A Cadaveric Knee Study of the Kinematics of the Tibiofemoral and Patellofemoral Joints in Total Knee Replacement.

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Submitted for MD (Res)

Declaration.

I can declare that the following body of work and the experiments contributing to the work are all original and produced by myself. I received advice from both my supervisors, Professor Amis and Professor Deehan regarding design and execution of the study but all work was carried out solely by myself. The work was supported by Stryker Orthopaedics who supplied the funding for the project as well as the knee prostheses and navigation system.

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There are a large number of people I would like to thank for helping me to produce this piece of work. I would like to thank my co-supervisors, Professor Amis DSc and Professor Deehan FRCS (Orth) for all their expert input. I would also like to thank Dr Bull PhD and the Mechanical Engineering staff for their help. I would not have been able to carry out the work without the help of Stryker UK and in particular Russell Miller and Gavin Mellor. Various other students contributed greatly to my work including Farhad Iranpour, Azar Merican, Milton Ghosh and Amer Karim. I am also indebted to my family for their support throughout the research and particularly the support of my wife Rebecca through the time in London and the writing up process.

Copyright.

Abstract.

Arthroplasty of the knee has become one of the commonest orthopaedic procedures performed today. In the UK alone over 75,000 were performed in 2011. Patients requiring arthroplasty are getting younger and have higher demands on their replaced joints leading to continued evolution of prosthetic design. This biomechanical work has compared two different designs of Total Knee Arthroplasty (TKA) in relation to each other and the native un-resurfaced knee. The TKAs differed from each other in design of the femoral component. One had a single radius design and a trochlea that ran from the lateral side proximally, to the medial side distally, and the other prosthesis had a multi radius design with a symmetrical trochlea, essentially an unsided femoral prosthesis.

The principal areas of study were the kinematics of the tibiofemoral articulation (TF), the patellofemoral joint (PFJ), the stability of the patella in the replaced knee joint and contact pressures of the tibiofemoral articulation. This was a cadaveric study using a knee navigation system to record the kinematic data for analysis. All the experiments involved cadaveric left legs of different genders and sizes. All the work was carried out at the same laboratory at Imperial College, London between July 2006 and October 2008.

Both TKAs allowed significantly greater laxity than the intact knee with an anterior drawer force applied as the knees moved from 40 degrees of flexion to full extension. No significant difference was found between the two TKAs used in this study in the TF work. For the PFJ, the multiradius design was significantly more stable when the patella was displaced medially than the intact knee ($p=0.016$) at 30 degrees of flexion. It was also more stable than the single radius design from 0-30 degrees of flexion. There were no significant differences found between the single radius TKA and the intact knee during any of the PFJ work. Both TKAs appeared to behave differently when assessing patellar flexion with marked differences shown graphically but no statistically significant difference shown on post testing.

In conclusion, both designs of TKA replicated the intact knee very well throughout all the experiments, apart from the differences noted above. This study was unable to show any significant advantage of using the newer single radius design when compared to the established multi-radius design. The single radius design did not appear to mimic the kinematics of the intact knee any closer than the established multiradius design.

Contents.

Figures and Tables.

Definitions and acronyms used throughout the Thesis.

TKA	**Total Knee Arthroplasty.**
TKR	**Total Knee Replacement.**
TF	**Tibiofemoral.**
PFJ	**Patellofemoral joint.**
SR	**Single radius TKA.**
MR	**Multi-radius TKA.**
UHMWPE	**Ultra High Molecular Weight Polyethylene.**
ACL	**Anterior cruciate ligament.**
PCL	**Posterior cruciate ligament.**
MCL	**Medial collateral ligament.**
LCL	**Lateral collateral ligament.**
PS	**Posterior Stabilised.**
CR	**Cruciate sacrificing.**

Chapter 1.

1.1 Introduction.

The human knee joint allows movement and transmission of forces between the long bones of the lower limb. This occurs as a result of complex interactions between muscles, ligaments and bones. As the largest joint in the human body it is prone to wear and tear and the prevalence of degenerative osteoarthritis increases in the aging and post traumatic knee as well as those knees that have previously undergone menisectomy.

Due to osteoarthritis and the increasing age of the population the management of degenerative knee disease has become a highly researched and contentious issue. Patients with osteoarthritis initially notice pain which progresses to a decreased range of movement and subsequently decreased mobility. The socioeconomic consequences may be vast, as the pain prevents individuals from working, continuing hobbies, rising from sitting and in some cases may lead to dependence on others (Lingard *et al* 2004).

The significance of this problem is seen in the recently published National Joint Registry Data for 2011. In England alone there were over 76000 primary knee replacements performed and 3719 revision knee replacements. The implications are therefore great to a large number of patients as well as the financial burden to healthcare trusts.

This thesis reports upon the kinematic behaviour of two different designs of prosthesis. One design (Triathlon, Stryker Orthopaedics, Mahwah, Indiana) had a single radius of curvature in the sagittal plane of the distal femur and an asymmetrical trochlear groove. The second design (Kinemax, Stryker Orthopaedics, Mahwah, Indiana), had a multi- radius design of the distal femur, a symmetrical trochlear groove and can be used in either knee irrespective of side. The findings for the four components of analysis between these three knee states will be documented. This study will compare the two TKAs to each other and also to the intact knee. The two prostheses will be referred to in the thesis as SR (single radius) and MR (multi-radius).

1.2 Development of the TKA.

Prior to the early 1970s when the condylar knee prosthesis was developed, massive hinged prostheses were used, and only in severe disability. The concept of replacing the tibiofemoral condylar surfaces with metal prostheses and cemented fixation was developed and refined. By the mid 1970s, replacing the patellofemoral joint and either preserving or sacrificing the cruciate ligaments had become standard practice. Subsequently, condylar knee designs were modified to include modularity, non cemented fixation, mobile bearings and partial knee replacements. Controversies still exist today as to the best type of TKA to use. It is outside the scope of this work to look at all the types of prostheses available. The two prostheses used in the experiments in this study were both posterior cruciate ligament retaining, cemented, fixed bearing devices.

The current challenge for the future of total knee design is to facilitate improved function whilst further enhancing wear performance. It is important to evaluate existing total knee designs relative to newer designs and then to move on towards clinical use and subsequent review to see if alterations to design have positive effects on patient outcome.

Different methods have been used to assess patient outcome following TKA. In the scientific literature there are large numbers of publications such as Weir *et al* (1999), Baker *et al (* 2008), Pandit *et al (*2009), which report outcomes of specific types of prostheses. There is also data collected via the hospital episode summaries (HES data) which focus on patient related outcome measures (PROMs) using a number of different questionnaires. It is therefore imperative with such reporting continuing that any new design or modification to existing designs is assessed appropriately both prior to use and also with adequate follow up. However, published data doesn't always mirror patient centred follow up with the most recent HES data showing just over half of patients had an improvement on the EQ-Vas (a visual analogue score) and 80%

showing improvement on the EQ-50 health questionnaire. One study by Bourne *et al* (2009) showed that only 81% of patients in their cohort of over 1700 were satisfied with their TKA with lower values of 70 % and 73% for activities such as getting in and out of the car and downstairs walking. The authors also highlighted patients in whom satisfaction rates were lower such as older patients, those who lived alone, those who had a poorer pre-op range of motion and those with extreme pain before surgery. Thus, a proportion did not have good restoration of function.

1.3 Range of movement of the normal knee.

The knee joint is a hinge joint allowing flexion/extension but also internal and external rotation as well as varus and valgus. Its importance in walking is obvious but varying degrees of flexion and extension are needed for kneeling, rising from a chair and many day to day activities. An individual requires the following amounts of flexion for each activity (Freeman and Pinskerova 2005) :

65 degrees of flexion for normal walking.
95 degrees of flexion for walking up and down stairs.
110 degrees of flexion in order to rise from a chair.
145 degrees of flexion for squatting.
150 degrees of flexion for praying.
160 degrees of flexion for kneeling.

In order to understand how a TKA could reproduce such a range of movement the kinematics and kinetics of the normal knee must first be understood. Four important definitions are required prior to the full explanations

Biomechanics: The science of the action of forces on the human body.

Kinetics: Static and dynamic analysis of forces and moments acting on a joint.

Statics: Study of forces and moments on a body in equilibrium.

Dynamics: Study of moments and forces acting on a body.

Kinematics: Study of the movement of the human body.

There are said to be six degrees of freedom of motion within the human knee :

Three translations along mutually perpendicular axes :
Anterior / Posterior.
Medial / Lateral.
Compression / Distraction.(Hitt, Shurman et al.2003).

Three rotations around mutually perpendicular axes :
Flexion / extension.
Internal / external.
+Varus / Valgus.(abduction / adduction).

During flexion the instantaneous centre of joint rotation (which is approximated at the intersection of the ACL and PCL in the sagittal plane in a 2 dimensional model) moves backwards, forcing rolling and sliding at the articular surface (polycentric centre of rotation) (Pinskerova, Iwaki *et al*. 2000).There have also been studies looking at the kinematics of knee movement using MRI scanning (Johal, Williams *et al*. 2005). The authors found that the lateral femoral condyle translated posteriorly relative to the tibia between -5 and 120 degrees of flexion. Furthermore, they found that between 120 to 140 degrees, there was a further movement almost leading to the subluxation of the lateral condyle. They found that the medial femoral condyle, between -5-+30 degrees of flexion, actually moved anteriorly. Beyond 90 degrees the medial femoral condyle then moved posteriorly eventually with a net movement of 1.2mm posteriorly. It is clear that there is a difference in movement between the two femoral condyles with the lateral femoral condyle moving backwards relative to the tibia with flexion. One may wish to replicate this behaviour in the replaced knee.

Wilson, Feikes *et al* 2006 assessed how passive knee movement was coupled to flexion angle through 0 to 120 degrees of flexion. They were aiming to establish if the internal rotation of the tibia was coupled to flexion or if it occurred by another mechanism. The authors found that the movement path in flexion was virtually identical to the movement path in extension. It was also found that if the femur was released after being displaced it sprang back to its original position on the motion path. If internal rotation was not coupled to flexion, the femur would have remained in the position in which it had been rotated.

It would appear that in the normal healthy knee, the femoral condyles are asymmetric, there are different amounts of movement of each of the condyles and the medial and lateral tibial plateaux are also quite different in their anatomy. It is important to appreciate how this may vary in the replaced knee. Komistek *et al* (2009) assessed a CS TKA with fluoroscopy and showed increased lateral femoral rollback (-23.0mm) compared to the medial side (-14.0mm) during flexion, and axial TF rotation of 10 degrees. The authors commented that the larger amount of medial femoral condyle rollback in the replaced knee compared to the native knee may overload the medial structures of the knee. Previous work from the same authors in 2003 analysed the native knee and showed for normal gait rollback of only 0.9mm medially and -4.3mm laterally, obviously a great difference. Even in deep flexion of the native knee rollback was -2.9mm medially and -12.7mm laterally. If we are to aim to reproduce this behaviour in the replaced knee then the new knee should allow, through internal constraint, geometry and preservation of soft tissues, a similar kinematic response to flexion and extension. This is the concept that has driven this body of work.

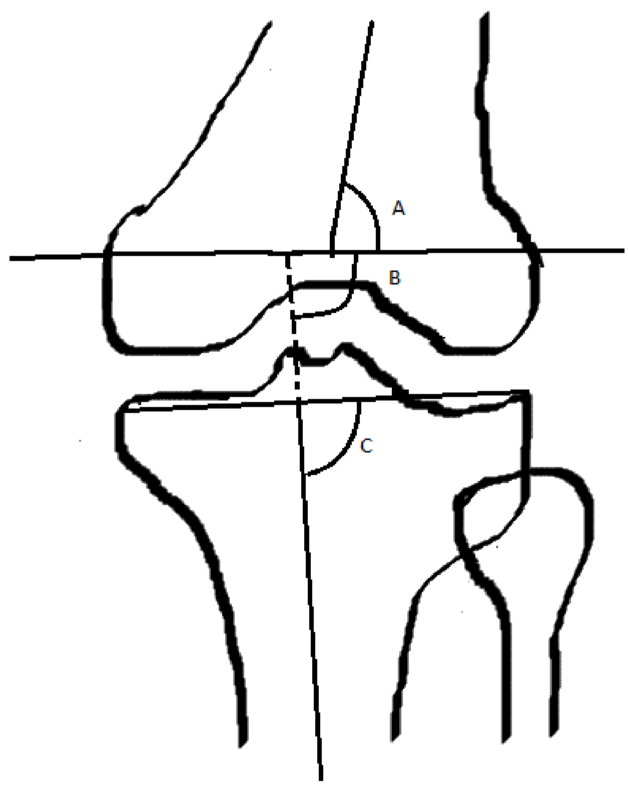
1.4 The Axes of Rotation in the Knee.

Several researchers, Hollister, Jatana *et al* 1993 have aimed to find the axes of rotation of the knee joint and their relationship to each other and to prove or disprove the theory that knee motion is thought to occur around a flexion / extension (F/E) axis that is perpendicular to the sagittal plane and a longitudinal rotation axis. Hollister et al were able to locate the two axes and found that the F/E axis ran through the origin of the collateral ligaments and superior to the intersection of the cruciate ligaments. The authors also went on to find that the same axis was not perpendicular to the sagittal plane but was fixed in the distal femur and was directed postero-inferiorly from medial to lateral (Hollister, Jatana *et al* 1993). With regards to the longitudinal axis of rotation of the tibia they showed that this was also not perpendicular to the F/E axis but was fixed in the tibia and moved around the F/E axis. As the F/E axis was not perpendicular to the sagittal plane, varus movement and internal rotation also occurred during flexion. Furthermore, the amount of external rotation of the tibia with knee extension was dependent on the initial position of the knee about the longitudinal axis and degree of offset of the F/E axis.

Similar conclusions were drawn by Churchill, Incavo *et al* (1998) who confirmed that the optimum flexion axis coincided with the transepicondylar axis which passes through the femoral epicondyles and the origins of the collateral ligaments. However, they pointed out that beyond 90 degrees of flexion the femur undergoes posterior translation which is not consistent with the fixed flexion axis.

Figure 10 is a simplified version below of the axes of rotation as described by Hollister *et al* 1993. This shows the axes in an AP view. A is the angle the Flexion/Extension axis makes with the shaft of the femur. B is the angle between the FE axis and the Longitudinal Rotation axis in the coronal plane. C is the angle between the LR axis and the tibial plateau in the coronal plane.

Figure 1 The Axes of Rotation of the Knee.



Similarly figure 2 shows the axes of rotation in the lateral view using work by Freeman and Pinskerova 2005 as a guide. A is the angle between the LR axis and the tibial plateau in the sagittal plane. B is the distance between the anterior femoral shaft and the centre of the posterior-medial femoral condyle. C is the radius between the FE axis and the surface of the posterior-medial femoral condyle. D is the perpendicular distance between the two axes. E is the AP dimension of the tibia and F is the distance of the LR axis from the anterior tibia. The definitions of these axes are important for this work in order to understand the normal kinematics of the knee and how this may be altered following a TKA and to help analyse the data that would be generated.

Figure 2 Axes of Rotation of the Knee (Freeman and Pinskerova)

1.5 The Kinematics of a TKA.

In order to improve on the current TKAs it is important to look at how they function and to what extent they manage to replicate normal knee function (Most, Li *et al* 2003). This work has examined only cruciate retaining (CR) prostheses as a way of standardising the comparison process but many other TKAs are cruciate sacrificing and their kinematics do vary.

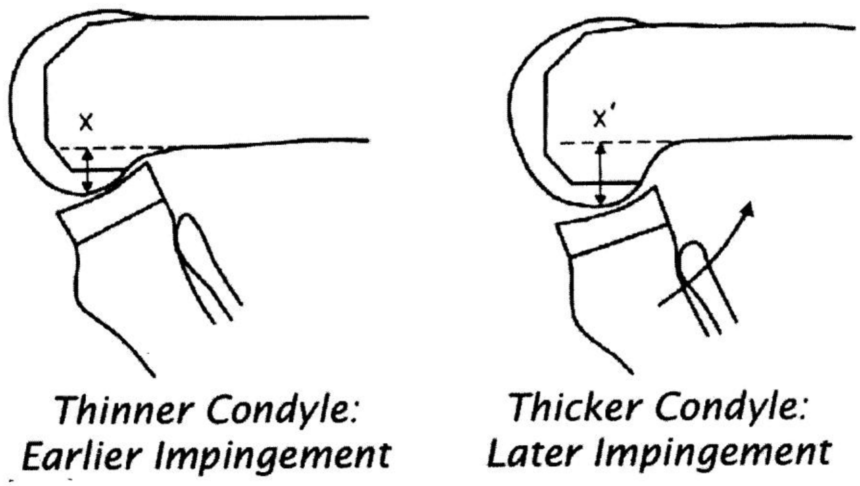
Siston, Giori *et al* (2006) looked at the kinematics of a PCL sacrificing TKA. In addition to the previously discussed altered femoral translation they also concluded that the centre of rotation may change post TKA by approximately 22mm anteriorly and 18mm distally. Banks, Bellemans *et al*. (2003) looked to determine if there were consistent differences in knee motions among three different types of TKA, namely posterior stabilised (Conditt, Thompson *et al*, 2005.), cruciate retaining (Aaron, Skolnick *et al*,2004.) and mobile bearing. The centres of rotation altered following arthroplasty in each of the three knee designs. In the PS knee the centre of rotation moved medially leading to posterior lateral femoral translation with flexion. In the CR knee 63% had a lateral centre of rotation leading to 2-3 degrees more of axial rotation. In the mobile bearing knees 86% had a lateral centre of rotation leading to anterior femoral translation with flexion. Therefore the kinematics of different types of TKAs are variable, as well as being different from a natural knee.

The kinematics of a CR TKA during stair climbing has also been assessed (Nozaki, Banks *et al.* 2002). They aimed to establish whether there would be physiological rollback of the femur in an anatomically shaped implant. 13 patients were included in the study and they managed to show that femoral rollback did occur along with tibial internal rotation as flexion occurred. As with the previous studies from Komistek *et al* (2003) they also showed that the lateral femoral condyle moved further posteriorly than the medial condyle and this was the case for both sets of patients operated on by the two different surgeons. Perhaps the most important conclusion drawn by these authors was that when doing a TKA with the same design and bone cuts, differences in soft tissue balance does occur between individual surgeons which may eventually lead to an altered pattern of knee movement.

Shannon *et al* (2007) looked at how much of the tibial attachment of the PCL was removed during supposed cruciate retaining surgery. They used MRI scans to determine the attachment of the PCL onto the tibia and whether tibial cuts using a standard cutting jig would disrupt this in any way. They found that in over 75% of cases the attachment was disrupted but often these patients remained asymptomatic and thus added to the debate on whether to retain or sacrifice the PCL. It follows that many studies that look at the outcomes of a cruciate retaining prosthesis may not truly be analysing a set of patients whose PCL is completely intact following their TKA.

Further work has been done into what factors determine the maximum flexion after TKA (Banks, Harman *et al*. 2003). They noted that deep flexion is vital for activities such as kneeling and praying. They also said that, as patients requiring a TKA get younger, a greater range of movement is required by the individual. This study focused on whether femoral AP translation influenced maximum flexion. They found that flexion was limited by bone/implant impingement in 72% of patients at an average of 122 degrees, represented by the following diagrams. A more posterior position of the femur led to later impingement and hence a greater degree of flexion, (Feikes, O'Connor *et al*, 2005)

Figure 3 Diagrammatic Representation of Posterior Impingement.



It was found that for each millimetre of AP translation there was an extra 1.4 degrees of flexion. The authors also suggested that posterior femoral translation decreased the stresses in the soft tissues leading to greater flexion.

Similar work by Malviya *et al* (2009) looked at the factors responsible for post operative range of movement and in particular the effect of tibial slope and posterior femoral condylar offset.

Figure 4 Radiograph showing calculation of posterior offset.

The previous radiograph shows two measurements, a and b where a is the posterior femoral offset. In order to avoid any inaccuracies as a result of magnification of the radiographs the authors proposed the posterior condylar offset ratio calculated by a/b where b is the diameter of the femur 2.5cm above the flare of the femoral condyles. It was found that the magnitude of the posterior condylar offset delayed impingement of the tibial insert against the posterior femur and thus allowed a greater range of flexion. The authors also found significant evidence that increasing the tibial slope led to increased flexion with passive flexion increasing by 2.6 degrees for each degree increase in tibial slope. This work was carried out in cruciate retaining prostheses.

One of the most contentious issues in knee arthroplasty surgery is whether to sacrifice the PCL (Victor and Bellemans *et al* 2005). They compared the kinematics of two types of TKA, one that retained the PCL and one that sacrificed it. The most significant difference was in the AP position of the medial contact location between the two groups. In the CR group there was medial condylar slide of 4mm anteriorly up to 80 degrees, whereas in the CS group there was much more posterior contact and significantly more lateral femoral rollback. It was suggested that the increased sliding on the medial side in the CS group may lead to increased polyethylene wear and thus decrease the longevity of the implant as a whole. When both prostheses were assessed clinically the outcomes were not significantly different. However, in the PCL sacrificing group the rollback and deep flexion were greater and it was this group that more closely mimicked the natural knee.

A slightly different view was taken by Wilton *et al* (2003). They compared patients who had been randomised to cruciate retention, excision or substituted with a posterior stabilised insert. They also ended up with a fourth group of patients whose PCL could not be retained due to soft tissue balancing and was thus released from its insertion. They did not find any difference in knee scores or range of movement in any of the groups, apart from those patients whose PCL had been released, who had a worse knee score and range of motion. However, they did identify a relatively short follow up in their study and that polyethylene wear would need to be assessed in more detail to see if early failure would be an issue in any of the groups

Key conclusions:

1. Trying to replicate the native knee kinematics is a key concept in TKA.
2. There are many different designs of TKA on the market. This thesis will report on two types of cruciate retaining prostheses.
3. There are differences in kinematic behaviour between the native and replaced knee, particularly in terms of the amount of femoral condylar rollback.
4. The axes of rotation of the knee have been defined in both the axial and sagittal planes. These will act as references and for data analysis.
5. Range of movement post TKA is associated with pre-operative movement but surgical experience and soft tissue balancing, as well as post-operative pain are all reflected in patient satisfaction rates.

Chapter 2

The Patellofemoral Joint.

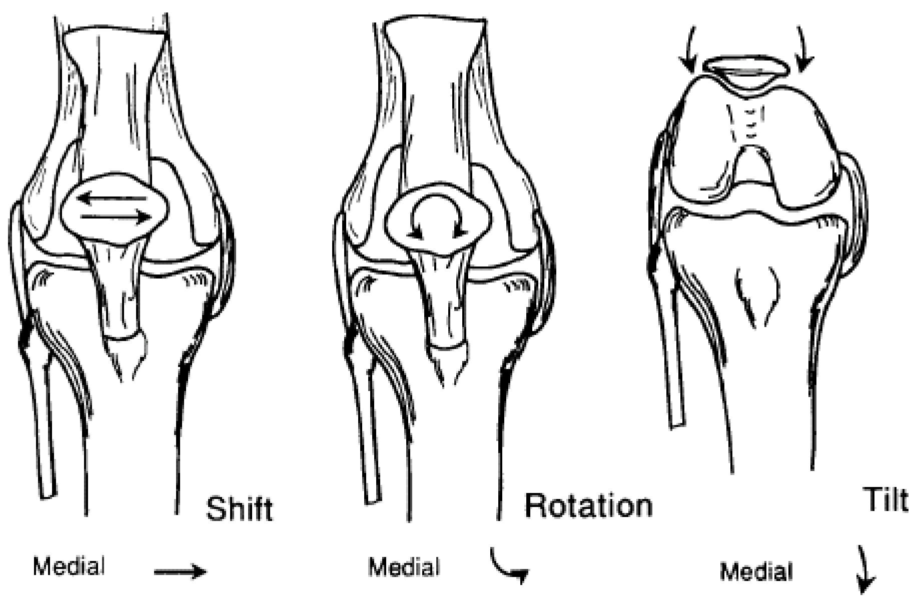
The second part of this thesis is focused on the PFJ and there are key concepts that need to be addressed:

1. The function of the PFJ.
2. The movements of the PFJ in the native knee.
3. The soft tissue and bony stabilisers of the PFJ.
4. Symptoms that patients may experience with an abnormal PFJ.
5. Different ways of defining patellar behaviour and how to measure them.
6. The contact pressures in the PFJ with different activities.
7. Whether to routinely resurface the patella in TKA or not.

2.1 Definitions.

It is important to define the direction of movements that are possible, (Nagamine, Otani *et al.*, 1995). Shift was defined as the medial or lateral translation perpendicular to the longitudinal femoral axis. Rotation was defined as medial when the patellar apex turned toward the medial condyle. Tilt was defined as medial when the medial patellar facet rotated toward the medial femoral condyle. These definitions of movements will be used in this thesis.

Figure 5 Patellar Movements.



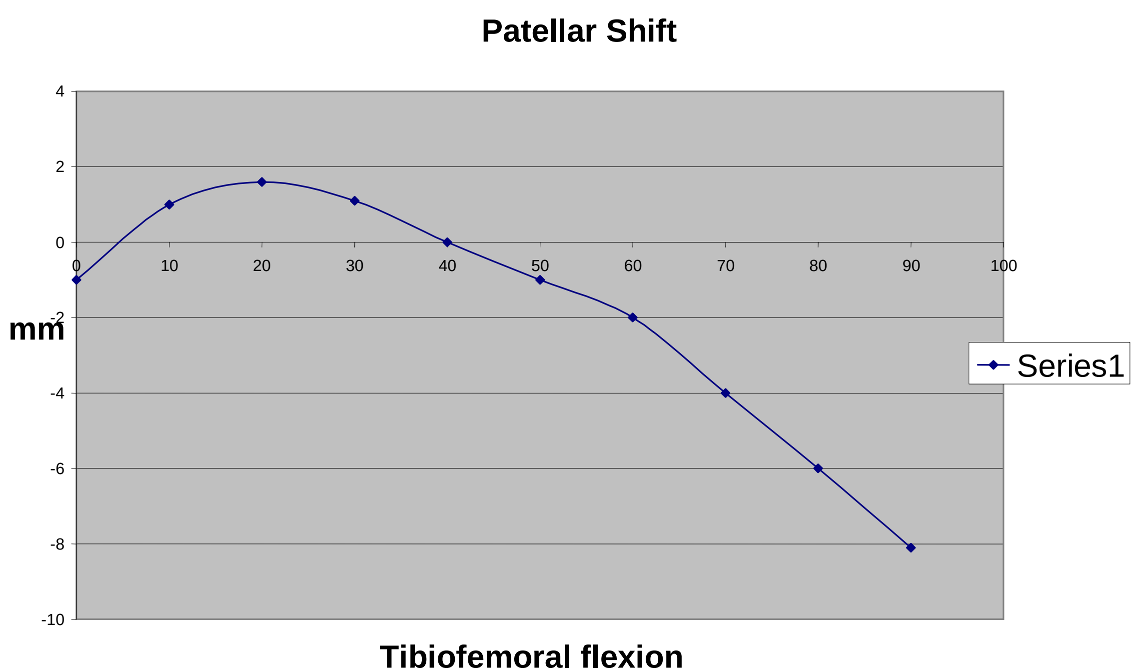
The PFJ has four separate functions (Diduch, Insall *et al*. 1997) :

1. Increase the lever arm of the quadriceps.
2. Gives stability under load to the femur.
3. Allows quadriceps force to be transmitted to the tibia during flexion / extension.
4. Provides a bony shield to the femur.

The tracking of the patella in a disease free knee and the points of contact have been studied extensively by Argenson, Komistek *et al*. (2004). In this study it was found that the irregular medial facet of the patella only articulated with the femur at angles of flexion of more than 135 degrees. As flexion angles increase, the contact area moves from distal to proximal on the patella and beyond 90 degrees of flexion the quadriceps tendon may come into contact with the proximal trochlea.

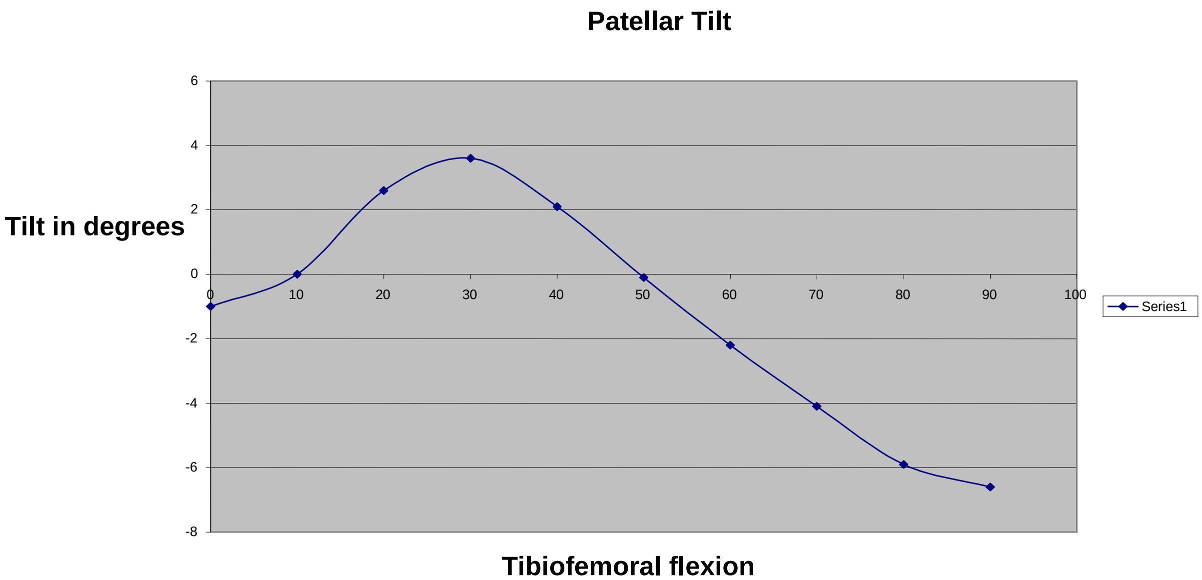
Similar work looked at the movement of the patella during concentric and eccentric contraction of the quadriceps (Brunet, Brinker *et al*. 2003). They found that there was net lateral patellar shift, tilt and patellar flexion through the range of tibiofemoral flexion. They also found that the patella contacted the femur at about 25-30 degrees of tibiofemoral flexion and as flexion increased the patellofemoral joint compression forces increased as a result of the changing orientations of the quadriceps tendon and the patellar tendon. From such work the authors were able to identify conditions such as a shallow trochlear groove, a flattened or dysmorphic patella and a dysplastic vastus medialis that all go on to affect patellar kinematics. The data presented in this paper was used to produce the following graphs showing the behaviour of the patella.

Figure 6. Graph Showing Patella Shift. Medial shift is positive.



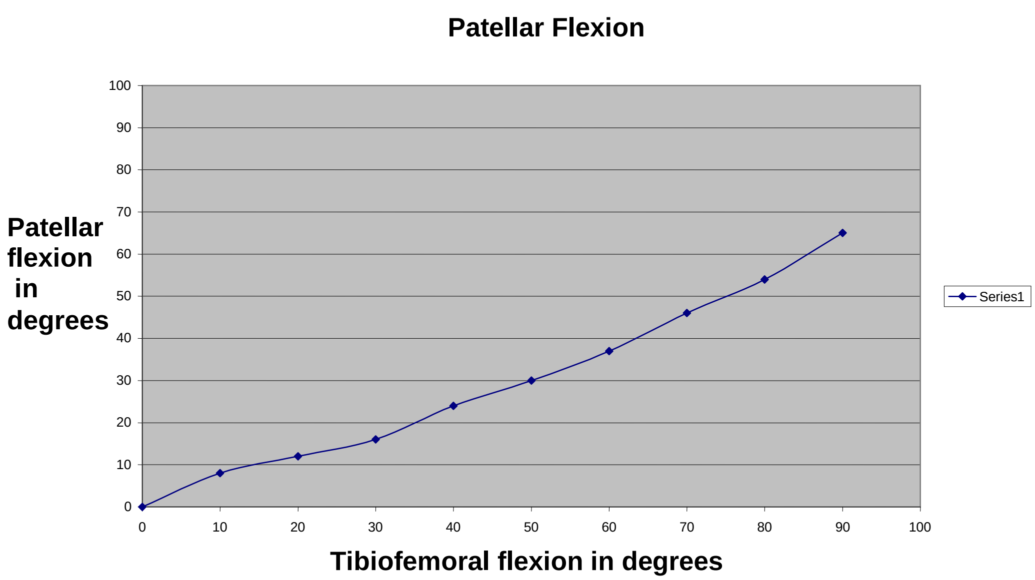
From the graph above you can see that during the initial 25 degrees of flexion the patella shifts medially and then at further angles of flexion shifted laterally to about 7mm at 90 degrees.

Figure 7 Graph showing Patellar Tilt.
(Positive values reflect medial tilt.)



When looking at patellar tilt, the results showed a similar pattern with movement in one direction initially and then a change of direction at around 25 degrees. In this instance the patella tilted medially initially and then laterally as tibiofemoral flexion angle increased.

Figure 8 Graph showing Patellar Flexion.



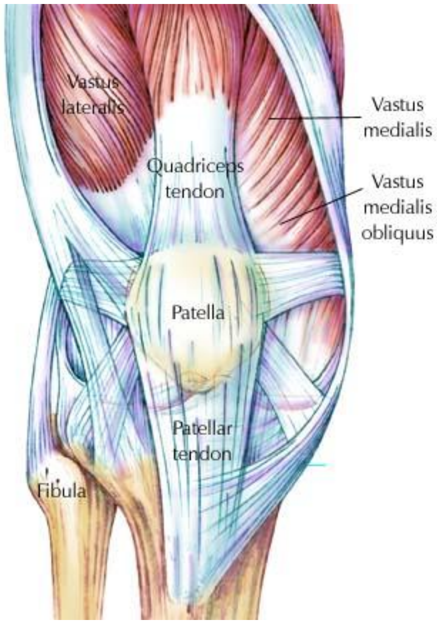
This graph shows that as the tibiofemoral angle increases, so does the patella flexion angle. This is not a 1:1 ratio but approximately 0.7, with patellar flexion of 40 degrees at 60 degrees of tibiofemoral flexion and 65 degrees at 90 degrees of tibiofemoral flexion.

2.2 Patellar Stability.

The importance of the patella is not only in the way it moves and tilts during knee flexion but also in how the position of the patella is maintained and the structures that are responsible for this. There are several different factors responsible for the stability including bony conformity, the static effects of ligaments and the dynamic effects of muscles. The small patella follows a smooth and stable path along the patellar groove through extension, mostly controlled by the actions of the quadriceps muscle which insert onto it. Any imbalance among these muscles will lead to maltracking, potential dislocation and early failure of a replaced patella. Initial first line management of the PFJ needs to address the quadriceps function and balance as well as the positioning of the joint line to prevent patella alta. The repair of the capsule is also key when repairing the arthrotomy once the TKA has been implanted.

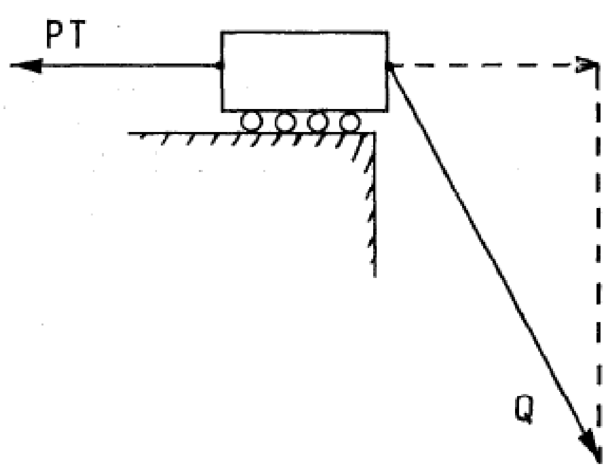
In order to correctly design the PFJ experiments it is imperative to understand the anatomy of the quadriceps and how they exert their forces. Attaching to the patella are three distinct layers of muscles as shown by the diagram on the following page. The first one is made up entirely of the rectus femoris which continues into the patellar tendon. The second layer is made up of the vastus medialis and vastus lateralis, which converge from either side to resist the medial and lateral displacing forces (Amis *et al*, 1996). The deep layer is made up of the vastus intermedius. Often the vastus medialis is said to have an almost separate muscle in the vastus medialis obliquus. As the name suggests this muscle approaches from such a direction, approximately 50 degrees to the femoral axis, that any dysfunction has a significant effect on patella medial/lateral stability.

Figure 9 The Extensor Mechanism of the Knee (McAllindun et al).



The following diagram shows the importance of the role of the soft tissues around the patella. If the patella is to be held stable the force of PT must be equal to the horizontal tension of Q. Therefore Q is obviously greater than PT, particularly with the knee flexed as above to maintain the position of the patella. All these actions take place in the sagittal plane but the stability also results from forces in the transverse plane of the patella.

Figure 10 Soft Tissue Stabilisers of the patella. (Amis et al 2002).



PT = Patellar Tendon.
Q =Quadriceps Tendon.

The truck represents the patella

There are other important stabilisers of the patella, most notably the medial and lateral retinacula. The most important of these is the deep medial patellofemoral ligament which provides most of the resistance to lateral patellar subluxation (Ghosh *et al 2010*), (Senavognse, Amis et al 2005).

The bony architecture of the patella also adds to its stability. The patella is a triangular sesamoid bone which is wider at its proximal pole than at the distal pole. The articular surface of the patella is divided by a vertical ridge, resulting in a smaller medial and a larger lateral articular facet. In full extension, the patella is above the superior margin of the femoral articular surface, with the lateral facet articulating with the lateral femoral condyle where as the medial facet barely articulates with the medial femoral condyle. With increasing flexion more pressure is applied to the medial facet and both facets have a more proximal point of contact with the femur. During a flexion / extension cycle the patella moves 7-8cm relative to the femur (Most *et al* 2002).

Work by Donell et al (2006) also looked at the amount of patellar stability that was a result of the femoral trochlear geometry. This work found that a more laterally placed trochlea with a deeper concave groove gave significantly more stability than a more shallow medial placed groove.

It is clear therefore that any process that alters the shape of the patella or the soft tissues can be directly responsible for maltracking and morbidity to the patient.

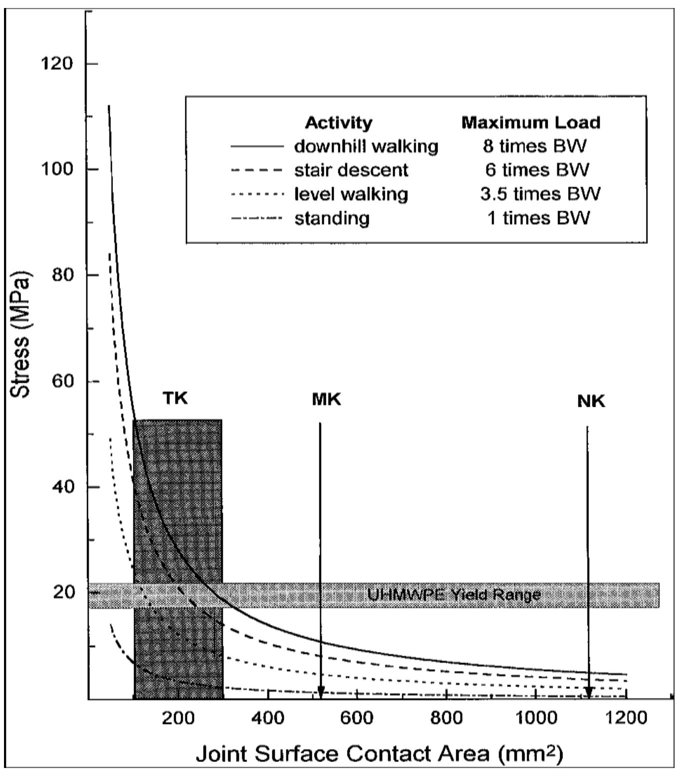
2.3 Contact Forces in the PFJ.

The patellofemoral joint, as with the tibiofemoral joint, has to withstand huge forces during daily activities. Forces on the PFJ rise rapidly with knee flexion even during daily activities. Level walking leads to 0.5 times body weight, compared to 3.5 times for stair climbing and 7.6 times body weight for deep knee bends (Miller et al 2008). Other authors Lee, Budoff *et al*. (1999) looked specifically at the contact pressures and contact areas of 10 cadaveric knees pre and post TKA. They found that post TKA the contact areas decreased up to 95%

depending on the degree of tibiofemoral flexion, whilst at the same time the contact pressures were going up by up to 30 fold. The authors concluded that the contact stresses produced in the PFJ often exceed the strength of the UHMWPE used in the inserts.

The following graph by Kuster *et al* (1997) shows their results for the joint force and contact areas in the replaced knee (TK), the knee after menisectomy (MK) and the native knee (NK) in various day to day activities. These values were produced using a computer mapping technique and load measuring force plates in patients who had undergone a TKA.

Figure 11 Contact Forces in Normal Activity in the PFJ.



Moro-oka *et al*. (2002) used MRI analysis of patellar tracking and femoral condylar geometry of the knee in deep flexion of 15 healthy subjects aged 16-51 years. As with previous work they found a net lateral shift of the patella following initial medial shift. At 135 degrees of flexion the patella sank into the femoral groove. At the same time contact pressure on the patella shifted from distal to proximal. The articular surface of the lateral condyle curved more steeply than the medial side, away from the centre of the intercondylar notch which appeared to allow the patella to track much more smoothly with a longer period of patellofemoral contact time.In this study the patella was found to tilt medially with the amount of tilt increasing as the tibiofemoral flexion angle increased. However, the authors acknowledge that a lot of inaccuracies are encountered in publications looking at the PFJ due to the definitions and measurements used. The authors do accept that their measurements were different to previous studies and that direct comparisons cannot always be made between different published work.

Katchburian, Bull *et al* (2003) highlighted some of the experimental flaws. Such problems include using different coordinate systems and reference points in correct identification of the axes of rotation of the knee. Other authors have compared the movement of the patella to different reference points on the femur and tibia. Nagamine, Otani *et al* (1995) used an external patellar positioning device to determine the medial-lateral shift, tilt, and rotation of the patella and that could be attached to a femoral kinematics rig. Using this equipment the authors were able to accurately measure patellar tracking in vivo, a method that can be reproduced for the post TKR knee as well. The authors were able to replicate their methods for different knees, check their referencing coordinates and track the knees through a range of flexion. As the methods are proven and reproducible they will be repeated in these experiments to determine the patellofemoral kinematics.

One further technique to measure the PFJ kinematics has been proposed very recently (after the experiments in this thesis) by Iranpour *et al* (2010). Their work focused on trying to eradicate the discrepancies in data collection and interpretation mentioned above. The authors used a novel trochlear axis formed from two spheres on the medial and lateral articular surfaces of the trochlea following CT scans of cadaveric limbs. The path of the patella during movement could then be related to the anatomical, mechanical and epicondylar axis of the femur. The authors felt that this method provided a more reproducible and clearer method of visualising the patellar movement than previously described methods.

2.4 What is the evidence for resurfacing the patella?

Resurfacing the patella or not is one of the contentious issues surrounding TKA. Some surgeons routinely resurface it whereas others never do. In order to answer this question there have been numerous studies in the literature, including several meta-analyses.

Pavlou et al (2011) performed one such meta-analysis looking at post operative scores, anterior knee pain and reoperation rates in the two groups. From the results of 18 studies they concluded that there was no evidence to suggest that either resurfacing the patella or the prosthesis design affected the outcome of TKA. They did identify an increased reoperation rate in the unresurfaced group who went on to have a resurfacing at a later date as a result of persistent anterior knee pain.

Similar findings were published by Fu et al (2011) in their meta-analysis. They found no evidence to suggest routine resurfacing should be carried out, a policy now adopted in their unit. However, they mention that patients should be counselled on the higher rate of reoperation as in the Pavlou group. They calculated that you would need to resurface 25 patellae in order to prevent one reoperation.

One further meta-analysis from France also published similar conclusions. They found no difference in the Knee Society Score, Hospital for Special Surgery Score or patient satisfaction scores in the two groups (Nizard et al 2005).

Despite these publications it was decided to perform these experiments with the patella resurfaced in order to standardise the testing and eliminate one possible variable. This may limit the impact of the results for those surgeons who never replace the patella.

Key Conclusions:

1. Patella disorders may present as pain, instability or both.
2. Addressing the PFJ in TKA is vital in ensuring a satisfactory outcome.
3. Stability of the patella is due to bony and soft tissue stabilisers.
4. Routine resurfacing of the patella is still a contentious issue.
5. Different designs of TKA have different design of trochlea groove.
6. Contact forces in the PFJ may be huge even with normal activity.

Chapter 3.

3.1 The two TKAs to be used in this study.

The principal aim of a TKA is pain relief. However, younger patients have higher functional demands. In order to achieve optimal function the prosthetic joint must confer stability, maximal movement and must allow proprioception at both the tibiofemoral and patellofemoral articulations.

A TKA is composed of a femoral component, tibial component and a polyethylene insert. The femoral component may be cemented or uncemented, single radius or double radius in a sagittal view. The tibial component is a flat metallic tray made of either titanium or cobalt chrome in the majority of cases. The NJR data for 2010 revealed that >90% of TKAs are cemented double radius femoral components with a cemented tibial tray. The patella, as mentioned in the previous chapter, may or may not be resurfaced as per the individual surgeon's preference.

The first prosthesis to be used was the newly developed Triathlon® Knee System, recently designed by the Stryker Orthopaedics Group. The second prosthesis, also manufactured by Stryker Orthopaedics, was the Kinemax TKA. Whilst this design is now largely an obsolete prosthesis it should be considered the gold standard with excellent long term follow up and was chosen due to its pronounced MR design.

Figure 12 The Principal Design Features of the two experimental Prostheses.

	Triathlon TKA (SR)	Kinemax TKA (MR)
CR or CS	CR.	CR.
Distal femoral geometry	Single radius.	Multi-radius.
Trochlear groove	Asymmetrical.	Symmetrical.
Patellar button	Accentuated medially.	Uniform shape.
Cemented or uncemented	Cemented.	Cemented.

The two most significant differences were in the distal femoral geometry and the trochlear groove, which will be discussed in more detail because these features are the ones that may potentially lead to different kinematic behaviour.

3.2 The Distal Femoral Radius.

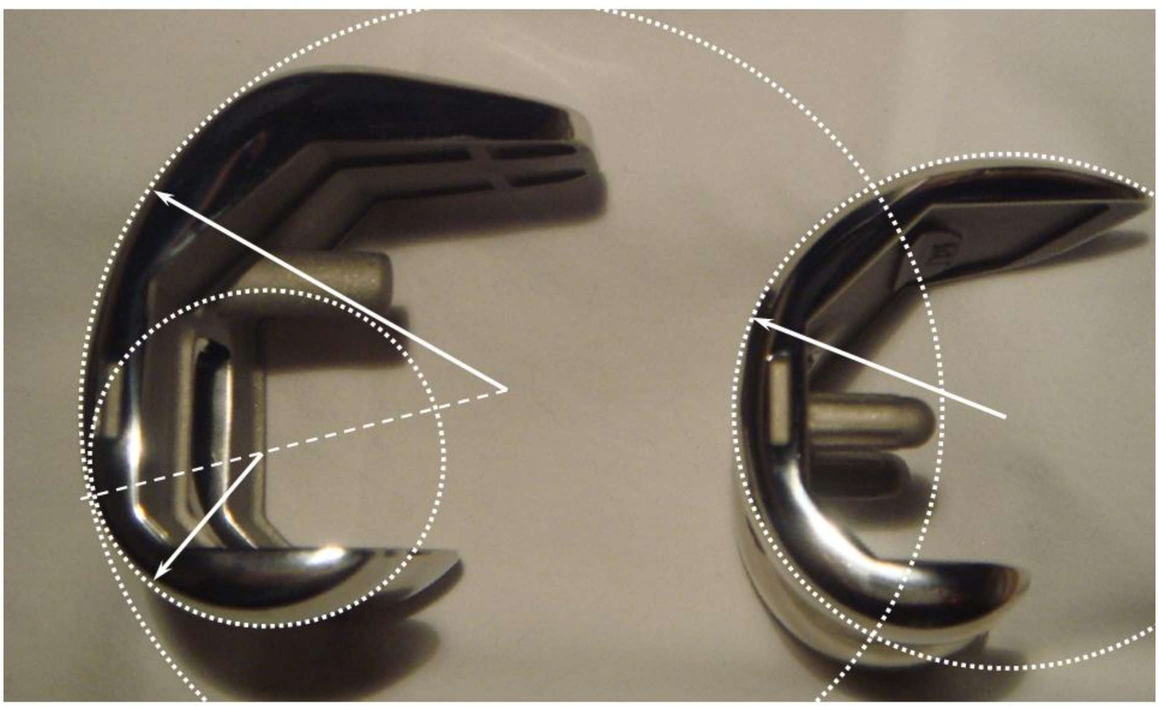
The design of the femoral component in the two TKAs is significantly different as shown by the photograph on the following page. The SR TKA was designed to recreate the normal distal femoral anatomy, and that this would allow better tensioning in the collateral ligaments throughout the range of movement and prevent mid flexion instability (Bellemens *et al*, 2006).

Pinskerova et al (2003) have performed MRI analysis of the natural knee and the shape of the femoral condyles in particular. Using MRI scanning the authors have shown that the natural shape of the femoral condyles had a single radius during knee flexion. Wang *et al* (2007) found that a different single-radius design reduced the quadriceps muscle activation in sitting-to-standing movements and decreased trunk flexion required for standing. They expected that these patients would mobilise more readily post-operatively but this claim was not proven by their work. Hall *et a*l (2005) found that a single-radius design had a larger quadriceps moment arm about the axis of knee extension than a multi-radius design but did not validate the clinical significance of this claim.

The MR design prosthesis has an excellent long term proven track record (Back *et al* 2001). Between 2003-2009 over 7000 of the MR design TKA were used compared with over 5300 of the SR design. Although its use is starting to decline the follow up data is very strong.

The following photograph shows the difference in the geometry of the two femoral components in the sagittal plane. The MR Kinemax design is shown on the left and the SR Triathlon design on the right. The photograph clearly illustrates the two radii of the Kinemax TKA, with deviation from a circular profile in the sagittal plane, compared to the SR of the Triathlon TKA.

Figure 13 The Different Sagittal Radii of the two components. The MR Design is on the left.



3.3 The Design of the Trochlea.

The other striking difference between the two prostheses is shown in the following photograph and was the design of the trochlear groove.

Figure 14 The Trochlear Grooves of the Two Implants.
The MR design is on the left.

The MR TKA is on the left of the photograph showing a much deeper trochlea which is symmetrical. Due to this design the femoral components were not “sided” which had large cost saving benefits during production and for the hospital as the prosthesis could be used in either knee.

In comparison the SR TKA on the right shows a shallower trochlea which is asymmetrical in design. The trochlear groove runs from the lateral side proximal to the medial side distally. This design is closer to the natural trochlear groove anatomy which has a larger lateral than medial flange. However, a shallower groove may lead to a greater chance of lateral patellar subluxation.

3.4 High Flexion TKAs.

The SR TKA was designed with flared posterior condyles to try to reduce soft tissue impingement and hopefully allow greater flexion. A number of orthopaedic companies have produced other “high flexion” designs to give the patient greater range of movement, particularly important in the younger, more active population.

However, such claims by the company have been disputed by work from Most et al (2006). Their work looked at the locations of the peak contact stress and contact areas of a conventional and a high flexion posterior cruciate retaining TKA. The two TKAs in this study were made by the same manufacturer with the main difference between the two femoral components being the posterior femoral condyle design. In the high flexion design the posterior condyles were 2 mm thicker than the conventional design. The company in this instance hypothesised that these design alterations in the high flexion design would lead to increased femoral translation and larger contact area at high knee flexion. This study showed that both TKAs had similar kinematics throughout the range of flexion although their contact behaviours differed. The area with peak contact stress for the high flexion TKA was more anterior than the conventional TKA for flexion angles greater than 90 degrees. The tibiofemoral contact reached the posterior edge of the UHMWPE at 150 degrees in the high flexion TKA but occurred 15-30 degrees earlier in the conventional TKA suggesting a decreased range of movement in the conventional design.

In the same study by Most et al (2006) the high-flexion component showed, on average, a larger contact area than the conventional component on both the medial and lateral sides in high flexion. This study, however, only used five cadaveric knees in non physiological load conditions, leading the authors themselves to question the impact of their own work. They also concluded that they could see no definite advantage of the high flexion TKA with respect to the tibiofemoral articular contact areas under the simulated muscle loads they used. In order to further assess the implications, studies in vivo are required to better understand the reasons why some patients fail to achieve deep flexion.

There have also recently been several meta-analyses looking at whether such high flexion prostheses are advantageous or not. Mehrin et al (2010) suggested there was no clinically relevant or statistically significant improvement in flexion with such prostheses. A further meta-analysis by Luo et al (2011) also demonstrated no improvement in flexion or knee outcome scores and agreed that no advantage could be gained.

There is also recent evidence from Bollars et al (2011) that there is an increased amount of detrimental femoral component loosening in the high flexion prostheses compared to conventional designs. They attribute this to alterations in the loading sharing between the prosthesis and condylar bone during flexion. Although limited to just one type of high flexion design, and not the one used in this study, they suggest caution and very careful patient selection for such a TKA.

Klein et al (2006) compared two types of TKA, namely the Scorpio knee® and the new NRG® knee replacement system both from Stryker Orthopaedics. In this instance the Scorpio Knee was used as the gold standard with long term survival data available and the NRG knee was selected as a high performance, high flexion TKR for comparison. The NRG has been adapted from other types of TKAs by having a more rounded geometry of the tibial component. This has led to less posterior constraint and was thought to allow larger amounts of femoral rollback, which helps the tibial plateau clear the posterior femur in the deeper angles of knee flexion. In this particular study the two TKAs were placed into the same cadaveric knees and their kinematics measured. Subtle changes to the architecture of the TKA did have an effect on the range of flexion, with average flexion post operatively of 128 degrees in the NRG Knee compared with 122 degrees for the Scorpio system.

One other similar study was performed by Argenson et (2005) who studied the Legacy Knee Replacement System (Zimmer Orthopaedics), another design of TKA marketed with claims of increased flexion. This type of TKA is a PCL substituting design, but interestingly this work presents some different ideas on how to achieve increased flexion. Argenson et al (2004) suggested that there are also key operative techniques involved for increasing the range of flexion, such as taking extra care to remove any posterior osteophytes, as well as releasing the posterior capsule. This particular study showed excellent clinical results with 2 patients achieving more than 140 degrees of flexion with average flexion of around 115 degrees. The authors were able to identify those features that they believed were pertinent to achieve increased flexion (Argenson, Komistek et al. 2004). These features included good femoral rollback to avoid posterior impingement, increased contact at higher flexion angles and a decrease in the chance of patellar ligament impingement. However, they were unable to define the influence of component design on achieving greater flexion.

A difference in opinion clearly exists between different manufacturers as to the best way to develop TKAs and also to the advantages that they give the patient. Although the experiments reported in this thesis will not produce data into deep flexion beyond 120 degrees they will address whether the kinematics vary throughout a more physiological range of movement.

Chapter 4.

4.1 Introduction to this research.

There are a large number of factors which show why continued development of knee arthoplasty is needed. An improvement in the kinematic behaviour of a TKA or in the survival of a TKA would be very significant. Increasing numbers of joint replacement surgery each year mean the financial implications to the health service are vast. The National Joint Registry for England and Wales shows 29143 primary knee replacements were carried out over 2003/4, compared with almost 80000 over 2010(NJR,2010). Such differences may be due to better auditing and collection of data but the increased number of operations cannot be denied.

The age at which patients are requiring a TKA is decreasing. Associated with this are the increased demands patients are putting on their TKA and the range of activities they want to carry out following surgery. Patient demand for increased quality of life is much greater. Thus improving longevity of implants and decreasing wear is a significant challenge. With younger patients receiving a TKA the revision rate is also climbing and the functionality of a TKA is under greater scrutiny. There were 1232 revision knee replacements carried out 2003/4 compared with over 4000 in 2010 (NJR 2010). With the increasing revision rate the importance of carrying out the correct operation at the correct time is even more important than ever before.

4.2 The Aims of This Research.

1. A comparison of the SR design of TKA to a MR design and also to compare both TKAs to the intact knee. This will be done by recording the tibiofemoral kinematic data when the knees are cycled through a range of movement.
2. To map the pressure characteristics of both TKAs, when loaded by the quadriceps tension.
3. To compare the stability of the patella in both the intact knee and the two TKAs when the patella has also undergone replacement.
4. To compare the kinematics of the patellofemoral joint in the three knee states, again following patella replacement in the TKRs.

In particular, it was hoped that the tibiofemoral experiments would provide evidence as to whether a single radius design would limit the phenomenon of mid range instability. It was hypothesised that the SR design would exhibit kinematic behaviour closer to the intact knee and thus eliminate the mid range instability seen at an intermediate arc of flexion where the ligaments are less taut, a problem that has been reported with the MR types of TKA.

4.3 The Experimental Work.

In order to fully compare the two TKA designs each of the TF and PF joints needed to be assessed. The first set of experiments therefore addressed the tibio-femoral joint and used a tracking system to map kinematics of the knee in each of the three states (Intact, SR and MR). This provided the data to see if either TKA replicated the movement of the intact knee. After developing the methods, 8 cadaveric knees were used in total.

Once this data had been collected, the pressure mapping measurements were made. This had to follow the kinematics work as a further arthrotomy was needed when inserting the pressure measuring devices.

The second large group of experiments addressed the patello-femoral joint (PFJ) and was split into two distinct areas. Firstly using a different tracking device (because the original tracking system couldn't measure the PFJ kinematics), the kinematics of the PFJ were measured and compared with the knees in the three different states. The second set of work looked at the stability of the patella at different degrees of knee flexion for the replaced patella in the two TKAs and the intact knee.

The PFJ work was carried out 18 months after the TF work. The experiments differed as the cadaveric specimens were just the knee joint and not the whole limb, and so it was not possible to use the same navigation system, as will be explained in the methods.

Chapter 5.

5.1 Methods, Materials and Protocol.

This research was focused around a cadaveric study with the comparison of the intact knee to the new SR design of TKA and the established MR design both made by Stryker Orthopaedics (Mahwah, Indiana, USA). In each experiment detailed below, each knee replacement was inserted into each cadaveric leg and the kinematics measured using the navigation system. A Tekscan sensor was then inserted into the joint space to measure the contact pressures of each of the prostheses at different angles of flexion.

Prior to starting the experiments, the protocol was approved by the Ealing and West London Mental Health Trust Research Ethics Committee and by the Imperial College research governance office, reference number 07/Q0410/4.The cadaveric legs used in this study were obtained from IIAM, Jessup, Pennsylvania, USA, a tissue bank affiliated to the Musculoskeletal Transplant Foundation and were freshly frozen and stored in accordance with the tissue handling guidelines. Prior to each experiment each leg was defrosted overnight in a refrigerator at 5°C to ensure free movement of the soft tissues. Each knee used in this study was free from any disease or signs of trauma or surgery, to prevent influence on the results obtained. Prior to each experiment, details were gathered on age, sex, and height of the donor. All experiments were carried out on left legs only. The cadaveric limbs were whole legs, disarticulated at the hip, with a complete foot. Before any dissection of tissues was carried out a formal examination of the knee was performed to ensure there was no gross ligamentous instability that may affect the eventual results.

5.2 Pilot studies.

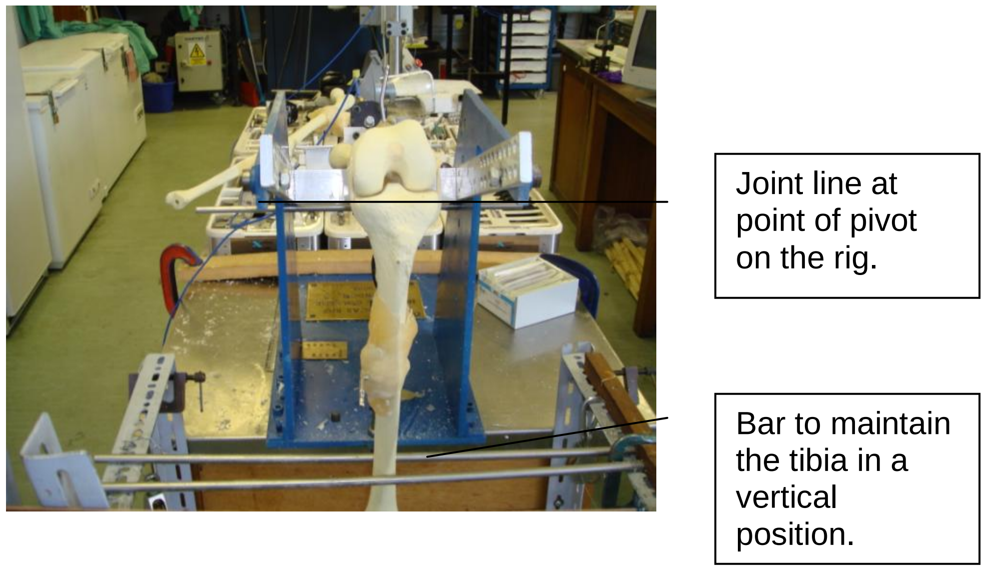
Prior to compiling the methods decided in this thesis, the author was able to help another MD student, Mr Amer Karim with his research experiments. He was also looking at a Stryker knee replacement system and in particular the ways in which a poorly positioned prosthesis, and the tibial posterior slope affected the kinematics of the replaced knee. Assisting with these experiments enabled drawing up the methods for loading each knee in the six degrees of freedom and also allowed the author to gain familiarity with the Stryker navigation system that would be used to insert the prostheses and also to measure the kinematics of the knees. This also offered familiarity with the way the data from the experiments was stored and the form in which it was presented to the researcher. By gaining an overall viewpoint of the research process, the author was able to plan the experiments and also how long data analysis and presentation would take.

A number of pilot tests were performed on sawbones in order to:

1. Gain familiarity with the operative techniques with the navigation system.
2. Gain familiarity with the instrumentation of each of the knee replacement systems. It was decided to use an anterior referencing method for the femoral cuts. Although many surgeons routinely use posterior referencing, anterior referencing and the navigation system would ensure accurate sizing and positioning of implants, and particularly be accurate for the PFJ.
3. To decide which TKA should be implanted first as the two different systems required different amounts of bone to be removed.
4. To be able to estimate the time each set of experiments would take so that the ordering of the cadavers from the USA could be planned.

Below are a series of photographs showing the sawbone mounted in the rig and the various stages of bone resection for the femoral and tibial components.

Figure 15. The sawbone attached to the experimental rig.



The cutting blocks of both TKAs were used, in order to become familiar with the steps involved in the knee replacements. Some of these steps are shown in the following diagrams.

Figure 16 The distal femoral cutting block in situ for the MR Knee.

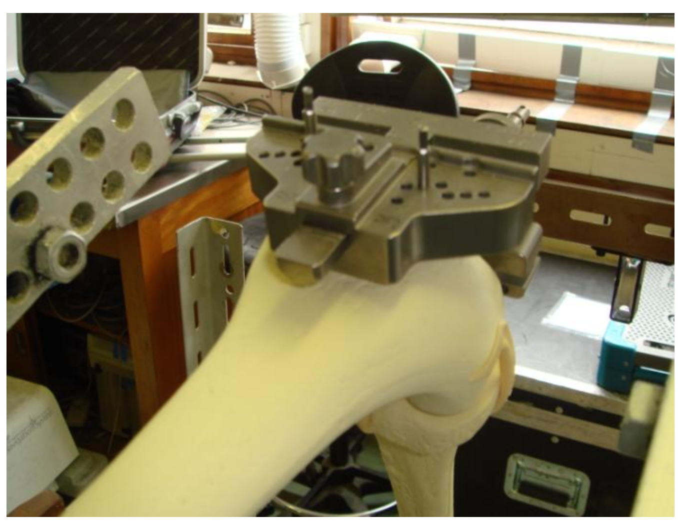


Figure 17. The sawbone following the femoral cuts and the tibial cutting block in situ.

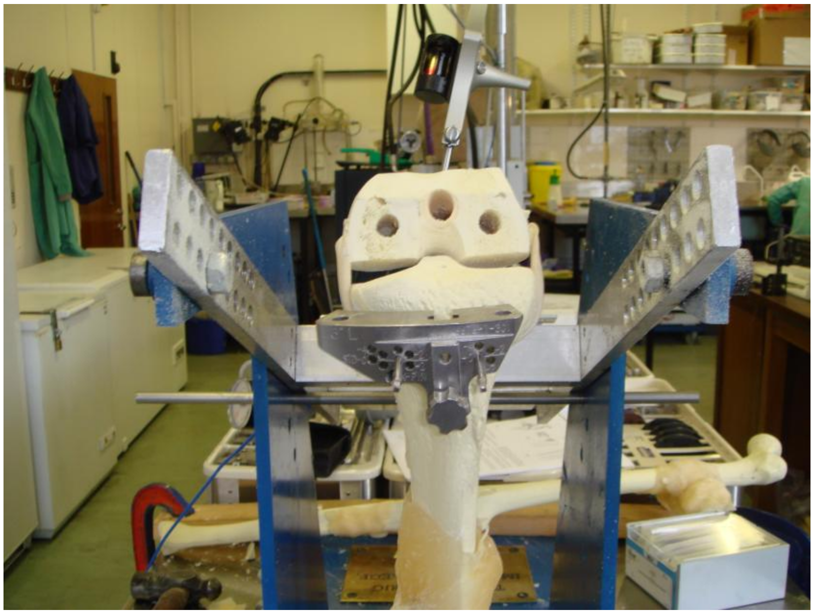


Figure 18. The completed TKA with the trial components in situ.

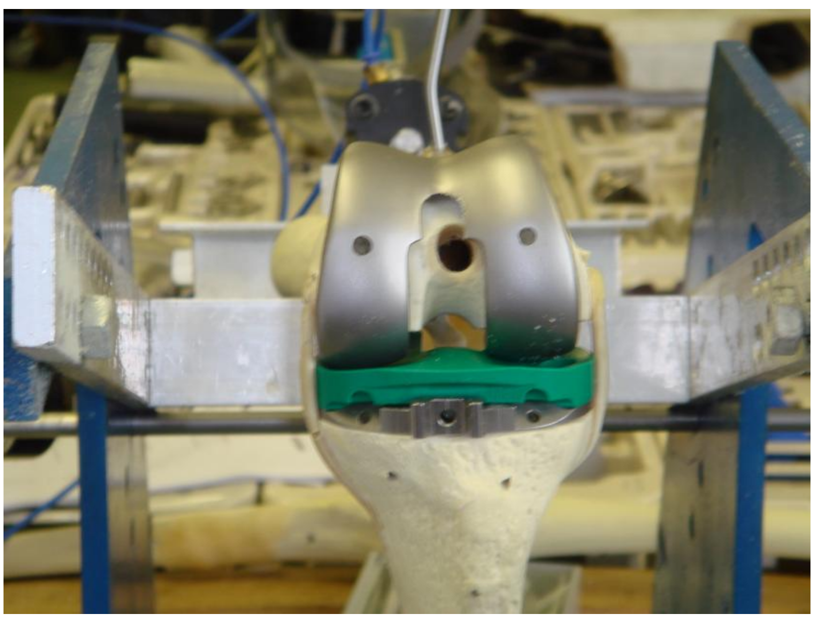
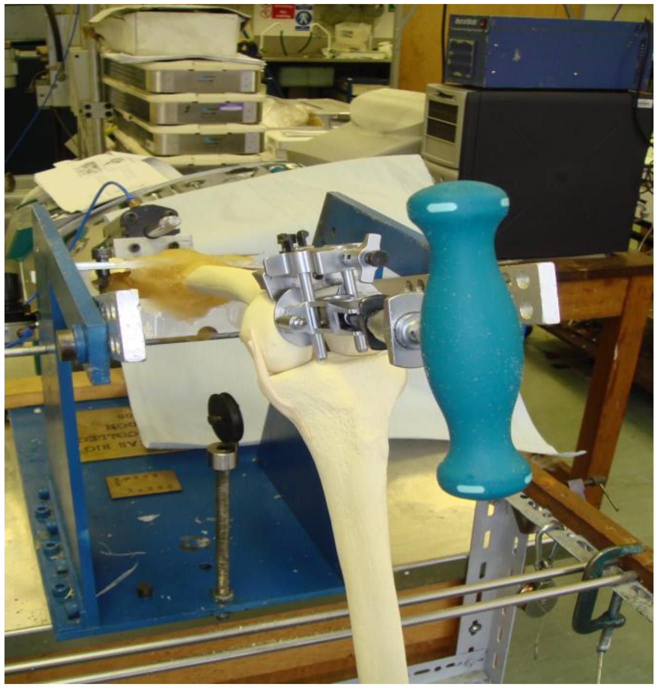


Figure 19. This photograph shows the different instrumentation needed for the newer SR TKA.



One of the most crucial parts of the experiments was deciding which of the prostheses to insert first, to ensure the second component was placed in an appropriate position that would not influence the results. From further sawbone work it was decided to insert the SR TKA first followed by the MR TKA. The SR design would be a press fit implant with the MR design requiring a very small amount of augmentation with bone cement on the posterior condyles and to prevent rotation of the tibial component as the two tibial stems were of different design.

It was necessary to assess how the sizes of the TKAs corresponded to each other. The SR design came in numbered components from 2-6, whereas the MR design was sized as S, M, L, and XL. The 2 corresponded well to the S, 3 to M and so on. Therefore changing the components would not affect the AP or M/L sizing, which could have affected the kinematic data.

5.3 Experimental Methods.

For each set of experiments three sets of data were produced. The first set was the kinematics of the closed natural knee without any implants in-situ. The same measurements were made on the SR and MR designs. This allowed not only comparison between the different types of knee replacements but also the individual cadaveric knees prior to insertion. In order to gain enough data for statistical analysis the experiments were performed on a total of ten cadaveric knees, with the first two used in the development of experimental methods. Data from a prior study (Kessler *et al* 2004) allowed a power study which showed that eight legs would allow us to identify differences of 1.5mm in AP translation, 2 degrees in internal-external rotation, and 1.6 degrees in varus-valgus angle with 95% confidence and 80% power. The following protocol outlines each individual step of this procedure. Each of the knees was cycled in each of the loaded states three times and the mean data used for analysis.

Prior to each experimental method the air pressure system was recalibrated. This was done as a result of the pilot studies. The initial readings of the Tekscan Sensors were found to be half those expected, because the air pressure device was only producing half the force expected. In order to calibrate the machine further, a series of weights were hung on it and the air pressure required to lift them was measured. This calibration gave the air pressure values to load the quadriceps to the appropriate force.

Figure 20 Calibration of the Air Pressure System.

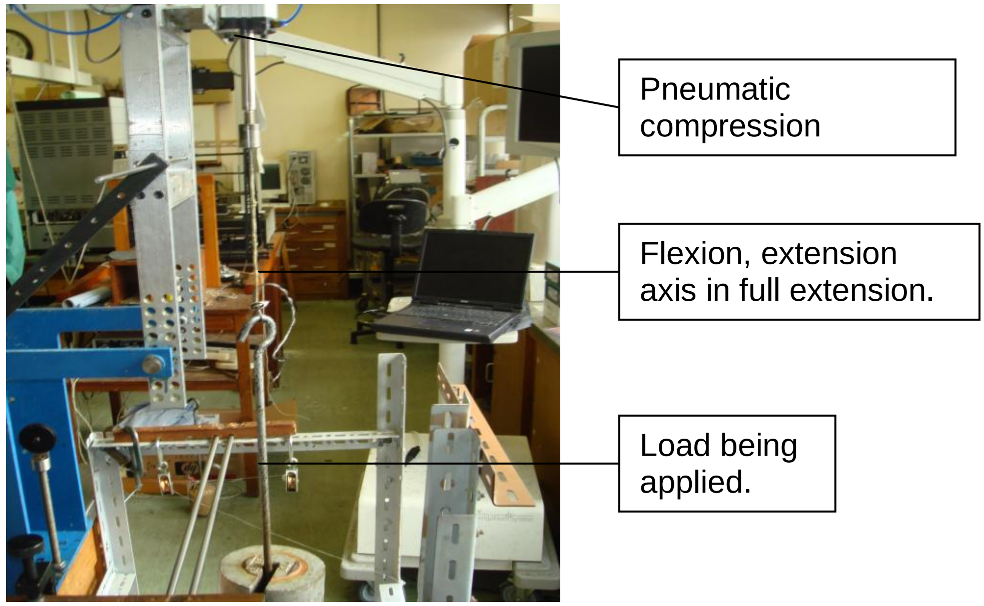


Figure 20 shows the rig in an exact vertical position with a known mass attached to it. From this set up it was then possible to accurately calibrate the system.

5.4 Preparation of the specimens.

Each leg required approximately 36 hours of defrosting in a refrigerator prior to use to allow the free movement of all the soft tissues. Once the navigation system had been attached as discussed in the next section the leg was placed on the test rig. In order to keep the leg in exactly the same position throughout all the experiments the leg was attached to the rig using bone cement and also a metal bar. This led to a very secure attachment, meaning that no movement occurred during the arthrotomy or exchange of implants. As a result, all the surgery required for the experiments could be carried out on the rig. This was a key point as movement during experimentation would have led to alterations in the tracking system and thus inaccurate data, leading to wasted time and in particular the expensive cadaveric legs.

5.5 Attachment of the Stryker Navigation System to the cadaveric legs.

In order to map the kinematics of the leg movement the navigation system had to be attached in a way that would track the movements of both the tibia and femur. A Stryker navigation system (Stryker Leibinger, Freiburg, Germany) was used for these experiments. To attach the trackers two 10cm incisions were made in the mid thigh and lower leg at 15cm from the knee joint line. Blunt dissection down to both the femur and the tibia were made to allow jubilee clips to encircle the whole bone. The trackers were then anchored in position using the clips and bone cement which also acted as reference points for reapplication of the trackers for further experiments or should they become unattached during movement. Once in position the jubilee clips were used to hold the mountings for the navigation trackers. The two incisions were then closed using a nylon suture.

The navigation trackers were attached away from the arthrotomy site so that they could be more easily visualised by the tracking device without the test rig interfering, and also to allow greater exposure and ease of operative work.

5.6 Digitisation of the anatomical landmarks using the navigation system.

To ensure accurate tracking of the moving limbs the navigation system needed to undergo an initial calibration. Navigation reference points at the centre of the femoral head, the femoral epicondyles and the centre of the ankle joint were used. The first step, using the computer as a guide, was to find the centre of rotation of the hip with the trackers in position on the femur and tibia. This was done by placing the head of the femur into a plastic cup and with the trackers recording the information, moving the leg in circumduction so that the navigation system was able to identify the centre of rotation.

Once this was found a medial parapatellar arthrotomy was used to allow digitisation of the surface anatomy. Specific points to be digitised included the medial and lateral epicondyles, the AP axis of the knee, the centre of the knee, the femoral notch and the medial and lateral aspects of the tibial plateau. The centre of the knee was defined as the highest point of the anterior-distal outlet of the intercondylar notch and the centre of the ankle was the midpoint of the line joining the malleoli.

To allow accurate placement of the components the navigation system needed to build up a picture of the orientation of the tibia. This was done using the stylus pointer and allowed the computer to build up a three dimensional picture of the architecture of the individual knee specimens. All the reference points were recorded by the computer. This process was important in several ways. Accurate digitization of points was needed for the navigation system to allow correct placement of the components, it also meant the kinematic data that was recorded was correctly referenced and also decreased the chances of errors being made throughout the knee replacement procedure.

Figure 21 The Femoral and Tibial Trackers and Pointer.

The femur and the tibia were both sectioned, leaving approximately 25cms of each bone behind, with the trackers undisturbed. Once all the points had been digitised the leg was then mounted in the test rig. The transepicondylar axis was aligned approximately to the flexion-extension axis of the rig, but as the navigation system measured bone-bone relative motion the exact alignment was not as important. Once the vertical position of the leg was confirmed it was cemented in place. The tibia hung free, allowing flexion of the knee (0-120^{0}) by moving the rig to which the femur was mounted. The arthrotomy was then closed in layers using a vicryl suture.

Figure 22 Picture of the whole leg with the navigation trackers applied to the femur and the tibia.

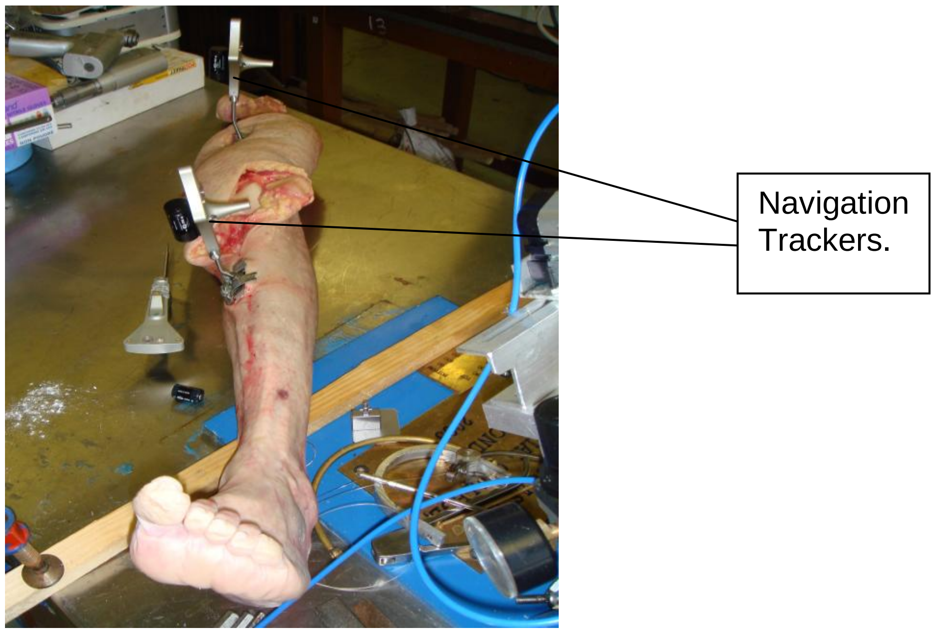
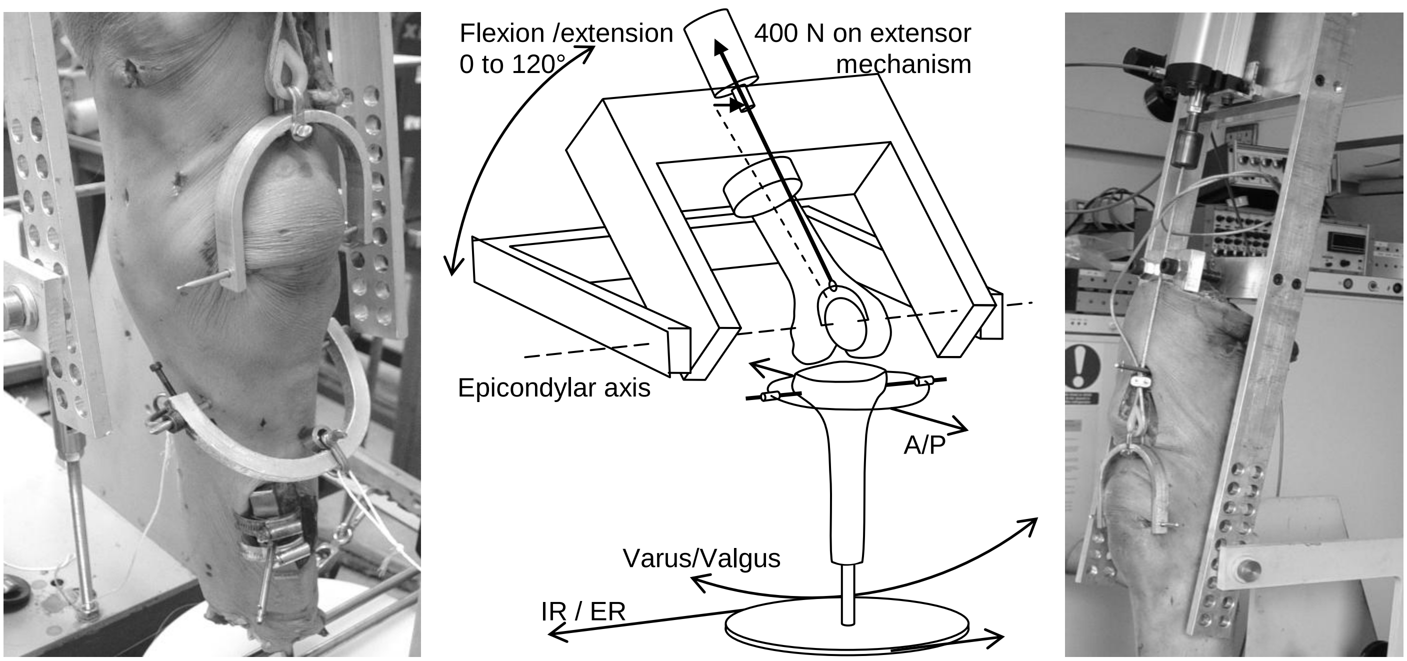


Figure 22 shows the whole leg with the trackers applied. Prior to mounting in the test rig both the femoral head and the foot were removed. The trackers can be seen pointing in a similar orientation which was very important to make sure all movements were picked up, allowing for the collection of all kinematic data. The foot and the hip were removed in order to allow easier mounting of the limb into the test rig and also to allow the displacing forces and moments to be applied to the tibia.

5.7 The Test Rig.

The test rig used in this set of experiments had been designed for previous work carried out at Imperial College, London. As can be seen from the following diagram and photograph the rig has quite a simple design.

Figure 23 The Test Rig.



The frame was mounted on a work bench and provided a secure base, with the main site for mounting the leg attached to it. Once attached to the rig the leg could be taken through its range of flexion by movement of the mounting. Also visible in the picture is the pneumatic system used to reproducibly load the extensor mechanism. The frame surrounding the rig could then be used to attach a system of pulleys. By attachment of weights to each of these pulleys the clinical laxity tests could be reproduced. It was important that the leg was mounted in the correct position with the joint orientated in the rig at the site of the pivot so that the angles of flexion were accurate and reproducible.

The rotational moments were applied using pulleys and weights loaded onto strong thread that was running around a disc that was secured to the IM rod cemented into the tibia. Varus / valgus moments were applied by placing a thread around the IM rod and loading medially or laterally with weights through the pulleys again. Special care was taken each time to make sure the weights were hanging free throughout the testing to make sure the forces were constantly being applied.

5.8 Measurement of Kinematic data for an intact natural knee.

The first set of data was collected on the intact knee prior to any TKA surgery. In order to do this it was important to be able to load the knee in the six degrees of freedom. In order to do this further apparatus was added to the knee. Firstly, a transverse hole was drilled across the widest part of the patella. A Steinman pin was passed through the patella, for mounting the knee extension mechanism. A second transverse K wire was drilled across the tibia 50mm below the joint line to allow the attachment of 2x semi-circular metal rods which were loaded to produce AP drawer without inhibiting secondary tibial rotations. A retrograde intramedullary rod was inserted into the tibia following careful reaming of the bone and cemented in place, leaving 150mm protruding distally. This rod allowed the attachment of a rotation disc. Strings attached to opposite edges of the disc pulled horizontally in opposing directions, and were led over pulleys to hanging weights used to apply the internal/external rotation and the varus- valgus moments.

This set up allowed the application of the stipulated loads. The following loads were applied to the knee across the range of flexion-extension once the rods and rotational disc had been attached.

400N axial tension in the extensor mechanism.

400N axial load and 5 Nm internal rotation torque.

400N axial load and 5 Nm external rotation torque.

400N axial load and 70N anterior drawer force.

400N axial load and 70N posterior drawer force.

400N axial load and 5Nm varus moment.

400N axial load and 5Nm valgus moment.

All these loads were applied whilst the 400N remained in position.

5.9 Arthrotomy of the knee.

Each knee in the study was operated on using a medial parapatellar approach following a midline incision of approximately 15cm. Once the knee joint had been opened, care was taken to remove any extra adipose tissue whilst ensuring the soft tissue structures such as the collateral ligaments were not removed. Both the medial and lateral menisci were also removed at this stage along with the ACL and adequate access to the knee was ensured.

5.10 Surgical protocol no.1 using the SR Knee.

The first TKA system to be implanted was the SR design. The Navigation System was used to confirm the appropriate position of the cuts for the femoral component to ensure that the experiments were reproducible. The distal femur was cut perpendicular to the mechanical axis in both the coronal and sagittal planes. This cut was a fixed distance, equal to the thickness of the femoral implant, distal surface of the lateral condyle. The rotation of the femoral component was 3^0 of external rotation to ensure a quadrangular flexion-extension gap and as per the manufacturer's guidelines (Berger *et al* 1999) and Whiteside's line (Whiteside *et al* 2002). The prosthetic components were held in position using a press-fit method to allow the exchange of implants later on.

The tibial component was attached in a similar fashion, using navigation and at 0 degrees of mechanical axis of valgus. 3 degrees of posterior slope of the tibial component was used for both prostheses and the cut was made perpendicular to its anatomical axis in the coronal plane. The rotational alignment of the tibial tray was referenced using the PCL and medial 1/3rd of the tibial tuberosity. The appropriate sized insert selected from the trial prostheses was placed in the knee joint and flexion performed to ensure an adequate range of movement before the recorded experiments began. Any soft tissue balancing procedures or resection of further bone were done at this point. However, as the cadaveric limbs had no signs of degenerative joint disease little soft tissue balancing was required. The patella was left unresurfaced in the TF experiments. The arthrotomy was then closed using a No 1 Vicryl suture (Ethicon, Somerville, NJ, USA) in the facial layers, 2/0 Vicryl in the fat and 4/0 Vicryl for the skin.

Although both designs of TKA would be cemented into place in clinical practice, this was not appropriate during this testing. If the components been cemented in place this would have eliminated possible movement of the prostheses during cycling. However, the main reason for limiting the use of cement was the fragile nature of the cadaveric bone. Having to remove cemented components would most likely lead to a loss of bone, bone defects, alteration in the joint line and possible inaccuracies in the results due to inaccurate placing of the second TKA.

Figure 24 The Final Set up of a Knee following arthrotomy.

All excess surgical waste produced during the resection of bone was bagged and disposed of in an appropriate manner. With the trackers in position the kinematics could then be recorded. As previously the only data recorded was as the leg was extended, with none of the flexion data recorded. Three cycles of leg movements were used with the data stored directly onto computer. Kinematics were measured as before using the same set of loads.

5.11Surgical protocol no.2 using the MR design.

In a very similar fashion the MR design system was implanted into the same knee with the tibial component still in 0 degrees of valgus. It was decided from the pilot studies with the sawbones that it would be most appropriate to fit the MR design second to the cadaveric leg. This was decided because the difference in bone cuts meant that the MR femoral component was only deficient in the posterior condyles and anteriorly where the 7^0 anterior flange cut of the SR needed to be accommodated. This was easily corrected by filling the gap with a small amount of bone cement and holding the prosthesis in place until the cement had set. Therefore it had the same position and was located onto the same anterior and distal bone cut surfaces.

Similarly, the tibial component required a slightly different surgical protocol. Because of the different bone cuts for the stems of the tibial components, with the SR cut being an arrowhead shape and the MR cut being round. It was decided that, following the bone resection, the MR tibia would be best held in place with a small amount of bone cement to prevent any rotation of the component in the increased bony defect. Only when both components were secure, the knee capsule was closed with the same sutures as used previously. The kinematics were then measured using the same set of loads as in the two previous experiments.

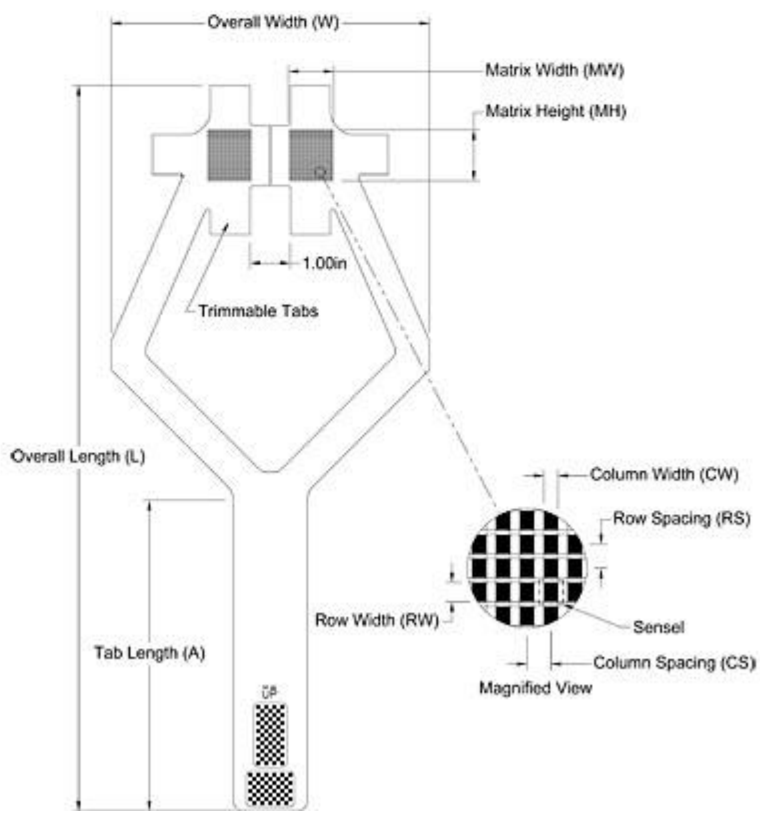
5.12 Data Collection.

All the data collected from the three sets of experiments was downloaded directly onto to the laptop computer attached to the navigation system. The format of this data was then converted to a more easily analysable form and presented as graphs, tables and statistical analysis. The data collected showed the position as coordinates of the femur and the tibia. Eventually this data could be used to produce graphs showing the envelope of laxity of each of the knees through an appropriate range of movement.

5.13 Pressure mapping in both Knee Replacement Systems.

The second major part of the experiments involved mapping the contact pressure and contact areas of both the TKRs. In order to do this Tekscan sensors were used, as illustrated below.

Figure 25 A Tekscan Pressure Sensor.



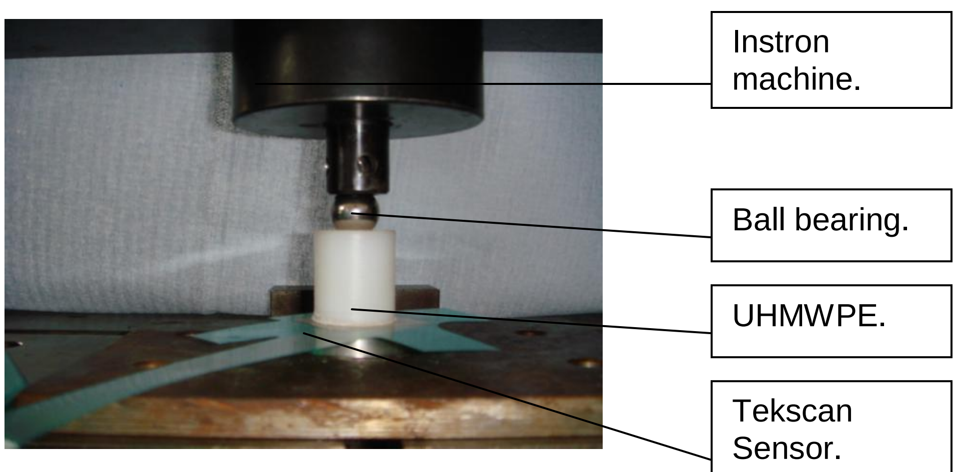
These sensors consist of two thin, flexible polyester sheets which have electrically conductive electrodes deposited in varying patterns. Before assembly, a thin semi-conductive ink is applied as an intermediate layer between the electrical contacts (rows and columns). This ink which is unique to Tekscan Sensors provides the electrical resistance change at each of the intersecting points. When the two sheets are placed on top of each other a grid is formed, creating a sensing location at each of the intersections. By measuring the changes in current flow, the applied force distribution pattern can be measured and displayed on the computer screen. Using the attached computer you can look at the data in 2 or 3-D as well as being able to look at the force and pressure changes throughout the test. A paper by Salo *et al* (2002) showed that the Tekscan sensors were more accurate and often easier to use than the Fuji film. They looked at the accuracy of the data recorded during testing, using the Tekscan sensors. In this study, controlled loads were applied to the different ranges of Tekscan sensors available. The data was then processed by the I-scan software that filters out the data with the lowest signal intensity that generally lay outside the periphery of the recorded area. The software was also able to produce a contact area accurately by eliminating data from sensels that were more than two standard deviations from the mean. They found a 2.3-8.2% error in the recording of the contact area. This was explained by the authors in that if any part of the sensor is loaded during the experiments then the whole surface area of that sensor is counted, thus leading to an over estimation. The authors also added that the sensors were sensitive to temperature, the length of time the force was applied and the medium in which the sensors were being held during testing. All of these findings require an adequate calibration process to try and remove all the mentioned variables that may impact on the accuracy of the results.

Harris, Morberg et al. (1999) looked specifically at two methods of performing the pressure studies with a view to assessing which one would give the most accurate information. The K scan sensors consisted of 2288 elements each 0.92mm^2 across and as with the Fuji film were placed directly between the tibial insert and the femoral component. The K-scan sensors gave more accurate and precise data. The Fuji film was also technically more difficult to use. However, these sensors are affected by temperature, can be awkward to position and their finite thickness may affect pressure measurements.

Prior to using this pressure measuring system the sensors had to be calibrated, so that the software would give completely accurate information throughout all the experiments. In order to do this , an Instron machine, which is able to exert accurate and constant forces in a particular direction, was used. By applying a range of forces the Tekscan computer was able to store the values making sure that the forces exerted by the Instron machine reflected the values recorded by the Tekscan sensors. This ensured the reproducibility of the results for the different knees. There were a range of sensors varying from those with two recording areas for beneath each femoral condyle and also sensors which work over different ranges of force. Through the calibration process it was possible to select the sensor that would give the most accurate readings in the particular amounts of force expected to be encountered during the experiments.

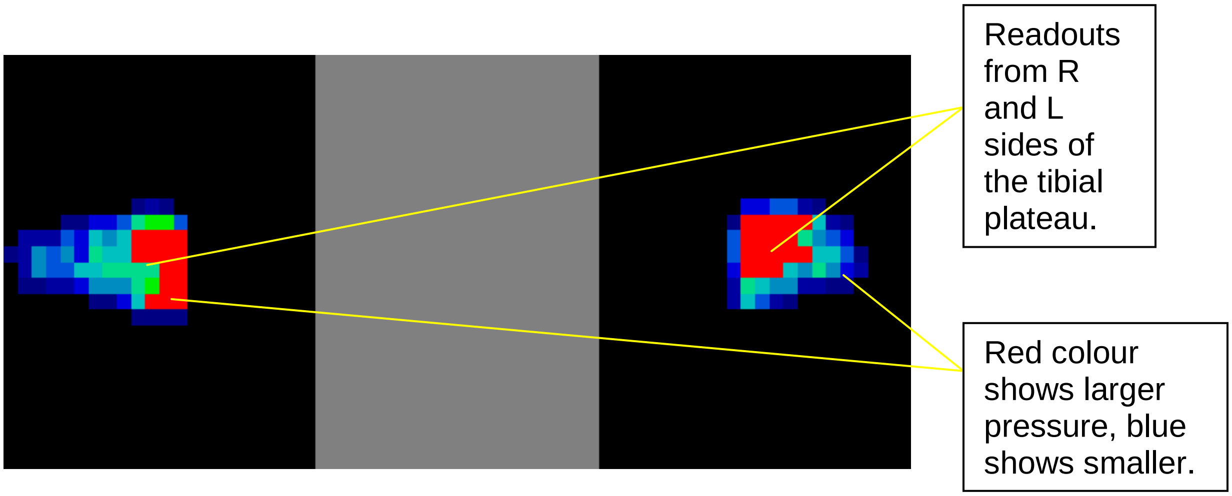
Through further calibration of the Tekscan sensor to be used, the readouts from the Instron machine and the sensor were compared. With the Instron machine reliably accurate, the variability was in the sensor. Through repeating the calibration and the forces applied during the calibration the Tekscan system was precisely calibrated.

Figure 26 Calibration of the Tekscan Sensor.



The calibration test is shown above. A cobalt chrome ball bearing and a large piece of UHMWPE were used in order to replicate as close as possible the experimental conditions as closely as possible. Different known loads were applied by the Instron machine and then stored as specific values on the Tekscan computer.

Figure 27 A readout from a Tekscan Sensor.



The graphic above shows an example of the results. The coloured squares represent those areas of the sensors that had load applied to them. Each of the sensors were individually monitored and the varying force reflected in the colour scheme with red representing the greatest force. As each of the Tekscan Sensors was split into two, each of the individual readouts above represents the force beneath each of the femoral condyles.

In order to make a true comparison between the two types of TKAs it was important to carry out the pressure mapping in both TKAs in the same knee and at different angles of flexion, as well as different loads on the knee. In order to do this there were other variables that need to be addressed.

To avoid damage to the sensors that may occur during movement only static pressure measurements were made with the knee at different degrees of flexion. In each of the two TKAs in turn measurements from 0-120 degrees in 10 degree increments were made. As a further experiment these measurements were repeated with the knee loaded in the 6 degrees of freedom using the loads as described previously in this chapter. This would allow assessment of what effects different loading conditions would have on the contact pressures and also give information as to where that pressure would be on the polyethylene insert.

The information produced was then used to compile various graphical representations of the data as well as giving pressure mapping data and specific values for the forces experienced.

5.14 Conclusion.

Once all the experiments had been performed the leg was removed from the test rig and the whole apparatus thoroughly disinfected. The knee was opened once more and the components removed and also disinfected. The human specimen was bagged and stored appropriately with the disposal of biological waste by incineration according to guidelines.

Chapter 6 The Patellofemoral Joint Experiments.

The second major part of this set of experiments looked specifically at the Patellofemoral Joint (PFJ) and if the different trochlear designs would alter the kinematics. The experiments concerning the PFJ would assess the tracking of the patella through a range of flexion and then the stability of the patella using an Instron machine to measure the forces required to displace the patella 1cm medially and 1cm laterally at different degrees of flexion. The set up and methods were quite different to those from previously and are as follows and each set of experiments, unlike the TF work, involved replacement of the patellar button.

6.1 The Preparation of Specimens.

For these tests the cadaveric specimens were just the knee with neither the hip nor the ankle still attached. The source was the same tissue bank in the USA and all the specimens were freshly frozen. Once they had been defrosted overnight in a fridge they were dissected. Each of the knees had the skin removed in order for an accurate dissection to take place. Once the skin had been removed different muscle groups were defined and separated in order for them to be loaded specifically. The muscles were separated and loaded as per the guidelines in the paper by Farahmand et al (1998). Individually loaded muscles were:

Vastus Lateralis Obliquus (VLO).

Vastus Lateralis (VL).

Iliotibial Tract (ITB).

Rectus Femoris and Vastus Intermedius (RF and VI).

Vastus Medialis (VM).

Vastus Medialis Obliquus (VMO).

The work by Farahmand *et al* (1998) used the physiological cross sectional areas of the muscles. They found that rectus femoris and vastus intermedius contributed 35% of the quadriceps strength, with 40% from the vastus lateralis and 25% from the vastus medialis. For these reasons each of the muscles were dissected and loaded accordingly in order to replicate physiological conditions.

A total of 175N of tension was applied across the quadriceps. This load is clearly not physiological but due to the fragility of the cadaveric tissues, any more load was not possible to use as the muscles failed and the load fell. Each of the individual muscles were loaded by wrapping strips of cloth around the proximal end of the muscle and attached by stitching through the muscles bulk. These cloth strips provided a greater resistance to pull out when the loads were applied.

6.2 Loading the specimen into the Instron Machine.

In order to gain the appropriate orientation for each of the knees it was paramount that they be attached to the Instron machine in such a way that when removed for the TKA to be performed they could be replaced in exactly the same position so that the next set of results would not be affected by any changes in position of the knee. This was achieved by cementing an intramedullary rod into the femur which could then be secured in a reproducible position. The tibia was sectioned at an appropriate level so that the knee could be flexed past 90 degrees and not impinge on the side of the Instron machine.

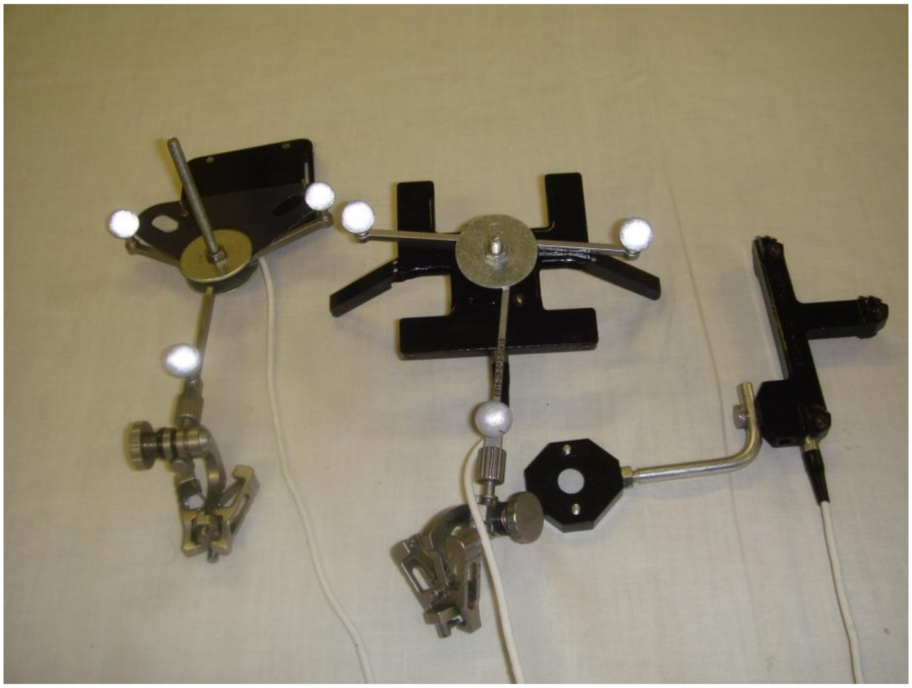
6.3 Anti Rotation Devices.

As a further precaution to prevent malpositioning and movement of the knees 2 large pins were drilled into the shaft of the femur and clamped using external fixation to the test rig. As well as preventing rotation these pins also served as a second reference point for relocating the knee into the rig.

6.4 The Attachment of the Tracker Devices.

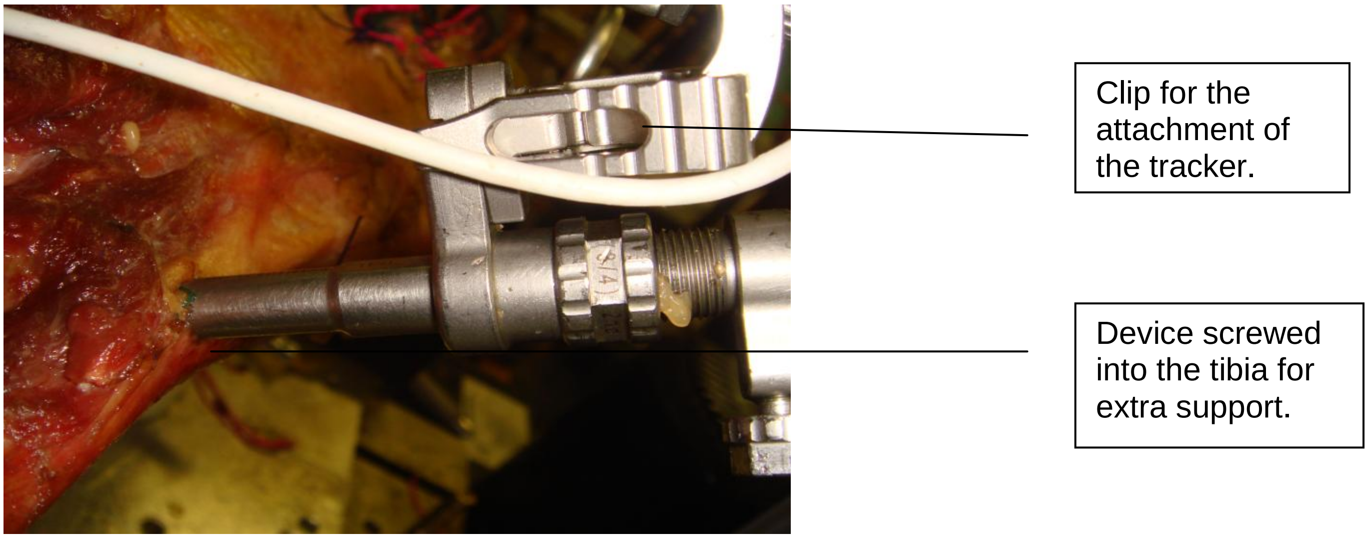
For the PFJ experiments an optical tracking system was used with trackers positioned on the femur, tibia and patella. This would enable trackingof the patella in respect to the long bones.

Fig 28. The Optical Tracking Devices.



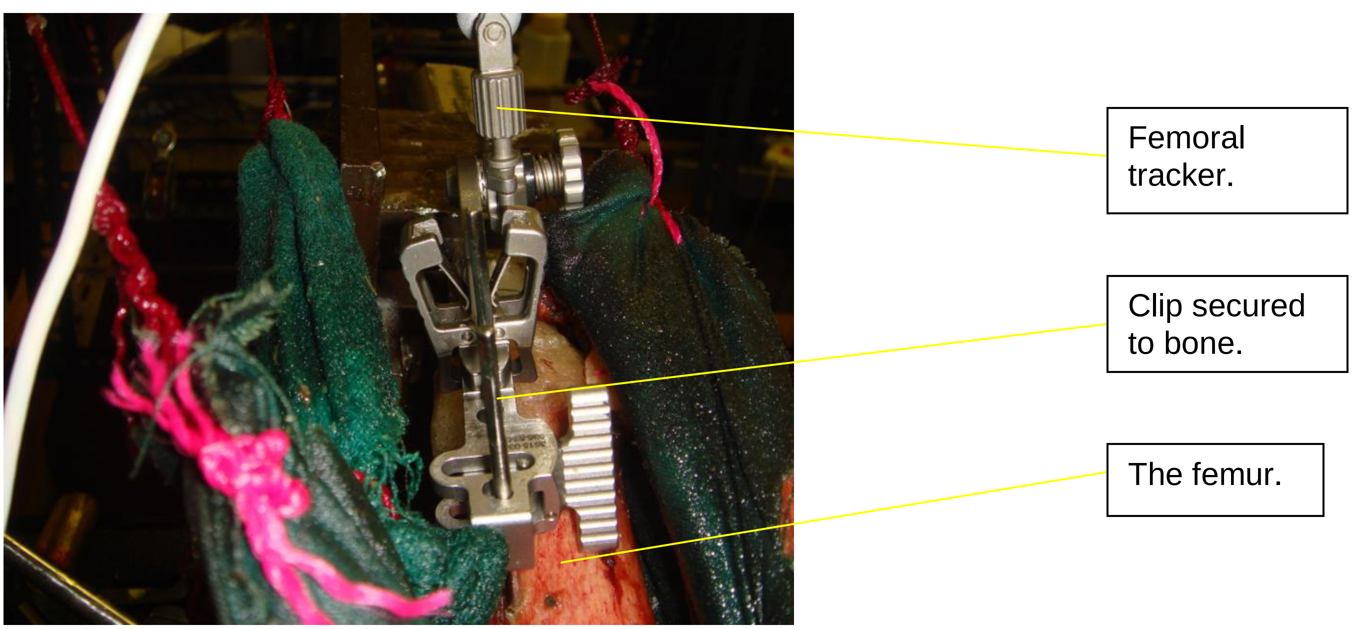
It was again imperative that these trackers did not move or the data extracted would be inaccurate. Each tracker was mounted on a port that could be attached securely to the bones by attachment to a thick pin, drilled through both cortices of the tibia. The tibial tracker was attached using another pin that was drilled into the tibia over the tibial crest and approximately 10 cm from the tibial tuberosity. The port for the tibial tracker was then screwed into bone and then tightened to ensure no movement.

Fig 29. The Attachment of the Tibial Tracker.



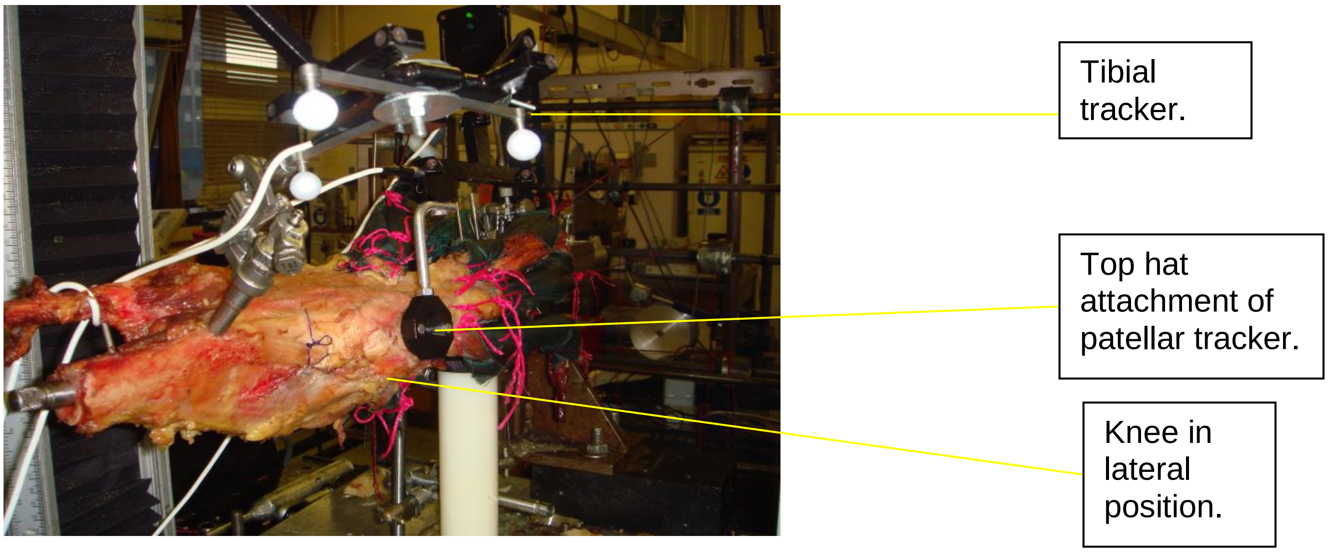
The Femoral Tracker was attached to a port secured to the shaft of the femur by two further threaded pins for extra security as shown by the photograph.

Fig 30. The Attachment of the Femoral Tracker.



Finally, the patellar tracker was secured in place. This was done by drilling into the patella at a position specifically over the patella groove and cementing in place a plastic device that would act as an attachment for both the Instron machine and also allowing the patellar tracker to be screwed into place time after time.

Fig 31. The Attachment of the Patellar Tracker.

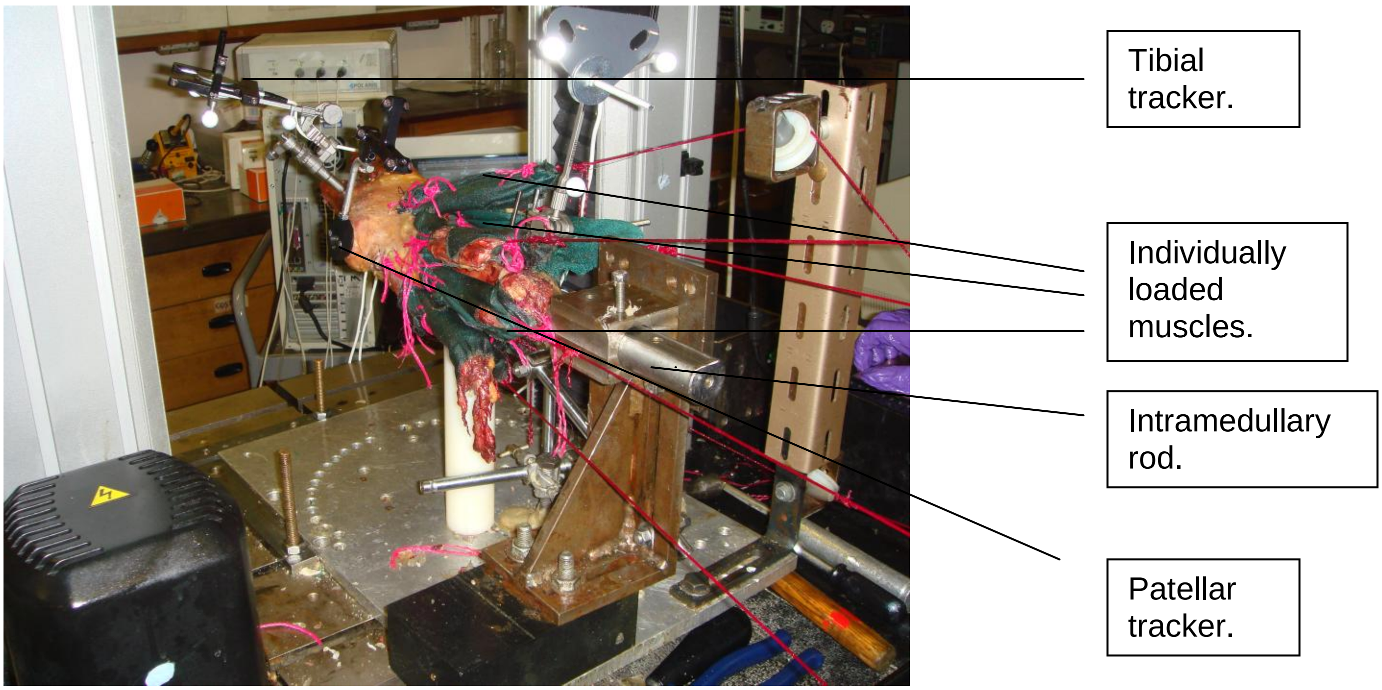


Once all the trackers were securely attached their position needed to be adjusted so they could all be seen by the optical tracker sensing machine. Once all visible to the machine their visibility was checked throughout the range of movement to ensure a complete set of data was obtained. Only then could recordings be taken.

Figure 32.

The Final Set Up.

This shows the individual muscle groups loaded, the knee in a lateral position, the trackers attached, the femoral rod cemented in place as well as the anti rotation pins.



6.5 Recording the data.

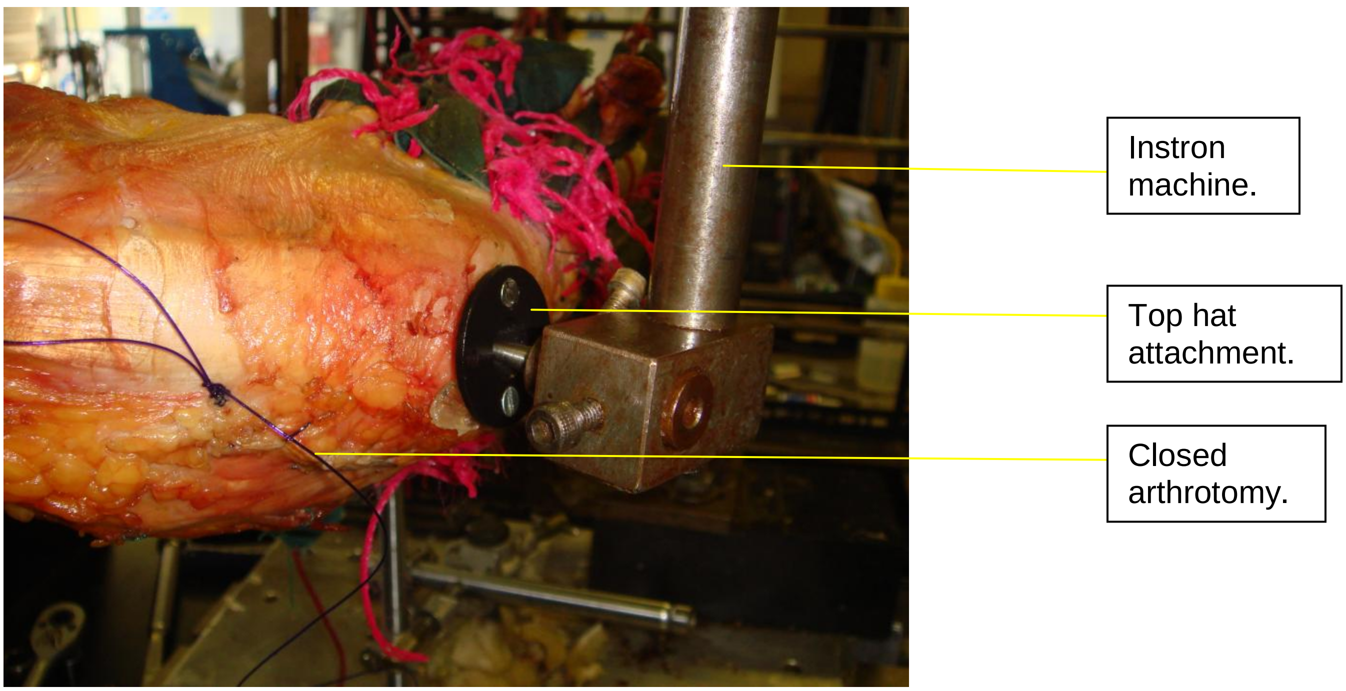
With the set up complete, data collection could start. This involved cycling the knee through its range of flexion. Due to the size of the Instron 5565 materials testing machine often this range of flexion was limited to around 90 degrees before the machine obscured the line of sight of the optical trackers from the stereo cameras. It was not possible to avoid this for these experiments and the same methods were used for all eight knees. Although all the cycling was done by hand rather than machine, special care was taken to allow the tibia to internally and externally rotate as it does naturally when the knee is extended and flexed. The data was saved onto a PC in spreadsheet form for later analysis.

The motion of the patella recorded was in relation to the femur. Flexion was a rotation about the epicondylar axis; tilt was a rotation about the long axis of the patella, defined as lateral if the lateral edge approached the femur; rotation in the plane of the patella was defined as positive if the distal pole moved laterally, into abduction; medial-lateral translation, or shift, was measured parallel to the epicondylar axis.

6.6 The Measurement of Patella Stability.

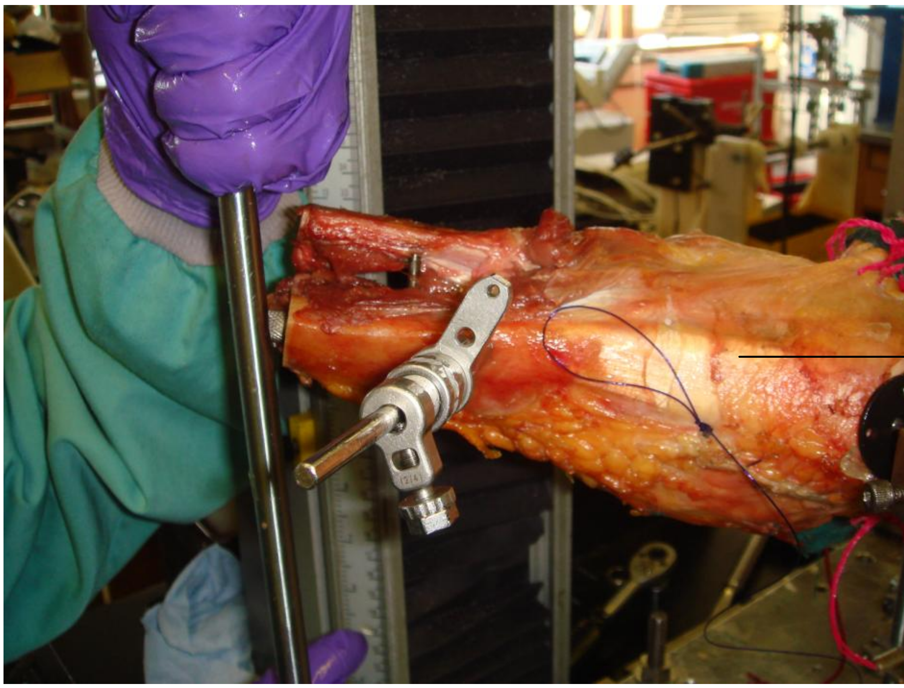
The assessment of stability was done by measuring the force needed to displace the patella by 10mm medially and 10mm laterally. In order to do this the patella was attached to the Instron Machine with a small ball bearing that sat inside the plastic “top hat” that had been cemented into the anterior surface of the patella. The instron machine could then be set to displace the required test distance and measure the force that was required to do this.

Fig 33. The Attachment to the load cell of the Instron Machine.



As long as the knee was in the same position for subsequent tests this would allow a direct comparison between the intact knee and the two TKAs. The Instron Machine produced a graph of the entire range of medial and lateral movement so different set points could then also be compared between different knee states. In all experiments measurements were made at 0, 20, 30, 60 and 90 degrees. The angles of flexion were selected so information was gained at full extension, 20 and 30 degrees of flexion as the patella begins to engage in the trochlea, mid flexion of 60 degrees and finally 90 degrees. These angles were measured each time using a goniometer and the knee kept in the required position through the measurements by a metal rod as shown below. By doing this the tibia was also able to rotate and move as necessary as it was loaded.

Fig 34. Positioning of Knee for Stability Testing.



Knee being held at 60 degrees of flexion.

6.7 Arthrotomy of the knee.

Each knee in the study was operated on using a medial parapatellar approach following a midline incision of approximately 15cm. Once the knee joint had been opened care was taken to remove any extra adipose tissue whilst ensuring the soft tissue structures such as the collateral ligaments were not damaged. Both the medial and lateral menisci were also removed at this stage and adequate access to the knee was ensured

6.8. The First TKA, the SR design.

The knee was removed from the Instron machine in order to perform the arthroplasty with utmost care taken to avoid movement of the tracker positioning. As with the first experiments looking at the tibiofemoral joint the SR TKA was performed first as the cuts were more conducive to implants exchange. However, technically this TKA was more challenging because the navigation system could not be used for implant positioning due to use of a different tracking device. There was also less length of tibia in order to reference the rotation of the tibial component. The components were again positioned in a press fit fashion to allow ease of implant exchange and to prevent possible bone loss between experiments that may occur if components had been cemented and then revised. The femoral components were between sizes 3 and 5 and were placed using anterior referencing to ensure accurate positioning of the anterior flange of the trochlea.

The patella was replaced with the specific SR patellar button as per the manufacturer’s guidelines and any soft tissue releases made to ensure the patella tracked satisfactorily. The patellar thickness was measured using callipers prior to selection of insert. The arthrotomy was then closed using PDS sutures and the knee was secured back into the Instron machine in the exact previous position. The patellar tracking and stability test could then be performed. In order to replace the knee back into the Instron machine, the cemented intramedullary rod had accurate markings on its side. These markings could be lined up again when the knee was replaced to make sure none of the tracking coordinates were altered during the experiments.

6.9 The Second TKA, the MR design.

In order to exchange the TKAs the knee was removed from the Instron machine once again. The arthrotomy was opened and the components exchanged. In all eight knees a small amount of bone cement was used to secure the components to prevent them becoming loose and to fill any small defects as a result of the slightly different bone cuts as discussed in the TF experiments. The patellar button was also exchanged to match the new TKA, as the SR button was a slightly asymmetrical design favouring the medial side. The knee was closed as previously and secured in the Instron machine for the same tests to be repeated for the third time.

6.10. Disposal of the Knees.

Once all the data had been collected for the knee in the three states, the final set of components was removed as well as the top hat, intra medullary rod and the anti rotation pins for use in the next set of experiments. The cadaveric tissue was then disposed of in a safe and appropriate manner.

Chapter 7

Results.

Examination of the kinematics of the tibiofemoral articulation generated large data sets. Complete sets of data were obtained for the kinematics of the tibiofemoral joint, the pressure mapping in the tibiofemoral joint, the patellar tracking experiments and also the patellar stability work. Each of the experimental results will be presented separately to avoid confusion and to show exactly how the data was analysed in each case. The rest of this chapter will deal with the tibiofemoral work with the patellofemoral results following in subsequent chapters.

All the experimental work for the tibiofemoral joint was carried out at the same work bench in the laboratory at Imperial College London. All the TF experiments were performed in a three week block in May 2007 with the same ambient light and temperature throughout. Each knee was examined through a range of motion from 0-120 degrees of flexion using the same test rig. The PFJ experiments were carried out in October 2009 over a two week period.

7.1 The Results of the Tibiofemoral Work.

A power calculation had shown that 8 sets of complete data were required in order to detect clinically significant differences that may be present. The raw data sets were analysed by Professor Bull (Imperial College) and transferred into a data spreadsheet (Excel, Microsoft, USA) and a format which could be analysed further. The results were compared to expected values and similar work produced in the same department to check that they were as expected prior to continuing with further sets of testing. Each set of data was analysed before the knee could be dissected further to allow the pressure mapping to occur as this required further dissection of the capsule, which would have affected the kinematics if it was necessary to perform the experiments again. Two sets of experimental data did not produce enough data for analysis and further experiments were carried out to ensure a complete set of data was produced. Such changes were important so they could be applied to all sets of data. Any data for hyperextension was excluded. The data analysis was limited to 105 degrees of flexion to ensure there were eight complete sets of data. Also as a result of this analysis slight changes and inaccuracies were highlighted, particularly regarding the digitization of the epicondyles.

This highlighted one of the potential limitations of using a knee navigation system. Jerosch et al (2002) highlighted the variation of individual surgeons in defining the points from which the digitisation should occur. If these points are wrong then the subsequent guidance will be wrong as well, leading to potential misalignment. Reviewing the results with Professor Bull decreased the chance of this happening subsequently.

One example of a data spreadsheet is on the following page. Each of the columns corresponds to the position of the knee and, for analysis, the correct data sets need to be selected. As all 8 knees in their 3 knee states had similar data tables produced there were 504 sets of data as each knee was cycled 3 times during each test. Other data tables are included in the appendix.

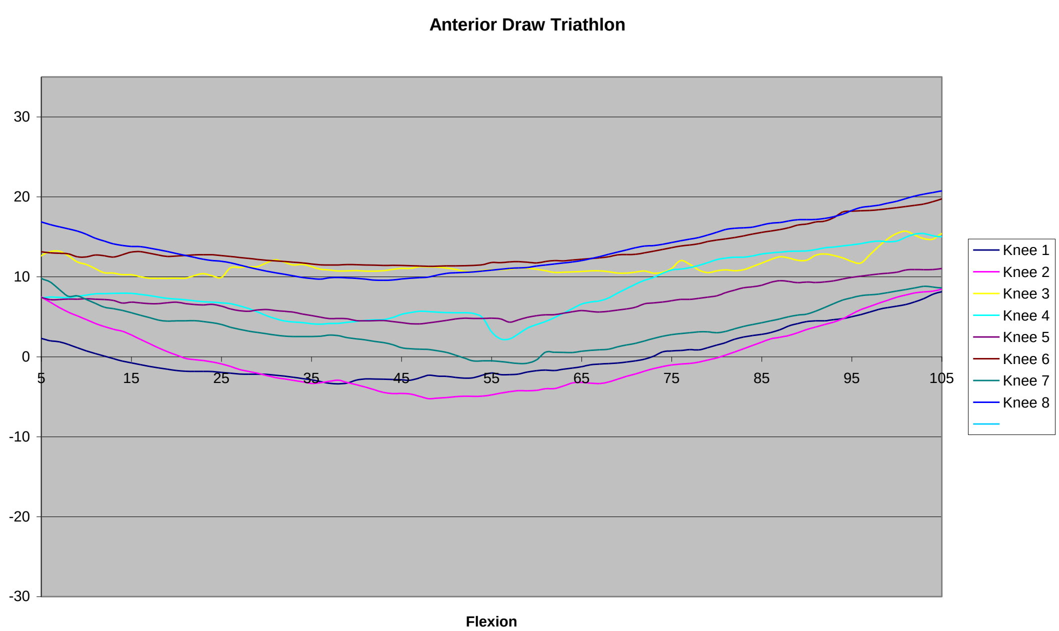
Figure 35 A Section of a Raw Data Table.

Angle of flexion (^{o}).	**Anterior (mm)**	**Posterior (mm)**	**Rotation (mm)**	**Varus (mm)**	**Valgus (mm)**
0	8	4	-5	12	18
1	8	4	-5	13	18
2	7	4	-5	12	18
3	7	4	-5	11	18
4	6	4	-5	11	18
5	6	4	-5	11	18
6	5	4	-5	11	18
7	5	5	-5	11	18
8	4	5	-5	11	18
9	4	5	-5	10	18
10	4	5	-5	10	18
11	3	6	-5	10	18
12	3	6	-5	9	18
13	2	6	-5	9	18
14	2	7	-5	8	18
15	1	7	-5	8	18
16	1	7	-5	8	18
17	0	7	-5	8	19
18	0	8	-5	7	19
19	0	8	-5	7	19
20	-0.3	8	-5	7	19
21	-0.7	8	-5	6	19
22	-1	8	-5	6	19
23	-1	8	-6	5	19
24	-2	8	-6	5	19

7.2 Statistical Analysis.

The next important step was to identify any sets of data on any of the individual knees that were very different to all the others. Any incorrect data would skew the data set and thus influence the final set of results. The sets of data for an individual state, e.g. Intact Knee Axial load, were combined into one database, leading to the graphs of the results using the Excel software (Microsoft, USA). By plotting all the different knees together any sets of data that obviously stood out from the others were identified, suggesting that further experiments would be needed to ensure correct conclusions could be made. An example is shown below.

Figure 36. Graph of Anterior Drawer in the SR Knee for all sets of data.



The graph above shows anterior drawer for all knees with the SR TKA implanted. All data sets follow the same graphical pattern with no one set of data lying significantly away from the others. However, some of the knees post TKA appeared to show a much greater amount of anterior drawer towards full extension. The overall curves throughout the range of flexion appear to be similar, so all 8 data sets could be used for analysis and averaged values could be produced. This process was repeated for each knee state in the seven conditions in all, thus producing 21 graphs of this nature.

7.3 The Graphs of the Averaged Values.

Any outlying data was then excluded from further analysis and the data sets transferred to a computer statistics software package Prism 5 (Graphpad Software, USA). This allowed further graphical analysis but also for the statistical tests to be performed on the data. The data analysis was limited for values between 10-110 degrees of flexion as all data sets were complete between these two values. If this range had been increased, inaccuracy would have resulted.

The first graph for the native knee in anterior drawer was superimposed onto the graphs for the SR knee and then MR knee to show a clear visual comparison, figures 38 and 39.

Figure 37 Intact Knee Anterior Drawer with Standard Deviations. (Mean of 3 repeats with each of 8 knees)

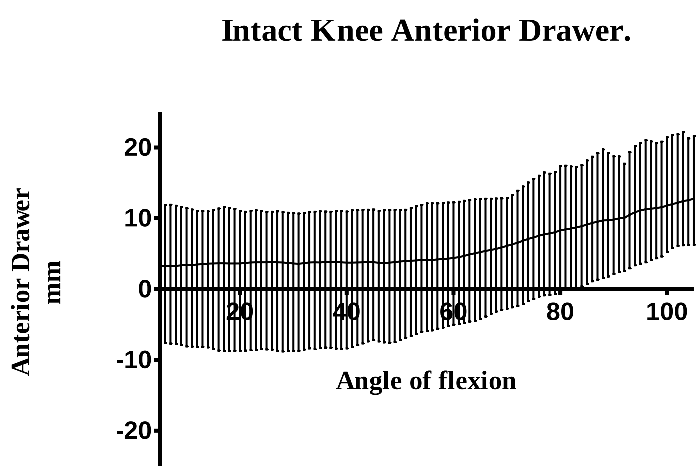


Figure 38 SR Knee Anterior Drawer.

(Mean of 3 repeats with each of 8 knees).

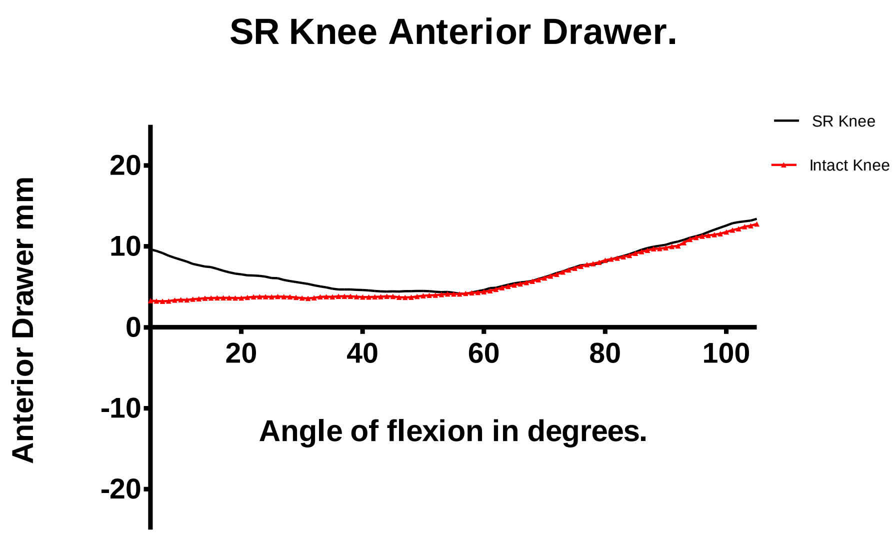
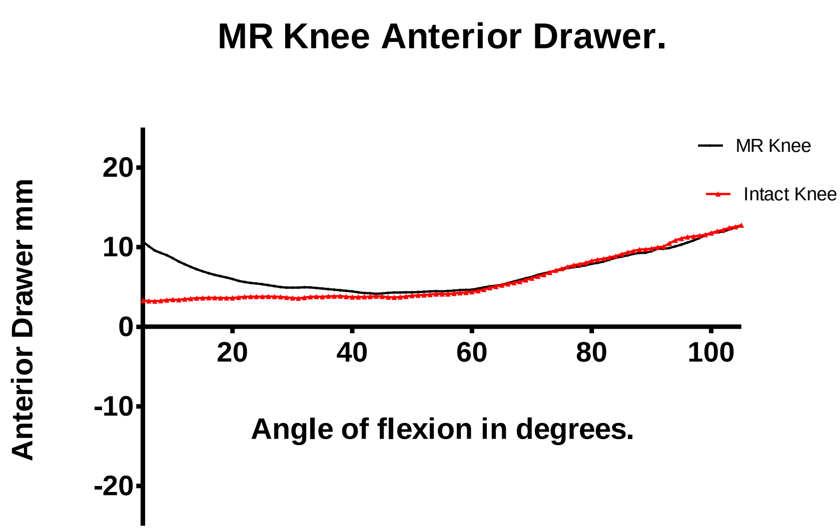


Figure 39 MR Knee Anterior Drawer.

(Mean of 3 repeats with each of 8 knees).



Similar graphs are shown in the appendix, for the knees in all experimental states. Statistical analysis and results will be discussed at a later point

7.4 Envelope of laxity for A/P Drawer.

Using the graphs produced previously it was now possible to combine the loading states with their opposite forces or torques in order to show graphs of the envelopes of laxity. For example anterior and posterior drawer were combined together, external and internal rotation and varus and valgus.

Figure 40 Mean Anterior and Posterior Drawer Envelope of Laxity for the Native Knee. (Mean of 3 repeats with each of 8 knees).

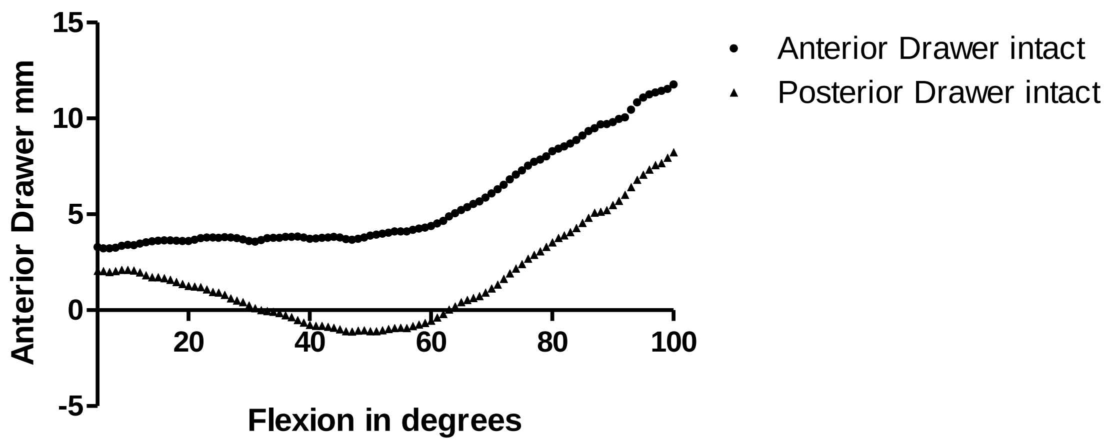


Figure 41 Anterior and Posterior Drawer Envelope of Laxity for the MR Knee. (Mean of 3 repeats with each of 8 knees).

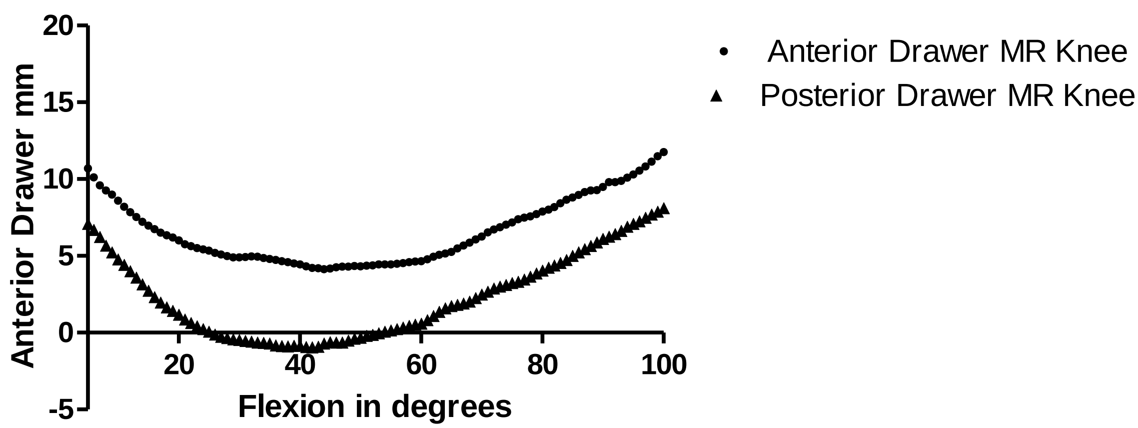
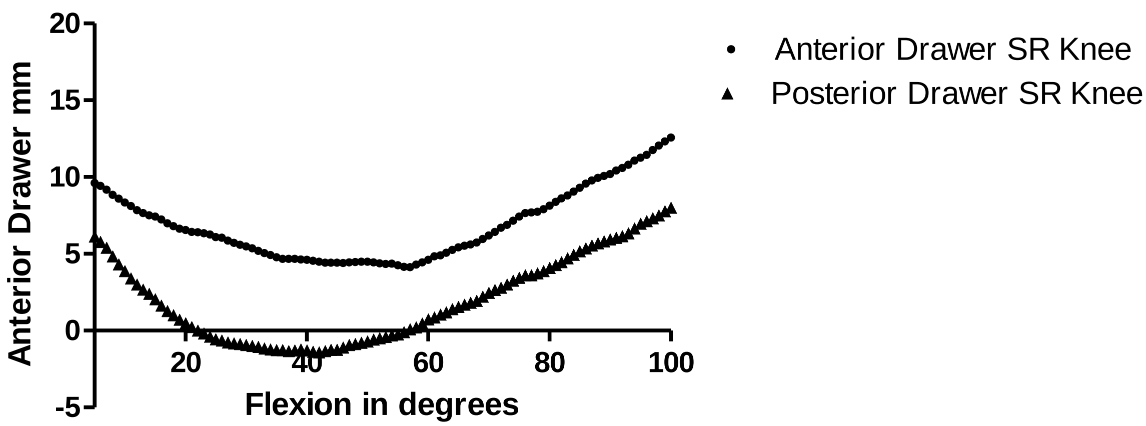


Figure 42 **AD/PD Envelope of laxity for the SR Knee. (Mean of 3 repeats with each of 8 knees).**



When the graphs for the two TKAs were laid over the corresponding graph for the intact knee, all three graphs showed the same overall pattern of movement. The movement of the two TKAs appeared to mirror that of the intact knee with the suggestion of slightly different results at the early range of flexion (<40 degrees). Statistical testing examined whether these differences were significant or not. A 2 way ANOVA statistical test with Bonferroni post tests was used. This allowed direct comparison of each data point to show if there were any significant differences ($p<0.05$) at any point in the data sets.

Similar results were also seen for the external and internal rotation graphs and the varus / valgus graphs (figures 46, 47 and 48). The statistical tests again will be discussed later on in this chapter. Although not identified to be of statistical significance in these experiments there was clear valgus laxity of the replaced knees towards full extension compared with the intact knee. This is a key point in considering the stability of the intact knee in extension. It would appear that the replaced knees have a little greater laxity, possibly as a result of the damage to the soft tissues.

Figure 43 **ER/IR Envelope of Laxity of the Native Knee. (Mean of 3 repeats with each of 8 knees).**

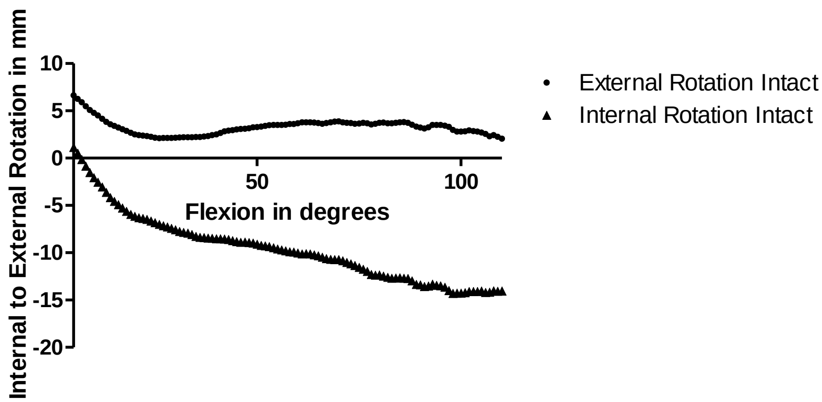


Figure 44 **ER/IR Envelope of Laxity for the MR Knee. (Mean of 3 repeats with each of 8 knees).**

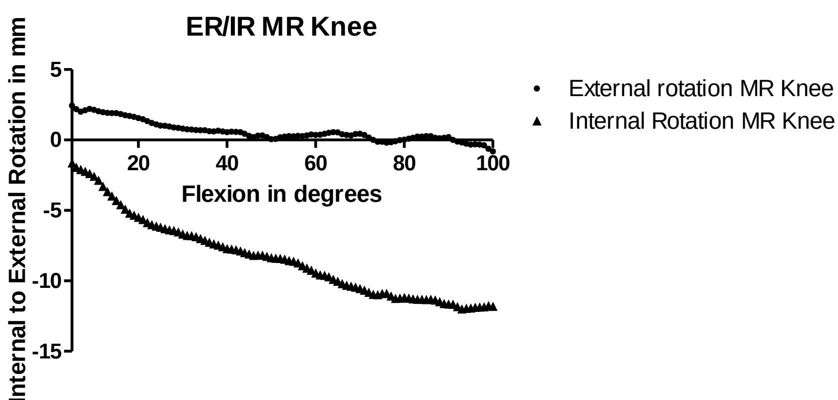


Figure 45 **ER/IR Envelope of Laxity for the SR Knee. (Mean of 3 repeats with each of 8 knees).**

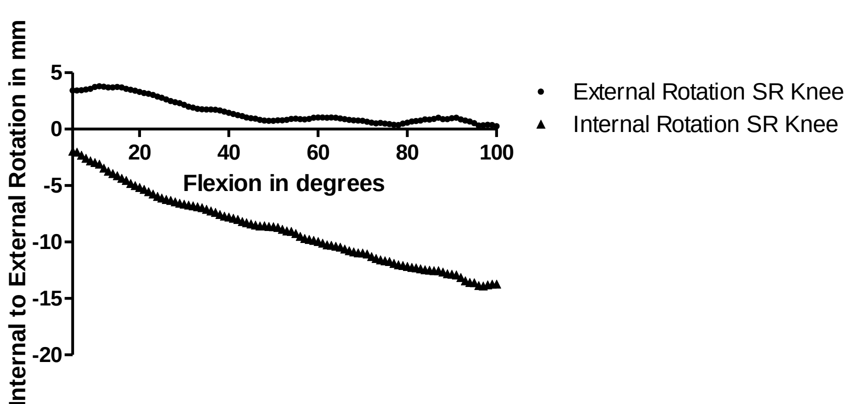


Figure 46 Varus/Valgus Envelope of Laxity for the Intact Knee. (Mean of 3 repeats with each of 8 knees).

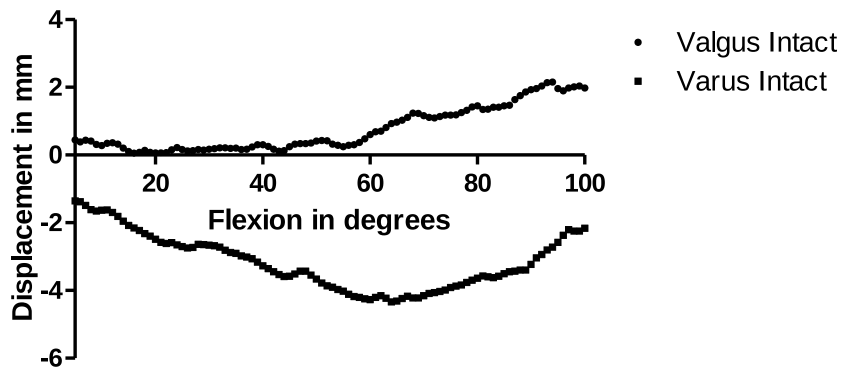


Figure 47 Varus/Valgus Envelope of Laxity for the MR Knee. (Mean of 3 repeats with each of 8 knees).

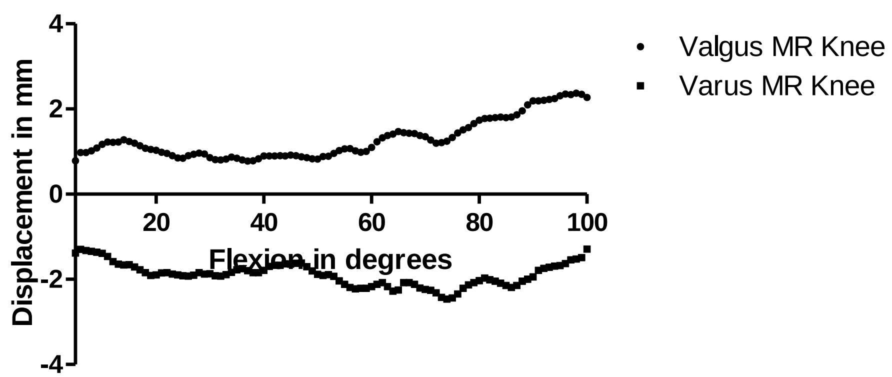
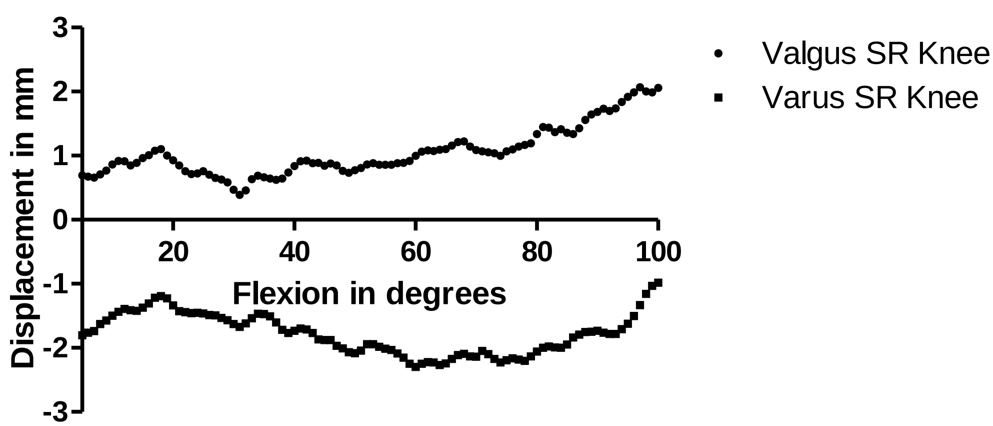


Figure 48 Varus/Valgus Envelope of Laxity for the SR Knee. (Mean of 3 repeats with each of 8 knees).



7.5 Standard Deviation Graphs.

To gain further statistical evaluation of the data, graphs showing the standard deviations of the averaged data were produced.

Figure 49 Anterior Drawer Native Knee

(Mean and Standard Deviations from 3 repeats in 8 knees).

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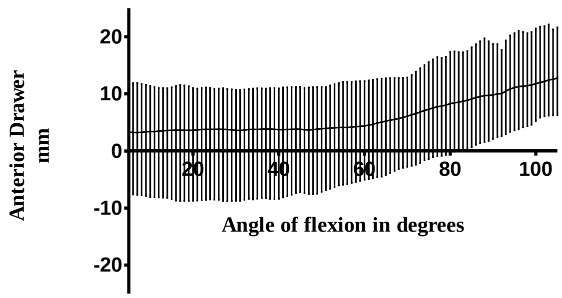


Figure 50 MR Knee Anterior Drawer

(Mean and Standard Deviations from 3 repeats in 8 knees).

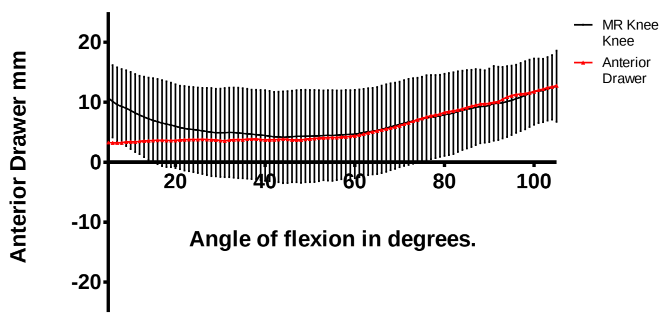
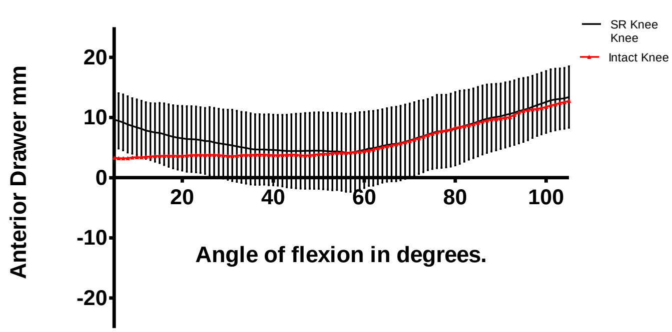


Figure 51 SR Knee Anterior Drawer.

(Mean and Standard Deviations from 3 repeats in 8 knees).



Once the standard deviations had been calculated and the graphs drawn the software (Graphpad Prism 5, USA) could be used to see if there were any significant differences between the three knee states in the six degrees of freedom

7.6 Statistical Analysis.

Each of the sets of statistical tests were performed on the raw data for the eight knees rather than the averaged data. This would give a more powerful set of results by comparing each individual knee in its three states.

Path of motion with neutral loading.

The path of motion of all three knee states with just the quadriceps being loaded without any other force being applied was also analysed. Although both TKAs followed the intact knee AP motion within +/-2.1mm (mean), both were significantly different to the intact knee overall ($p<0.001$ by ANOVA): the MR knee tended to have greater femoral roll-back in flexion than the intact knee, while the SR knee tended to have less. The neutral path of motion with the MR was 4.4mm anterior to that of the intact knee at 10° flexion ($p<0.05$ by post-hoc testing), but significant differences were not found at other degrees of flexion. Significant differences were not found between the neutral path of the SR knee and the natural knee with post-tests.

The key results were:

1. Both prostheses allowed greater anterior drawer laxity than the intact knee near full extension (MR 5.2mm, SR 5.6mm) reducing to less than 2mm excess laxity by 30 degrees of flexion and less than 0.5mm at 60 and 90 degrees of flexion.

2. Both prostheses were significantly different for anterior translation laxity overall to the intact knee. With the post tests the MR TKA showed significant differences at individual degrees of flexion up to 15 degrees ($p<0.05$) and the SR TKA showed similar results up to 18 degrees of flexion.

3. The two prostheses were not significantly different to each other overall but showed no significant differences at any specific degrees of flexion with the post-tests.

4. From 20 degrees to deeper flexion there was no significant differences seen between either of the two prostheses or between the prostheses and the intact knee.

Interpretation of the differences found:

A possible explanation for the significant differences that were found is that in the replaced knees, the ACL had been excised and as a result the tibia moved anterior in relation to the femur as full extension was approached. Otherwise, both TKA systems appear to replicate the kinematics of the native knee very well.

Posterior Drawer.

Similar graphs were produced for the knees loaded in posterior drawer. However, in both instances as shown by the two following graphs, there are not the same obvious discrepancies between the two TKAs and the intact knee. Both knees were tighter in posterior drawer than the intact knee at 10 degrees of flexion (MR 2.7mm, SR 1.8mm), but matched intact posterior drawer within +/- 1.2mm from 30 to 90 degrees of flexion. Statistically there were no significant differences between the two TKAs and the intact knee or between the two TKAs when compared to each other at any degree of flexion. Both appeared to replicate the kinematics of the intact knee to a good extent (figures 52, 53 and 54).

Figure 52 Posterior Drawer for the Native Knee. (Mean +/- SD, n=8, with 3 repeats of each knee).

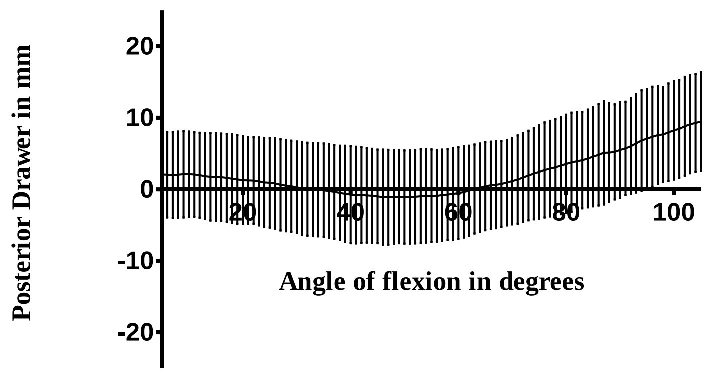


Figure 53 MR Knee Posterior Drawer. (Mean +/- SD, n=8, with 3 repeats of each knee).

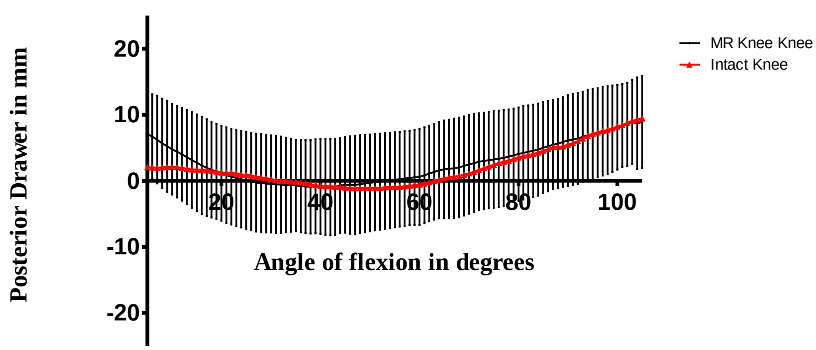
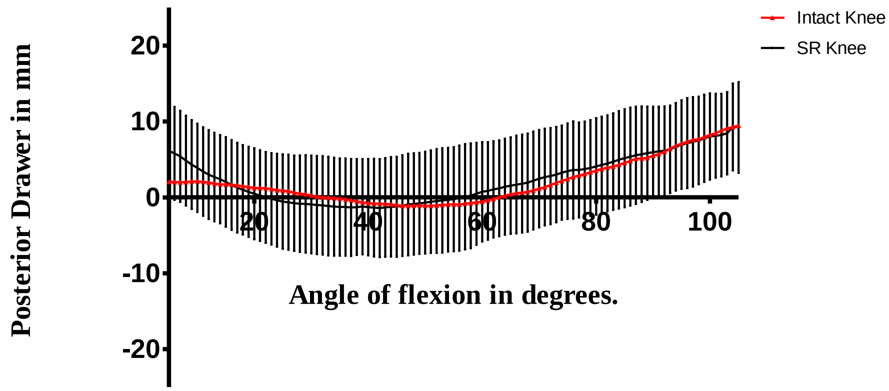


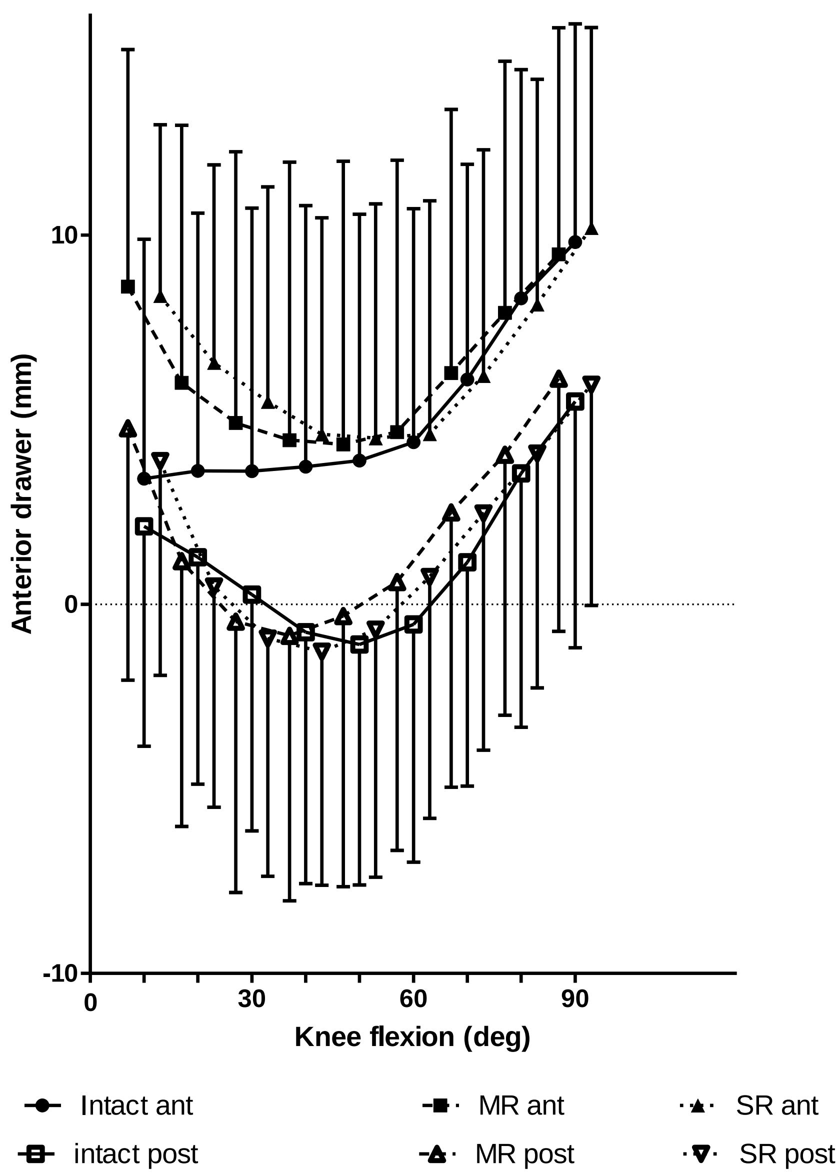
Figure 54 SR Knee Posterior Drawer. (Mean +/- SD, n=8, with 3 repeats of each knee).



In the final 20 degrees of extension there was a difference between the two TKAs and the intact knee. Both TKAs showed that the tibia was more anterior than in the intact knee. This, as with the anterior drawer experiments, was most likely due to the absence of the ACL stabilizing the knee. Although this difference was apparent on the graphs there was no statistically significant difference seen, unlike the anterior drawer results.

Figure 55 The Envelope of laxity in AP drawer for both TKAs and the Intact Knee.

The above graphs and data were combined to produce figure 55. This shows the anterior-posterior limits of knee laxity, in response to + or – 70N drawer force. Both TKAs showed increased anterior translation laxity from approximately 30 degrees to full extension. Data points represent each 10 degrees of knee motion but are offset for clarity.



Internal Rotation.

Both TKAs matched the rotation of the intact knee very well. All internal rotations were within 2 degrees of the intact knee. It is however, evident that both TKAs were tighter at around 90 degrees of flexion (figures 57 and 58).

Figure 56 Native Knee Internal Rotation. (Mean +/- SD, n=8, with 3 repeats of each knee).

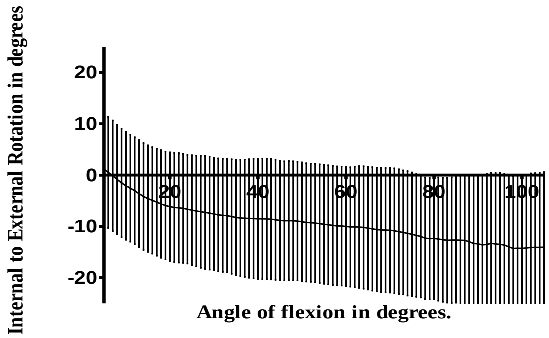


Figure 57 MR Knee Internal Rotation. (Mean +/- SD, n=8, with 3 repeats of each knee).

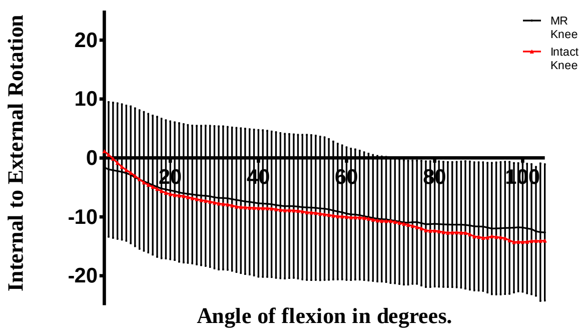
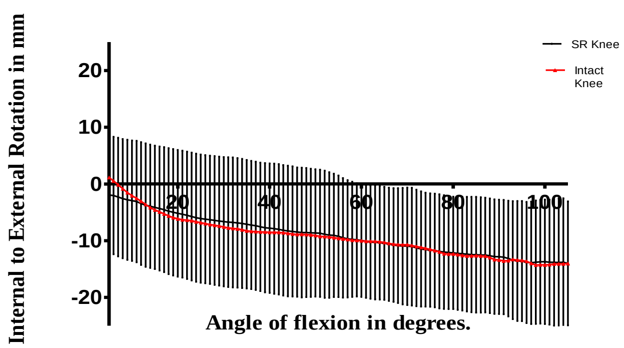


Figure 58 SR Knee Internal Rotation. (Mean +/- SD, n=8, with 3 repeats of each knee).



It is clear from the graphs that both TKAs mimicked the intact knee through internal rotation. Statistically the MR TKA was different to the intact knee ($p<0.05$) overall but no differences were found with post-tests. There was no such difference between the intact knee and the SR TKA. The two prostheses also showed an overall significant difference but again, no differences with post testing.

In both TKAs there was a reduced screw home mechanism as full extension was reached. This is clear when looking closely at the last 20 degrees of extension. However, this was not statistically significant. This may have become significant had a larger number of cadaveric specimens been tested.

There were also larger amounts of rotation seen from 45 degrees of flexion upwards. This was the same in the intact knee and was not significantly different in the TKAs.

External Rotation.

With the tibia loaded towards external rotation the results were very similar to when it was internally rotated. Both TKAs matched the kinematics of the intact knee through the range of flexion as shown by figures 59, 60 and 61. External rotation showed slightly more variation than internal rotation but all values remained within 4degrees of the intact knee. The native knee kept an almost constant value of internal-external rotation while extending from 90^0 to 30^0 , after which it rotated externally by a mean of 7 degrees, the “screw home” movement.

As with internal rotation, no difference was found between the MR knee and the SR knee at any degree of flexion. In external rotation the two TKAs mimicked the movements of the intact knee very well. Overall, both TKAs were significantly different to the intact knee ($p<0.05$) but neither produced any positive results with post testing.

Figure 59 Native Knee External Rotation. (Mean +/- SD, n=8, with 3 repeats of each knee).

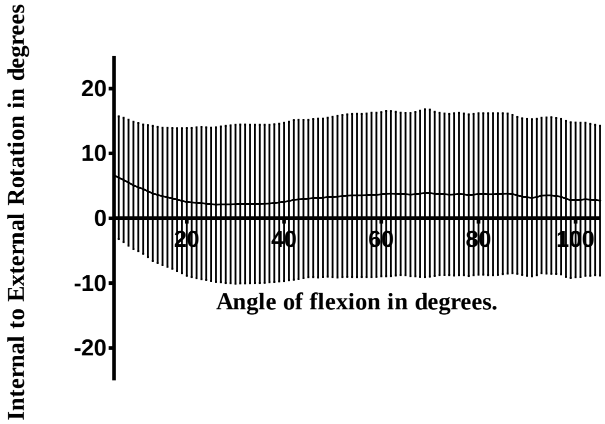


Figure 60 MR Knee External Rotation. (Mean +/- SD, n=8, with 3 repeats of each knee).

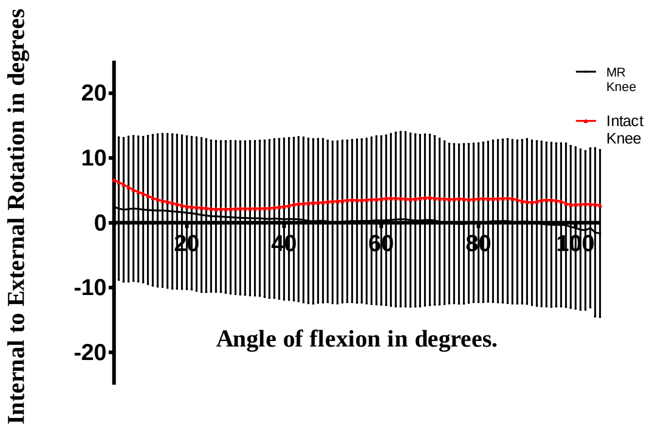
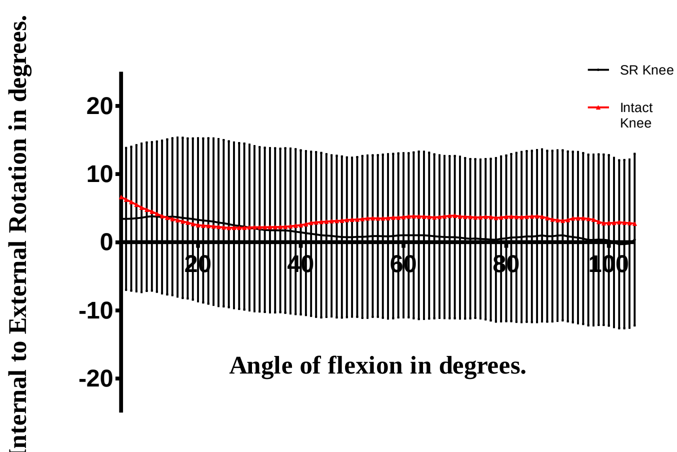


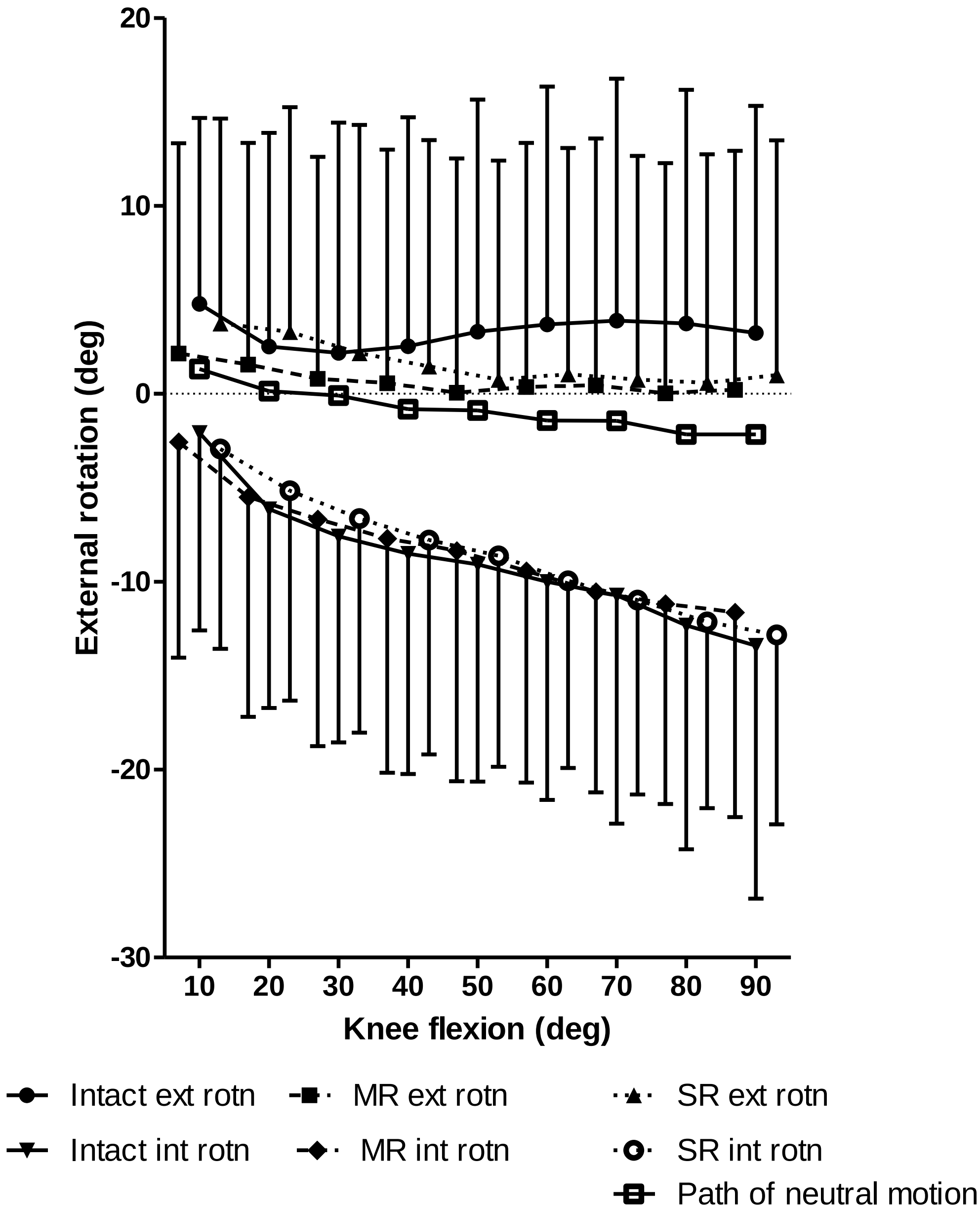
Figure 61 SR Knee External Rotation. (Mean +/- SD, n=8, with 3 repeats of each knee).



Although not significantly different, both TKAs appeared to behave differently from the intact knee when looking at the graph. From 40 degrees of flexion neither of the TKAs altered rotation laxity, but both prosthetic knees were almost in neutral with no rotation seen. Up until this point there was more variation between the three knee states.

Figure 62 Internal-External Rotation Summary graph.

The following figure shows a summary of all data for each of the three knee states for internal-external rotation.



Varus.

For varus, the graphs showed that both TKAs had similar patterns of laxity to the intact knee. There was a slight difference between the two prostheses and the intact knee at the mid range of flexion, around 60 degrees. Statistically both prostheses were different to the intact knee overall but showed no positive results with the post-tests.

Figure 63 Intact Knee in Varus. (Mean +/- SD, n=8, with 3 repeats of each knee).

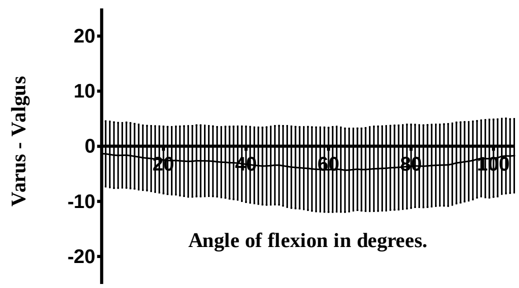


Figure 64 MR Knee in Varus. (Mean +/- SD, n=8, with 3 repeats of each knee).

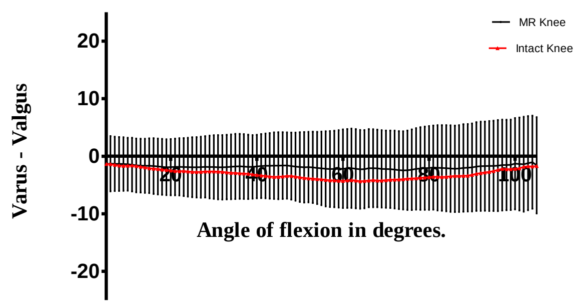
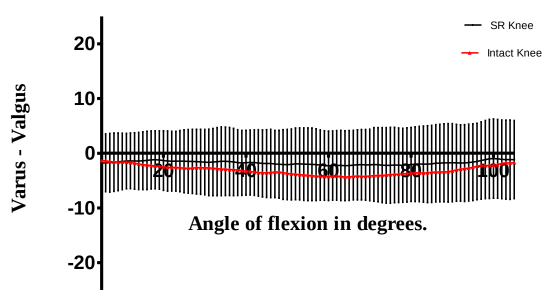


Figure 65 SR Knee in Varus. (Mean +/- SD, n=8, with 3 repeats of each knee).



The graphs of varus laxity (Figures 64, 65) it is clear that both the TKAs were tighter than the intact knee throughout the range of movement and that the intact knees had a larger amount of varus laxity, particularly in mid flexion. However, the general overall path of movement was very similar. No significant difference could be shown.

Valgus

Two TKAs replicated the intact knee; both sets of lines were almost identical. As with the varus results both prostheses were significantly different overall but not with post-tests. The valgus laxity was small across the range of knee flexion in all three states of the knees.

Figure 66 Intact Knee in Valgus. (Mean +/- SD, n=8, with 3 repeats of each knee).

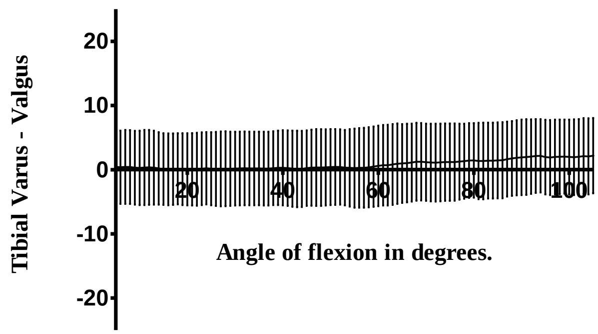


Figure 67 MR Knee in Valgus. (Mean +/- SD, n=8, with 3 repeats of each knee).

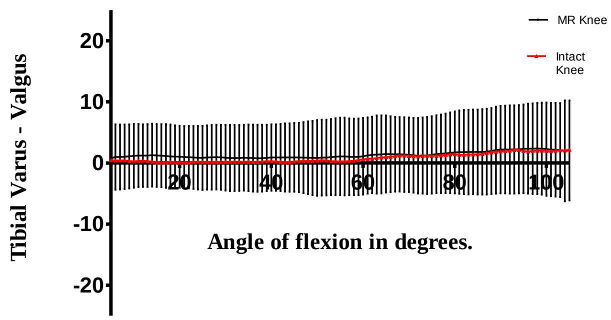


Figure 68 SR Knee in Valgus. (Mean +/- SD, n=8, with 3 repeats of each knee).

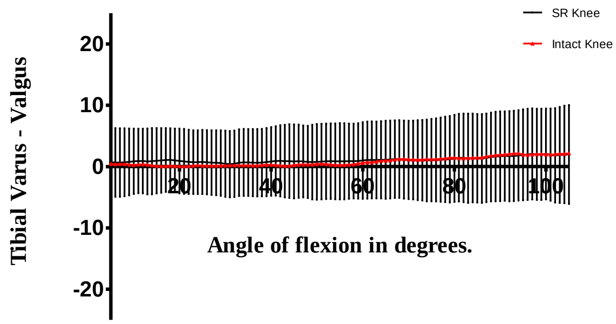
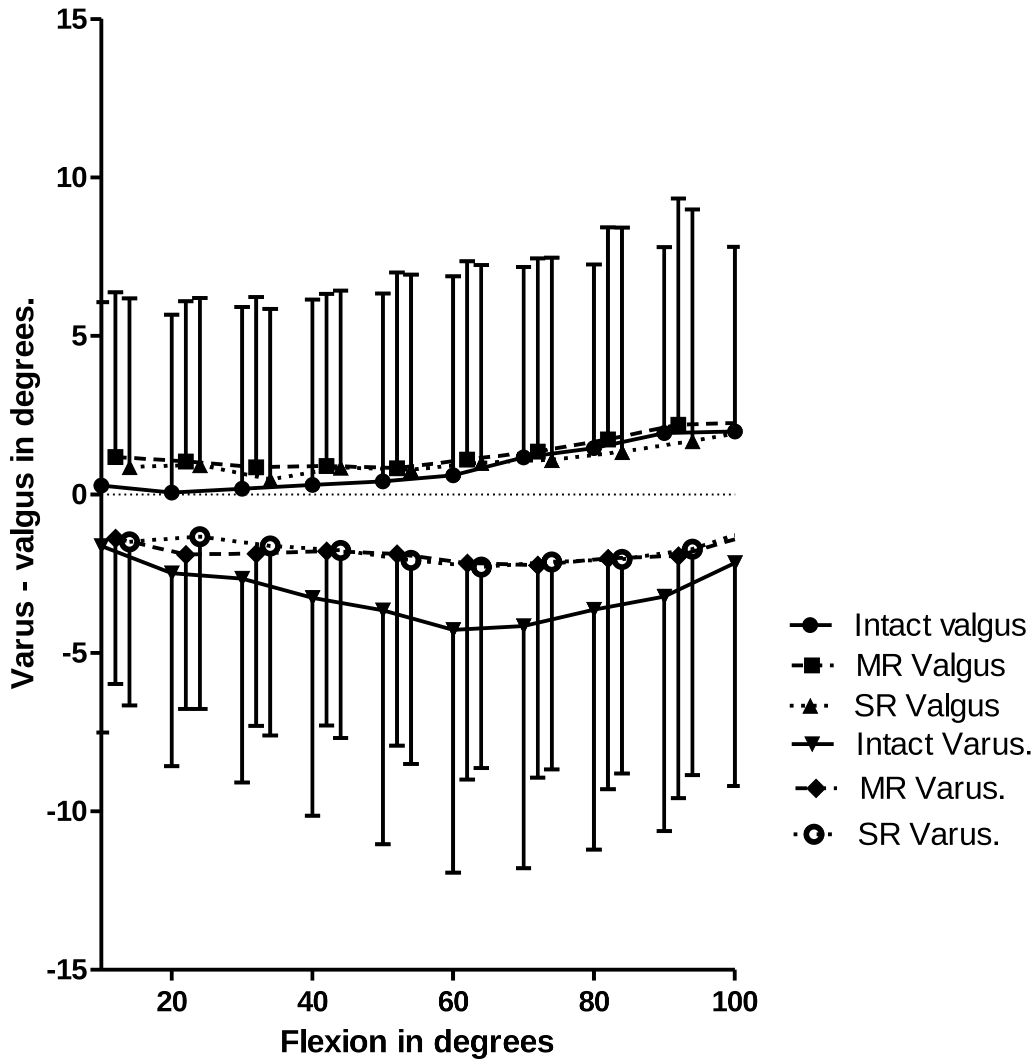


Figure 69 Summary graph for all knees in varus-valgus.

The following graph shows all the knee states and the envelope of laxity in varus-valgus. As with the previous two similar graphs the data points have been offset for clarity.



7.7 Summary of Results.

As a summary of these results valuable conclusions can be drawn.

1. Both TKAs followed the paths of motion and limits of laxity of the intact knee for almost all conditions of AP drawer, varus/valgus and internal and external rotation.

2. The only significant differences with post testing between the two TKAs and the intact knee was increased anterior drawer near to full extension, thought to be due to the resection of the ACL.

3. All the knees were implanted accurately with the navigation system

Chapter 8.

8.1 The Results of the Pressure Measurements.

The second section of work was to compare the pressures generated within the knee joint within the two types of knee replacements systems. As the sensors had to be placed within the knee, surgical arthrotomy was required so as to gain access to the knee capsule. The flimsy nature of the Tekscan sensors caused concern that the readings would be influenced by crinkling and excessive wear, so static measurements were recorded at 0,30,60,90 and 120 degrees of flexion.

8.2 Problems encountered with data collection.

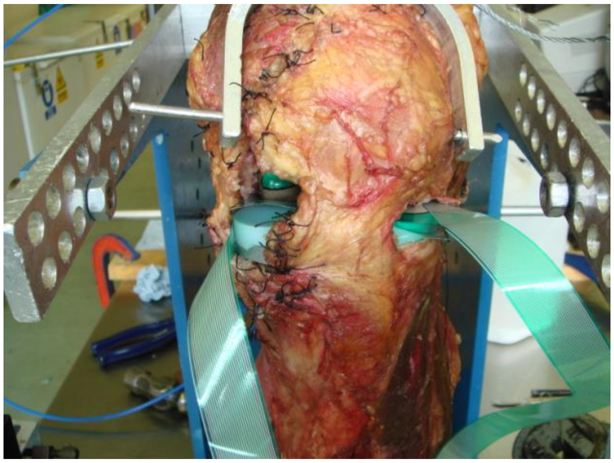
A number of issues were encountered when taking these measurements which made the collection of results more difficult.

1. Access to the Knee.

In order to get the sensors into the knee extra incisions into the knee capsule were needed, also to give an adequate enough view to make sure that the sensors were not bunching up on movement and thus interfering with data collection. The incisions required for this were quite large and could not be closed fully in order not to disrupt how the sensor was sitting within the knee joint. Also seen medially in this specimen are the extra incisions that led to a laxity in the capsule, a factor that could have affected the readings obtained, especially if one was required to re-record the kinematic data.

There was also no way of holding the sensors in place once positioned in the knee. Suturing them in place was attempted but the plastic was too flimsy and tore easily, affecting the recording parts of the sensor. As these particular sensors were developed with two recording squares, one for each of the medial and lateral plateaus, the problem of positioning was twofold.

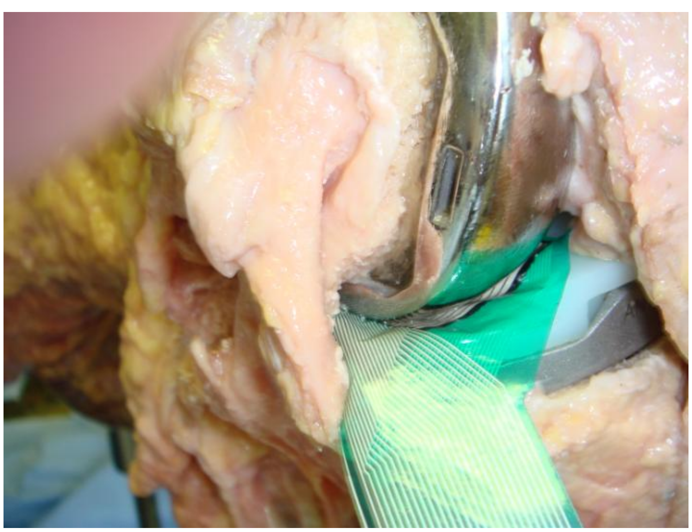
Figure 70 A Tekscan Sensor within the knee.



2. The Positioning of the Sensors.

As the experiments progressed problems were encountered with the sensors crumpling up and moving within the knee as shown by the following photograph (figure 71). Here you can see the recording pad of the sensor rolled up and not sitting flush with the polyethylene, a situation that would obviously alter the results. It was therefore difficult to obtain readings that would have been directly comparable between the medial and lateral compartments as it was impossible to secure the two sensing areas in the same place on each of the sides of the tibial plateaus.

Figure 71 A Crumpled Tekscan Sensor.



In order to combat this problem glue was used to hold the sensor in position. However, this led to alterations in the conductance capacity of the sensor and inaccurate results. Also, because of the curvature and the rollback of the femur it was not possible to secure the sensor to the soft tissues as the fragility of the sensors meant they tore when the leg was moved. Therefore, the position of the sensor had to be checked each time before both recordings and the application of force began. The mobility of the sensors limited any conclusions that could be made about specific points of contact in the two prostheses.

3. Inaccurate Readings.

The maximum force recorded in this part of the experiments was only half of what had been expected. The air pressure regulator therefore, had to be recalibrated for the rest of the experiments. However, problems arose with the data; the output of the pressure sensors did not equate to load imposed on the knee by the air cylinder, and there were variations between two sets of data recorded with the same knee and the same implant at the same degree of flexion. It appeared the only potential way to combat this would have been to perform the experiments with the prostheses tested without implantation into the cadaveric limbs.

8.3 Axial Load Contact Data.

The following two tables show the results for both TKAs through a range of values of flexion, including total force, total area and also peak contact pressure. There are also similar tables in the appendix for each of the knee replacements with internal and external rotations applied as well as varus and valgus moments.

Figure 72 MR Knee Contact Data with 400N Axial load (Knee 1).

TF Flexion -degrees	0	10	20	30	40	50	60	70	80	90
Total Force (N)	306	109	106	110	95	101	116	102	116	163
Total Area (mm2)	131	47	44	52	48	35	42	35	42	56
Total force L (N))	278	39	21	21	26	10	26	12	21	13
Total force M (N)	27	70	84	89	68	90	89	87	95	150
Total area L (mm2)	85	16	21	26	29	20	21	22	21	16
Total area M (mm2)	46	31	23	26	19	15	21	13	21	40
Peak force L (N)	32	18	11	13	16	4	15	7	11	6
Peak force M (N)	41	21	53	49	42	48	52	53	47	53
Peak contact pressure(MPa),lateral compartment	6	7	8	7	7	7	8	8	7	8
Peak contact presure M (MPa), medial compartment	1	3	2	2	3	1	2	2	2	12

Figure 73 SR Knee Contact Data with axial load (Knee 1).

	0	10	20	30	40	50	60	70	80	90
Total Force (N)	248	140	217	226	215	167	171	149	218	233
Total Area (mm2)	56	50	55	52	50	53	52	45	58	63
Total force L (N))	160	77	124	135	129	89	96	86	117	124
Total force M (N)	87	63	92	91	85	78	75	62	101	108
Peak force L (N)	53	28	45	53	54	41	38	41	51	50
Peak force M (N)	52	28	41	39	38	32	31	29	37	34
Peak contact pressure (MPa), lateral compartment	8	4	7	8	8	6	5	6	5	7
Peak contact pressure(MPa), medial compartment	8	4	6	6	6	5	4	4	8	5

The following graph (figure 74) shows how the total contact force varied with increasing flexion.

Figure 74 Knee 1 Total Contact forces with Axial Load.

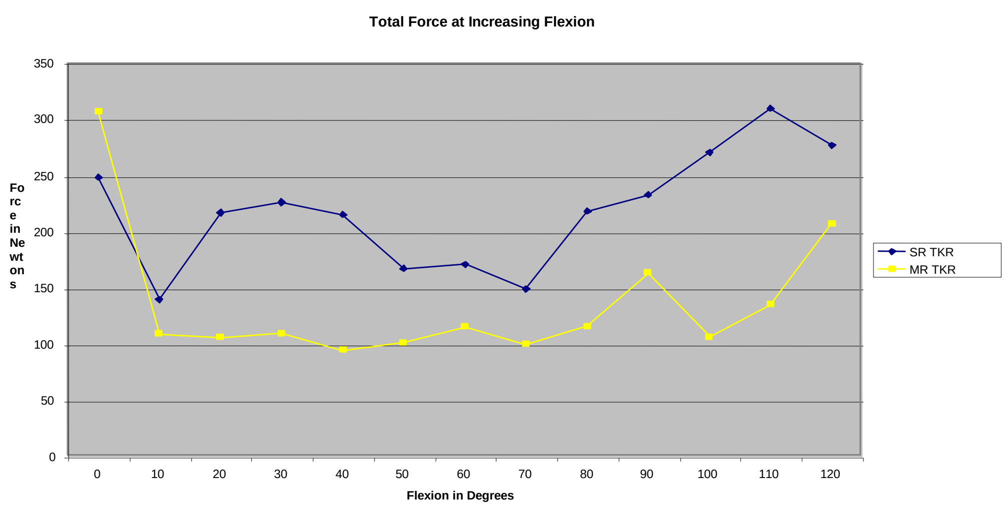


Figure 76 Total Contact Area in Knee 1.

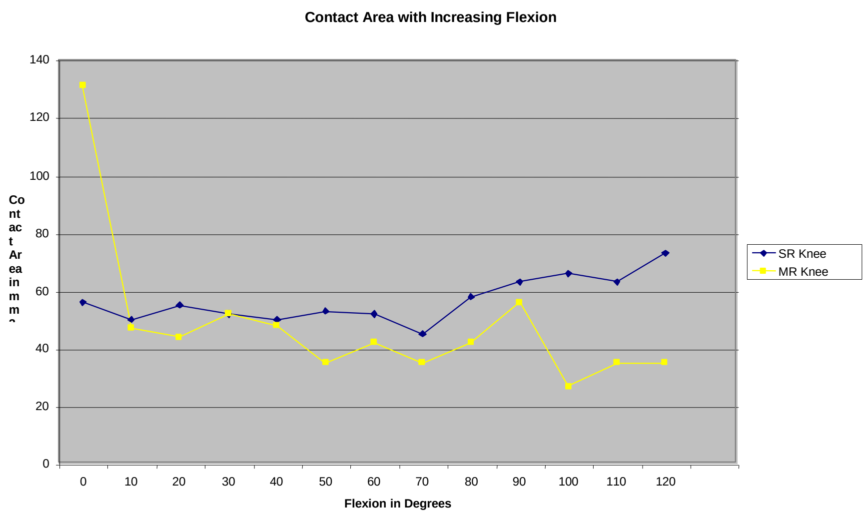
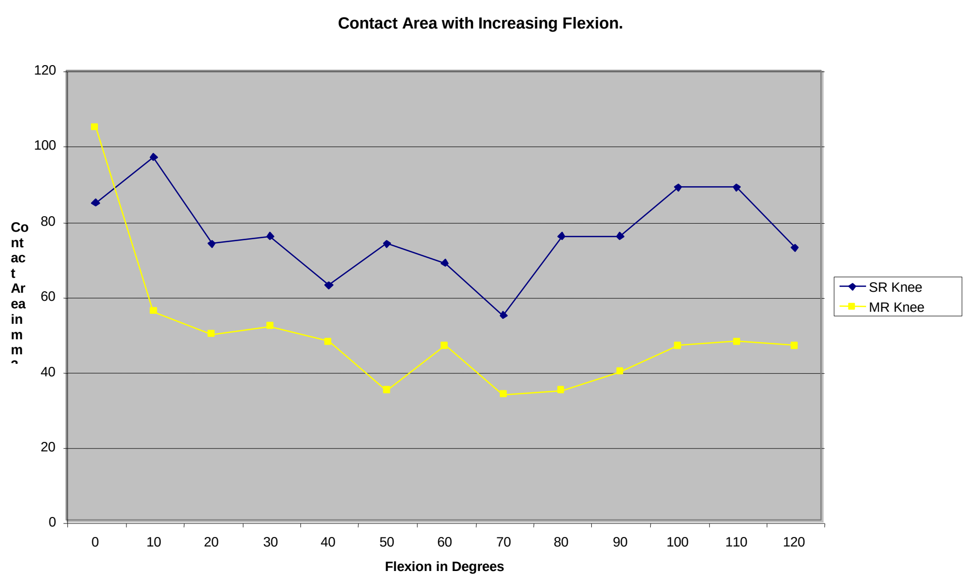


Figure 77 Total Contact Area in Knee 2.



When looking at these graphs there are values that appear to stand out as not following a trend. For example there is a huge difference between the contact areas at full extension and only 10 degrees of flexion in both MR knees. It is difficult to explain why this should be the case. However, throughout the whole range of flexion the SR TKA showed a more consistent and greater contact area in both knees measured. This may be due to increased conformity of implant and may have implications again in the wear of the UHMWPE. Perhaps most significantly is that from around 90 degrees of flexion the SR TKA appeared to have twice as much contact area in both knees than the MR TKA.

Also important in the wear rate of these TKAs is the load sharing between the medial and lateral tibial plateaus. The following graphs illustrate this

Figure 78 Load Distribution in Knee 1.

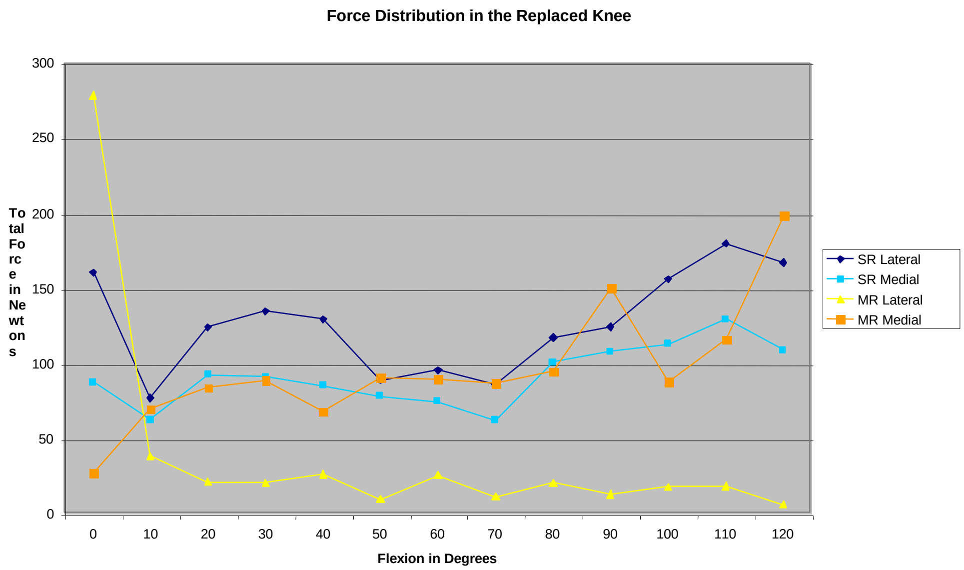
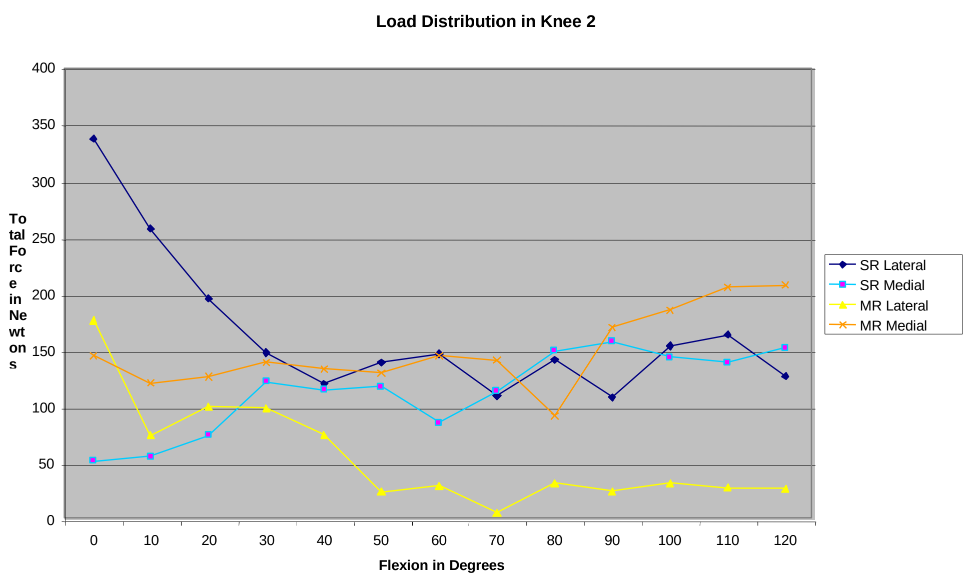


Figure 79 Load Distribution in Knee 2.



When both knees are considered there is little force acting on the lateral tibial plateau apart from at full extension. If this is the case then you would expect much more accelerated wear on the medial side. However, the limitation again of this data is such that the total forces shown at any degree of flexion do not total 400N as expected, thus restricting any significant conclusions being made.

8.4 Internal Rotation Data.

Pressure measurements were also taken with an internal rotation moment applied. Due to the fragile nature of the Tekscan sensors the measurements were made at fewer angles of flexion to preserve the sensors for as long as possible. These particular experiments proved quite problematic for the placement of the sensors and sometimes for even recording any values at all. The sensors had to be repeatedly altered and moved to produce any data. The validity of the data obtained was therefore a concern. There were very different readings with the same knee with the same prosthesis with just a slight altering in position of the sensor. As it was not possible to secure the sensors, either to the UHMWPE or to the soft tissues, it was felt that the data would not be accurate enough to be analysed further as errors would be found and the conclusions drawn incorrect. The following data tables and subsequent graphs show the gross variation in values and how consistently the force derived from the pressure sensors did not approach 400N that was being applied to the knee.

In view of these limitations, no further results are presented.

8.5 Summary of these results.

As has become abundantly clear the results obtained from the pressure measurement experiments had many inaccuracies. Only two knees were tested due to the results that were obtained and the data recording difficulties. These were also only static measurements due to the fragility of the Tekscan sensors. Therefore not enough knees were tested to carry out any statistical analysis and they did not provide any guide as to how the pressure measurements may have altered with active flexion. Also, as the sensors could not be secured to the weight bearing part of the joint, no information could be gained on where each of the prostheses produced most force when loaded physiologically.

Any meaningful data was therefore hard to produce. The tables and graphs have illustrated trends that may be present. However, how much emphasis to give to these is not clear when some of the other results appear so inaccurate. In order to gain more information much larger numbers of knees would need to be analysed with some alterations to the methods, either regarding the pressure measurement system used or as to how to secure the sensors within the joint.

The most limiting part of this part of this work is that it only compared the two TKAs to each other. Because this section of work used the same cadaveric specimens as for the kinematic work, the bone cuts had already been made and thus no data could be gained on the native knee. To gain further, more useful information completely new knees would need to be used. There would also be benefit to devising a way of taking active measurements so that the results could be more usefully applied to everyday circumstances.

Chapter 9.

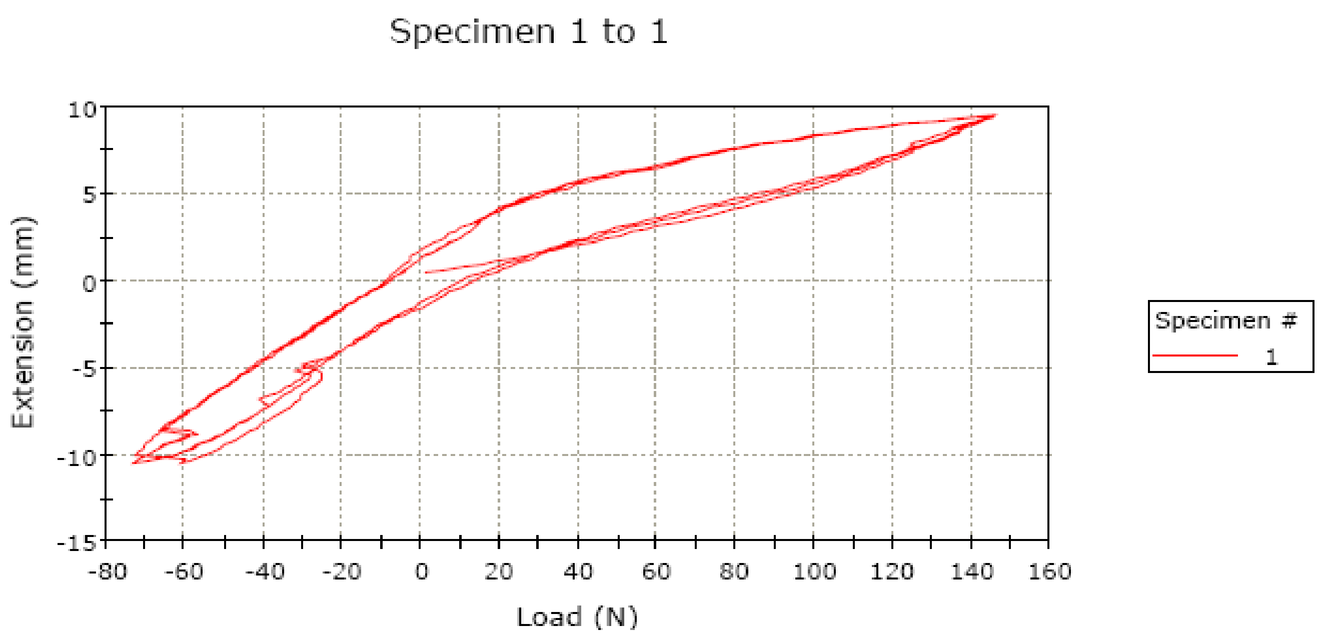
The Results of the Patellar Stability Experiments.

These experiments were carried out in the Instron 5565 materials testing machine and all experiments produced results at 0, 20, 30, 60 and 90 degrees knee flexion. The desired data were the maximum values for force required to displace the patella 10mm medially and laterally. Essentially the larger the force needed to gain such movement showed a more stable patella. Eight knees were used for these experiments.

These experiments were carried out after the patella had been resurfaced. In each case the type of patellar prosthesis was swapped so that it corresponded with the two different femoral components being tested. Each was positioned according to the manufacturer’s guidelines. Data was not produced regarding the unresurfaced patella, which would help those surgeons who do not feel this is a valuable part of this overall procedure.

The force was recorded by the Instron machine but can also be read easily from one of the graphs produced such as the one on the following page. The key values in the testing process are the two maximum values. The patella was continuously cycled from medial to lateral as the data was collected. This meant there was no need to reposition the cadaveric specimens or adjust the Instron machine, between the measurements of medial and lateral stability that could all have led to the introduction of further variables.

Figure 80 Hysteresis loop for stability testing.



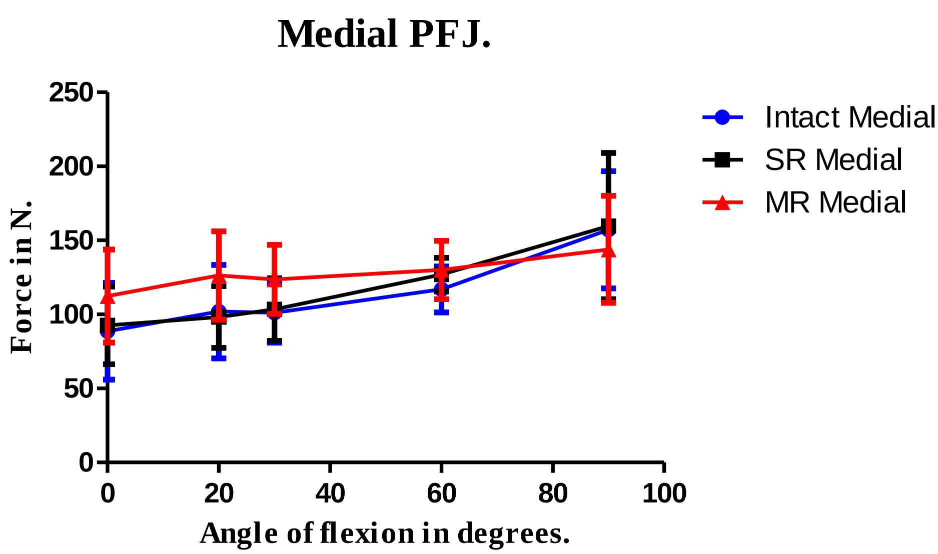
This graph shows the force versus displacement curve recorded when the patella was displaced 10mm medially (the negative extension) and laterally (the positive extension). This was repeated for the intact knee and the two TKAs at the different degrees of flexion. Data was analysed using Microsoft Excel and then Graphpad Prism 5. A copy of a section of the complete data table is shown on the next page.

Figure 81 Raw data table for stability experiments.

Intact Knee									
Lateral									
Angle of flexion	Knee 1	Knee 2	Knee 3	Knee 4	Knee 5	Knee 6	Knee 7	Knee 8	Median
0	96	142	146	132	108	98	84	96	103
20	90	152	150	106	88	60	64	68	89
30	84	154	134	88	86	60	60	60	85
60	68	182	120	106	74	62	84	78	81
90	68	148	202	92	100	80	92	76	92
Medial									
0	102	54	150	115	72	68	58	90	81
20	87	64	148	134	82	122	66	112	99
30	91	70	128	122	86	118	92	102	97
60	105	128	150	106	114	104	118	110	112
90	195	192	156	192	164	130	150	78	160
SR knee									
Lateral									
0	92	96	124	108	146	120	78	104	106
20	126	105	112	100	112	124	76	110	111
30	124	124	126	92	90	132	74	112	118
60	119	160	122	96	140	112	84	102	115
90	108	154	142	130	130	132	126	100	130
Medial									
0	117	44	118	92	116	80	72	102	97
20	102	54	116	92	118	106	88	110	104
30	93	60	108	98	122	108	108	130	108
60	141	110	138	128	130	130	110	128	129
90	230	178	120	205	196	142	110	96	160

Figure 82 Medial Stability Results. (Mean, n=6, with 3 repeats of each knee).

This data led to the following two graphs, showing the different amounts of force required to displace the patella 10mm from its equilibrium position (mean+/- SD, n=8).

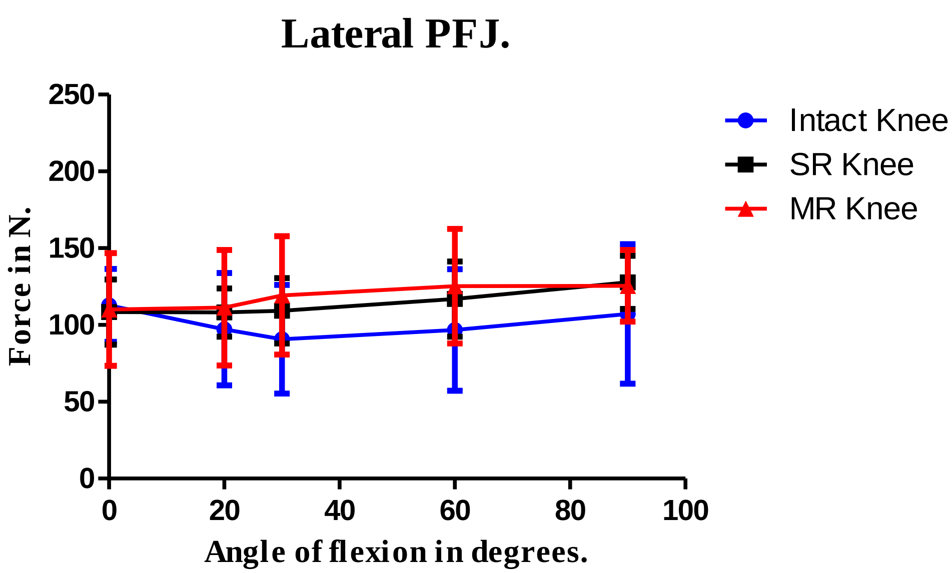


This graph above shows that as the knee flexed, more force was required to move the patella 10mm medially in all three scenarios. The MR TKA showed almost a straight line ranging from 115N at 0 degrees to 130N at 90 degrees. The intact knee and the SR TKA showed a different trend with a gradual rise from around 90N at full extension, up to around 150N at 90 degrees of flexion.

In the intact knee, the mean force rose from 90N at 0 degrees of knee flexion to 160N at 90 degrees (p=0.059) and a similar trend is seen by the SR TKA (p=0.162). The mean forces were more constant for the MR TKA ranging from 115N at 0 degrees flexion to 130N at 90 degrees, (p=0.084).

The resistance to patellar medial displacement of each of the three knee states were compared to each other at different specific angles of flexion. At 20 and 30 degrees of flexion the MR TKA was significantly more stable than the intact knee (p=0.0160 and p=0.0195). Significant differences were not found at any angle of flexion between the SR TKA and the intact knee (p=0.093). A comparison of the two TKAs found the patella was more stable with the MR TKA than the SR TKA from 0 to 30 degrees of knee flexion (p=0.022 at 0 degrees, p=0.008 at 20 degrees and p=0.0395 at 30 degrees. This is most likely due to the deeper and symmetrical trochlear groove in the MR design, rather than the asymmetrical SR design that runs from lateral proximally to medial distally and had a smaller trochlear facet on the medial side.

Figure 83. Lateral Stability Results (mean, n=6, with 3 repeats of each knee).



The force required to move the patella 10mm laterally was smaller than moving it 10mm medially. The mean force to displace the patella 10mm laterally ranged from 85N to 130N from 0 to 90 degrees of knee flexion. For the intact knee the mean force reduced from 115N to 85N between 0 and 30 degrees of flexion, then increased to 105N at 90 degrees, p=0.809.

For both TKAs the lateral displacing force rose from 115N to 130N between 0 and 90 degrees of knee flexion. The increase in lateral stability was significant with the SR TKA, p=0.039, but not with the MR TKA, p=0.328. Significant differences of patellar lateral stability were not found among the intact and replaced knee at any angle of flexion.

Chapter 10.

Patellofemoral Tracking Results.

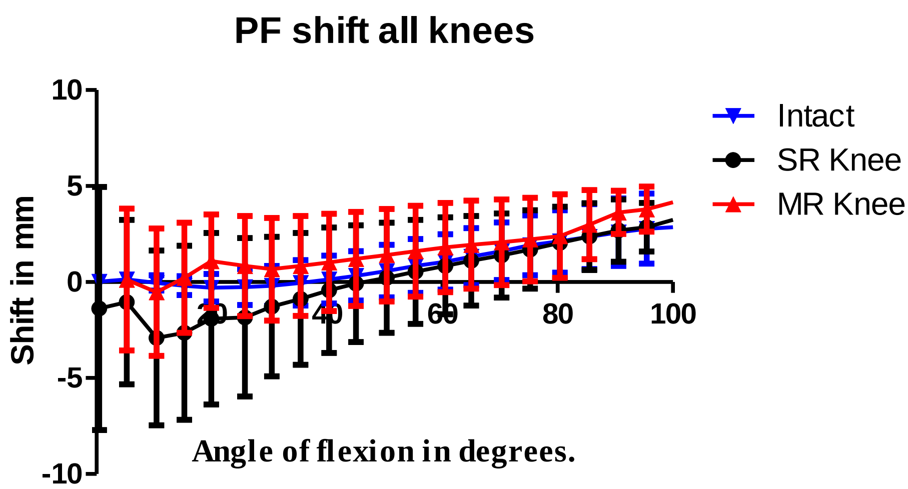
Data was collected on six knees, each cycled three times; this was then averaged for all the knees through a range of flexion. Data was processed using Graphpad Prism 5.

10.1 Patellar Shift.

Shift was defined as lateral translation of the patella in relation to the equilibrium position of the patella in the natural knee at full extension (0mm on the graph). The patella in all three states moved laterally as tibiofemoral flexion increased. There was greater variability in amount of shift in all the knees in extension but with less variation as flexion increased. With both types of TKA, the mean path of the patella was always within 2.5mm of that of the intact knee across the arc of flexion examined.

The optical tracking system used the anatomical axis of the leg to make its measurements. It has been proposed by Blankevoort et al 1996 that results on kinematics may vary significantly depending on the choice of coordinate system used. In their experience inter-specimen variation was seen less when an anatomical tracking system, like the one in this set of experiments was used. As this system was used for all the patellofemoral tracking work, the methods remained constant throughout.

Figure 84 Patellar Shift. (Mean +/- SD, n=6, with 3 repeats of each knee).

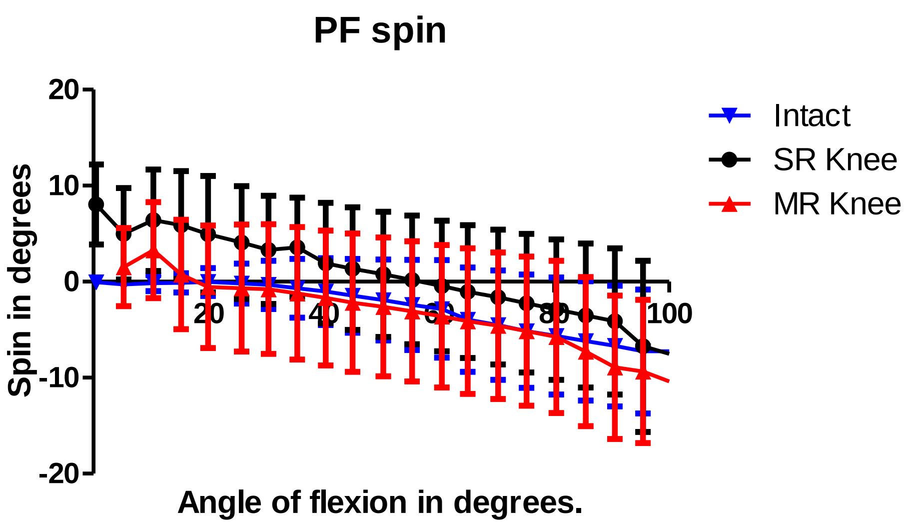


Statistical testing using 2 way repeated measures ANOVA testing with Bonferroni post tests was carried out on the data. There were significant differences between the intact knee and the SR knee from 10-40 degrees of flexion with $p<0.001$ between 10-25 degrees. At this range of flexion the patella was much more medial than in the intact knee. This was perhaps compatible with the asymmetrical design of the SR trochlea. It was also significantly different to the MR TKA at the same range of flexion with $p < 0.05$. From 30 degrees onwards the patella then continued to shift laterally to eventually sit at the same position as seen in the intact and MR knees. There was, however, no significant difference overall between the SR TKA and the intact knee or the MR TKA. There were no significant differences between the intact knee and the MR TKA at any degree of flexion.

10.2 Patellar Spin.

Spin of the patella was defined as negative if the patella became more adducted. The knee in all states rotated into adduction as the tibiofemoral flexion increased. In the intact knee the patella rotated from a neutral position to around 7 degrees of adduction. The patellae in the replaced knees both started in an abducted position when the knee was extended and moved 15 degrees and 11 degrees respectively for both the SR and MR knees as they rotated to match the position seen in the intact knee in flexion.

Figure 85 Patellar Spin. (Mean +/- SD, n=6, with 3 repeats of each knee).

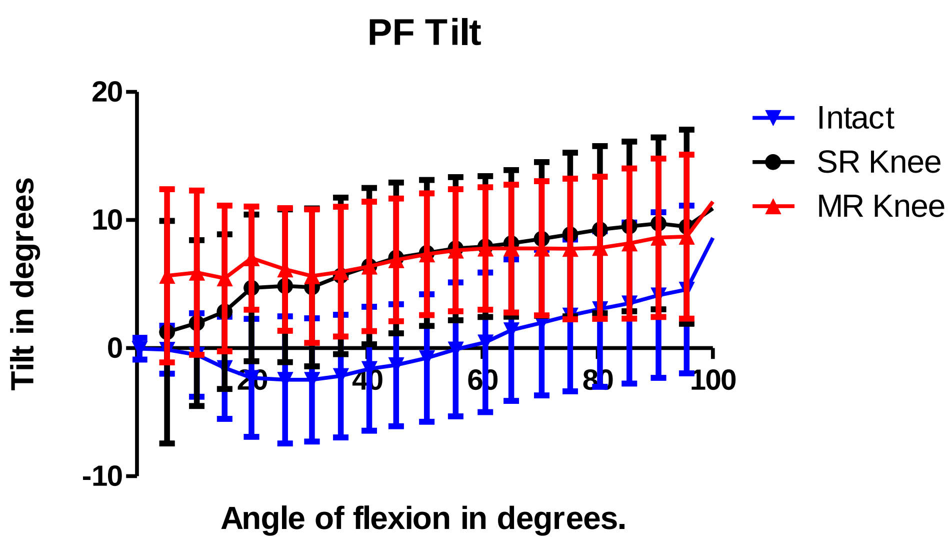


The same statistical calculations were carried out as with previous shift experiments. When comparing the intact knee to the SR TKA and the MR TKA there was no overall difference seen across the entire range of flexion. The two TKAs compared to each other showed again no significant differences at any angle of tibiofemoral flexion.

10.3 Patellar Tilt.

It was expected that the patellar tilt would follow the shift pattern and would go from medial to lateral as tibiofemoral flexion increased.

Figure 86 Patellar Tilt. (Mean +/- SD, n=6, with 3 repeats of each knee).



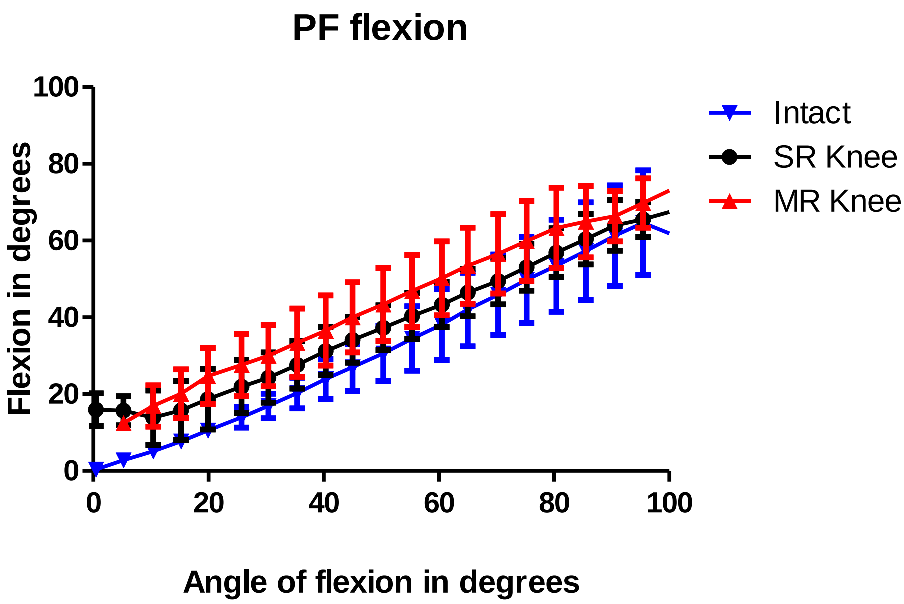
For the intact knee, the patella initially tilted medially by a mean of 3 degrees up to 30 degrees of TF flexion. It then tilted laterally to a mean of 4 degrees at 90 degrees of knee flexion. This was different to the two prostheses which were both found to be tilted laterally towards full extension. The MR knee was tilted by a mean of 6 degrees and the SR knee by 2 degrees. Both prostheses continued to tilt laterally to 7 degrees at 50 degrees of TF flexion and then remain constant as flexion increased.

There were overall differences between the intact knee and the two TKAs, $p<0.0001$ by ANOVA. The post hoc tests were unable to demonstrate significant differences at specific angles of tibiofemoral flexion when comparing any of the three knee states. However, with increased numbers of specimens the differences seen towards extension may have proven to be significantly different.

10.4 Patellar Flexion.

The following graph shows that the overall pattern of patellar flexion was the same in all three knee states. Flexion of the patella is often about 70% of the value of tibiofemoral flexion. This was true in all the instances below with values of 45 degrees of patellar flexion at 60 degrees of TF flexion and 70 degrees at 100 degrees of TF flexion for the knee in all three states.

Figure 87 Patellar Flexion. (Mean +/- SD, n=6, with 3 repeats of each knee).



Both of the prostheses show the patella was flexed at around 16 degrees at full extension of the knee. This suggests that the two designs of patellar button did not support the distal end of the patella as in the normal knee, and this caused it to fall into a flexed position. From 20 degrees of knee flexion onwards the two TKAs converged towards the intact knee values.

The statistical analysis of this data found a significant difference overall with ANOVA ($p<0.001$) between the intact knee and the two TKAs. The post hoc testing did not find significant differences between the intact knee and the SR

TKA at any specific angle of knee flexion. In comparison, these tests did reveal that the patella in the MR TKA was more flexed than in the intact knee from 10-50 degrees of knee flexion. There were no significant differences between the two TKAs.

Given the graphical appearances seen in patellar flexion towards full extension, it was surprising that they were not statistically significant. This may be a reflection of the experiments being carried out on a small number of knees.

Chapter 11

Discussion.

This body of research has looked at new single radius design of femoral component with altered trochlear geometry. The tibiofemoral and patellofemoral kinematics of this knee prosthesis were compared with the intact knee and also an established multi radius design of TKA. The contact pressures and areas of both TKAs and have also been assessed along with the stability and kinematics of the patella and replaced patellar button in all three knee states.

This study examined the hypothesis that a TKA with a single-radius femoral component would provide a closer match to the kinematics and limits of laxity of the natural knee than would a TKA with a multi-radius design. This hypothesis was not supported by the experiments: no significant differences in the paths of motion or the limits of laxity were found, between the two implants tested. This work did not find evidence to support the existence of 'mid-range flexion instability': both TKA designs led to limits of laxity which did not differ significantly from normal across the mid-range arc of knee flexion, from 30 to 60 degrees, and so these experiments did not offer a rationale for changing the contour of the femoral component.

Only fixed bearing devices were studied, and their paths of motion and limits of laxity across a range of knee extension induced by quadriceps tension were examined in all 6 degrees-of-freedom. A difference was found between the intact knee and the two prostheses in the arc of extension from 20 to 0 degrees when an anterior translation (drawer) force was imposed on the tibia: the lack of ACL restraint after TKA then allowed the tibia to move significantly further anteriorly than in the intact knee for both types of TKA. No other differences were found up to 100 degrees of flexion, in either AP, internal-external rotation, or varus-valgus limits of laxity or path of motion.

The experiments were designed to allow a full assessment of the tibiofemoral kinematics of the three knee states. The use of a navigation system further enhanced data collection by ensuring accurate conformity of the two knee types. Not only did the navigation system record the relevant kinematic data, it also confirmed the correct positioning of the implants, tensioning of the ligaments, and limb alignment prior to any kinematic measurements being made. A further advantage of the experimental design was that it allowed repeated testing, and repeated-measures statistical analysis, of the same knees in each of the three states, thus eliminating variables such as the state of the ligaments, gait differences, etc, which affect the power of clinical studies. Thus, although the graphs show large standard deviations, the pair-wise analyses of data points from each of the knees allowed significant effects to be discerned. It is possible that the results have been affected by the normal knees used being different from the arthritic knees which receive a TKA clinically. However, apart from the difficulty of obtaining suitable arthritic specimens, the pathology would add further variability to mask the differences between the implant designs.

In these experiments a single-radius femoral design was compared to a J-shaped multi-radius design. The design rationale for a single-radius design was assessed in-vivo by Wang *et al* (2006). They found that the single-radius design reduced the quadriceps muscle activation in sitting-to-standing movements and decreased trunk flexion required for standing. They concluded that there were benefits to their patients from a single-radius design and expected that these patients may mobilise quicker post operatively and with greater ease. This was explained biomechanically by Hall *et al (2004)*, who found that a single-radius design had a larger quadriceps moment arm about the axis of knee extension than a multi-radius design; that variable was not measured in this study. These findings are not incompatible with the present study, which examined the path of motion during knee extension and the limits of ligamentous laxity, across the range of motion.

The only significant difference, among the intact and replaced knees in this study, was that both TKA designs allowed significantly greater tibial anterior drawer than the natural knee between 0 and 20 degrees of flexion. This difference was probably due to the excision of the ACL, the primary restraint to anterior drawer, at the time of surgery. This effect was not significant from 20 degrees of flexion onwards. No difference was found when the two TKAs were compared to each other throughout the entire range of motion.

Although these results are design-specific for the two prostheses used in the experiments, they do not support the reports in the literature of mid range instability, which was not identified by this work. The use of both normal knees and the navigation system meant that the surrounding soft tissues could be tensed correctly during the TKA procedures, and the repeated use of the same knees eliminated this variable, when comparing the two TKA designs. Thus, this was a powerful way to show up any differences caused by the implants themselves, and that was not significant. Thus, this experiment suggests that mid-range instability is not related to the shape of the femoral component, but to other factors encountered at surgery as both TKAs reflected the intact knee well from 30-80 degrees of flexion. Neyret's group (2006) have suggested that the instability results from lack of recognition of ligament laxity patterns during surgery, which may be secondary to malpositioning of components and the resulting abnormal patterns of ligament slackening which follow when the knee flexes. With non arthritic specimens used in these experiments there were no joint contractures or deformities to correct, or any particular knee balancing issues meaning the prostheses were the only significant variable being tested.

Therefore in conclusion, both of the TKAs tested in this study reproduced the kinematics of the native knee very well, and so a significant difference could not be demonstrated between them. That suggests that the single-radius design did not show a clear kinematic benefit in trying to avoid mid-range instability. These results suggest that mid-range instability may not be a consequence of the implant design, in line with the suggestion that this problem might relate to surgical technique.

Such kinematic differences were not identified by this particular study and would probably require patient studies to show any possible advantages. Do such studies also imply that transference of biomechanical design philosophy cannot be accurately recreated in the clinical outcome due to confounding variables or perhaps the measurements of the wrong variables as end points in these in vitro studies.

One such study by Harwin *et al* 2008 reported the first four year review of patients undergoing a Triathlon TKA. The authors reported a low complication rate with deep infection in 0.8% of patients, 1 revision of a tibial baseplate (0.05%) and 2 polyethylene exchanges for late instability (0.1%). They also reported a quicker return to activity and a mean level of flexion of 126 degrees (range 85-150degrees). In this study, however, there was no comparison made between implants and follow up was limited to four years at the most. Longer follow up will be needed to confirm whether such benefits give a long term advantage of the new prosthesis. Although one of their patients achieved 150 degrees of flexion, their mean value was not different to other more traditional designs, thus questioning the claims of increased flexion made by the manufacturer.

Similar results have been found by authors looking at other manufacturers' designs. Nutton *et al* (2008) performed a double-blind study to assess whether there was any difference between the Zimmer NexGen standard prosthesis and the high flexion prosthesis. The high flexion component in this instance differed by having an extension of the posterior femoral condyles, along with modifications of the cam and tibial spine. They found no significant difference regarding outcome, including maximum flexion or increase in knee scores, between the two components.

One particular reason for both these scenarios may be the difficulty in designing a high flexion component and exactly how to replicate the deep flexion of the intact knee. Pinskerova *et al* (2009) performed a cadaveric study and MRI scanning to determine the precise movements of the intact knee at flexion between 120 and 160 degrees. They found that at full flexion the femur did not contact the tibia at all but that the bones were separated by the posterior horn of the medial meniscus and this process began at around 140 degrees. The authors referred to a separate arc of hyperflexion which could not occur simply as a continuation of the normal flexion arc as this would not result in the posterior movement of the medial femoral condyle, separation of the femur and tibia medially and the displacement of the posterior horn of the medial meniscus. In conclusion, the authors said that in their opinion the design of a true high flexion prosthesis would be almost impossible.

The strongest indicator of the post operative range of flexion achieved by the patient is pre operative range of movement (Sultan *et al* 2003). A stiff knee pre operatively will struggle to gain deep flexion according to the authors due to bony structural changes, periarticular soft tissue fibrosis and extensor mechanism stiffness. None of these factors can be easily addressed at arthroplasty surgery and thus a prosthesis that did allow flexion to beyond 150 degrees may have no benefit in many patient groups.

Further difficulty arises in assessing whether achieving deeper flexion is at all advantageous to the patients themselves. Park *et al* (2007) assessed patients post operatively using three scoring systems and compared the results between two groups who were selected according to their maximum range of flexion. They found a significant difference between patients who could achieve 120 degrees of flexion compared to those who could reach 135 degrees. They did find some subtle differences using the WOMAC score which is subjective and patient driven but no differences in the SF36 or a physician scoring system. In their opinion, high flexion activities may jeopardise implant survival, so they were not going to strive for deeper flexion in their patients. It is important to point out that the prostheses used in their study were not designed specifically for high flexion compared to those discussed in other studies.

Pressure Studies.

This was the most difficult part of all the experiments to interpret. A range of experiments were performed on some of the knees but not all. Although some trends were seen in the values, there were large discrepancies present and as a result these particular tests were discontinued.

The main problems encountered were with the Tekscan sensors. Namely, securing them in position to allow readings of contact position to be made, how to gain access to the knee to allow sensors to be placed under each condyle and also preventing the sensors crumpling up during measurements and thus affecting the results.

It was difficult to explain why, when the knee was loaded with the air pressure unit to 400N, the highest reading obtained by the Tekscan sensors was only around 310N. To exclude experimental error the air pressure unit was recalibrated as well as the sensors themselves and no discrepancy was found in either. One possibility was that some of the force may have been taken up by the soft tissues or even in the cable running from the pressuriser to the Steinman pin that was loading the patella, but it is more likely that not all of the load-transmitting area of the knee had been covered by the sensor..

Perhaps one factor that was difficult to quantify was the degeneration of the cadaveric specimens. By the time the pressure studies were performed the knees had been through repeated cycling and stressing, as well as 2 different arthroplasty procedures. It was felt that with such repeated use the soft tissues may have begun to stretch and had lost their elasticity which could certainly have contributed to the difficulty in reproducing results.

It was decided that such great variation in the readings meant the results could not be used accurately for analysis. Perhaps of greatest concern was when some of the experiments were repeated immediately after one set of data had been recorded and quite different results were obtained.

Some of the figures recorded did correspond to some published literature. Nakayama *et al* (2004) recorded contact areas and stresses in different prostheses, but they were not tested in vivo. They recorded contact areas of

65mm^2 compared to recordings of 56mm^2 for the MR knee and 63mm^2 for the SR knee and mean contact stress of 8MPa at 90 degrees of flexion compared with present values of 7.8MPa for the SR TKA and 6.4MPa for the MR TKA. Although the values in these experiments are comparable it was the lack of reproducibility of the results which was concerning enough to question their accuracy and thus the relevance.

A potential solution for further work would perhaps be to test each of the prostheses without implantation into a cadaveric knee. If the components could be mounted onto a block and cycled then the issues of implantation into the knee would be avoided. The experiments may also be more accurately repeatable and give better results. However, the limitations of such a system would be that there could be no comparison between the TKAs and the native knee, and also that it would have limited application to a clinical scenario.

The rationale behind the pressure measurements was to prove or disprove the suggestion that the constant-radius femoral geometry and flared posterior condyles would lead to a greater range of movement and also a larger contact area. The significance of the larger contact area was that this would in theory lead to decreased wear, greater longevity of the prostheses and thus reduce the morbidity and mortality of revision surgery. Unfortunately, only limited results for this part of the research were obtained and further testing would be required to look at this in more detail.

Patellofemoral Kinematics.

The second year of the experiments focused on the patellofemoral joint with kinematic data as well as stability data being recorded. As with the tibiofemoral data, overall, statistically significant differences were found between the native knee and the two TKAs and between the two TKAs in various tests, but in the post tests for patellar flexion, spin, shift and tilt, there were no statistically significant differences found.

All of these experiments were carried out with a replaced patellar button. Not all surgeons advocate replacing the patella during knee arthroplasty surgery but it was felt this option allowed assessment if the patellar components but also meant the standardisation of one further step to eliminate a possible source of variability. There are currently no published papers that recommended the routine resurfacing of the patella. Large meta-analyses such as those discussed in the introduction have shown no advantage to patellar resurfacing, no increased adverse effects if the patella were to be resurfaced and no difference in knee scores between the two groups.

Importantly the new SR TKA did not show any inconsistencies or worrying patterns of behaviour that would jeopardise its future with regards to the PFJ. However, there was not any obvious advantage of the new design over the established MR TKA.

Both TKAs exhibited the same behaviour when compared to each other with regard to patellar tilt and flexion. In both TKAs the patella was slightly tilted laterally at full extension when compared to the intact knee, which initially tilted medially and then subsequently laterally from 30 degrees. It therefore seems that the different geometry between the two femoral components, shown in the photograph on the following page, did not appear to affect patellar tracking. The asymmetrical design of the SR knee did no more to replicate “normal” knee kinematics than the deeper trochlear groove and symmetrical trochlea of the MR design.

Figure 88. Photograph showing the different trochlear geometry. The MR TKA is shown on the left.

The deepened trochlear groove in the SR design in deep knee flexion potentially would relax the extensor mechanism of the knee, allowing deeper flexion and reduced stresses across the patella. Due to the design of the test rig, it was not possible to compare the two TKAs at more than approximately 110 degrees of flexion, but any differences between the two prostheses were found towards extension and as the degree of flexion increased the TKAs became a closer and closer match to each other. It would still be interesting to see how the two prostheses behaved into deep flexion. It is also important to compare this work with those results already published in the literature, partly because of concern caused by using only 6 cadaveric knees.

Regarding patellar tilt it was found that the knee initially tilted medially by 3 degrees in the intact knee and then 4 degrees laterally at 90 degrees of flexion. The two TKAs were however, tilted laterally at knee full extension (MR 6 degrees and SR 2 degrees), both increasing to 9 degrees at 90 degrees of knee flexion. Jenny *et al* (2005) found in their study a similar path of motion in healthy knees, with initial medial tilt to 30 degrees of knee flexion, followed by lateral flexion. They reported slightly greater amounts of tilt of 10 degrees each way, but this suggests the way these experiments were performed was correct and reproducible. Chew *et al* (2006) also found that the patella was tilted laterally by 6 degrees compared to the intact knee at full extension, almost matching the present results.

In all three states the patella adducted (or rotated externally) while knee flexion increased from 0-90 degrees. In the intact knee the patella rotated by 7 degrees and with the TKAs by greater amounts (MR 15 degrees and SR 11 degrees). This is different to the work by Heinert *et al* (2011), who found that the patella in the natural knee externally rotated with knee flexion but this movement was not replicated in the TKAs they tested. This view is also held by Lesko *et al* (2007), who found in deep flexion in the natural knee that there was patellar rotation but again this was not replicated in the replaced knees. Katchburian et al (2003) as one of their conclusions on the PFJ kinematics of the intact knee, commented that in their view the patellar rotation is much more difficult to define and is much less predictable, which may explain the different viewpoints.

It was found that, during knee flexion, the patella shifted laterally in relation to the femoral anatomical axis in all three states. In the two TKAs the patella was both times more medial in full extension than the resting position in the intact knee. Katchburian *et al* (2003) found that the patella shifted medially and then laterally, as did Patel et al who recorded medial shift of 3.2mm at 30 degrees of knee flexion before returning to 0 at 60 degrees of flexion. Chan *et al* (2006) showed that the patella rested in a more medial position near to full extension in the replaced knee than in the intact knee.

The results for the intact knee in this study are also very similar to published results by Amis *et al* (2006). They showed that as the knee flexed, the patella flexed by 0.7x that of the tibiofemoral angle. This was exactly the value found from these experiments. However, in this work the replaced patella following TKA was more flexed near to full extension (MR was 7 degrees, SR was 9 degrees) but converged to the behaviour of the intact knee as flexion progressed to 90 degrees. Other results from the work by Amis *et al* (2006) regarding tilt and shift were also comparable to these results for the intact knee.

The focus on the PFJ work was to examine the hypothesis that the newer single radius femoral component design would allow more anatomical tracking than the more established multi radius design. However, as seen from the results and statistical tests, this work does not support that. Although significant differences were found at some specific degrees of tibiofemoral flexion, overall there were no differences between the two TKAs and the intact knee. Both TKAs showed the same behavior with regard to patellar flexion and tilt. The SR TKA was significantly different to the intact knee with regards to patellar spin from 55 degrees of tibiofemoral flexion ($p<0.05$), as well as to the MR TKA. For patellar shift the SR TKA was different to the intact knee from 10-40 degrees and different to the MR TKA in the range 10-25 degrees. However, overall there were no differences seen between the three knee states in the tracking experiments.

These results do not support the hypothesis that the newer, single radius design of femoral component with an altered trochlear groove produces a more anatomical patellar tracking than the multi radius design. Both TKAs tested in these experiments showed good replication of knee kinematics when compared to the intact knee. However, no difference was found between the two TKAs, which shows no advantage to the SR TKA but also reassuringly shows, as a new prosthesis that its kinematic behaviour is comparable to the intact knee and also an established prosthesis with a long published follow up.

Patellar Stability.

This particular section produced points for further discussion. Although no statistically significant differences were found, the SR TKA appeared subjectively to mirror the native knee more closely than the MR TKA. As expected in all three knee states the patella required more force to displace it medially than laterally and also required greater force for displacement as the tibiofemoral angle of flexion increased. This was similar to the results published by Senavongse *et al* (2003) who found the intact knee was much more resistant to medial displacement that lateral displacement. For lateral displacement of 10mm at 0, 20 and 90 degrees they published values of 126N, 75N and 125N. These are compared to the values of 115N, 85N and 105N for the same degrees of flexion in this study, suggesting the methods used in these experiments were accurately producing data equivalent to other published literature. Similarly, their data for medial displacement at 0 and 90 degrees of flexion were 144N and 219N showed the same trend as this work with values of 90N and 160N required for the same amount of displacement.

When looking at the graph for medial stability the MR knee showed an almost constant value of 110N for displacement throughout the range of flexion. The SR knee was much more similar to the native knee, requiring over 150N for displacement at 90 degrees of flexion. Although the data was not statistically different this may suggest the patella in the SR knee could be perceived as more stable by the patient and in turn give them greater confidence. The SR TKA has a deeper trochlear groove than the MR knee and it may be this design feature that accounts for this difference. This variation in results may also have been found to be significant had greater numbers of knees been used, rather than the 6 complete sets of data that were available. Relatively low muscular forces were used due to the failure of the extensor muscles when loaded to a more physiological magnitude.

The main feeling of patellar instability for most patients comes from lateral instability and the patella attempts to sublux over the lateral femoral condyle. Despite the changes in the geometry of the femoral component there was no increased lateral stability in the new single radius design. Other than the articular groove geometry, the primary active and passive restraints to lateral patellar subluxation are the VMO and the medial retinaculum. By loading each of the muscles separately it was hoped to load the knee in a balanced way to avoid further inaccuracies as the knees were loaded at sub-physiological values, for the reasons previously explained.

It is also important to identify the limitations of cadaveric work, particularly when trying to assess patellar stability. These cadaveric specimens were just the knee articulation and thus this work was not studying the whole knee as part of a fully loaded lower limb. The muscles were also loaded at the same force for each angle of flexion that the stability measurements were made at. However, in life, tensions within muscles change with tibiofemoral flexion. This scenario would have been difficult to replicate in the laboratory. These in vitro results did not show differences in patellar stability despite alterations in femoral component design when different designs were implanted into the same knees which were all tested in the same laboratory under the same conditions with the same experimental errors.

It would also be very naive to suggest that the most important restraint to lateral patellar subluxation is the design of the femoral component. Chin *et al* (2005) looked at the commonest reason for revision surgery for dislocating patellae post TKA and found that inadequate soft tissue balancing was the commonest cause. They also observed that a misaligned or poorly positioned femoral component would also account for patellar problems but did not see a significant difference between individual designs reviewed in their study. It would therefore seem reasonable to conclude in this work that with the implants being tested in the same cadaveric knees under the same conditions that we would expect the stability results to be the same for both TKAs. If a difference had been detected this may have been a reflection of poor surgical technique or inaccuracies in the experimental methods.

11.2 Limitations of this work.

As with most research, and in particular work involving cadaveric specimens there were limitations to this work and these will be addressed these in this section.

Firstly, the experiments could have been performed on more cadaveric knees to enhance the power of the statistical tests that were performed and also to eliminate any possible of type 1 or 2 errors occurring. As mentioned during the thesis there were some differences seen which may have been more significant if the numbers had been greater. This is particularly pertinent in the PFJ experiments where due to time, technical problems and resources, data was only collected from 6 knees. Although there is published cadaveric work using similar numbers of specimens the analysis of more knees would increase the impact of this work. However, these experiments were limited in terms of time, availability of cadaveric limbs and budget which meant extending the study was not possible.

The muscle force was similar to that required in unloaded knee extension exercises against gravity, rather than loads equivalent to those when 'mid-range instability' might occur, such as when descending stairs. The load imposed was limited by failure of the tissues of the extensor mechanism of the cadaveric specimens, in particular in the PFJ experiments, where only 175N was used due to the flimsy nature of the individually dissected out muscles. Conversely, it could be argued that the relatively low compressive joint force would have allowed the limits of laxity to expand and, thus, be expected to show up any altered stability more clearly than normal. The effect of these factors was reduced by carefully dissecting the muscles, loading them as per their cross sectional area and physiological orientations and reproduction of the same methods for each set of data.

It was not possible to produce a reliable set of results for the pressure studies. Given more time, different pressure measuring systems could have been used, or even the prostheses tested without implantation into the cadavers, but mounted onto a test rig to be used along with the Instron machine. In particular, it would be ideal to find a way of measuring the pressure effects throughout a range of dynamic movement. The Tekscan sensors seemed only appropriate for static measurements before they failed. Accuracy could be increased further with a system used for the measurements that could be inserted through the medial arthrotomy rather than requiring dissection of the lateral capsule as was the case with the Tekscan sensors.

One possibility for improving the patellar experiments would be to perform the same tests but without resurfacing the patella. This would provide further data for comparison to see if either prosthesis behaved differently. It would also provide more useful data to those surgeons who do not routinely resurface the patella as to how the new design of prosthesis performs. However, it was felt for these experiments that resurfacing the patella removed one further possible variable.

Due to the equipment and experimental jigs used for this set of experiments there was a limit in the range of flexion in which the experiments could be carried out. Some data was obtained for up to 120^0 of flexion but in many cases this was incomplete and thus not appropriate to be included in the statistical evaluation as not all knees produced data at the extremes of movement. Redesigning the rigs and experiments may give more information on the behaviour of the prostheses into deeper flexion. However, because of the loading conditions required for the PFJ experiments unless a different type of navigation system could be used it would be very difficult to obtain values for more than 90 degrees of knee flexion as the optical tracking devices would always be obscured by the Instron machine. Further development of the navigation system used in these experiments may provide the opportunity to produce the patellar tracking data at the same time as the tibiofemoral work. This would also have the advantage of allowing the TKAs to be positioned with the navigation system, which was not possible in the PFJ experiments due to the attachment to the Instron machine. If this were the case the patellar kinematic detail could be recorded before the knees were transferred to the Instron machine for the stability testing to be performed separately.

In order to exclude possible variables in the data collection all these experiments were performed on knees with no evidence of osteoarthritis. As shown in publications previously discussed, the kinematic behaviour of a knee with OA may alter over time. It would perhaps be relevant therefore that the experiments could be repeated in further cadavers with signs of OA to see if the results were different. This would lead to difficulties in data interpretation due to different degrees of arthritic changes, possible deformities, ligament balancing problems, muscle bulk and already altered knee kinematics.

Perhaps the greatest limitation of this work is that it was carried out in cadaveric specimens and not in vivo. Difficulties therefore arise in interpreting the work for a normal living subject. There are widely reported studies in the literature that used such cadaveric specimens. Other authors such as Senavongse et al (2006) comment on the limitations of using isolated joints rather than a fully, appropriately loaded lower limb. It was hoped that using freshly frozen cadaveric limbs would eliminate problems with soft tissue degradation, tension and reaction to stress to give as accurate a set of results as possible. However, due to this study assessing a new design of TKA, cadaveric studies were more appropriate in case significant problems had been identified. Evaluating the SR TKA in living subjects is beyond the scope of this work.

11.3 Further possible work.

The data obtained from this body of work has confirmed that the SR TKA performed well in comparison to the intact knee. These experiments found no reason that it should not be used in modern day orthopaedics practice. However, there was no significant difference found when compared to the established MR TKA. As mentioned in the limitations section, increasing the numbers of cadaveric knees used may demonstrate some subtle differences but the next stage of research could be patient centred and focus on their experiences of the SR TKA.

Traditionally knee replacements have been judged on their survivorship and there are many different publications such as Weir *et al* (1996) that deal with the survival of one particular type of TKA, in that instance the Kinemax TKA. However, such publications take many years of follow up to produce enough meaningful data for publication. The type of follow up that is more difficult to produce would be one patient's individual viewpoints with current opinion that around 70% of patients are satisfied following TKA, Lingard *et al (*2004).

It would be a very difficult task to find patients who had had two different TKRs, one being the SR design and one being another design, in order to make direct comparisons. Validating such research can also be difficult with many different knee scoring systems such as the Oxford Knee Score, the WOMAC score, the SF 36 and the Knee Society Score used in published literature. Patients' perceptions of post operative function, limitations and pain have been shown to vary greatly with regard to expectations (Dawson *et al* 1998), which may also affect the power of such a study. Recent work by Singh *et al (*2010) showed that outcome may well be a reflection of individual's personality as they showed that naturally pessimistic patients did worse following their TKA.

Although survivorship of prostheses has been a traditional way for comparing individual designs it may not always reflect a good patient outcome. A patient whose knee survives for 15 years because it is too painful and stiff to walk on arguably has a much worse outcome than the patient whose knee only survives 10 years as they have worn it out as it has provided a good, pain free range of movement allowing them to get back to greater activity.

With any new prosthesis released onto the market it is also important that any early failures of the SR TKA are evaluated closely and reported. Some new designs have been reported in the literature such as the Kinemax Plus TKA, reported by Reay *et al* (2009), to have a catastrophic early failure rate. Presumably, such a design will have been evaluated in a similar fashion to the SR TKA but still has such problems. As yet it is difficult to say whether the alterations in design in the SR TKA will not lead to early loosening or aseptic wear and thus a higher early revision rate.

As previously mentioned in the discussion, perhaps there are differences present but the in vitro experiments described in this thesis were unable to pick them up. Does this raise the question that this work needs to be adapted and the hypothesis assessed in a different fashion? Early publications on the follow up of patients receiving a SR design of TKA did suggest improved patient satisfaction (Greene *et al* 2006). The key question is whether these patients' perceptions could be anticipated by results from testing in a laboratory. It is certain that the numbers of younger patients requiring TKA is going to increase along with their demands for increased function. This younger age group need assessing in further detail to ensure that the greatest possible function and longevity of prostheses is found. No longer can a knee replacement be viewed as simply a pain relieving operation in these patients as function is becoming increasingly important.

In summary, therefore, this research has shown the new single radius TKA to follow the kinematics of the intact knee very closely in both the tibiofemoral and patellofemoral joints. However, continued clinical evaluation with long term follow up will be required to show whether or not the new design features do have an effect in improving patient outcome and whether there is an overall advantage to the newer designs featuring a single radius design of femoral component when compared with the established multi radius designs. The work has been unable to show a clear advantage of using the newer single radius TKA over an established multi radius design when considering tibiofemoral and patellofemoral kinematics or patellar stability.

Chapter 12.

Publications from this work.

As a result of this body of work, papers have been submitted to peer-reviewed journals for publication. Currently the following paper on the tibiofemoral kinematics and in particular the contentious issue of mid range instability has been accepted for publication by the Journal of Orthopaedic Research. The second paper, on the kinematics and stability of the PFJ and the effect of the different component designs, has been submitted to Knee Surgery, Sports Traumatology and Arthroscopy.

The final piece of work is a copy of the poster that was presented on the PFJ work at the 2010 British Association for Surgery of the Knee (BASK), held in Oxford.

ABSENCE OF MID-RANGE INSTABILITY AFTER TKA –

THE KINEMATICS AND STABILITY OF SINGLE-RADIUS VERSUS MULTI-RADIUS FEMORAL COMPONENTS.

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ABSTRACT:

Purpose: There continues to be some dissatisfaction with the function of total knee arthroplasties (TKA). ‘Mid-range instability’ has been linked to multi-radius femoral components allowing transient ligament slackness and instability during knee flexion. Single-radius designs have been introduced to avoid this. Methods: We compared the kinematics and stability of eight natural knees versus multi-radius and single-radius TKAs, in-vitro. The loading conditions imposed across the range of active knee extension were anterior-posterior drawer forces, internal-external rotation torques, and varus-valgus moments. Results: Significant differences were not found between the biomechanical behavior of the two TKAs. Both were significantly different from the natural knee in allowing greater anterior drawer laxity near extension, probably caused by excision of the anterior cruciate ligament, but there was no difference beyond 30° flexion. No differences were found for any of the other degrees-of-freedom of movement. Conclusions: These kinematic and stability tests did not find evidence of mid-range instability of the knees, and so they could not demonstrate enhanced mid-range stability of the single-radius knee system over the older multi-radius implant. This suggests that mid-range instability may relate to unrecognised ligament laxity during surgery, rather than being inherent to a specific feature of implant design.

Keywords: total knee arthroplasty; kinematics; mid-range instability; prosthesis geometry; ligament laxity

Introduction

The femoral components of total knee arthroplasties (TKA) have often had a J-shaped radius of curvature, in which the sagittal plane geometry of the femoral component had a large radius anteriorly, which gradually reduced posteriorly, and were originally designed for an elderly population. The aim was to reproduce the then-accepted anatomic shape[1]. Despite good survivorship data and the introduction of ‘high-flexion’ designs intended to improve function[2,3], many patients remain dissatisfied with the level of function achieved post TKA[4]. Greater numbers of procedures are being offered to a younger population, who desire a higher level of function from such an implant in addition to pain relief. Therefore, newer knee designs must not only match the excellent survivorship of existing implants, they should also offer improved functional performance without adverse biomechanical effects.

During implantation, the surgeon must “balance” the knee by a combination of alignment and ligament tensioning to ensure stability; this is usually established at only 0 and 90° flexion[5]. However, it is believed that there may sometimes be an intermediate arc of flexion where the ligaments are slacker, leading to so-called ‘mid-range instability’ with the multi-radius prostheses[6,7]. This instability may occur with both posterior cruciate ligament-retaining and posterior cruciate-sacrificing designs[8,9]. The use of a single-radius femoral component has been proposed to ensure consistent tension in the collateral ligaments throughout the functional range of movement. This design has been reported to improve anterior knee function, stability, and flexion with greater proprioception[10]. This should also address the patient’s perceptions of clinical instability when the partly flexed knee is loaded, such as when descending stairs. However, the authors are not aware of biomechanical studies which support this proposition. The hypothesis of this study, therefore, was that a single-radius design of TKA would avoid mid-range instability and mimic the natural knee joint kinematics and stability better than a multi-radius TKA.

Materials and Methods

The kinematics and stability were measured, with a range of loading conditions and across the arc of knee extension, of intact knees in-vitro, and the same knees implanted with a multi-radius TKA and a single-radius TKA.

The multi-radius TKA was the Kinemax and the single-radius design was the Triathlon (both by Stryker, Mahwah, NJ) (Fig 1). The Kinemax, which is obsolete, was chosen because of its distinctly multi-radius geometry; it was anticipated that there would be a clear evolution of performance when contrasted with the Triathlon. These were conventional posterior cruciate-retaining TKAs with cobalt alloy femoral components articulating on UHMWPE inserts supported in metal tibial trays with short stems. The patella was not resurfaced. The principal difference between the TKAs was that the femoral components had single- or multi-radius geometry in the sagittal plane. In addition, the tibial insert of the Triathlon had arcuate bearing areas, intended to facilitate tibial rotation, and the anterior trochlea of the Triathlon was asymmetric (more prominent anterolaterally), while the Kinemax was symmetric.

Specimen preparation

Eight adult fresh-frozen left-sided lower limbs, disarticulated through the hip, were obtained from a tissue bank (Life Legacy Foundation, Tuscon, Arizona), with informed consent and Research Ethics Committee approval. Data from a prior study[11] allowed a power study which showed that eight legs would allow us to identify differences of 1.5

mm in anterior-posterior (AP) translation, 2^{o} in internal-external rotation, and 1.6^{o} in varus-valgus angle, with 95% confidence and 80% power. All specimens had no evidence of malalignment, gross arthritic changes, ligament instability or previous surgery. Navigation trackers (Stryker knee navigation system, Stryker Leibinger, Freiburg, Germany) were fixed rigidly to the femur and tibia 150 mm from the knee joint line[11,12]. Navigation reference points at the center of the femoral head, the femoral epicondyles and the ankle were digitized. The epicondyles were located via small incisions. The center of the femoral head was estimated after moving the leg in circumduction around a fixed 'acetabular' socket via the navigation software. The center of the knee was defined as the highest point of the anterior-distal outlet of the intercondylar notch, and the center of the ankle was the mid-point of the line joining the malleoli. These points were all digitized in the intact leg. The femur and tibia were transected 50 mm above and below the navigation trackers, respectively, and the knee mounted in a kinematics rig.

The trans-epicondylar axis was aligned approximately to the flexion-extension axis of the rig; the navigation system measured bone-bone relative motion, so alignment to the rig was unimportant. The rig allowed unconstrained tibial motion relative to the femur, apart from control of flexion-extension. The tibia hung free, allowing flexion of the knee (0-120°) by moving the rig to which the femur was mounted. Displacing loads were applied to the quasi-static tibia, to test knee laxity[11,12]. After arthrotomy and standard wound closure using sutures to create a consistent 'intact' condition for each knee, tibio-femoral kinematics were measured by the optical navigation system.

Surgical Procedure

A midline skin incision with a medial parapatellar approach was used. The single-radius TKA (Triathlon) was inserted first. The distal femur was cut perpendicular to the mechanical axis in both coronal and sagittal planes. This cut was a fixed distance equal to the thickness of the femoral implant proximal from the unaffected distal surface of the lateral condyle to avoid the confounding influence of varus disease. The femoral component was positioned in 3° external rotation from the epicondylar axis determined by using both epicondyles[13] and Whiteside's line[14]. The posterior femoral condylar resection was equivalent for both prostheses. The final cuts were made after ensuring accurate AP positioning with the navigation system. The prostheses were sized as per the manufacturer's instructions. The tibial cut was 3° posterior slope for both prostheses, and perpendicular to the anatomic axis in the coronal plane. The rotational alignment of the tibial tray was referenced using the PCL and medial 1/3rd of the tibial tuberosity. The Triathlon tibial component was partly-cemented and the femoral component press-fitted. Collateral ligament 'tenting' was avoided by removing any osteophytes, in particular posterolateral ones. The collateral ligament tension was reviewed throughout the range of movement. The arthrotomy was closed with continuous suturing with No1 Vicryl (Ethicon, Somerville, NJ, USA) in the fascial layers, 2/0 Vicryl in the fat and 4/0 Vicryl for the skin. After collecting the kinematic data with the single-radius Triathlon TKA, the knee was opened and the TKA was replaced with a multi-radius design (Kinemax). No further bony cuts were needed, so the components retained the same alignment. The Kinemax components were cemented, to accommodate for the distal femoral component being 0.6mm thinner than the Triathlon, and the arthrotomy was closed. A third set of kinematic data was collected.

Knee Loading and Data Collection.

To simulate the extensor mechanism 400 N tension was applied to the patella via a transverse Steinman pin attached by a cable to a pneumatic cylinder which pulled parallel to the femur[11,12]. Tibial internal-external rotation torque was applied via a disc attached to the distal end of a cemented tibial intramedullary rod (Fig 2). Strings attached to opposite edges of the disc pulled horizontally in opposing directions, and were led over pulleys to hanging weights. Tibial varus-valgus moments were applied using a cord and hanging weight system attached to the distal end of the intramedullary rod. Anterior-posterior (AP) drawer forces were applied via a hoop mounted around the proximal tibia using a K-wire, thus allowing coupled tibial rotations. The test rig, and the femur mounted in it, was extended and flexed manually, the 400N extensor mechanism tension being insufficient to lift the weight of the test rig unaided. Each cycle took approximately 5 seconds. The navigation system recorded the movement of the femur and tibia during the active knee extension motion from 120 to 0° for the following loading conditions:

Internal rotation torque (5 Nm), external rotation torque (5 Nm), anterior drawer (70 N), posterior drawer (70 N), varus moment (3.5 Nm), valgus moment (3.5 Nm), and neutral (no additional loading other than the simulated extensor load)[11,12].

Statistical Analysis

Repeated-measures two-way ANOVAs tested the hypothesis that there was no overall difference in the kinematics or limits of laxity between the three different states of the knees. The independent variable was knee flexion-extension, the dependent variables were the primary motions of the knee, i.e. AP translation, internal-external rotation, and varus/valgus angulation. Differences at specific angles of interest were examined by post-hoc paired t-tests. A P value of 0.05 was used throughout. The mean of three extension cycles over the range 90-0^0 was used for analysis as 8 complete sets of data had been collected for this range of movement.

Results

Anterior-posterior translation

Significant differences of AP translation were not found between the two TKAs (P>0.05 by post-hoc testing) at any angle of flexion for the neutral path of motion and both the anterior and posterior limits of laxity. Statistically significant differences (P<0.05 by ANOVA) were found between both TKAs and the intact knee.

Path of motion with neutral loading

Although both TKAs followed the intact knee AP motion within +/-2.1mm (mean), both were significantly different to the intact knee overall (P<0.001 by ANOVA): the Kinemax tended to have greater femoral roll-back in flexion than the intact knee, while the Triathlon tended to have less (Fig.3). The neutral path of motion with the Kinemax was 4.4mm anterior to that of the intact knee at 10° flexion (P<0.05 by post-hoc testing), but significant differences were not found at other degrees of flexion. Significant differences were not found between the neutral path of the Triathlon TKA and the natural knee with post-hoc tests.

Anterior drawer

The anterior limit of laxity for each of the TKAs was significantly different to the intact knee across the range of flexion-extension (P<0.001 by ANOVA). They both allowed greater anterior drawer laxity than the intact knee near extension: Kinemax 5.2mm, P<0.001; Triathlon 5.6mm at 10^o flexion, P<0.001; Fig 4. The Kinemax showed significant differences (P<0.05) from 15 degrees to extension, the Triathlon from 19 degrees. The excess anterior drawer laxity was less than 0.5mm from 60° to 90° flexion. A significant difference from intact anterior laxity was not found as the replaced knees extended from 90° to 20°.

Posterior drawer

Overall, the posterior limit of laxity for each of the TKAs was not significantly different to the intact knee across the range of knee extension (P>0.120 by ANOVA). Both TKAs tended to be tighter than the intact knee in posterior drawer near extension (Kinemax 2.7mm, Triathlon 1.8mm at 10 degrees flexion; P>0.05), and matched intact posterior drawer within +/-1.2mm from 90° to 30° extension (Fig.4).

Internal - external rotation

Path of motion with neutral loading

The intact knee kept a nearly constant value of internal-external rotation while extending from 90° to 30°, after which it rotated externally by a mean of 7 degrees, the 'screw-home' movement.

Internal rotation

Both TKAs matched the internal rotation laxity of the intact knee, across the range of extension, within 2° (Fig 5). Significant differences were not found between the intact knee and either of the TKAs, or between the TKAs.

External rotation

Both TKAs matched the external rotation laxity of the intact knee within 4° (Fig 5) and tended to be more constrained than the intact knee from 90° to 45° extension. Significant differences were found overall between the intact knee and the two prostheses but no differences were found on post-tests. The mean range of IE laxity of both TKAs tended to be less than the intact knee at 90° flexion: Triathlon -3^0, Kinemax -5^0, Fig 5, but significant differences were not found.

Varus-valgus

Varus-valgus laxity

When stressed into varus or valgus, both TKAs matched the native knee very well (Fig 6). Again, significant differences were found between the TKAs and the native knee overall, but not with post-tests.

Discussion

This study examined the hypothesis that a TKA with a single-radius femoral component would provide a closer match to the kinematics and limits of laxity of the natural knee than would a multi-radius design, avoiding mid-range instability. This hypothesis was not supported by the experiment: significant differences between the paths of motion or the limits of laxity of the two TKAs were not found. This work did not find evidence to support the existence of 'mid-range flexion instability': both TKAs had limits of laxity which did not differ significantly from normal across the mid-range arc of knee flexion, from 30 to 60 degrees, and so this experiment did not offer a rationale for changing the contour of the femoral component. This study deliberately used an obsolete design of multi-radius TKA because, while it had good clinical results when in use, it had more pronounced multi-radius geometry than more modern designs; thus, if the femoral geometry were to be demonstrated to be a cause of mid-range instability, this choice should have made it clear. Near extension, both TKAs had significantly larger anterior translation (drawer) laxity than the intact knee, reflecting the excision of the ACL. No other differences were found in AP translation, internal-external rotation, or varus-valgus limits of laxity or path of motion.

The navigation system recorded the relevant kinematic data and confirmed the correct positioning of the implants, tensioning of the ligaments, and limb alignment prior to the kinematic measurements. An advantage of the experimental design was that it allowed repeated testing, and repeated-measures statistical analysis, of the knees in each of the three states, thus eliminating variables such as the state of the ligaments, gait differences, etc, which affect the power of clinical studies. The pair-wise analyses of data points from each of the knees allowed significant effects to be discerned. The results may have been affected by the age-normal knees used being different from arthritic knees, but their behavior was a good reference for what TKA surgery is intended to restore; the pathology of arthritic specimens would add further variability to mask the differences between the implant designs. A further limitation of this work was the use of a relatively low muscle force, which was similar to that required in unloaded knee extension exercises against gravity, rather than loads equivalent to those when 'mid-range instability' might occur, such as when descending stairs. The load imposed was limited by failure of the tissues of the extensor mechanism of the elderly specimens. Conversely, the relatively low joint force would have allowed 'mid-range instability' to appear more clearly than normal when tibial displacing loads were applied. Similarly, hamstrings muscle actions would have increased the joint force, due to the need to balance antagonists, again masking the instability which we sought to demonstrate. Larger displacing loads, such as varus-valgus moments and anterior-posterior drawer forces, may possibly have shown up larger laxity effects, but the present protocol has shown clearly how well the prostheses matched the intact knee behavior and there is no evidence to suggest that that might change at higher loads. Work in-vitro can only show the behavior of the knee immediately post-surgery, and some stretching-out of the soft tissues may allow instability to appear later. The soft tissues may have stretched during these experiments, but that would have favoured the demonstration of mid-range instability, because the multi-radius TKA was always tested last.

In these experiments a single-radius femoral design (Triathlon) was compared to a multi-radius design (Kinemax). Wang et al[10] found that the single-radius design reduced the quadriceps muscle activation in sitting-to-standing movements and decreased trunk flexion required for standing. They expected that these patients would mobilise more readily post-operatively. Hall et al[15] found that a single-radius design had a larger quadriceps moment arm about the axis of knee extension than a multi-radius design. These findings are not incompatible with the present study, which examined the path of motion during knee extension and the limits of ligamentous laxity, across the range of motion.

Although these results are design-specific for the two prostheses used in the experiments, they do not support the reports in the literature of mid-range instability, which was not identified by this work. The use of normal knees and the navigation system meant that the soft tissues were tensed correctly during the TKA procedures, and repeated measurement of the same knees eliminated this variable, when comparing the two TKAs. Thus, this was a powerful way to show up any differences caused by the implants themselves, and significant differences between their stabilities were not found. Thus, this experiment suggests that mid-range instability is not related to the shape of the femoral component, but to other factors encountered at surgery. Neyret's group[7] have suggested that it results from lack of recognition of ligament laxity patterns during surgery, which may be secondary to malpositioning of components on eroded bones. A varus deformity at surgery may require a medial soft tissue release to correct the leg alignment, and that in turn might lead to flexion instability. In that situation, it is possible that differing implant designs will retain more or less stability, but this speculation was not examined in the present work. Vince et al[17] suggested that 'mid-range' instability may result from the surgeon checking the knee in full extension, when valgus stability results from tightness in the posterior tissues, and then a medial collateral ligament deficiency may allow valgus instability when the knee flexes and so relaxes the posterior tissues. A single-radius design oriented along the trans-epicondylar axis should reproduce the natural knee kinematics[18] and maintain isometry of the medial collateral ligament. Clinical studies[8,19] have found that functional scores were reduced only when AP laxity exceeded 10 mm, which is greater than seen in this experiment, and is related to ligament laxity rather than a relatively small change in implant geometry, between single and multi-radius femoral components. More knowledge of TKA function could be gained by further experiments, in which component positions, ligament tensions and loading conditions are varied using methods described previously[11,12]. This experiment failed to induce 'mid-range instability' as a consequence of changing the implant geometry from single to multi-radius; taking this with clinical evidence[7,8,19] suggests that it must relate to ligament laxity, which may not be recognised during surgery.

In conclusion: both of the TKAs reproduced the kinematics and limits of laxity of the native knee very well, and so we could not demonstrate a significant difference between them. This work did not support the hypothesis that the single-radius design would be beneficial in trying to avoid mid-range instability.

Acknowledgements

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Patellofemoral stability and tracking after TKA: the influence of recent design evolution

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Abstract

Poor knee extension function after total knee arthroplasty (TKA) is associated with factors including articular geometry and alignment. Femoral trochlear geometry has evolved from symmetrical to become more prominent proximal-laterally, with the groove aligned proximal-lateral to distal-medial. This study *in-vitro* tested the hypothesis that a modern asymmetrical prosthesis would restore patellar tracking and stability to more

natural behaviour than an older symmetrical prosthesis. Six knees had their patellar tracking measured optically during active knee extension. Medial-lateral force versus displacement stability was measured at fixed angles of knee flexion. The measurements were repeated after inserting each of the TKAs. Significant differences of patellar lateral displacement stability, compared to normal, were not found at any angle of knee flexion. The patella tracked medial-laterally within 2.5mm of the natural path with both TKAs. However, for both TKAs near knee extension, the patella was tilted laterally by approximately 6 degrees and was also flexed approximately 8 degrees more than in the natural knee. No other significant kinematic differences were found. The hypothesis that the new asymmetrical trochlear geometry would restore the patellofemoral behaviour closer to normal was not supported; both prostheses matched both the kinematics and medial-lateral patellar stability of the intact knee well.

Introduction

Anterior knee pain and poor knee extension function following total knee arthroplasty (TKA) may affect activities such as stair climbing, rising from a chair and kneeling, and may be caused by factors including abnormal soft tissue tensions, articular geometry and patellar maltracking [1,2,3]. Patellar resurfacing remains controversial, with differing opinions on its routine use. Barrack and Burak [4] found that only 50% of cases revised with patellar resurfacing to treat anterior knee pain after TKA had alleviation of symptoms, so other factors must have been involved.

Patellar resurfacing entails a balance between conflicting requirements: the desire to insert an adequate thickness of polyethylene may lead to over-stuffing the patellofemoral joint, with stretching of the retinacula [5], while excessive patellar resection will predispose it to fracture [6]. Recognising this dilemma, the femoral components of TKAs have evolved, with changes including a larger antero-distal radius intended to reduce retinacular tension in mid-flexion, and asymmetrical trochlear flanges, intended to 'capture' the laterally-tracking patella and ensure more stable and physiological tracking. However, these prostheses do not have the same trochlear groove orientation as the natural knee [7]. It has been proposed (by Stryker, the manufacturer of the prostheses in this study) that the newer design with a deepened trochlear groove would relax the extensor mechanism, allow deeper flexion and reduce the stresses in the patella. Although prosthesis designs have evolved, the authors were not aware of evidence that this has led to improvements in patellar stability and tracking.

This study tested the hypothesis that a modern TKA design with a prominent lateral trochlear flange and with the trochlear groove oriented from proximal-lateral to distal-medial would exhibit patellofemoral joint stability and kinematics which were significantly closer to the behaviour of the natural knee than those resulting from use of an older implant design with a symmetrical trochlea.

Methods

Knee prostheses.

The implants chosen (Kinemax and Triathlon, Stryker Orthopaedics Co., Mahwah, NJ, USA) exhibited the evolution from the Kinemax, where the trochlea had symmetrical medial and lateral flanges and a straight central groove, to the asymmetrical design of the Triathlon, which had a larger lateral flange, with the trochlear groove oriented from proximal-lateral to distal-medial (Figure 1). These were both conventional posterior cruciate ligament-retaining designs with cobalt-chromium-molybdenum alloy femoral and tibial components with UHMWPE bearing inserts. The patella was resurfaced using a polyethylene ‘button’ with both TKAs.

Cadaveric Specimen Preparation.

Six adult fresh-frozen left-sided knees were obtained from a tissue bank (Life Legacy Foundation, Tuscon, Arizona) with informed consent from relatives, and approval from the Ealing and West London Mental Health Trust Research Ethics Committee. All specimens were assessed subjectively to have normal alignment and no evidence of gross arthritic changes, ligamentous instability or previous surgery, and all achieved passive full extension. The skin was removed and the quadriceps muscle heads separated so that they could be loaded in physiological directions and their tensions shared according to their physiological cross-sectional areas [8,9]. An intramedullary rod was cemented into the femur, allowing the specimen to be mounted in a reproducible position in the testing rig before and after TKA. Another intramedullary rod was cemented into the tibia.

Surgical Protocol.

The Triathlon TKA was inserted first, using a medial parapatellar approach, because it was expected that it would stretch the retinacula less than the Kinemax implant and because the ‘box’ cuts on the femur would not need to be altered to then accommodate the Kinemax component. The prostheses were sized as per the manufacturer’s instructions and were placed using anterior referencing to ensure accurate positioning of the anterior flange. Femoral cuts were perpendicular to the femoral mechanical axis at 5 degrees valgus from the femoral anatomical axis, and 3 degrees external rotation from the epicondylar axis [15]. The tibial cut had 3 degrees posterior slope and was perpendicular to the anatomical axis in the coronal plane [1]. The rotational alignment of the tibial tray was referenced using the PCL and medial 1/3rd of the tibial tuberosity.

The patella was resurfaced using the polyethylene ‘button’ specific for each TKA. The patellar thickness was measured using callipers and restored with the implants within +/- 0.5mm. The patellar components were sized and positioned as per the manufacturer’s protocols for each TKA. The Triathlon tibial component was partly-cemented, the femoral component press-fitted (to allow non-destructive revision) and the arthrotomy was closed with continuous suturing. After collecting the kinematic data from the Triathlon knee, the joint was opened and the prosthesis was replaced with the Kinemax prosthesis. The femoral component was placed on the same distal and posterior bone cuts to retain the same alignment and was cemented, to accommodate the different internal geometry, and the arthrotomy was closed. A third set of kinematic data was then collected.

Patellar Tracking Experiments.

Optical trackers were mounted on the femur, tibia and patella (Polaris; NDI Ltd, Waterlooville, Canada). This allowed the position of the patella in respect to the femur, and knee flexion, to be calculated. The femoral and tibial trackers were attached with thick transcortical pins outside the zone affected by the TKA procedures. The patellar tracker was attached to a nylon socket that was cemented into the centre of the patella from the superficial aspect. Data were collected while the knee was pushed into flexion against the quadriceps action, using a transverse rod pressing onto the tibial intramedullary rod, and then allowed to extend actively. This method did not inhibit secondary tibial rotations.

Patellar motion in relation to the femur was described in a standard format (Figure 2) [10,11]. Tilt was a rotation about the long axis of the patella, defined as lateral if the lateral edge approached the femur; rotation in the plane of the patella was defined as positive if the distal pole moved laterally, into abduction.

Measurement of patellar mechanical stability.

Patellar mechanical stability *in-vitro* (which is not the same as subjective symptomatic instability *in-vivo*) was defined by the force needed to displace the patella 10mm medially or laterally from its equilibrium position in the trochlear groove [9,12]. The patella was attached to the moving crosshead of an Instron 5565 materials testing machine (Instron Ltd, High Wycombe, UK) with a ball bearing inside the nylon socket at the centre of the patella, which allowed secondary rotations. The test machine displaced the patella at 100 mm/min, and measured the force. This was done at 0, 20, 30, 60 and 90 degrees knee flexion, while the quadriceps was loaded to 175N tension [9,12] and the ilio-tibial band was tensed to 30N [13,14]. The angle of knee flexion was maintained using a fixed rod placed across the anterior aspect of the tibial intramedullary rod, preventing further knee extension yet allowing small secondary movements of the tibia.

Data analysis

The stability and kinematics data were analysed using repeated-measures two-way analyses of variance, where the dependent variables were the three states of the knee (intact and two prosthesis types), and the angle of knee flexion. Comparisons at specific angles of knee flexion were performed by post-hoc paired t-tests with Bonferroni corrections; $P<0.05$ was taken to be significant.

Results

Resistance to lateral and medial displacement

The mean force required to displace the patella 10mm laterally remained in the range of 85 to130N from 0 to 90 degrees knee flexion for the natural knee and both of the TKAs (Figure 3). For the natural knee, the mean force was 115N at 0 degrees flexion, 85N at 30 degrees, and 105N at 90 degrees (P=0.809). The mean lateral displacing force for both TKAs rose from 115 to 130N, between 0 and 90 degrees of knee flexion (P =0.039 for the Triathlon and P =0.328 for the Kinemax). Significant differences of patellar lateral stability were not found among the intact and replaced knees at any angle of flexion (P>0.181).

The force required to displace the patella 10mm medially increased with knee flexion (Figure 4), from 90N at 0 degrees knee flexion to 160N at 90 degrees in the natural knee (P=0.059). A similar trend was followed by the Triathlon TKA (P=0.162) and the Kinemax (P=0.084).

At 20 and 30 degrees flexion the patella in the Kinemax TKA was more stable than the natural knee, (P=0.0160 and P=0.0195 respectively). Significant differences were not found at any angle of flexion between the Triathlon TKA and the natural knee (*P*>0.093). The patella was more stable against medial displacement with the Kinemax TKA than with the Triathlon TKA from 0 to 30 degrees knee flexion (*P*=0.022 at 0 degrees, *P*=0.008 at 20 degrees, *P*=0.0395 at 30 degrees).

Patellar kinematics

Patellar medial-lateral translation.

The patella moved laterally with knee flexion, in relation to the femoral anatomical axis, for the natural knee and both TKAs (Figure 5). After both types of TKA, the mean path of the patella was within 2.5mm of that of the natural knee. After the Triathlon TKA, the patella was medial to the natural knee near to extension (*P*<0.001 from 10 to 25 degrees knee flexion; *P*<0.05 from 25 to 40 degrees flexion). Significant differences were not found between the intact knee and the Kinemax TKA.

Patellar Tilt.

In the natural knee, the patella initially tilted medially from its orientation at full extension, by a mean of 3 degrees by 30 degrees knee flexion, then reversed to a mean of 4 degrees lateral tilt at 90 degrees flexion (Figure 6). The patella tended to tilt more laterally after both TKRs; the Kinemax by a mean of 6 degrees near extension, the Triathlon 2 degrees, both increasing to approximately 9 degrees mean lateral tilt at 90 degrees flexion.

There were significant overall differences of patellar lateral tilt among the intact knee and the two prostheses, across the range of knee flexion (*P*<0.0001 by ANOVA). The post-hoc tests did not demonstrate significant differences at specific angles of flexion, between the intact knee and either of the TKA, nor between the TKAs.

Patellar Rotation.

The patella rotated into adduction (the distal pole moved medially) from 0 to 90 degrees knee flexion, when the knee was intact and after both TKAs (Figure 7). In the intact knee, the patella rotated from 0 to 7 degrees adduction. The patella started in an abducted position in both TKAs and rotated into adduction, by 15 degrees and 11 degrees for the Triathlon and Kinemax, respectively, so that the patellar rotation matched the intact knee in flexion. The ANOVA showed a significant overall difference between the states of the knee (*P*<0.0001), but significant differences were not found by post-hoc testing between any of the knee states at any of the specific angles of flexion examined.

Patellar Flexion

Patellar flexion was similar in all three knee states (Figure 8), at approximately 70% of knee (tibiofemoral) flexion. The patella was flexed more than in the natural knee, after both TKAs, near extension: the Triathlon by a mean of 9 degrees and the Kinemax by 7 degrees, at 10 degrees knee flexion. The patellar flexion after TKA converged towards the intact values as the knee flexed.

The ANOVA found a significant difference ($P<0.0001$) in patellar flexion overall, among the intact and replaced knees. The post-hoc testing did not find significant differences between the intact knee and the Triathlon TKA. The patella in the Kinemax TKA was flexed more than in the intact knee from 10 to 50 degrees knee flexion. Significant differences were not found between the TKAs.

Discussion.

This study found that the evolution of the design of the trochlea, from the symmetrical groove of the older Kinemax prosthesis to the prominent lateral flange of the Triathlon prosthesis, did not lead to significant changes in patellar lateral stability or in lateral tilt. The hypothesis that the newer femoral component with a trochlear groove oriented from lateral proximally to medial distally would produce more anatomical tracking and improved stability than the older design was not supported. This was despite making the comparison against the Kinemax prosthesis which, although it had good clinical results in its time [16], is now regarded as a ‘heritage’ design, so the experiment was expected to show the effects of much design evolution. The patella with both prostheses was tilted laterally and flexed more than in the natural knee near extension. This reflected the lack of restraint from the polyethylene buttons, which do not support the edge of the patella well when it tends to tilt.

Although this study used established methods [9,12-14], it was on relatively few knees in-vitro and so caution must be used when extrapolating the findings to the clinical scenario. The compatibility of the data with previous results supports the findings. The implants were from only one manufacturer and they may not represent the behaviour of other prostheses. The patella was replaced in these experiments, ensuring that it articulated with the trochlea as envisaged by the TKA designers; however, not all surgeons advocate the routine replacement of the patella in primary TKA [2]. The configuration of the test rig in the material testing machine caused the optical trackers to disappear from view beyond 90 degrees knee flexion, so kinematic data could not be collected in deeper flexion. A larger number of knees would have given greater power to the statistical tests, but the intra-specimen pair-wise comparisons between the prostheses, a manoeuvre which cannot be used in-vivo, eliminated between-knees variability. In addition, the previously-validated methods used carefully defined and controlled loading, ensuring repeatable tests.

The mechanical stability testing results matched data published previously for intact knees in-vitro [9,14].The lack of difference of patellar stability between the prostheses may have resulted from the overriding influence of the medial patellofemoral ligament near extension [12] , where the patella is disengaged from the trochlea in the natural knee, and the geometry of the trochlea would have had its lowest effect. The 'skyline' view (Figure 1) shows that the older Kinemax prosthesis had a wider and deeper trochlear groove than the Triathlon near extension.

The kinematic results will be discussed in each of the degrees-of-freedom of motion. The patella tilted laterally near full knee extension in both TKAs (Kinemax 6 degrees and Triathlon 2 degrees), both increasing to 9 degrees at 90 degrees knee flexion. Merican et al [13] found a kinematic pattern the same as in this study for intact knees in-vitro, with 2 degrees medial tilt followed by 3 degrees lateral tilt during 90 degrees knee flexion. Jenny[17] et al found a similar pattern in non-arthritic knees in-vitro, with medial tilt to 30 degrees flexion, followed by lateral tilt, of 10 degrees each way. Chew et al [18] found 6 degrees lateral tilt after TKA compared to the intact knee at full extension, similar to this study. Patellar lateral tilt after TKA may cause pain arising from impingement on the lateral edge of the trochlea[19], a tendency increased by medialisation of the patellar button [20].

The patella translated laterally in relation to the femoral anatomical axis as the knee flexed in all three states. Katchburian et al [21] reviewed the literature and found that the patella shifted medially and then laterally during knee flexion, as did Patel et al [22]. Chan et al [23] found that the patella was more medial near to full extension after TKA than in the intact knee, as with some of the Triathlon knees in this study.

The patella rotated into adduction in all three states as the knee flexed from 0-90 degrees, with more rotation in the TKAs. Heinert et al [24] found patellar abduction in the natural knee during flexion, but not in the TKAs they tested. Katchburian et al [21] noted that patellar rotation is difficult to define and is much less predictable than the other components of motion, which may explain the differing findings.

Patellar flexion was 70% of tibiofemoral flexion in the intact knee, as reported previously [25]. After TKA, the patella was more flexed than in the intact knee near to full extension: the Kinemax by 7 degrees, the Triathlon by 9 degrees, suggesting lack of support of the distal pole by the polyethylene button.

The mean mediolateral tracking of the intact knees (Figure 4) had constant value from 0 to 30 degrees flexion, then increasing lateral tracking from 30 to 90 degrees, in relation to the anatomical axis of the shaft of the femur, similar to previous data [13,25]. Iranpour et al [26] showed that this data was the same as having the patella moving in line with the femoral mechanical axis from 20 to 90 degrees knee flexion, and moving more lateral from 20 degrees to full extension. That matches the symmetrical trochlea of the Kinemax prosthesis, with the centreline of the trochlea in line with the femoral mechanical axis. The natural trochlea has part-spherical surfaces either side of the groove, creating a pulley shape which has its axis perpendicular to the femoral mechanical axis [27]. Results in-vivo[28] have shown that the change to the single-radius design of femoral component (as in the Triathlon knee) has been beneficial for knee extension activities, but that does not relate directly to patellar tracking or stability in a transverse plane.

This work failed to demonstrate any large differences in patellofemoral kinematics or stability between the three states of the knee, whether with the native anatomy or the older or newer prostheses. These data do not support the current trend for modifying an accepted prosthetic design, only to give another with equivalent clinical results. The new design with an asymmetrical trochlea showed little difference in patellar tracking or stability behaviour to the much older design with a symmetrical and axially-aligned trochlear groove: both prostheses matched both the kinematics and medial-lateral patellar stability of the intact knee well.

Imperial College London

Comparative Study of the Patellofemoral Kinematics and Stability of TKRs with Symmetrical versus Asymmetrical Trochlea, Versus the Natural Knee.

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Aim of the study:

To compare the patellar kinematics and stability of a new TKR with an enlarged anterior lateral flange versus an established symmetrical TKR and the natural knee. It was hypothesised that tracking with the new TKR would be a better match to the natural knee and that anatomical patellar tracking would provide a more stable patella.

Methods:

A cadaveric study using physiological loads and an optical tracking system examined the kinematic behaviour of the tibiofemoral and patellofemoral compartments in 6 knees for the native, Kinemax and Triathlon knees. We used an Instron machine to record the stability of the natural and replaced patellae.

Figure 1. The trochlear shapes of the Kinemax and Triathlon prostheses.

Triathlon Prosthesis. Kinemax Prosthesis.

Figure 2.The knee set up for testing.

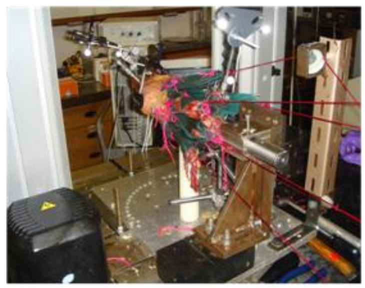
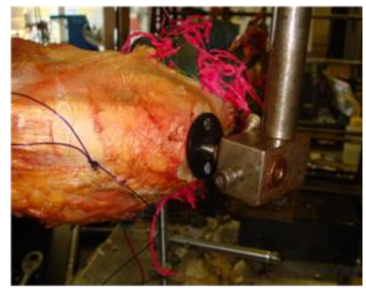
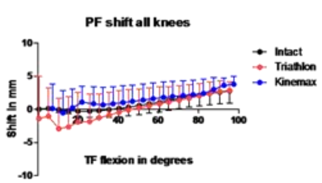


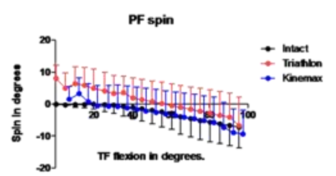
Figure 3. The Connection to the Instron Machine.



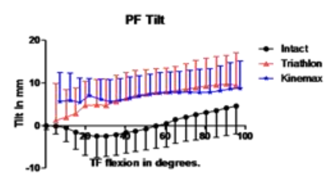
Results.



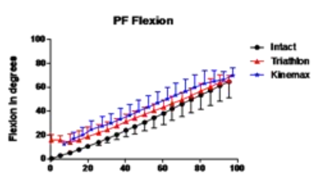
The Triathlon TKR shifted more medially than the natural tracking towards extension (p<0.001 from 30 to 0 degrees).



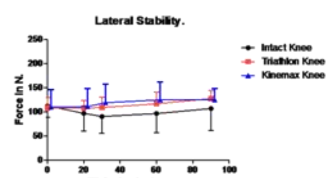
The Triathlon patella spun laterally versus the Kinemax and natural knee as the knee extended (p<0.05 from 55 to 0 degrees).



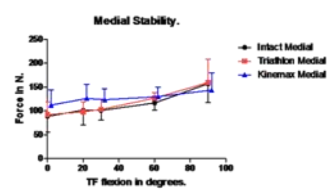
Both TKRs tilted laterally about 7 degrees at mid flexion compared to the intact knee (p<????)



The patellae were flexed about fifteen degrees in both TKRs versus intact values. (p<0.05 for Kinemax versus intact knee between 15-60 degrees).



To move the patella laterally it took around 100N of force to move 10mm. This value was almost constant throughout the range of tibiofemoral flexion.



To move the patella 10 mm medially, the Kinemax required 112 to 143 N across the range of tibiofemoral flexion, while the intact knee and the Triathlon required 88 to 160N with increasing flexion.

Discussion:

Both TKRs gave a good match to the patellar stability of the natural knee. However, there were instances such as patellar tilt, spin and flexion where significant differences of patellar kinematics were found. This work did not support the hypothesis that the new asymmetrical trochlear geometry would restore the patellofemoral behaviour closer to normal.

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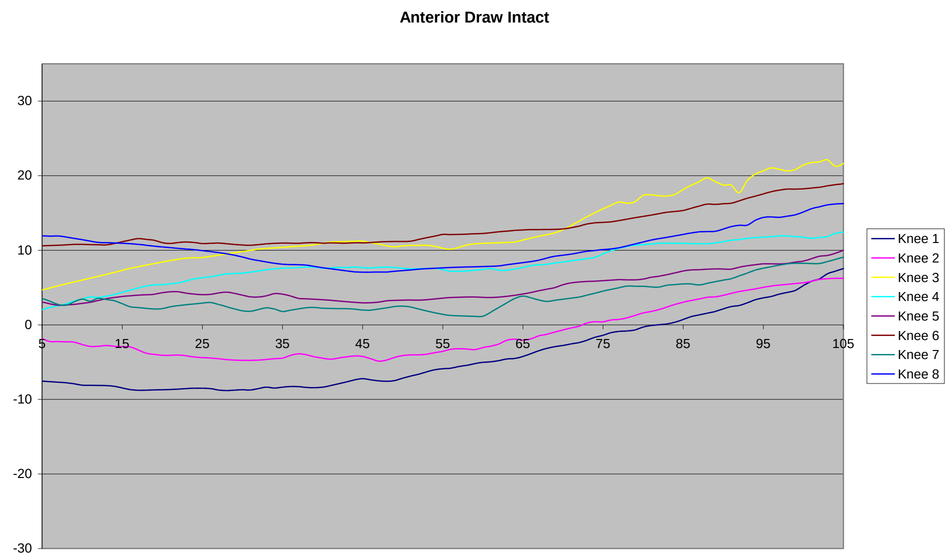
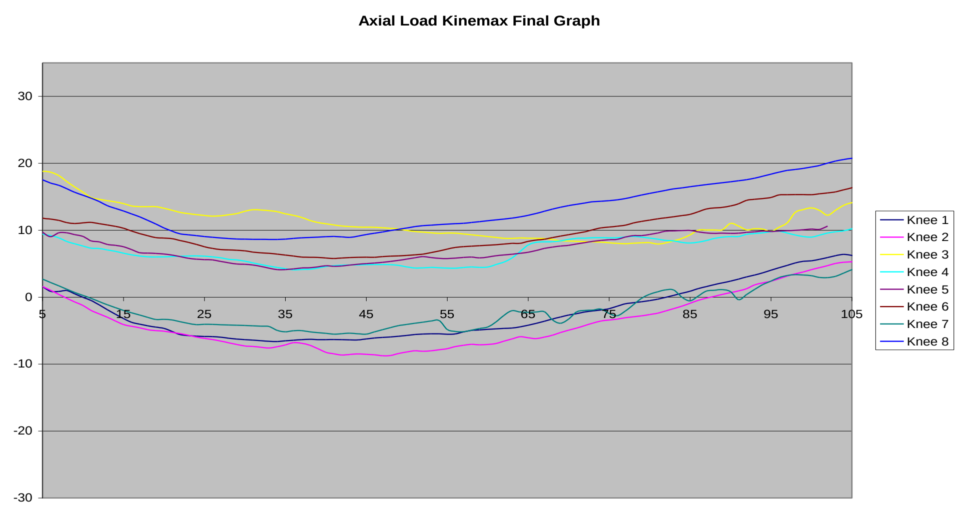
Acknowledgement: This study was funded by Stryker (UK) Ltd.

Appendix

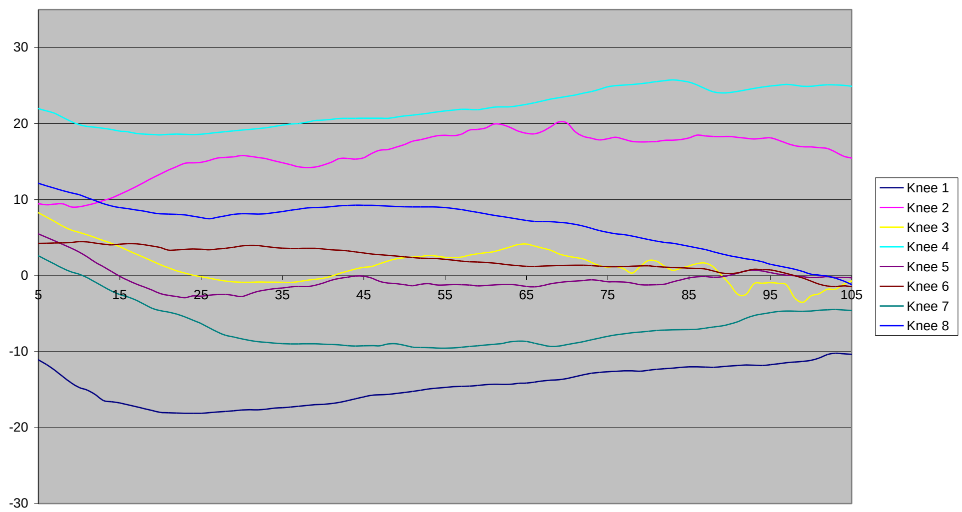
The following graphs, data tables, graphics and photographs have been included in the appendix to further illustrate how some of the experimental methods and results were devised. There are many similar illustrations in the main body of the thesis but the appendix will hopefully complete the picture of how the work progressed.

The following sets of graphs show a selection of the data for each of the three knee states in the six degrees of freedom. These graphs were used to check for outlying values prior to statistical analysis taking place.

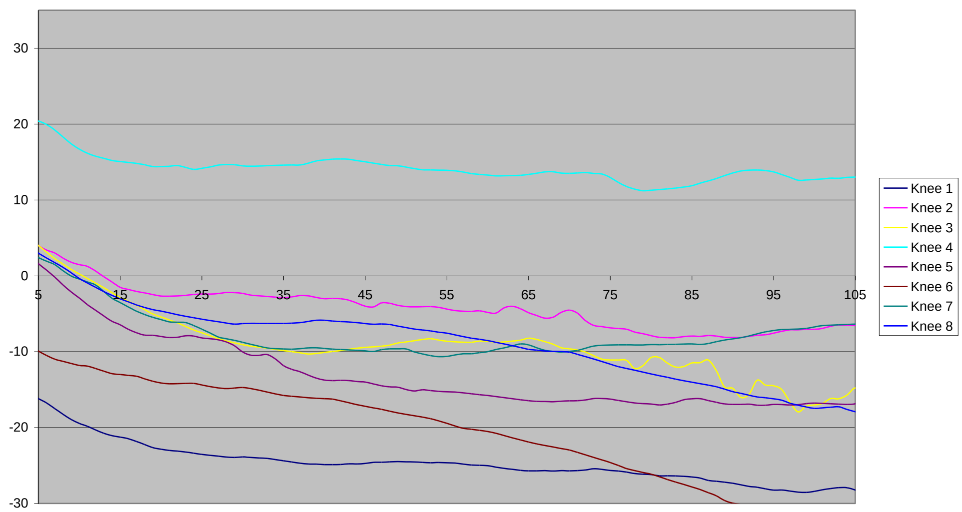




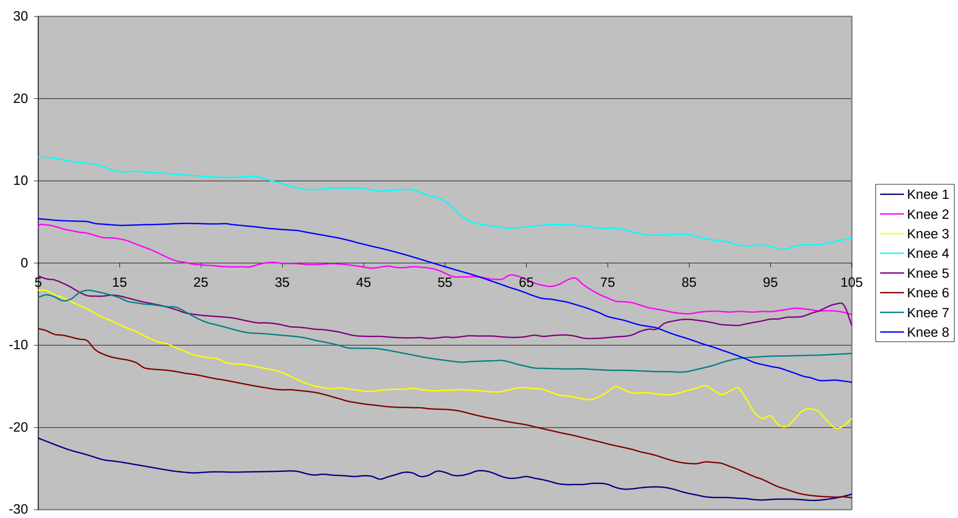
External Rotation Intact Final Graph



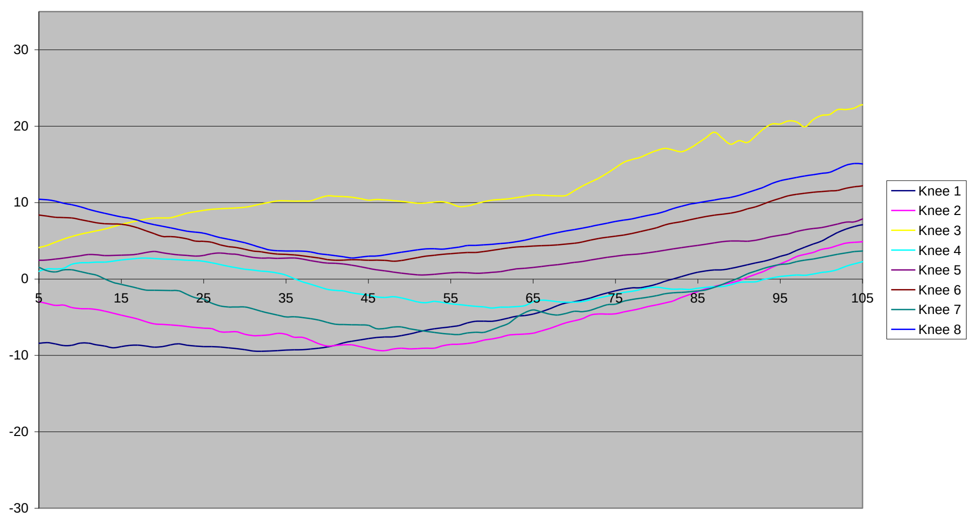
Internal Rotation Intact Final Graph



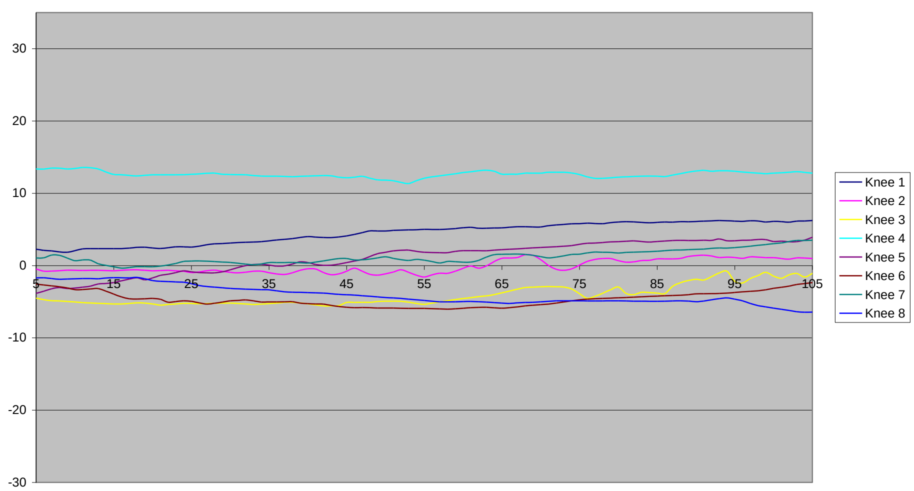
Internal Rotation Triathlon Final Graph



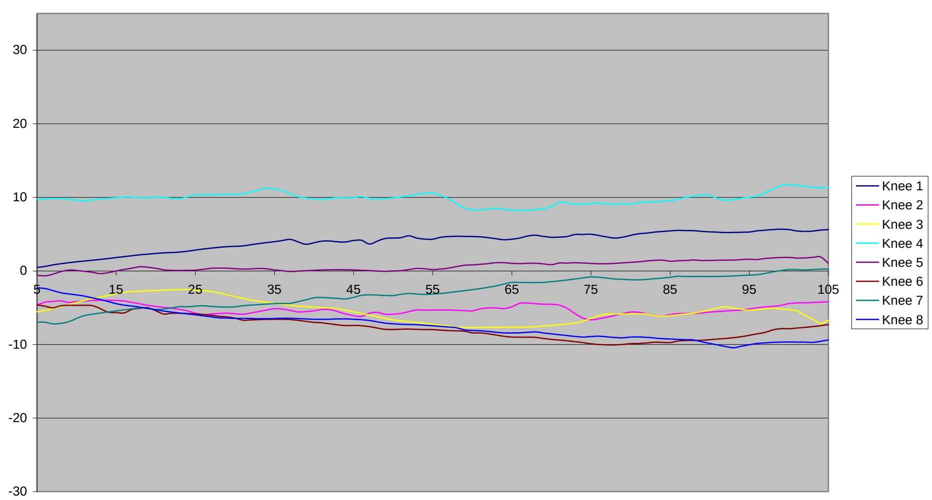
Posterior Intact Final Graph



Valgus Intact Final Graph



Varus Triathlon Final Graph



All these graphs show that each of the eight knees tested showed similar patterns with no outliers that would have affected the mean values significantly. However, following testing two of the early cadaveric knees some of the data was seen to be grossly different and inaccurate so two further specimens were obtained.

The following table shows an example of the data obtained during the pressure measurements with the Tekscan sensors. It was following similar data collected with other cadaveric specimens that the erratic nature of the results and even the variation between two sets of data obtained from the same knee a matter of minutes apart was appreciated. It was for this reason that this group of results were not pursued further.

	K0	K30	K60	K 90	K 120	T0	T 30	T 60	T90	T 120
Total Force (N)	133.6	85.11	66.84	58.02	86.17	165.93	68.36	62.2	68.37	63.05
Total Area (mm2)	79	39	34	29	44	82	35	31	34	34
Total force L (N))	46.28	41.27	25.2	36.26	37.32	49.81	41.68	30.9	42.04	36.05
Total force M (N)	86.98	43.83	41.65	21.76	48.82	116.12	26.7	31.3	26.3	27
Total area L (mm2)	37	18	16	16	18	32	22	15	19	15
Total area M (mm2)	42	21	18	13	26	50	13	16	15	19
Peak force L (N)	21.42	25.58	15.84	24.52	24.77	18.17	20.72	18.1	23.9	23.46
Peak force M (N)	24.58	25.48	22.47	12.16	21.78	25.58	11.98	17.7	17.89	14.8
Peak contact L (MPa)	3.31	3.97	2.45	3.8	3.83	2.91	3.21	2.8	3.7	3.64
Peak contact M (MPa)	3.81	3.95	3.48	3.77	3.37	3.96	3.71	2.73	2.77	2.29

The following graphic is a further example of the type of readout obtained from the Tekscan sensors. The red colours show where the force in concentrated the most and the overall pattern shows where on the tibial tray the force is being applied. Unfortunately due to the fragile nature of the Tekscan sensors it was not possible to secure them in place in order to test how the contact area varied at different degrees of flexion.

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