chapter).

- If you are an STM Signatory or your work will be published by an STM Signatory and you are requesting to reuse figures/tables/illustrations or single text extracts, permission is granted according to STM Permissions Guidelines: http://www.stm-assoc.org/permissions-guidelines/

For any electronic use not mentioned in the Guidelines, please contact Springer at permissions.springer@spi-global.com. If you request to reuse more content than stipulated in the STM Permissions Guidelines, you will be charged a permission fee for the excess content.

Permission is valid upon payment of the fee as indicated in the licensing process. If permission is granted free of charge on this occasion, that does not prejudice any rights we might have to charge for reproduction of our copyrighted material in the future.

-If your request is for reuse in a Thesis, permission is granted free of charge under the following conditions:

This license is valid for one-time use only for the purpose of defending your thesis and with a maximum of 100 extra copies in paper. If the thesis is going to be published, permission needs to be reobtained.

- includes use in an electronic form, provided it is an author-created version of the thesis on his/her own website and his/her university's repository, including UMI (according to the definition on the Sherpa website: http://www.sherpa.ac.uk/romeo/);

- is subject to courtesy information to the co-author or corresponding author.

Geographic Rights: Scope

Licenses may be exercised anywhere in the world.

Altering/Modifying Material: Not Permitted

Figures, tables, and illustrations may be altered minimally to serve your work. You may not alter or modify text in any manner. Abbreviations, additions, deletions and/or any other alterations shall be made only with prior written authorization of the author(s).

Reservation of Rights

Springer reserves all rights not specifically granted in the combination of (i) the license details provided by you and accepted in the course of this licensing transaction and (ii) these terms and conditions and (iii) CCC's Billing and Payment terms and conditions.

License Contingent on Payment

While you may exercise the rights licensed immediately upon issuance of the license at the end of the licensing process for the transaction, provided that you have disclosed complete and accurate details of your proposed use, no license is finally effective unless and until full payment is received from you (either by Springer or by CCC) as provided in CCC's Billing and Payment terms and conditions. If full payment is not received by the date due, then any license preliminarily granted shall be deemed automatically revoked and shall be void as if never granted. Further, in the event that you breach any of these terms and conditions or any of CCC's Billing and Payment terms and conditions, the license is automatically revoked and shall be void as if never granted. Use of materials as described in a revoked license, as well as any use of the materials beyond the scope of an unrevoked license, may constitute copyright infringement and Springer reserves the right to take any and all action to protect its copyright in the materials.

Copyright Notice: Disclaimer

You must include the following copyright and permission notice in connection with any reproduction of the licensed material:

"Springer book/journal title, chapter/article title, volume, year of publication, page, name(s) of author(s), (original copyright notice as given in the publication in which the material was originally published) "With permission of Springer"

In case of use of a graph or illustration, the caption of the graph or illustration must be included, as it is indicated in the original publication.

Warranties: None

Springer makes no representations or warranties with respect to the licensed material and adopts on its own behalf the limitations and disclaimers established by CCC on its behalf in its Billing and Payment terms and conditions for this licensing transaction.

Indemnity

You hereby indemnify and agree to hold harmless Springer and CCC, and their respective officers, directors, employees and agents, from and against any and all claims arising out of your use of the licensed material other than as specifically authorized pursuant to this license.

No Transfer of License

This license is personal to you and may not be sublicensed, assigned, or transferred by you without Springer's written permission.

No Amendment Except in Writing

This license may not be amended except in a writing signed by both parties (or, in the case of Springer, by CCC on Springer's behalf).

Objection to Contrary Terms

Springer hereby objects to any terms contained in any purchase order, acknowledgment, check endorsement or other writing prepared by you, which terms are inconsistent with these terms and conditions or CCC's Billing and Payment terms and conditions. These terms and conditions, together with CCC's Billing and Payment terms and conditions (which are incorporated herein), comprise the entire agreement between you and Springer (and CCC) concerning this licensing

transaction. In the event of any conflict between your obligations established by these terms and conditions and those established by CCC's Billing and Payment terms and conditions, these terms and conditions shall control.

Jurisdiction

All disputes that may arise in connection with this present License, or the breach thereof, shall be settled exclusively by arbitration, to be held in the Federal Republic of Germany, in accordance with German law.

V 12AUG2015

Questions? customercare@copyright.com or +1-855-239-3415 (toll free in the US) or +1-978-646-2777.

**ELSEVIER LICENSE
TERMS AND CONDITIONS**

Feb 21, 2016

This is a License Agreement between Camilla Halewood ("You") and Elsevier ("Elsevier") provided by Copyright Clearance Center ("CCC"). The license consists of your order details, the terms and conditions provided by Elsevier, and the payment terms and conditions.

All payments must be made in full to CCC. For payment instructions, please see information listed at the bottom of this form.

Supplier	Elsevier Limited The Boulevard,Langford Lane Kidlington,Oxford,OX5 1GB,UK
Registered Company Number	1982084
Customer name	Camilla Halewood
Customer address	Imperial College London
	London, SW7 2AZ
License number	3813620690858
License date	Feb 21, 2016
Licensed content publisher	Elsevier
Licensed content publication	The Journal of Arthroplasty
Licensed content title	Anteroposterior Laxity After Bicruciate-Retaining Total Knee Arthroplasty Is Closer to the Native Knee Than ACL-Resecting TKA: A Biomechanical Cadaver Study
Licensed content author	Camilla Halewood,Alison Traynor,Johan Bellemans,Jan Victor,Andrew A. Amis
Licensed content date	December 2015
Licensed content volume number	30
Licensed content issue number	12
Number of pages	5
Start Page	2315
End Page	2319
Type of Use	reuse in a thesis/dissertation
Portion	excerpt
Number of excerpts	10
Format	both print and electronic
Are you the author of this Elsevier article?	Yes
Will you be translating?	No
Title of your thesis/dissertation	TOTAL KNEE REPLACEMENTS: DESIGN AND PRE-CLINICAL TESTING METHODS
Expected completion date	Mar 2016
Estimated size (number of	260

Terms and Conditions

INTRODUCTION

1. The publisher for this copyrighted material is Elsevier. By clicking "accept" in connection with completing this licensing transaction, you agree that the following terms and conditions apply to this transaction (along with the Billing and Payment terms and conditions established by Copyright Clearance Center, Inc. ("CCC"), at the time that you opened your Rightslink account and that are available at any time at http://myaccount.copyright.com).

GENERAL TERMS

2. Elsevier hereby grants you permission to reproduce the aforementioned material subject to the terms and conditions indicated.

3. Acknowledgement: If any part of the material to be used (for example, figures) has appeared in our publication with credit or acknowledgement to another source, permission must also be sought from that source. If such permission is not obtained then that material may not be included in your publication/copies. Suitable acknowledgement to the source must be made, either as a footnote or in a reference list at the end of your publication, as follows:

"Reprinted from Publication title, Vol /edition number, Author(s), Title of article / title of chapter, Pages No., Copyright (Year), with permission from Elsevier [OR APPLICABLE SOCIETY COPYRIGHT OWNER]." Also Lancet special credit - "Reprinted from The Lancet, Vol. number, Author(s), Title of article, Pages No., Copyright (Year), with permission from Elsevier."

4. Reproduction of this material is confined to the purpose and/or media for which permission is hereby given.

5. Altering/Modifying Material: Not Permitted. However figures and illustrations may be altered/adapted minimally to serve your work. Any other abbreviations, additions, deletions and/or any other alterations shall be made only with prior written authorization of Elsevier Ltd. (Please contact Elsevier at permissions@elsevier.com)

6. If the permission fee for the requested use of our material is waived in this instance, please be advised that your future requests for Elsevier materials may attract a fee.

7. Reservation of Rights: Publisher reserves all rights not specifically granted in the combination of (i) the license details provided by you and accepted in the course of this licensing transaction, (ii) these terms and conditions and (iii) CCC's Billing and Payment terms and conditions.

8. License Contingent Upon Payment: While you may exercise the rights licensed immediately upon issuance of the license at the end of the licensing process for the transaction, provided that you have disclosed complete and accurate details of your proposed use, no license is finally effective unless and until full payment is received from you (either by publisher or by CCC) as provided in CCC's Billing and Payment terms and conditions. If full payment is not received on a timely basis, then any license preliminarily granted shall be deemed automatically revoked and shall be void as if never granted. Further, in the event that you breach any of these terms and conditions or any of CCC's Billing and Payment terms and conditions, the license is automatically revoked and shall be void as if never granted. Use of materials as described in a revoked license, as well as any use of the materials beyond the scope of an unrevoked license, may constitute copyright infringement and publisher reserves the right to take any and all action to protect its copyright in the materials.

9. Warranties: Publisher makes no representations or warranties with respect to the licensed material.

251

10. Indemnity: You hereby indemnify and agree to hold harmless publisher and CCC, and their respective officers, directors, employees and agents, from and against any and all claims arising out of your use of the licensed material other than as specifically authorized pursuant to this license.

11. No Transfer of License: This license is personal to you and may not be sublicensed, assigned, or transferred by you to any other person without publisher's written permission.

12. No Amendment Except in Writing: This license may not be amended except in a writing signed by both parties (or, in the case of publisher, by CCC on publisher's behalf).

13. Objection to Contrary Terms: Publisher hereby objects to any terms contained in any purchase order, acknowledgment, check endorsement or other writing prepared by you, which terms are inconsistent with these terms and conditions or CCC's Billing and Payment terms and conditions. These terms and conditions, together with CCC's Billing and Payment terms and conditions (which are incorporated herein), comprise the entire agreement between you and publisher (and CCC) concerning this licensing transaction. In the event of any conflict between your obligations established by these terms and conditions and those established by CCC's Billing and Payment terms and conditions, these terms and conditions shall control.

14. Revocation: Elsevier or Copyright Clearance Center may deny the permissions described in this License at their sole discretion, for any reason or no reason, with a full refund payable to you. Notice of such denial will be made using the contact information provided by you. Failure to receive such notice will not alter or invalidate the denial. In no event will Elsevier or Copyright Clearance Center be responsible or liable for any costs, expenses or damage incurred by you as a result of a denial of your permission request, other than a refund of the amount(s) paid by you to Elsevier and/or Copyright Clearance Center for denied permissions.

LIMITED LICENSE

The following terms and conditions apply only to specific license types:

15. **Translation**: This permission is granted for non-exclusive world **English** rights only unless your license was granted for translation rights. If you licensed translation rights you may only translate this content into the languages you requested. A professional translator must perform all translations and reproduce the content word for word preserving the integrity of the article.

16. **Posting licensed content on any Website**: The following terms and conditions apply as follows: Licensing material from an Elsevier journal: All content posted to the web site must maintain the copyright information line on the bottom of each image; A hyper-text must be included to the Homepage of the journal from which you are licensing at http://www.sciencedirect.com/science/journal/xxxxx or the Elsevier homepage for books at http://www.elsevier.com; Central Storage: This license does not include permission for a scanned version of the material to be stored in a central repository such as that provided by Heron/XanEdu. Licensing material from an Elsevier book: A hyper-text link must be included to the Elsevier homepage at http://www.elsevier.com . All content posted to the web site must maintain the copyright information line on the bottom of each image.

Posting licensed content on Electronic reserve: In addition to the above the following clauses are applicable: The web site must be password-protected and made available only to bona fide students registered on a relevant course. This permission is granted for 1 year only. You may obtain a new license for future website posting.

17. **For journal authors:** the following clauses are applicable in addition to the above:
Preprints:
A preprint is an author's own write-up of research results and analysis, it has not been peer-reviewed, nor has it had any other value added to it by a publisher (such as formatting, copyright, technical enhancement etc.).

Authors can share their preprints anywhere at any time. Preprints should not be added to or

252

enhanced in any way in order to appear more like, or to substitute for, the final versions of articles however authors can update their preprints on arXiv or RePEc with their Accepted Author Manuscript (see below).

If accepted for publication, we encourage authors to link from the preprint to their formal publication via its DOI. Millions of researchers have access to the formal publications on ScienceDirect, and so links will help users to find, access, cite and use the best available version. Please note that Cell Press, The Lancet and some society-owned have different preprint policies. Information on these policies is available on the journal homepage.

Accepted Author Manuscripts: An accepted author manuscript is the manuscript of an article that has been accepted for publication and which typically includes author-incorporated changes suggested during submission, peer review and editor-author communications.

Authors can share their accepted author manuscript:

- immediately
    - via their non-commercial person homepage or blog
    - by updating a preprint in arXiv or RePEc with the accepted manuscript
    - via their research institute or institutional repository for internal institutional uses or as part of an invitation-only research collaboration work-group
    - directly by providing copies to their students or to research collaborators for their personal use
    - for private scholarly sharing as part of an invitation-only work group on commercial sites with which Elsevier has an agreement
- after the embargo period
    - via non-commercial hosting platforms such as their institutional repository
    - via commercial sites with which Elsevier has an agreement

In all cases accepted manuscripts should:

- link to the formal publication via its DOI
- bear a CC-BY-NC-ND license - this is easy to do
- if aggregated with other manuscripts, for example in a repository or other site, be shared in alignment with our hosting policy not be added to or enhanced in any way to appear more like, or to substitute for, the published journal article.

Published journal article (JPA): A published journal article (PJA) is the definitive final record of published research that appears or will appear in the journal and embodies all value-adding publishing activities including peer review co-ordination, copy-editing, formatting, (if relevant) pagination and online enrichment.

Policies for sharing publishing journal articles differ for subscription and gold open access articles:

Subscription Articles: If you are an author, please share a link to your article rather than the full-text. Millions of researchers have access to the formal publications on ScienceDirect, and so links will help your users to find, access, cite, and use the best available version.

Theses and dissertations which contain embedded PJAs as part of the formal submission can be posted publicly by the awarding institution with DOI links back to the formal publications on ScienceDirect.

If you are affiliated with a library that subscribes to ScienceDirect you have additional private sharing rights for others' research accessed under that agreement. This includes use for classroom teaching and internal training at the institution (including use in course packs and courseware programs), and inclusion of the article for grant funding purposes.

Gold Open Access Articles: May be shared according to the author-selected end-user license and should contain a [CrossMark logo](), the end user license, and a DOI link to the formal publication on ScienceDirect.

Please refer to Elsevier's [posting policy]() for further information.

18. **For book authors** the following clauses are applicable in addition to the above: Authors are permitted to place a brief summary of their work online only. You are not allowed to download and post the published electronic version of your chapter, nor may you scan the printed edition to create an electronic version. **Posting to a repository:** Authors are permitted to post a summary of their chapter only in their institution's repository.

19. **Thesis/Dissertation**: If your license is for use in a thesis/dissertation your thesis may be submitted to your institution in either print or electronic form. Should your thesis be published commercially, please reapply for permission. These requirements include permission for the Library and Archives of Canada to supply single copies, on demand, of the complete thesis and include permission for Proquest/UMI to supply single copies, on demand, of the complete thesis. Should your thesis be published commercially, please reapply for permission. Theses and dissertations which contain embedded PJAs as part of the formal submission can be posted publicly by the awarding institution with DOI links back to the formal publications on ScienceDirect.

Elsevier Open Access Terms and Conditions

You can publish open access with Elsevier in hundreds of open access journals or in nearly 2000 established subscription journals that support open access publishing. Permitted third party re-use of these open access articles is defined by the author's choice of Creative Commons user license. See our [open access license policy]() for more information.

Terms & Conditions applicable to all Open Access articles published with Elsevier:

Any reuse of the article must not represent the author as endorsing the adaptation of the article nor should the article be modified in such a way as to damage the author's honour or reputation. If any changes have been made, such changes must be clearly indicated.

The author(s) must be appropriately credited and we ask that you include the end user license and a DOI link to the formal publication on ScienceDirect.

If any part of the material to be used (for example, figures) has appeared in our publication with credit or acknowledgement to another source it is the responsibility of the user to ensure their reuse complies with the terms and conditions determined by the rights holder.

Additional Terms & Conditions applicable to each Creative Commons user license:

CC BY: The CC-BY license allows users to copy, to create extracts, abstracts and new works from the Article, to alter and revise the Article and to make commercial use of the Article (including reuse and/or resale of the Article by commercial entities), provided the user gives appropriate credit (with a link to the formal publication through the relevant DOI), provides a link to the license, indicates if changes were made and the licensor is not represented as endorsing the use made of the work. The full details of the license are available at [http://creativecommons.org/licenses/by/4.0]().

CC BY NC SA: The CC BY-NC-SA license allows users to copy, to create extracts, abstracts and new works from the Article, to alter and revise the Article, provided this is not done for commercial purposes, and that the user gives appropriate credit (with a link to the formal publication through the relevant DOI), provides a link to the license, indicates if changes were made and the licensor is not represented as endorsing the use made of the work. Further, any new works must be made available on the same conditions. The full details of the license are available at [http://creativecommons.org/licenses/by-nc-sa/4.0]().

CC BY NC ND: The CC BY-NC-ND license allows users to copy and distribute the Article, provided this is not done for commercial purposes and further does not permit distribution of the Article if it is changed or edited in any way, and provided the user gives appropriate credit (with a

link to the formal publication through the relevant DOI), provides a link to the license, and that the licensor is not represented as endorsing the use made of the work. The full details of the license are available at http://creativecommons.org/licenses/by-nc-nd/4.0. Any commercial reuse of Open Access articles published with a CC BY NC SA or CC BY NC ND license requires permission from Elsevier and will be subject to a fee.

Commercial reuse includes:

– Associating advertising with the full text of the Article
– Charging fees for document delivery or access
– Article aggregation
– Systematic distribution via e-mail lists or share buttons

Posting or linking by commercial companies for use by customers of those companies.

20. **Other Conditions**:

v1.8