

# **DESIGN AND FABRICATION OF KNEE SIMULATOR TESTING MACHINE**

Submitted in fulfillment of the requirements for the award of  
Bachelor of Engineering degree in Mechatronics

by

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**DEPARTMENT OF MECHATRONICS  
SCHOOL OF MECHANICAL ENGINEERING**

## **SATHYABAMA**

**INSTITUTE OF SCIENCE AND TECHNOLOGY  
(DEEMED TO BE UNIVERSITY)**

**Accredited with Grade "A" by NAAC | 12B Status by UGC | Approved by AICTE  
JEPPIAAR NAGAR, RAJIV GANDHI SALAI, CHENNAI - 600 119**

**MAY - 2023**



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## **DEPARTMENT OF MECHATRONICS**

### **BONAFIDE CERTIFICATE**

This is to certify that this Project Report is the bonafide work of **Ponmuthu.P (39090701)** and **Deepak sai.C.M (39090702)** who have done the project work entitled “**Design And Fabrication Of Knee Simulator Testing Machine**”, under our supervision from June 2022 to May 2023.

**Internal Guide**

**Dr. S. Sivasaravanan M.B.A., M.E., Ph.D.**

**Head of the Department**

**Dr. S. Prakash M.E., Ph.D.**

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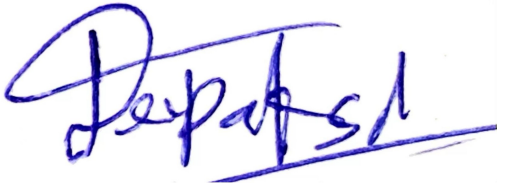
**Submitted for Viva Voce examination held on \_\_\_\_\_ May 2023**

**Internal Examiner**

**External Examiner**

## DECLARATION

We **Ponmuthu.P (39090701)** and **Deepak Sai.C.M (39090702)** hereby declare that the Project Report entitled “**Design And Fabrication Of Knee Simulator Testing Machine**” done by us under the guidance of **Dr.S.Sivasaravanan M.B.A., M.E., Ph.D.** is submitted in fulfillment of the requirements for the award of Bachelor of Engineering degree in Mechatronics.

1. 
2. 

**DATE:** \_\_\_\_ May 2023

**PLACE:** Chennai, Tamil Nadu

**SIGNATURE OF THE CANDIDATE`S**

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I Would like to express my sincere and deep sense of gratitude to my Project Guide Dr.S.Sivasaravanan M.B.A., M.E., Ph.D for his valuable guidance, suggestions and constant encouragement paved the way for the successful completion of my project work.

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## **ABSTRACT**

The Knee joint consists of a hinge type synovial joint. Over the past five years a greater number of primary knee replacements were performed and today, total knee replacement (TKR) is a successful procedure that offers pain relief to a lot of patients. However, failure of such implants is still a matter under investigation and wear is among the primary cause of this failures. It is well known that the knee is a complex system of tissues that provide mobility and support to the body. This joint allows the movement in both forward and backward directions while performing daily tasks. The compression forces because of these daily activities are 4 to 10 times the load of the human body. These moments and loads applied on the joint articulated tissue causes the pain in knees. It experiences different motion conditions and it is therefore subjected to multiple loads as a person walk, run, or does any other type of load-bearing activity. Drilling micro level holes (Dimples) on the surface of material like Titanium Alloy ( Ti6Al4V ) and to check the Wear and Tear of the material (textured and untextured) and compare the characteristics of the material to find the best suited material with less wear and tear.

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## LIST OF ABBREVIATIONS

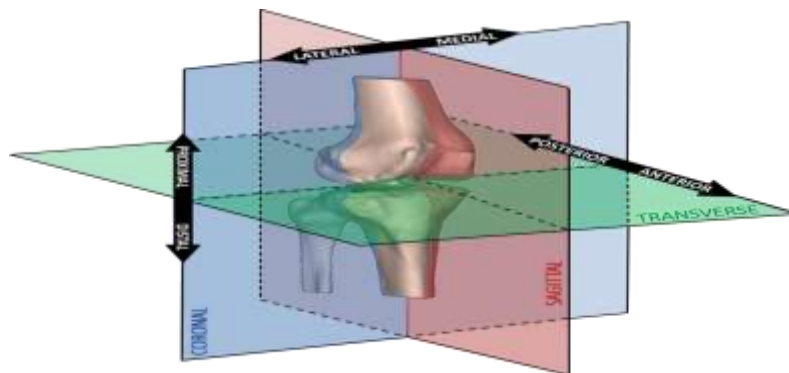
|     |                             |
|-----|-----------------------------|
| TKR | Total Knee Replacement      |
| ACL | Anterior Cruciate Ligament  |
| PCL | posterior cruciate ligament |
| MCL | medial collateral ligament  |
| LCL | lateral collateral ligament |
| ITB | Inner Thick Band            |
| PFJ | Patellofemoral joint        |
| MRI | magnetic resonance imaging  |
| AP  | anteroposterior             |
| ML  | mediolateral                |
| PD  | proximodistal               |
| FE  | flexion extension           |
| IE  | internal-external           |
| VV  | varus-valgus                |
| OA  | osteoarthritis              |

# CHAPTER I

## INTRODUCTION

### 1.1 INTRODUCTION

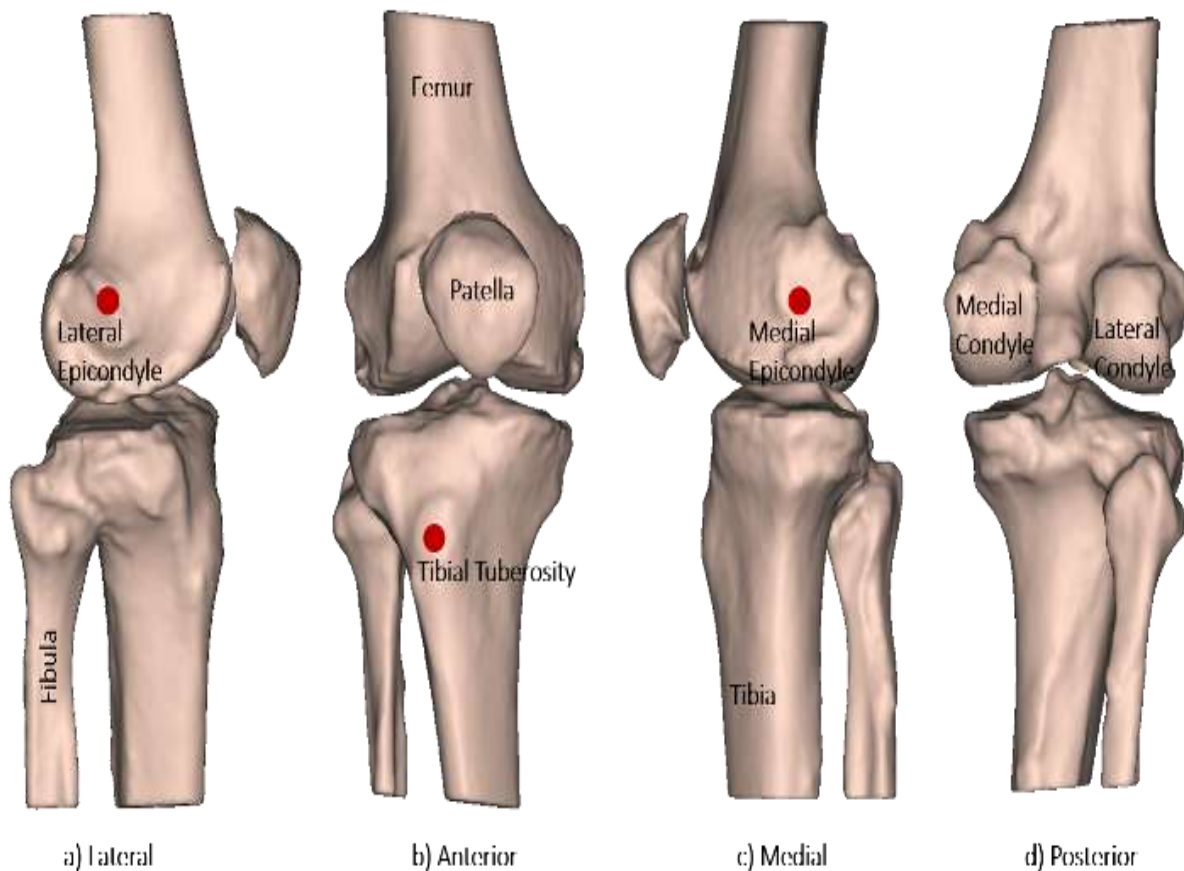
The tibiofemoral joint is the primary weight-bearing joint of the knee and is classified as a modified hinge joint, allowing for flexion and extension as well as a small degree of internal and external rotation. The femur has two rounded condyles that articulate with the tibial plateau, which is divided into two articular surfaces by an intercondylar eminence. The patellofemoral joint is a gliding joint formed by the articulation of the posterior aspect of the patella with the trochlear groove of the femur. The patella acts as a pulley to increase the leverage of the quadriceps muscle during knee extension. The superior tibiofibular joint is a plane joint that allows for a small amount of gliding movement between the lateral tibial condyle and the head of the fibula. The stability of the knee joint is maintained by a complex system of ligaments, muscles, and tendons. That's correct! The knee joint serves important functions in enabling human movement and transmitting forces between the foot and the rest of the body. The loading in the knee is largely due to the compressive forces created by the muscles around the joint, and this can lead to high forces being experienced during everyday activities like standing up from a chair. The smooth articulation of the joint surfaces is facilitated by hyaline cartilage and synovial fluid, which helps to reduce friction and enable smooth sliding and rolling of the surfaces over one another.



***Fig: 1.1 An illustration of the three main planes of the human body and anatomical terms of location using a right sided knee model as reference***

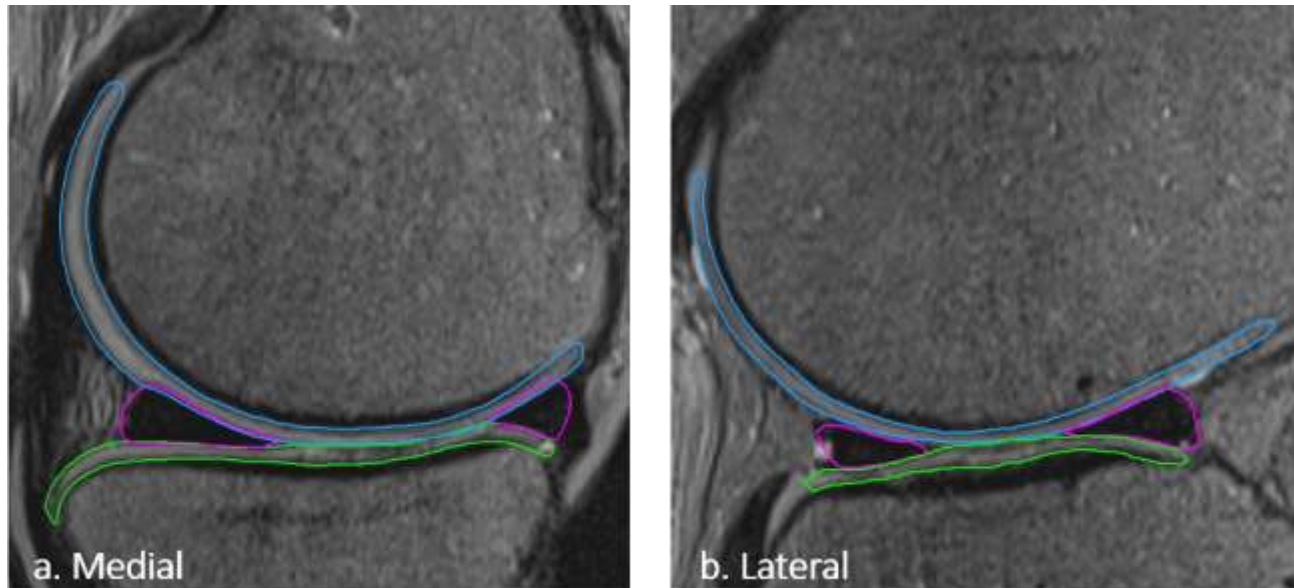
## 1.2 THE GEOMETRY OF THE ARTICULATING SURFACES IN THE TIBIOFEMORAL JOINT

To further elaborate on the tibiofemoral joint, the medial and lateral menisci also play an important role in load transmission and joint stability. These are crescent-shaped fibro cartilaginous structures that sit on the tibial plateau, deepening its articulating surface, and providing cushioning and shock absorption (Scott, 2011). The menisci also act as secondary stabilizers by improving the fit between the femoral condyles and the tibial plateau and help to distribute loads evenly across the joint. In addition, the joint is reinforced by a number of ligaments including the anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial collateral ligament (MCL) and lateral collateral ligament (LCL), which provide stability and prevent



**Fig: 1.2 An illustration of the bones of a right sided knee joint, shown from four different aspects**

excessive motion in various directions (Gray, 2008). The coordination of all these structures is crucial for the knee joint to function optimally during weight-bearing activities.



**Fig: 1.3 Sagittal slices of an MRI scan of a right sided cadaver knee.**

The femoral articular cartilage is outlined in blue, the menisci outlined in pink and the tibial articular cartilage is outlined in green. The difference in the articulating geometry between the concave medial and convex lateral sides can be clearly seen.

### 1.3 THE LIGAMENTS OF THE KNEE JOINT

The anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) are located within the knee joint and are responsible for providing stability to the joint by limiting the amount of anterior-posterior translation of the tibia relative to the femur. The ACL is particularly important in preventing the tibia from moving too far forward with respect to the femur, while the PCL prevents the tibia from moving too far backward. The MCL and LCL are located outside the knee joint and are responsible for providing stability to the knee in the medial-lateral plane. The ITB is a thick band of connective tissue that runs from the ilium to the lateral tibia and contributes to the lateral stability of the knee. The PMC and PLC are soft tissue structures located in the back of the knee that help to

stabilize the joint during rotational movements. The menisci are C-shaped pieces of fibrocartilage that sit on top of the tibia and provide shock absorption and load distribution within the knee joint. They are connected to the tibia and femur by various ligaments and are essential for proper joint function.

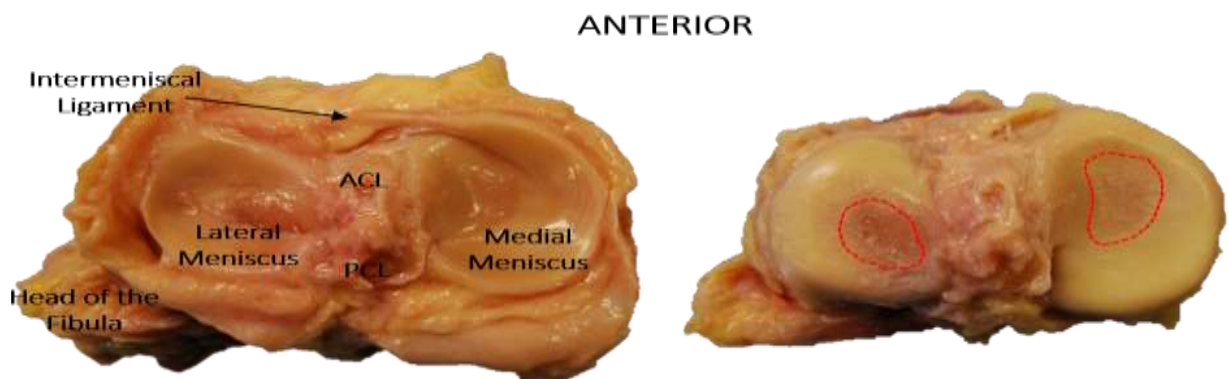
#### 1.4 THE BASICS

The menisci also play an important role in joint lubrication and nutrition. They have poor vascularisation and rely on diffusion for nutrient and waste exchange with the synovial fluid. In addition, they help to distribute the synovial fluid across the joint surfaces, providing lubrication and reducing friction between the femur and tibia during movement.

The menisci have a complex structure, consisting of a network of collagen fibres and proteoglycans. They are shaped like crescents, with the thicker outer edges firmly attached to the joint capsule and the thinner inner edges more mobile. The outer part of the meniscus is also more vascularised than the inner part, which makes it more able to heal in case of injury.

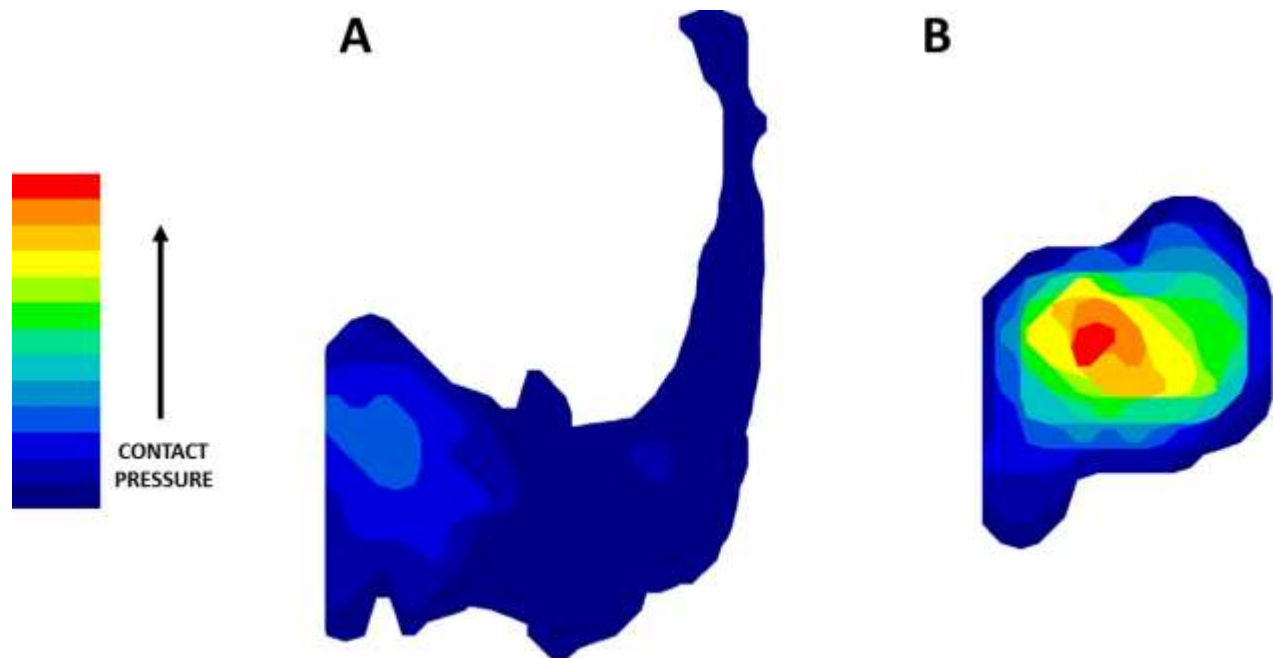
In summary, the menisci are important structures in the knee joint, providing stability, load distribution, joint lubrication, and nutrition. Damage or removal of the menisci can lead to altered joint loading and the potential development of OA.

translation and external rotation of the tibia at certain angles of flexion (Gupte et al., 2003



**Fig: 1.4 Photographs of a left sided tibial plateau of a 65 year old female with moderate patellofemoral (PFJ) OA and mild tibiofemoral OA.**

In the left hand image, the menisci are intact: the longer, “C” shaped medial meniscus is on the right, the smaller, more “c” shaped lateral meniscus on the left. In this image the intermeniscal ligament is also visible, as are the attachment points of the ACL and PCL. The right hand image shows the same tibial plateau with the menisci removed. Areas of cartilage damage where the menisci were not protecting the articular cartilage in the medial and lateral compartments are outlined by the red dotted lines.



***Fig: 1.5 Contact pressure maps using Tek scan of the medial tibiofemoral compartment of a cadaver knee at 60° flexion and 1000 N axial loading. Pressure maps with (A) an intact medial meniscus and (B) post- meniscectomy; the function that the meniscus is performing is clear.***

## 1.5 BIOMECHANICS OF THE KNEE

Additionally, the knee joint also relies on the dynamic stabilization provided by the surrounding muscles and their ability to generate joint torques in response to external loads or perturbations. The neuromuscular control of the knee joint is a complex process that involves the coordination of multiple muscles and the modulation of their activation patterns in response to changes in the joint kinematics and kinetics. The proprioceptive feedback from the joint and the muscles also plays an important role in maintaining the stability and the coordination of the knee joint. Therefore, a comprehensive understanding of the knee biomechanics requires an integrated approach that combines the knowledge of the anatomy, the mechanics, and the neuromuscular control of the joint.

Yes, that's correct. With advancements in imaging techniques such as magnetic resonance imaging (MRI) and computational methods such as finite element analysis, researchers were able to create more accurate 3D models of the knee joint, which helped in better understanding the complex motion of the joint. This led to a better understanding of how the ligaments, muscles, and other structures contribute to knee stability and function.

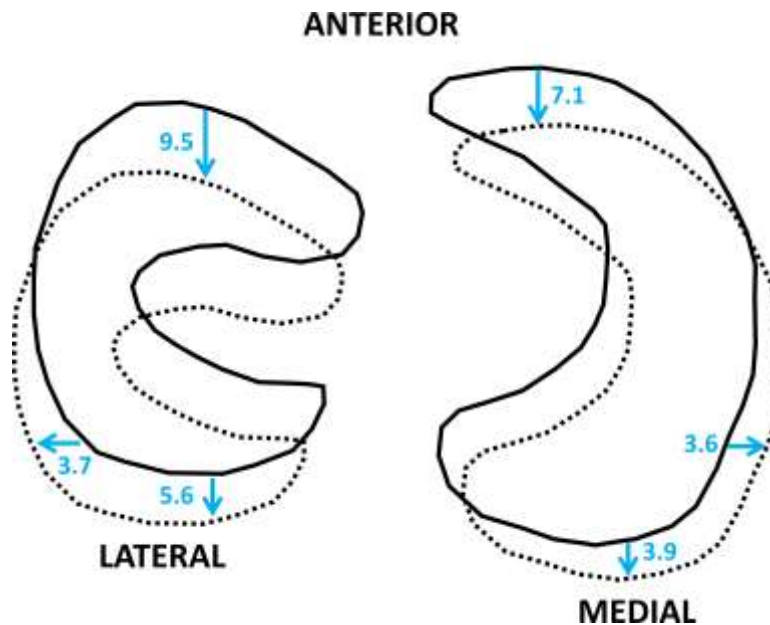
However, it is important to note that there is ongoing debate and research regarding the exact nature of knee joint motion during activities such as walking and squatting. While the medial rotation concept has gained acceptance in the field, some studies have suggested alternative mechanisms of knee motion, such as lateral rotation or combined rotational and translational motion (Li et al., 2013; Shelburne et al., 2013). Additionally, individual variations in knee anatomy and biomechanics may play a significant role in determining knee joint motion patterns. Further research is necessary to fully understand the complexities of knee joint motion and how it can be optimally restored in surgical interventions like total knee replacement.



***Fig: 1.6 An illustration of the six degrees of freedom of the tibiofemoral joint, looking towards the posterolateral corner of a right sided knee.***

There are three translational directions: anterior-posterior (anteroposterior; AP); medial-lateral (mediolateral; ML) and proximal-distal (proximodistal; PD). The main rotation is flexion and extension (FE) and the secondary rotations are internal-external (IE) and varus-valgus (VV). The soft tissues and patella are left out of this diagram for clarity.

It seems that the traditional understanding of knee motion as a combination of rolling and sliding in the sagittal plane has been challenged by more recent studies examining knee motion during essential activities of daily living such as walking, running, and ascending and descending stairs. These studies suggest that the centre of rotation of the knee is actually activity-dependent and may rotate around the lateral side of the knee for a majority of the stance phase during gait. Banks suggests that the knee rotates around the medial compartment during flexion and the lateral compartment during extension activities. This poses a challenge for designing TKRs that can restore "normal" knee motion, and may make the goal of achieving a "forgotten knee" an unachievable ambition.



**Fig: 1.7 The motion of the menisci during weight bearing knee flexion from full extension to 90° measured in patients using dynamic magnetic resonance imaging (MRI).**

The menisci move a similar amount in the peripheral direction but the lateral meniscus moves more in the AP direction. The diagram was made using data from Vedi et al. (1999). (Not to scale)

## 1.6 PATHOLOGY AND FAILURE

population per year, with the majority of injuries affecting the ligaments or menisci (Katz et al., 2013). Anterior cruciate ligament (ACL) injuries are one of the most common types of knee injury, with an estimated 200,000 ACL injuries occurring in the USA each year (Brophy et al., 2009). The incidence of knee osteoarthritis (OA) is also high, with an estimated 14 million people affected in the USA alone (CDC, 2020). Knee OA is a leading cause of disability, and its prevalence is expected to increase due to aging populations and rising obesity rates (Vos et al., 2012). Understanding the biomechanics of the knee joint can help clinicians and researchers develop better prevention and treatment strategies for knee injuries and diseases.

Knee osteoarthritis (OA) is another common condition affecting the knee joint. It is estimated that approximately 13.8% of adults aged 25 years or older have symptomatic knee OA, and this number increases with age (Lawrence et al., 2008). Knee OA is associated with pain, stiffness, and reduced mobility, and can lead to a decreased quality of life. In severe cases, total knee replacement surgery may be necessary to alleviate symptoms and improve function. The prevalence of knee replacement surgery has been increasing over the years, with approximately 1.2 million procedures performed in the United States alone in 2010 (Kurtz et al., 2014).

Yes, that is correct. The knee is a complex joint and any injury or disorder can lead to alterations in its biomechanics, which may ultimately increase the risk of developing knee osteoarthritis (OA) later in life. In particular, structural abnormalities such as trochlear dysplasia and joint misalignment can cause abnormal loading of the joint, leading to increased wear and tear on the articular cartilage. Knee hyperextension can also increase stresses on the anterior cruciate ligament (ACL) and the posterolateral corner of the knee, which can lead to further joint damage over time. Additionally, inadequate recruitment of certain muscle groups, such as the quadriceps, can result in reduced range of motion during walking gait and hamstring muscle overactivity, which can alter the joint mechanics and increase the risk of developing knee OA. Knee OA not only affects the physical health of individuals, but also their mental well-being and quality of life. Chronic pain, loss of mobility and independence, and social isolation due to limitations in daily activities are common consequences of the disease. The economic burden of knee OA is also significant, as it results in increased healthcare costs, loss of productivity, and decreased quality of life for both patients and their families. Therefore, prevention and effective management of knee OA are crucial for reducing the burden of this disease on individuals and society as a whole.

Indeed, knee biomechanics can play a significant role in the development of knee injuries and subsequent development of OA. Injury to the knee can result in alterations in knee biomechanics, leading to increased stresses and wear on the joint. This can ultimately result in the development of OA. In turn, the altered joint mechanics resulting from OA can further exacerbate the disease and lead to further joint degeneration.

Surgical treatments for knee injuries and OA, such as ligament reconstruction and knee replacement surgery, also have significant impacts on knee biomechanics. For example, knee replacement surgery involves the removal of damaged joint surfaces and the implantation of a prosthesis. This can result in changes to knee biomechanics and can sometimes lead to issues such as implant loosening or instability.

Therefore, understanding the complex relationship between knee biomechanics, injury, OA, and surgical treatment is critical for the development of effective treatment and prevention strategies for knee disorders.

Indeed, understanding the complex nature of knee biomechanics and its relationship with OA is crucial for developing effective prevention and treatment strategies. Early diagnosis and intervention are key to preventing OA from progressing and causing further damage to the joint. Treatment options may include lifestyle modifications, such as weight loss and exercise, as well as medications, physical therapy, and surgical interventions, depending on the severity of the disease. Further research is needed to identify new targets for treatment and to develop personalized approaches based on individual patient characteristics and disease progression.

## 1.7 TREATMENT OPTIONS, TECHNIQUES AND LIMITATIONS

### 1.7.1 Non-surgical interventions

Therefore, non-surgical options such as physiotherapy and bracing may be more appropriate for some patients. In addition, conservative measures such as weight loss and physical therapy can also be effective in managing knee OA symptoms and slowing the progression of the disease (NICE, 2014). Ultimately, the decision of whether to pursue non-surgical or surgical treatment options will depend on the individual patient's symptoms, the severity of their condition, and their preferences and goals. There is still a lack of evidence to support systematic surgical intervention; in some studies the incidence of OA does not differ between the surgically treated patients and the non-surgically treated ones in the long-term (Tsoukas et al., 2015; Delincé and Ghafil, 2012). This may be due to the inadequacies in current ACL reconstruction techniques, the fact that a reduction in laxity in one direction (in the case of the ACL, the AP direction) does not necessarily mean

that the knee is restabilised, or the fact that concomitant injuries, such as meniscal tears, are often left unrepaired during ACL reconstruction procedures. In addition to exercise, other non-surgical treatment options for knee OA include weight loss, physical therapy, use of assistive devices such as knee braces or canes, and pharmacological interventions such as nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, or hyaluronic acid injections (NICE, 2014). However, it is important to note that these treatments may only provide temporary relief and do not halt the progression of the disease. In cases where non-surgical interventions are not effective, surgical options may be considered. These can include arthroscopy, osteotomy, or joint replacement surgery. Arthroscopy involves the use of a small camera to visualize the inside of the knee joint and remove damaged tissue or debris, while osteotomy involves cutting and repositioning the bones in the knee to redistribute weight-bearing forces. Joint replacement surgery involves replacing the damaged joint with an artificial one. The choice of surgical intervention will depend on the severity and location of the knee pathology, as well as the patient's age, overall health, and lifestyle.

#### 1.7.2 Ligament reconstruction and meniscus repair

Correct, surgical repair of knee ligament injuries is often necessary for serious athletes who need to return to sports quickly. Ligaments play an important role in knee stability and can become stretched or torn due to trauma or overuse. ACL reconstruction is the most common ligament reconstruction surgery in the knee because it is a primary stabilizer of the joint and is frequently injured in athletes. The surgical procedure can involve using autografts (such as tendons from the patient's own body) or allografts (from a donor), and can be performed using different techniques and tunnel positions. Double bundle reconstruction is a newer technique that involves reconstructing both the anteromedial and posterolateral bundles of the ACL, potentially improving the function and stability of the reconstructed knee.

Indeed, the ideal ACL reconstruction technique has yet to be developed. Although current techniques can help restore knee stability, they often do not completely restore pre-injury knee biomechanics, which may lead to further complications in the future. In addition, several factors can influence the success of the procedure, such as the patient's age,

level of activity, graft choice, and surgical technique. Therefore, rehabilitation following surgery is crucial to minimize the risk of further injury and to improve the long-term outcomes of the procedure.

treated with conservative management, such as physical therapy and pain management, before considering surgery. However, when surgery is necessary, efforts should be made to preserve as much of the meniscus as possible to prevent further joint degeneration. The choice of treatment will depend on the type and extent of the meniscal tear, as well as the patient's age, activity level, and overall health status. A surgeon will evaluate each case on an individual basis to determine the best course of treatment.

That's correct. While meniscal surgery has been shown to be effective in improving symptoms in the short-term, the long-term benefits and risks, particularly in relation to the development of OA and the need for knee arthroplasty, are still not well understood. Further research is needed to determine the most effective treatment strategies for meniscal injuries and to minimize the risk of OA development.

### 1.7.3 Joint realignment

That is correct. Patient-specific cutting guides and 3D printed fixation plates are becoming more popular in the field of high tibial osteotomy. These technologies allow for more accurate placement of the osteotomy and better alignment of the leg, which can improve outcomes and reduce the risk of complications. In addition, computerized planning tools can help surgeons determine the optimal location and size of the osteotomy, as well as the appropriate degree of correction needed to achieve the desired alignment. This personalized approach to surgery is a promising development in the treatment of knee osteoarthritis.

Correct alignment of the lower limb is crucial for optimal knee joint function and prevention of OA. However, it is important to differentiate between different types of misalignments. A misaligned knee joint occurs when the tibia and femur do not articulate in a straight line, and the joint line is not parallel to the ground. An oblique joint line occurs when the knee joint line is diagonal to the ground, resulting in an inclination angle of the tibial plateau. In contrast, the entire lower limb being in varus or valgus refers to the alignment of the entire

leg from the hip to the ankle. Understanding these differences is important when planning for an osteotomy procedure.

Advancements in technology have allowed for more methodical and precise osteotomy procedures. Patient-specific cutting guides and 3D printed fixation plates can be used to create an individualized plan for each patient, resulting in better outcomes and fewer complications

#### 1.7.4 Arthroplasty

Patellofemoral joint replacement (PFJR) is a less commonly performed procedure, which replaces the joint between the patella and the femur, often used in cases of isolated patellofemoral OA. PFJR can be performed as a partial or total replacement and can involve different implant materials and designs, such as all-polyethylene, metal-backed or mobile-bearing implants. PFJR has shown good short to mid-term outcomes in terms of pain relief and function improvement (Sisto and Sarin, 2015). Total knee replacement (TKR) is the most common knee arthroplasty procedure, and involves replacing all three compartments of the knee joint. The implant components can be made of metal, ceramic or polyethylene, and can be fixed to the bone with or without bone cement. TKR provides excellent pain relief and functional improvement, but may result in some loss of proprioception, muscle strength and range of motion, particularly in more active patients (Hofmann et al., 2012). The decision to perform a specific type of knee arthroplasty depends on various factors such as the extent and location of the knee joint damage, the patient's age, weight and activity level, and the surgeon's experience and preference. In general, knee arthroplasty is a safe and effective option for patients with end-stage knee OA, with high success rates and low complication rates (Baker et al., 2013).

Correct, a total knee replacement (TKR) replaces all three compartments of the knee joint with metal and plastic components. The femoral component typically replaces the entire distal femur and includes a groove to articulate with the patella. The tibial component replaces the top surface of the tibia and often includes a stem that extends down the tibia to provide additional stability. The plastic component, or polyethylene insert, sits between

the femoral and tibial components and provides a smooth gliding surface. TKR is a more invasive procedure than UKR or PFJR, but can provide excellent pain relief and restoration of function in patients with severe knee OA.

## **CHAPTER 2**

### **LITERATURE SURVEY**

Andrew Duster et al (2009), studied a dynamic knee simulator was developed to simulate knee motions during many daily activities. The simulator can be placed in a vertical position to simulate deep squat and in a horizontal position to simulate rowing. This unique feature provides this simulator with a great potential, proving itself as a valid testing apparatus that will be used in future research efforts to determine the three-dimensional response of the knee joint in deep flexion.

Angela K. Lange et al (2008), Resistance training improved muscle strength and self-reported measures of pain and physical function in over 50–75% of this cohort; 50–100% of the studies reported a significant improvement in all but 1 performance-based physical function measure (walk time). The effects of resistance training on health-related quality of life and depression are yet to be confirmed. More research needs to be conducted to establish dose-response relationships and the effect of resistance training on long-term disability, disease pathology, and progression. A comprehensive systematic database search for randomized controlled trials was performed. Two reviewers independently assessed studies for potential inclusion. Study quality indicators, arthritis symptoms, muscle strength, functional performance, and psychological outcomes were extracted. The relative effect sizes (ES) were calculated with 95% confidence intervals.

Angus M, et al (2010), this article presents a case of using spinal cord stimulation in the management of chronic knee pain following total knee replacement. The patient reported improvement in her pain and function. Her baseline OKS was 39 and fell to 26 one-year post implantation of an SCS representing a reduction of pain and disability from severe to moderate. Chronic pain after total knee replacement is common but remains poorly understood. Management options for patients with this condition are traditionally limited to pharmacological approaches.

Cervero Pochades' et al (2022), The combination of two purely sensitive blockages (saphenous and IPACK block) allows adequate analgesic control without motor blockade, ideal for ambulatory surgery. This could be the basis of future protocols for ambulatory knee arthroscopy.

Daryl Lawson et al (2021), the results provided evidence of immediate pain relief in individuals with mild-to-moderate knee OA when TENS is applied along with functional activities, that usually induced pain in people with knee OA. The use of transcutaneous electrical nerve stimulation (TENS) in pain management is still unclear. In this study, the analgesic effects of TENS in people with knee osteoarthritis (OA) were found effective when applied along with functional activities. Therefore, study findings provided clinical evidence for the use of TENS during functional activities as a conservative approach to reduce knee OA pain.

Gaurav Chauhan et al (2023), studied the number of joint replacement surgeries, especially knee replacement surgeries, is rising with the rising geriatric population. Chronic unremitting knee pain post-total knee replacement surgery is a common phenomenon. Usually, the pain responds to conservative measures, including physical therapy and medical management. In some patients, the pain post-knee replacement surgery can be refractory and unremitting. In such scenarios, peripheral nerve stimulation, or neuromodulator, can be an effective option.

Jane O'Brien et al (2018), This study seeks to address a significant gap in current osteoarthritis management practice by providing evidence for the effectiveness of an exercise programme combined with behaviour counselling for adults waiting for hip and knee arthroplasty. Theory-driven evidence-based strategies that can improve an individual's exercise self-efficacy and self-management capacity could have a significant impact on the development of secondary chronic disease in this population. Information gained from this study will contribute to the evidence base on the management of adults waiting for hip and knee arthroplasty.

Jul. et al (2013), Optimal exercise programs for knee OA should have one aim and focus on improving aerobic capacity, quadriceps muscle strength, or lower extremity performance. For best results, the program should be supervised and carried out 3 times a week. Such programs have a similar effect regardless of patient characteristics, including radiographic severity and baseline pain. Forty-eight trials were included. Similar effects in reducing pain were found for aerobic, resistance, and performance exercise (SMD 0.67, 0.62, and 0.48, respectively;  $P = 0.733$ ). These single-type exercise programs were more efficacious than programs that included different exercise types (SMD 0.61 versus 0.16;  $P < 0.001$ ). The effect of aerobic exercise on pain relief increased with an increased number of supervised sessions (slope 0.022 [95% confidence interval 0.002, 0.043]). More pain reduction occurred with quadriceps-specific exercise than with lower limb exercise (SMD 0.85 versus 0.39;  $P = 0.005$ ) and when supervised exercise was performed at least 3 times a week (SMD 0.68 versus 0.41;  $P = 0.017$ ). No impact of intensity, duration of individual sessions, or patient characteristics was found. Similar results were found for the effect on patient-reported disability.

Marlene Franssen et al (2015), High-quality evidence indicates that land-based therapeutic exercise provides short-term benefit that is sustained for at least two to six months after cessation of formal treatment in terms of reduced knee pain, and moderate-quality evidence shows improvement in physical function among people with knee OA. The magnitude of the treatment effect would be considered moderate (immediate) to small (two to six months) but comparable with estimates reported for non-steroidal anti-inflammatory drugs. Confidence intervals around demonstrated pooled results for pain reduction and improvement in physical function do not exclude a minimal clinically important treatment effect. Since the participants in most trials were aware of their treatment, this may have contributed to their improvement. Despite the lack of blinding we did not downgrade the quality of evidence for risk of performance or detection bias. This reflects our belief that further research in this area is unlikely to change the findings of our review.

Min Li et al (2017), Functional electrical stimulation (FES) has shown great potential in helping patients to achieve their joint movements. Since muscle system exists non-linear, time-varying and external disturbances, conventional controllers are difficult to achieve the precise control. In order to improve the accuracy of FES for knee joint movement, in this paper, a RBF neural network based sliding mode control method is designed. An electrical stimulation model of knee joint is first established, the nonlinear performance of RBF neural network is used to approximate the lower limb joint model uncertainties and external disturbances. To determine the width of hidden layer units and the architecture of the neural network, genetic algorithm is introduced to optimize the network structure parameters. Experimental results show that neural network sliding mode control based on genetic algorithm can accurately control the electrical stimulation to obtain the desired joint motion, and can be effectively compensated in the case of external disturbances.

Raymond J Walls et al (2010), This pilot study assessed the compliance of a home-based, NMES rehabilitation programme in patients undergoing total knee arthroplasty (TKA). We evaluated its effect on preoperative and postoperative isometric quadriceps femoris muscle (QFM) strength, QFM cross-sectional area (CSA) and clinical function (subjective and objective). Seventeen subjects were recruited with 14 completing the study (NMES group  $n = 9$ ; Control group  $n = 5$ ). Overall compliance with the programme was excellent (99%). Preoperative QFM strength increased by 28% ( $p > 0.05$ ) with associated gains in walk, stair-climb and chair-rise times ( $p < 0.05$ ). Early postoperative strength loss (approximately 50%) was similar in both groups. Only the NMES group demonstrated significant strength (53.3%,  $p = 0.011$ ) and functional recovery ( $p < 0.05$ ) from 6 to 12 weeks post-TKA. QFM CSA decreased by 4% in the NMES group compared to a reduction of 12% in the control group ( $P > 0.05$ ) at 12 weeks postoperatively compared to baseline. There were only limited associations found between objective and subjective functional outcome instruments.

Shea Palmer et al (2013), The study was a randomized, sham-controlled clinical trial. Patients referred for physiotherapy with suspected knee OA (confirmed using the American College of Rheumatology clinical criteria) were invited. Exclusion criteria included comorbidities preventing exercise, previous TENS experience, and TENS contraindications. Prospective sample size calculations required 67 participants in each trial arm. A total of 224 participants (mean age 61 years, 37% men) were randomized to 3 arms: TENS and knee group (n = 73), sham TENS and knee group (n = 74), and knee group (n = 77). All patients entered an evidence-based 6-week group education and exercise program (knee group). Active TENS produced a “strong but comfortable” paraesthesia within the painful area and was used as much as needed during the 6-week period. Sham TENS used dummy devices with no electrical output. Blinded assessment took place at baseline and 3, 6, 12, and 24 weeks. The primary outcome was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) function subscale at 6 weeks. Secondary outcomes included WOMAC pain, stiffness, and total scores; extensor muscle torque; global assessment of change; exercise adherence; and exercise self-efficacy. Data analysis was by intent to treat.

Terranova. G et al (2022), this novel wireless neuro stimulator proved effective in controlling a chronic knee pain, improving person’s quality of life. The absence of a required subcutaneous unit is a clear advantage for the managing of this device, especially in the outpatient setting. However, it needs to be implanted by expert operators and requires a careful follow-up.

Valerie J. Williams, et al (2012). To compare the reliability and responsiveness of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Knee Outcome Survey activities of daily living subscale (KOS-ADL), and the Lower Extremity Functional Scale (LEFS) in individuals with knee osteoarthritis (OA). All 3 outcome measures demonstrated reasonable reliability and responsiveness to change. Reliability and responsiveness tended to decrease somewhat with increasing follow-up time. There were no substantial differences between outcome measures for reliability or any of the 3 measures of responsiveness at any follow-up time. The results do not indicate that one outcome measure is more reliable or responsive than another when applied to subjects

with knee OA. We believe that all 3 instruments are appropriate outcome measures to examine change in functional status of patients with knee OA.

Wei-Ju Chang et al (2017), This study had several limitations. First, by design the study included a small sample size that was not intended to provide sufficient power to definitively determine the efficacy of adding tDCS to exercise treatment for knee OA. Therefore, the results must be interpreted with caution. Second, the short follow-up period in this study may have been too brief to determine between-group differences. A larger clinical trial with longer follow-up periods is required. Third, we did not record any changes in the participants' medication (type and dosage) during this trial. The dosage of the participants' usual medication was only recorded at the baseline. Future trials should record any changes in participants' use of medication during the trial to evaluate the relationship between pain and the use of medication. Finally, the treating physiotherapists delivered both the tDCS and exercise treatment, and were not blind to group allocation. However, our exercise protocol was well established with clear instructions for how to progress each exercise and the treating therapists were instructed to strictly adhere to the protocol to minimise any potential bias. Future trials should seek to blind the treating therapists to the tDCS condition.

## **CHAPTER 3**

### **AIM AND SCOPE OF THE PROJECT**

#### **3.1 AIM**

Examining the biomechanics of the replaced knee to gain a better understanding of how TKR devices interact with the remaining soft tissue structures in the knee joint.

Investigating laboratory-based pre-clinical assessment options for knee replacements to improve the testing methods and ensure the safety and effectiveness of new devices before they are implanted in living patients.

Comparing different TKR designs in the pre-clinical setting to identify design differences that contribute to improved knee biomechanics and patient outcomes.

Informing better test methods to provide more accurate and comprehensive assessments of TKR devices, ultimately leading to the development of more effective and safe devices.

Suggesting improved or different implant solutions based on the findings from the study to improve the design and functionality of TKR devices. Overall, the research aims of this thesis seek to advance the understanding of TKR devices and improve the pre-clinical testing and design of these devices to enhance patient outcomes and quality of life

#### **3.2 SCOPE OF THE PROJECT**

The thesis described in this passage aims to investigate the functional inadequacies of total knee replacement (TKR) devices and how they can be improved through pre-clinical testing. TKR is a successful treatment for severe osteoarthritis of the knee, but some patients remain dissatisfied despite pain relief. The dissatisfaction is believed to be due to a combination of factors, including the design of the TKR, removal of one or both cruciate ligaments, and alteration of other soft tissues in the knee joint. There have been many designs of TKR over the years, reflecting attempts to solve these problems and improve patient satisfaction. Pre-clinical testing of new devices can help in understanding functional inadequacies and aid in developing better designs. The thesis aims to investigate whether design differences between TKRs contribute to improved knee biomechanics and how this can be assessed in the pre-clinical setting.

## **CHAPTER 4**

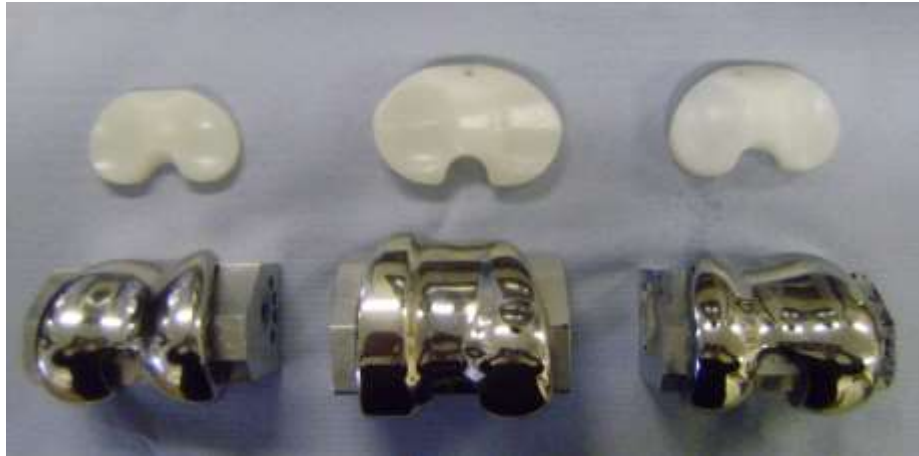
### **MATERIALS AND METHODS**

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

#### **4.1 AP TESTING RIG**

A previously designed and constructed test rig, which could accommodate the femoral and tibial components of a TKR was used for testing (Figure 4.1). This rig fixed the flexion angle, AP, ML and IE position of the femoral component but allowed it to freely rotate in VV and translate proximodistal. The tibial component was constrained in flexion/extension, VV rotation and proximodistal translation, but free to rotate in IE and translate in ML, while the AP translations were imposed on the component. Therefore, all 6 DOF of the knee were present and, except for flexion, unconstrained during testing.

The femoral component was mounted using polymethylmethacrylate (PMMA) bone cement onto an aluminum alloy cross-bar, shaped to match the component's internal geometry, similar to the shape of the distal femur as prepared during surgery (Figure 4.1). The flexion angle could be adjusted by rotating and then fixing the cross-bar into position. This rotation occurred around an axis parallel to the distal most aspect of the condyles, which was perpendicular to the line of action of the axial compressive force so this force was always acting along the same line in the sagittal plane. A pivoting frame was used so that the femoral component was free to rotate in varus-valgus, about an anterior-posterior axis at the level of the flexion axis, not far from the joint line. In previously used testing rigs in other studies, this VV rotation axis had been situated high above the joint line which is not physiologically accurate.

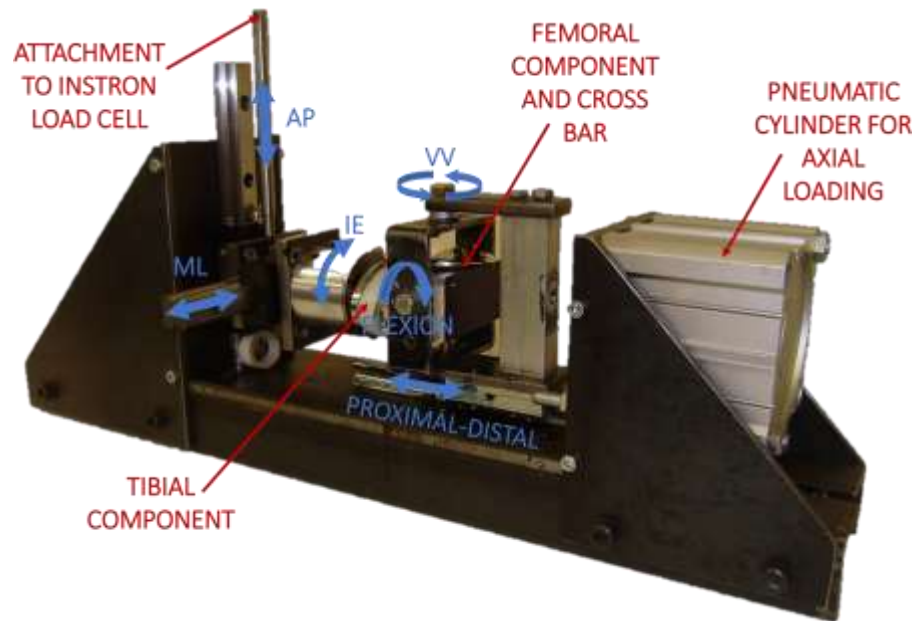


**Fig: 4.1 Three Mat Ortho TKRs ready for testing. From left to right: mobile-bearing Saiph; MRK; fixed-bearing Saiph.**

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

The tibial components were mounted onto the end of a freely-rotating shaft, which allowed internal-external rotation. A wedge could be placed in between the tibial tray and the shaft in order to adjust the amount of posterior slope if required by the TKR operational technique. This assembly was mounted onto a linear bearing which allowed free medial-lateral translation in the horizontal plane. In turn, this whole tibial assembly was then mounted onto another linear bearing, which allowed anterior-posterior

translation (a vertical motion in the experimental set-up). The tibial assembly was attached directly to the load cell of a single-axis Instron 5565 MTM which provided the AP motion and measured the force (N) required to translate the tibial component (mm).



**Fig: 4.2 AP translational stability testing rig.**



**Fig: 4.3 Rotational stability testing rig.**

#### **4.2 ML TRANSLATION RIG**

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

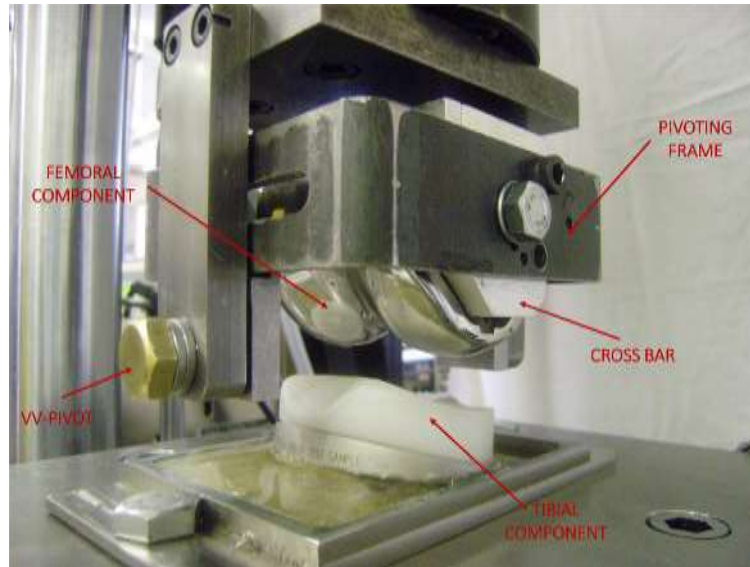
#### **4.3 IE ROTATION RIG**

The tibial component was cemented into a shallow mounting on a low friction bearing X-Y translation table which prevented rotations and was bolted to the base of the servohydraulic dual-axis tension-torsion Instron (8874) (Figure 4.3). An aluminium alloy wedge could again be placed below the tibial tray to adjust the posterior slope (Figure

4.4). The femoral component was mounted using a similar cross-bar and VV pivot frame as in the translation tests, allowing free varus-valgus rotation about an anterior-posterior axis at the level of the joint line, but this was now mounted onto the end of the Instron load cell (Figure 4.4). The Instron imposed internal external rotation to the femoral component at the desired axial compressive force and angle of flexion, while the tibial component was able to translate in both AP and ML via the X-Y table and rotate in VV (Figure 4.3). The Instron measured the torque (Nm) and rotation ( $^{\circ}$ ) of the femoral component. With the Instron programmed to maintain a constant compressive joint force, the hydraulic crosshead lifted the femoral component to allow it to “climb” out of the concavities of the tibial bearing surfaces as required during the testing, in a similar way to the pneumatic cylinder in the AP stability tests.

#### **4.4 TRANSLATIONAL STABILITY TEST METHOD**

The crossbar with the femoral component mounted onto it was fixed inside the pivoting frame at the desired flexion angle and then translated to the required M:L position for the loading distribution of interest. The vertical position of the tibial component was adjusted until an approximate “neutral” position of the TKR was found and the load cell was balanced, to neutralize the weight of the tibial assembly. The more precise neutral position was then found by applying a 350 N axially compressive load and applying small AP/ML translations to the tibia ( $\pm 2$  mm for 5 cycles). The neutral position was then defined as the position where the hysteresis loop of the force versus displacement graph was symmetrical about the zero load axis (Figure 4.5). Once the components were in the precise neutral position, the axial load was then increased to the required level, and the AP/ML limits were found by translating the tibial component gradually until the force-displacement graph started to plateau,



**Fig: 4.4 A close image of the rotational stability testing rig.**

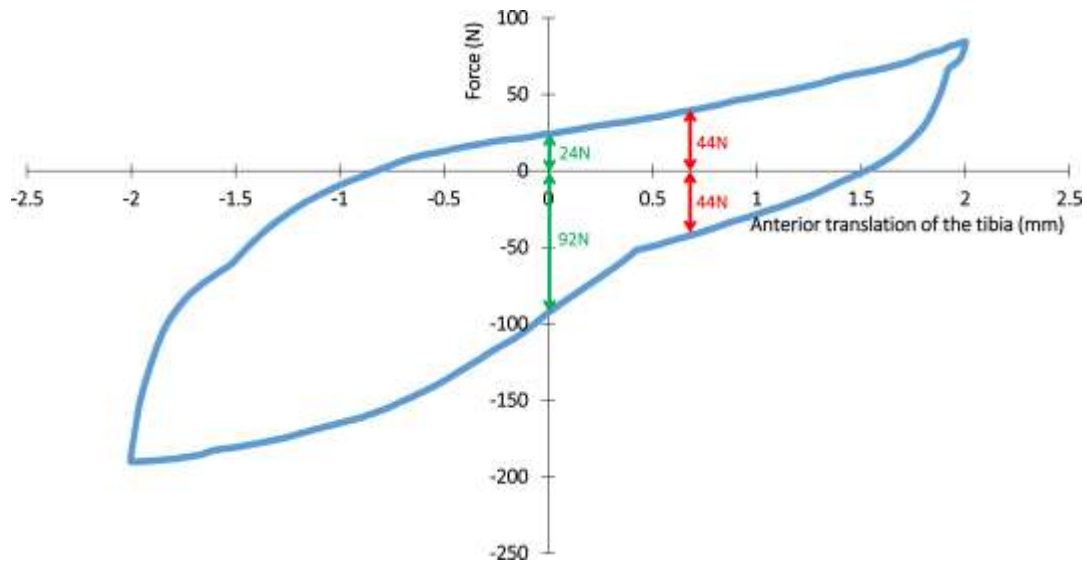
first in the anterior/medial direction (the posterior/lateral limit of the UHMWPE bearing) and then in the posterior/lateral direction (the anterior/medial limit of the bearing). ASTM stipulates that the translation and rotation limits are defined as the point at which subluxation of the device is imminent. However, the plateau point was chosen instead in order to avoid any permanent deformation of the edge of the UHMWPE bearing caused by the components subluxing, which would have affected the results of future tests using the same implant. These displacement limits in both directions were recorded, the TKR was returned to the neutral position, lubricated with water, reloaded axially and cycled between the limits. Three “pre conditioning” cycles were completed and data were collected on the fourth cycle (Figure 4.6).

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

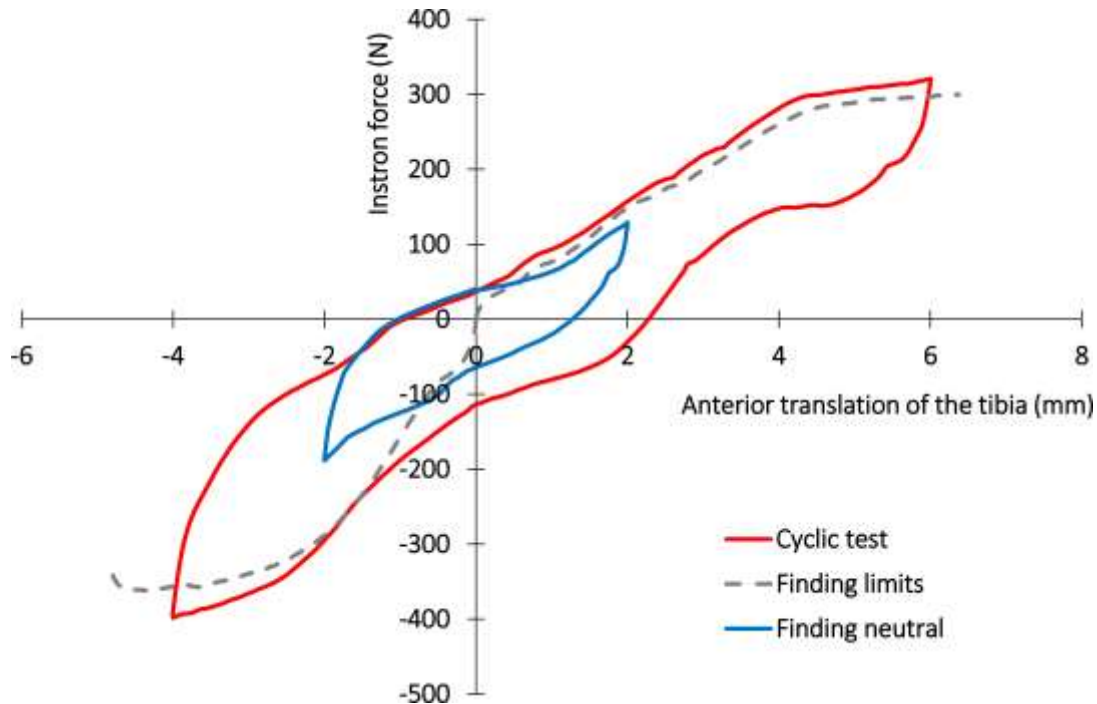
#### **4.5 ROTATIONAL STABILITY TEST METHOD**

The method for the IE stability testing was very similar to the AP testing. With the components mounted in the rig, the axial load was increased to 350 N via the Instron and the neutral point found. Then the internal and external rotational limits were found by

rotating the femur until the torque- rotation curve started to plateau, or when 25° from the neutral rotation was reached, whichever occurred sooner. The components were then cycled between those limits. Again, each test was repeated for different flexion angles, axial loads and M:L loading distributions.



**Fig: 4.5 A graph showing the neutral point locating method for AP stability testing. The graph shows that the approximate neutral position (indicated by the green arrows at 0 mm translation) was around 0.7 mm posterior of the precise neutral position (shown by the red arrows).**



**Fig: 4.6** A graph showing the 3 stages of stability testing of TKRs. 1) Finding the neutral relative position of the femoral and tibial components. 2) Finding the anterior and posterior (or internal and external for rotational stability testing) limits. 3) The final cyclic stability test between the previously found limits.

#### 4.6 IMPLANTS

Three TKRs were tested using the AP, ML and IE stability testing protocols. The Medial Rotation Knee (MRK) which has been in clinical use for over ten years and a fixed and mobile bearing version of a new device, the Saiph Knee (all 3 are manufactured by MatOrtho, Leatherhead, UK). These devices are medial-sphere, highly congruent condylar stabilised (CS) type TKRs, with asymmetrical condylar geometry (Figure 4.7). The mobile bearing version of the Saiph has the same femoral component as the fixed bearing device but has a more conforming lateral compartment on the UHMWPE bearing and is able to rotate 15° internally and externally around a post on the polished tibial tray without any translation (Figure 4.7). In addition to these devices, the AP stability of the Stryker Triathlon (Stryker Ltd., Kalamazoo, MI, USA) was measured using the same rig at a range of compressive loads and M:L loading distributions. The Triathlon

is a conventionally designed, PCL-retaining, single-radius TKR with symmetrical condylar geometry. These results, as well as data from the literature, will be used to contextualize the stability results from the medial pivot devices.



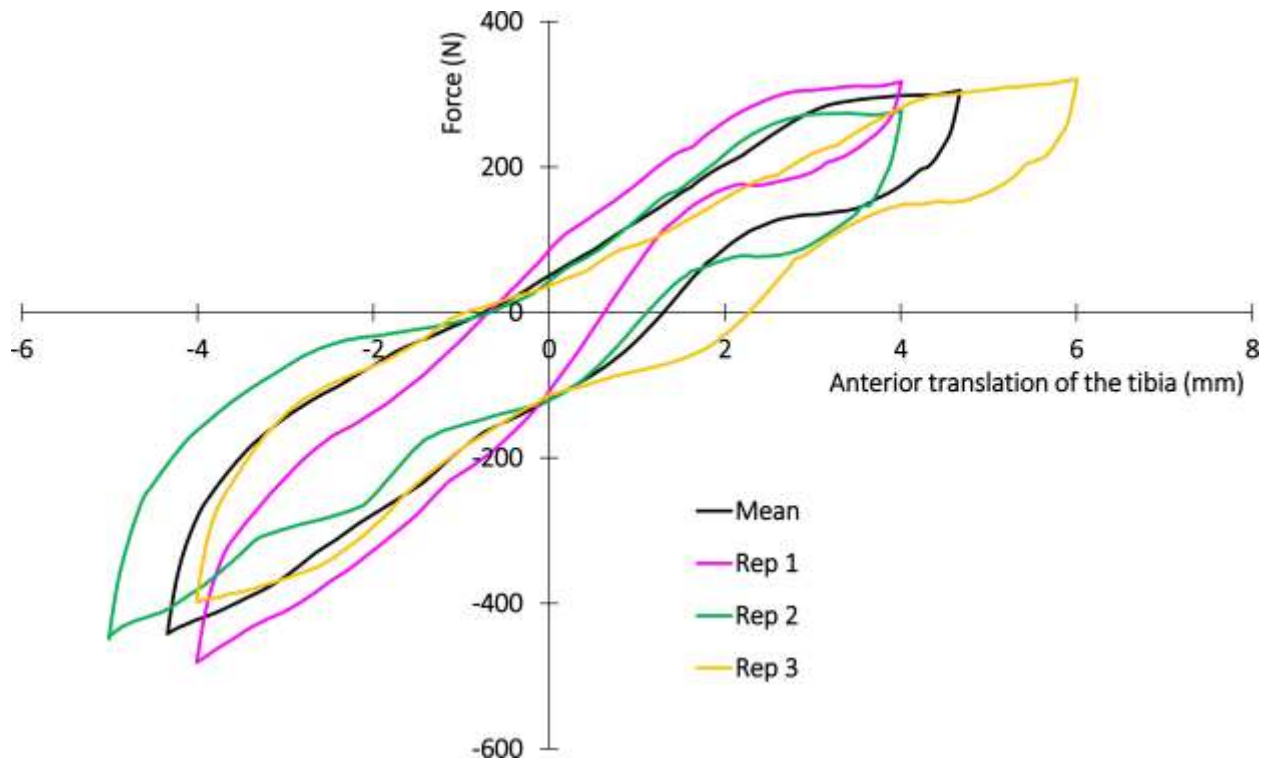
***Fig: 4.7 The mobile bearing version of the Saiph Knee. Top left: the polished tibial tray with post. Top right: the backside of the UHMWPE tibial bearing with the rotation slot visible in its centre. Bottom: a right-sided bearing in place on top of the symmetrical tibial tray at the internal (left), neutral (centre) and external (right) limits of its rotation.***

## CHAPTER 5

### RESULTS AND DISCUSSION

#### 5.1 COMPARISON BETWEEN SAMPLES

Three samples of the Saiph knees from the same manufacturing batch were tested, in order to assess repeatability of results between supposedly identical devices. An example is shown in Figure 5.1, where the implants show good agreement between one another. This repeatability was consistent across the various tests, despite the inherent variability in implant cementing, Medio lateral alignment and the subjective nature of defining the imminent subluxation point.

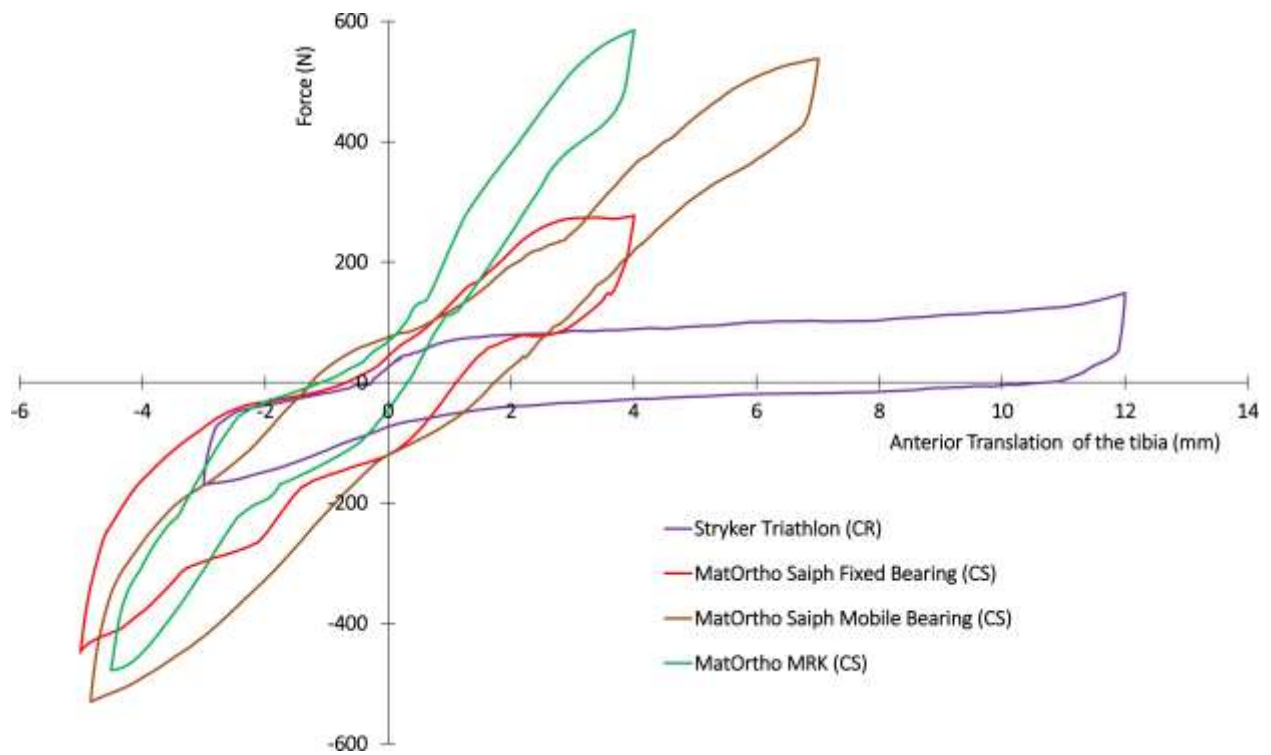


**Fig: 5.1 AP stability of three samples of the Saiph fixed bearing knee at 0° flexion and 50:50 M:L.**

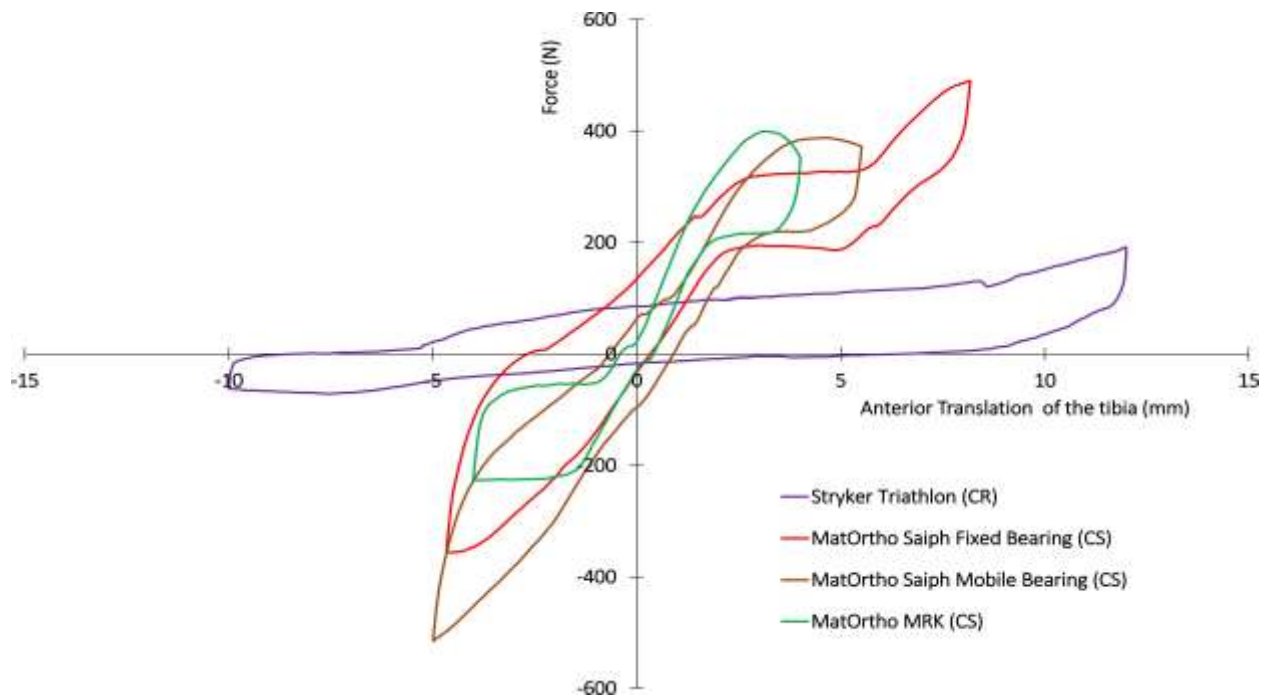
## 5.2 AP STABILITY AND COUPLED TIBIAL ROTATION

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

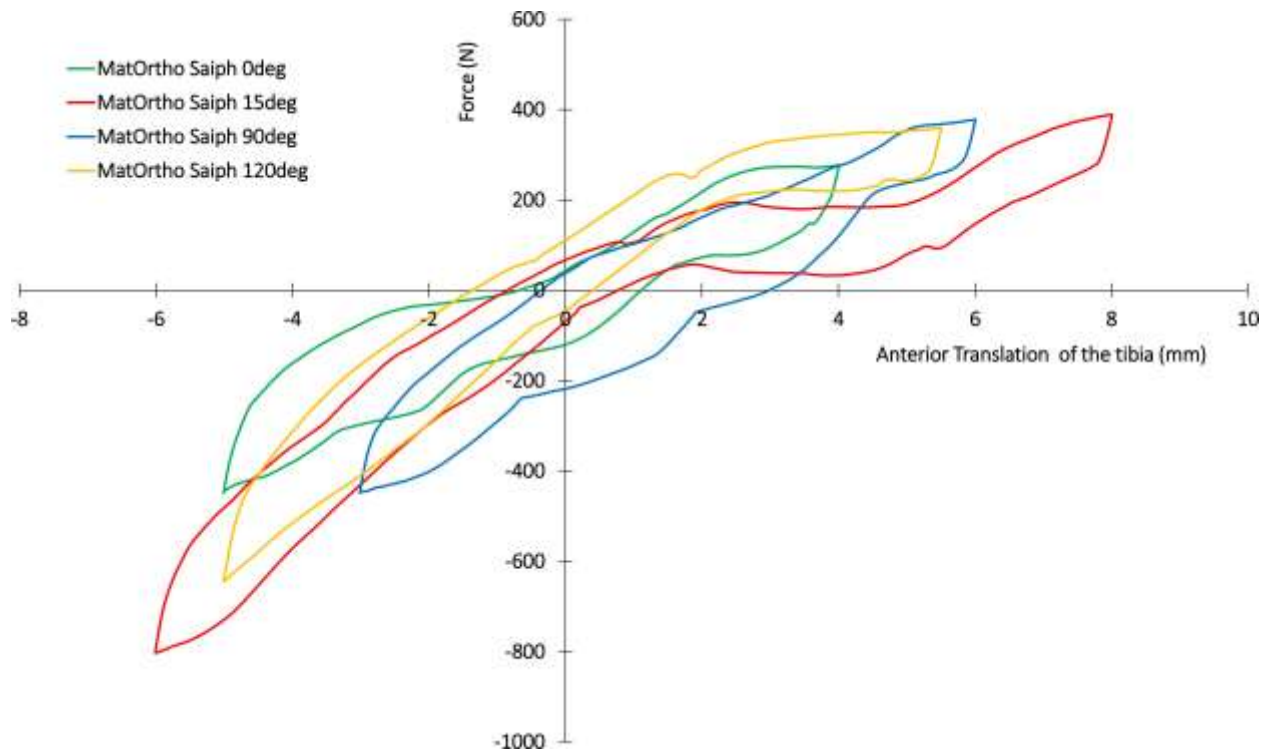
At full extension and 50:50 M:L loading distribution, total AP translation between the instability limits ranged from 8.5 mm with the MRK to 15 mm with the Triathlon. At 90° flexion, the MRK and Saiph again showed similar stability characteristics to each other, while the Triathlon allowed a larger range of AP translation, 22 mm, largely in the anterior drawer direction. In all three cases, changing the M:L loading distribution to 60:40 had only a small effect on the AP stability characteristics, although the total AP translation did increase for both the MRK and fixed bearing Saiph devices, particularly at 90° flexion (Figure 5.2). This increase in total translation that could take place before subluxation appeared to be due to increased coupled tibial rotation that was observed during this test.



**Fig: 5.2 AP stability at 0°flexion and 50:50 M:L loading for 4 different TKRs.**



**Fig: 5.3 AP stability at 90°flexion and 60:40 M:L loading for 4 different TKRs.**

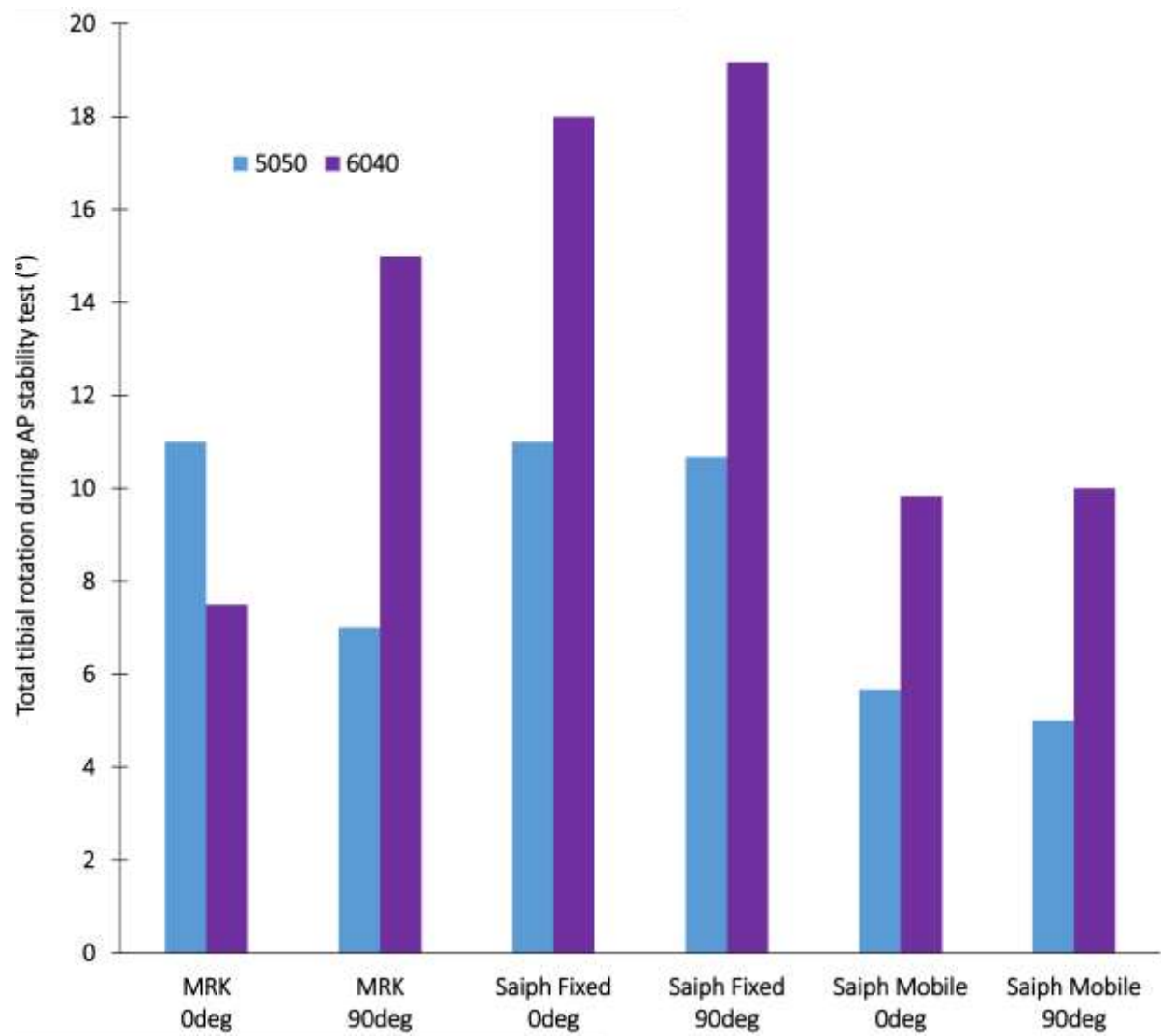


**Fig: 5.4 Stability of the Saiph TKR at different angles of flexion, 50:50 M:L loading distribution.**

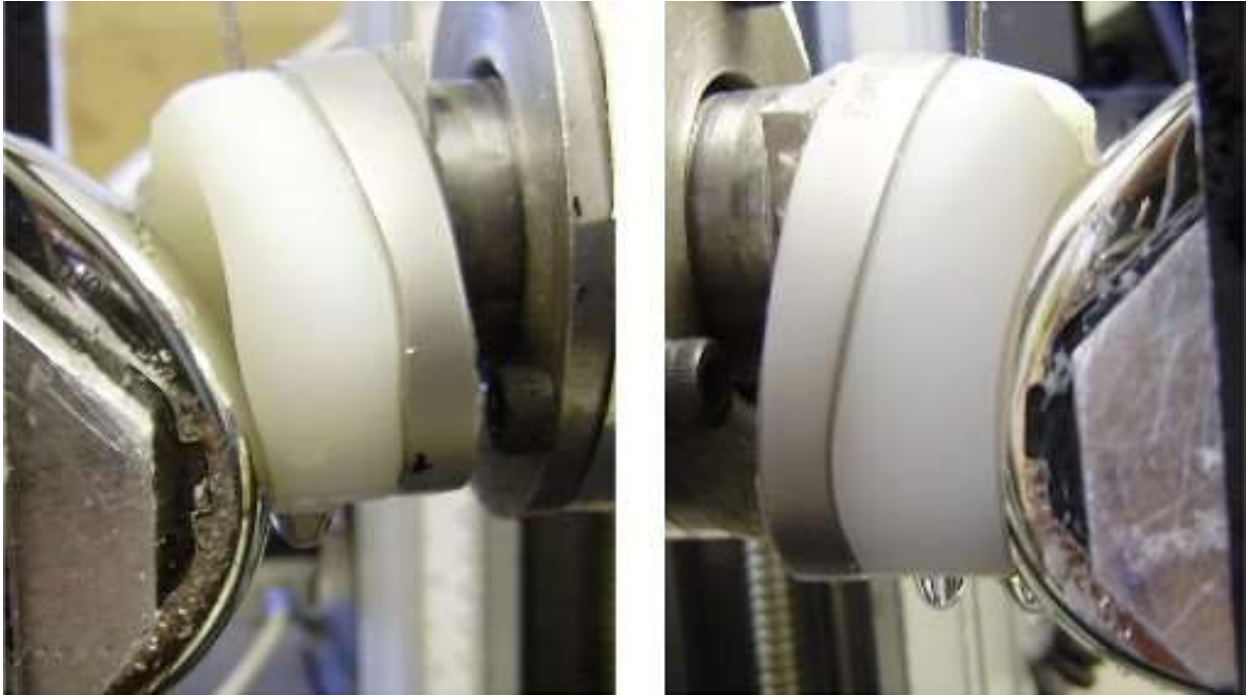
The medial-sphere type TKRs exhibited more coupled tibial IE rotation in AP translation at the 50:50M:L loading distribution than the symmetrical Triathlon, which displayed almost 0° rotation in both translation directions at full extension and 90° flexion. This finding is consistent with the design objectives of the devices. Total tibial rotation at both 0° and 90° flexion for both the fixed bearing Saiph and MRK was 11° at the 50:50 M:L loading condition. For the mobile bearing Saiph, the tibial bearing only rotated a total of 5.5°. When the loading distribution was shifted towards the medial side to give a 60:40 loading condition, an increased amount of tibial rotation was observed with the MRK, fixed bearing Saiph and mobile bearing Saiph at 90° flexion, with total rotation increasing to 15°, 19° and 10° respectively (Figure 5.5). This secondary tibial rotation in the MRK and fixed bearing Saiph resulted from greater movement in the less constrained lateral compartment (Figure 5.6).

At full extension, rotation only increased for the Saiph TKRs. It should also be noted that the direction of the majority of the rotation varied between the three devices. For the fixed bearing Saiph, most of the coupled rotation occurred during anterior tibial drawer in the internal direction; it was fairly balanced with the mobile bearing Saiph but with the MRK, it tended to be mainly external rotation during posterior tibial drawer. When the axial load was increased, there was an associated increase in the range of stability for the devices; not only were the subluxation limits further away from the neutral point of the implants, but the gradient of the force-displacement curve tended to be slightly steeper too (Figure 5.7)

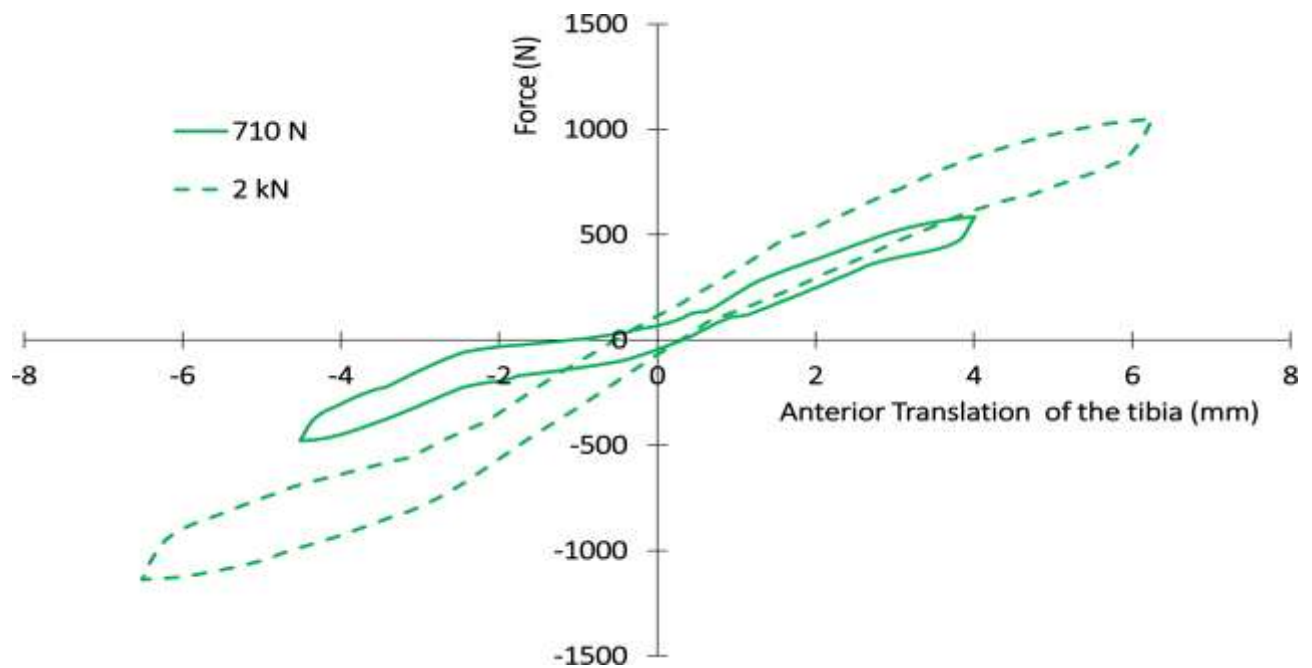
The Triathlon TKR underwent AP stability tests at a range of different M:L loading distributions, from 30:70 to 70:30, at 0° and 90° flexion. Both the magnitude and direction of the associated tibial rotation were very sensitive to the M:L load balance (Figure 5.8). The Triathlon was also assessed for AP stability at different axial compressive loads at 90° flexion. The stability increased with the compressive load: for 5 mm anterior translation, the displacing force required was 43, 117 and 150 N, for compressive loads of 710 N, 2 kN and 3 kN, respectively, after frictional effects were considered (Figure 5.9).



**Fig: 5.5 Total tibial rotation during AP translation.**



**Fig: 5.6 Coupled tibial rotation of the MRK during AP translation. Left: the unconstrained lateral compartment approaching subluxation during anterior translation of the tibial component. Right: the medial sphere compartment in the same device at the same point of anterior tibial translation.**



**Fig: 5.7 AP stability of the MRK TKR under different axial loads.**

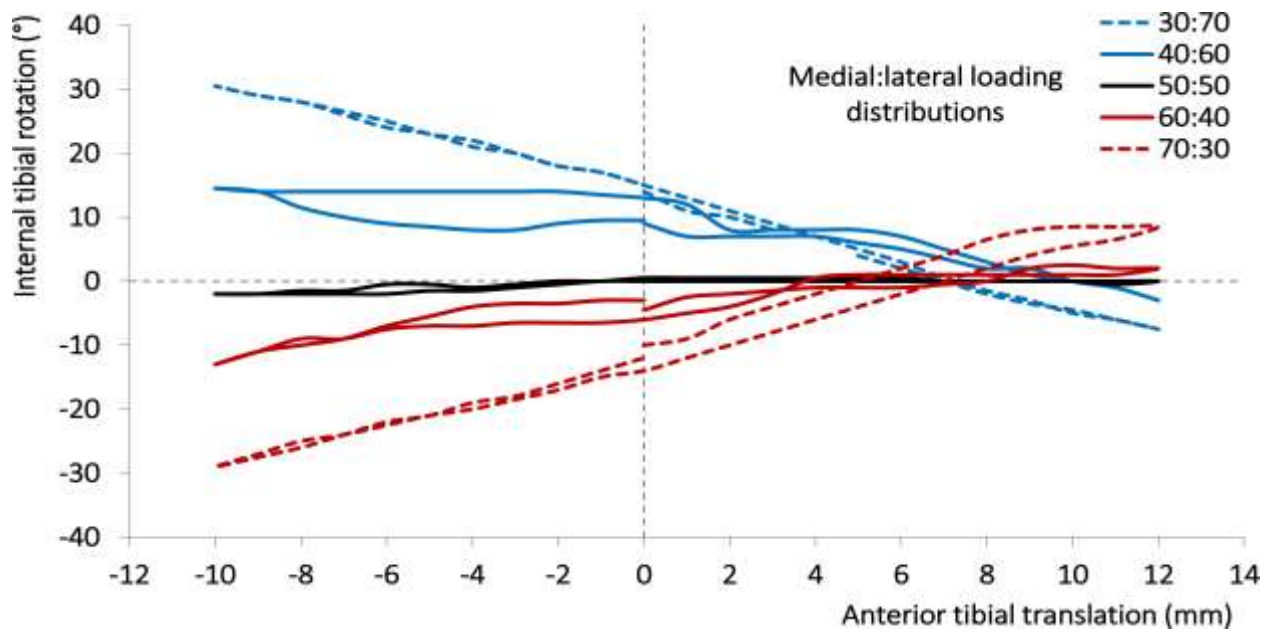


Fig: 5.8 Variation of coupled rotation with M:L loading distribution for the Stryker Triathlon at 90° flexion.

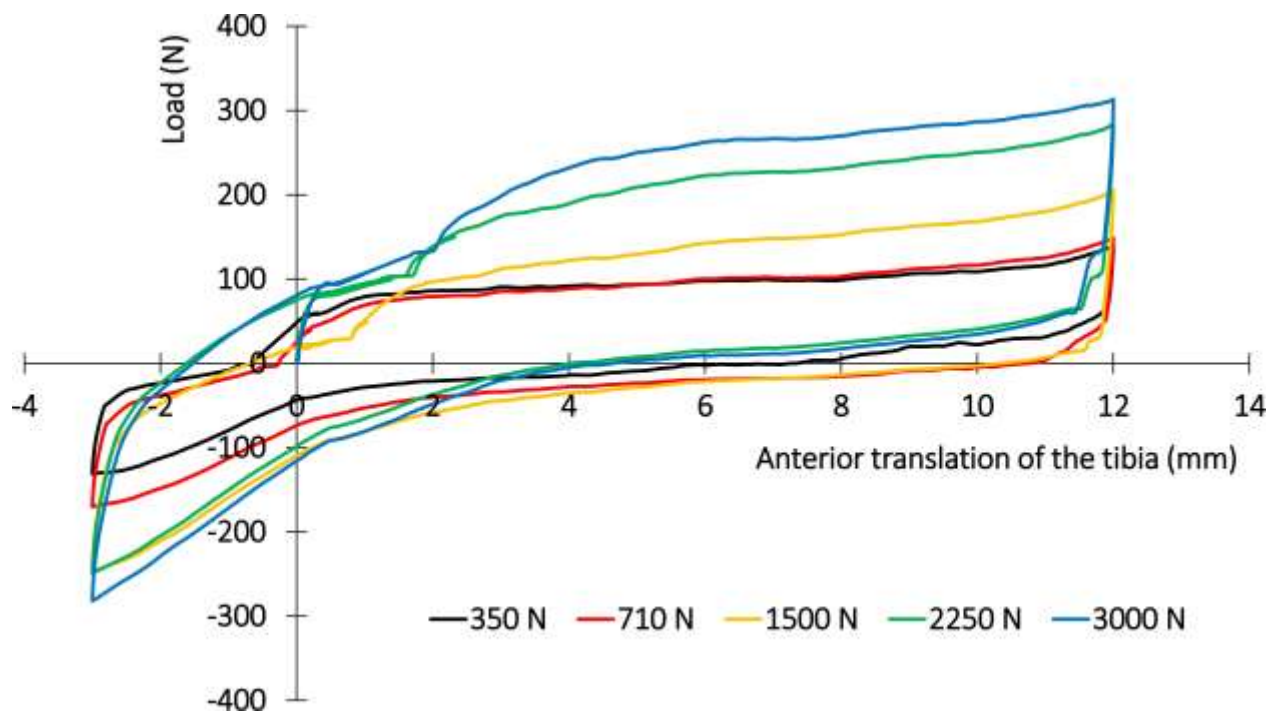
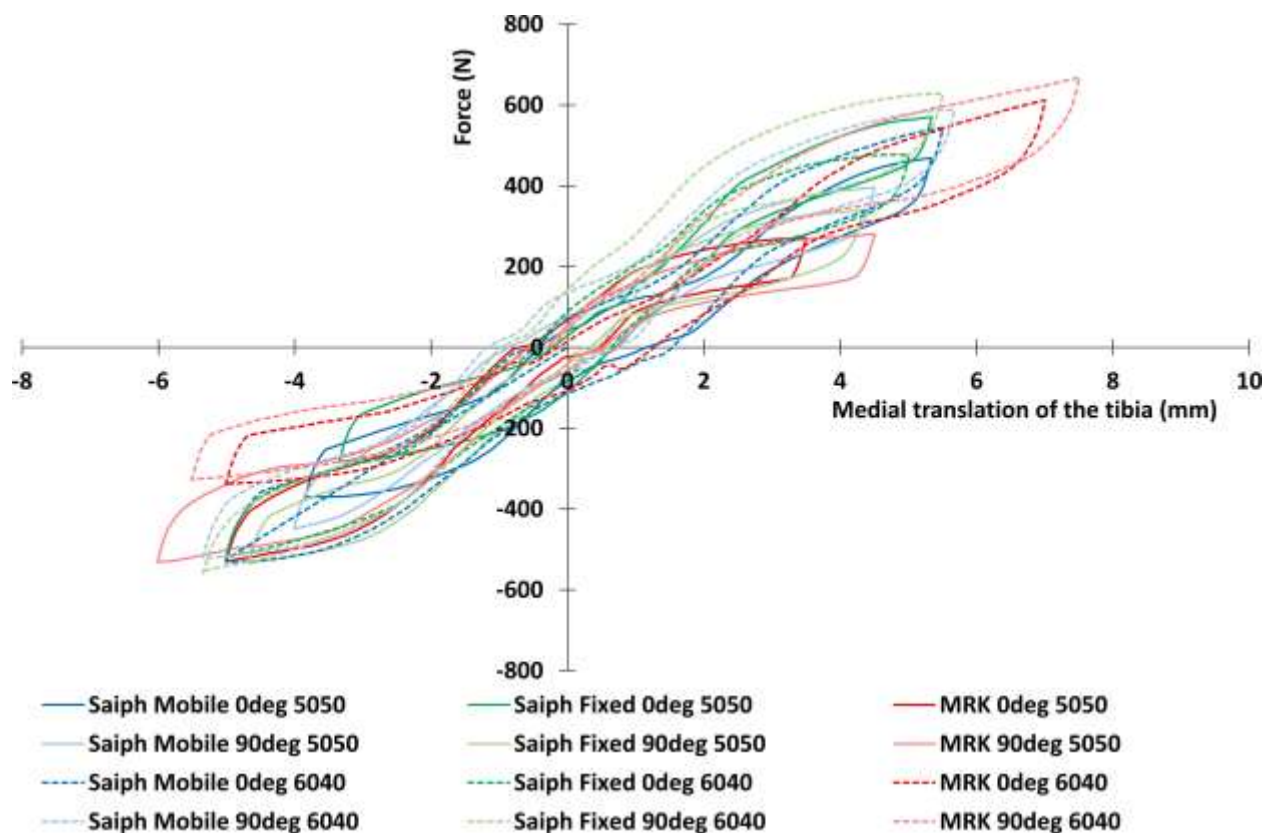


Fig: 5.9 Variation of AP stability with compressive loads for the Stryker Triathlon at 0° flexion and 50:50 M:L loading distribution.

### 5.3 ML STABILITY

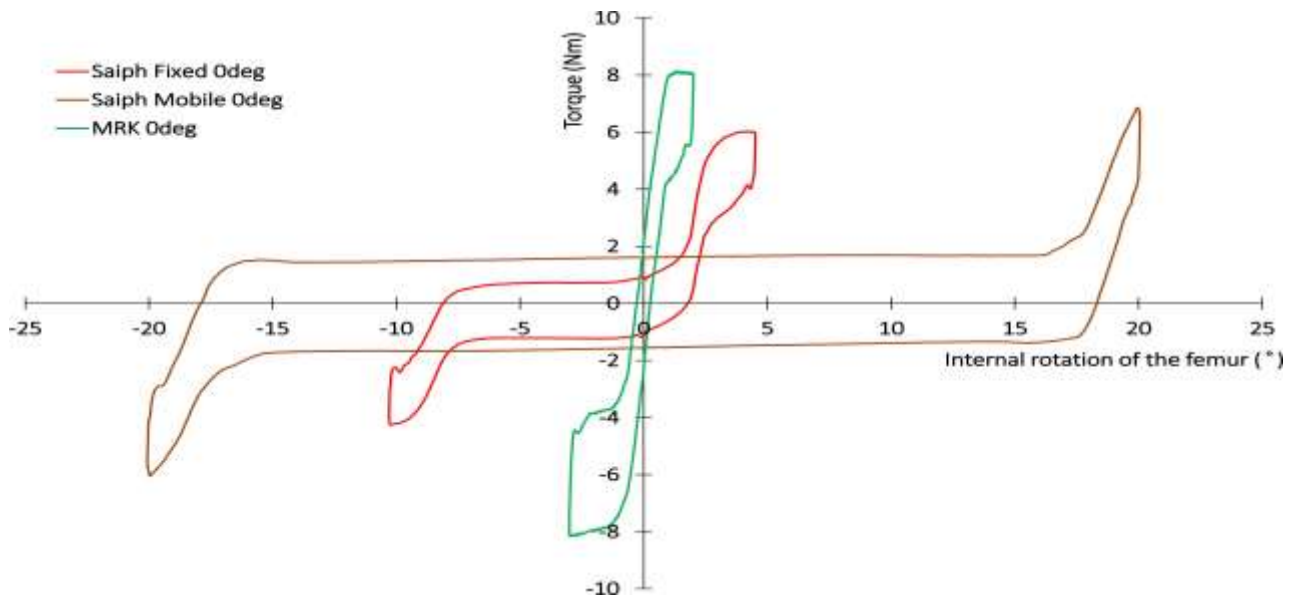
Stability in the medio-lateral direction did not vary greatly between devices, load distribution or flexion angle, with total ML translation only varying from 9 to 11 mm across the whole range of tests and devices. Both the MRK and both types of Saiph appeared to be stable in medial and lateral translation, although the MRK was slightly more laterally constrained than the Saiph, which may be due to the MRK's distinct lateral ridge. In medial tibial translation the Saiph design was less stable, reaching the limit of instability sooner (Figure 5.10).



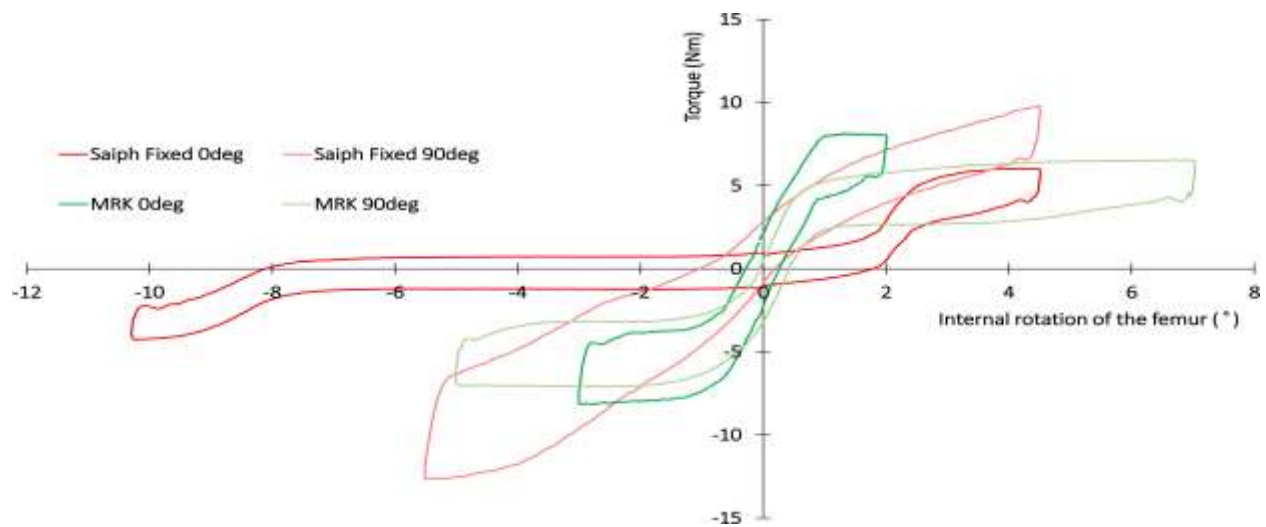
**Fig: 5.10 ML stability graphs for 3 different TKRs at 0° and 90° flexion and 50:50 and 60:40 M: L loading distribution**

## 5.4 IE ROTATIONAL STABILITY

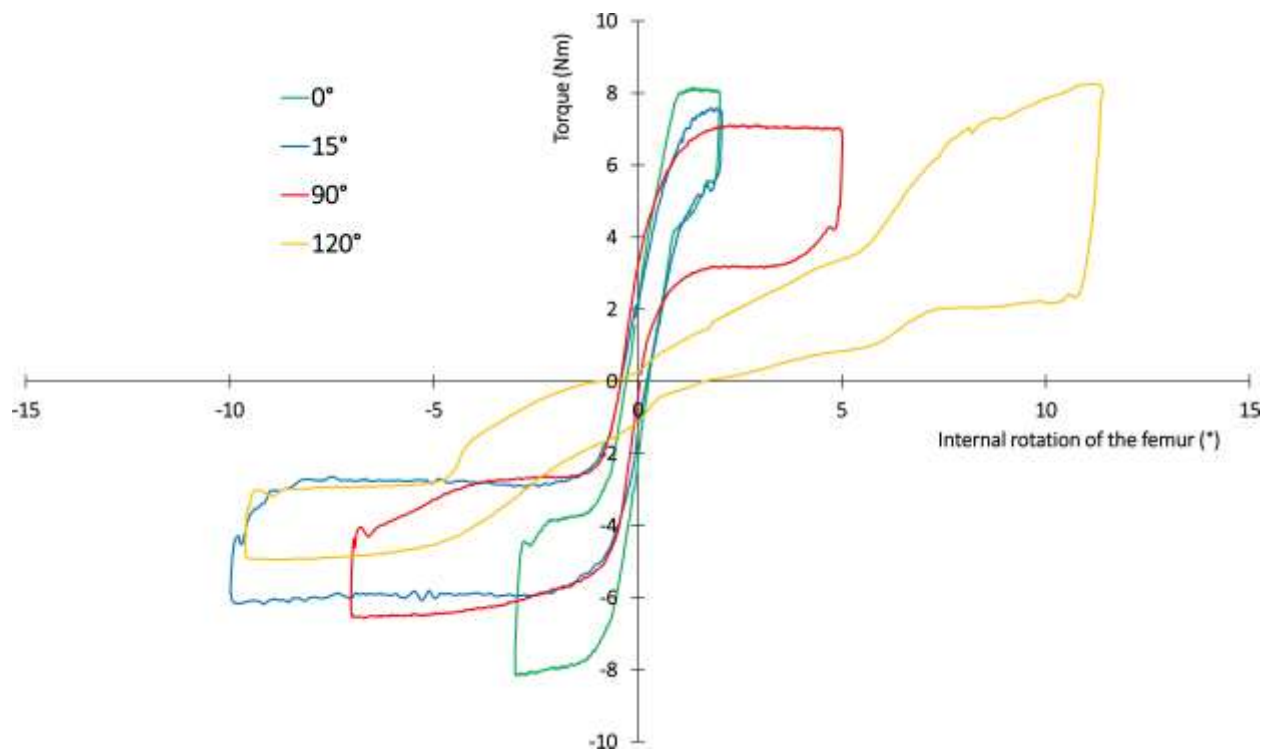
For the fixed bearing devices (MRK and Saiph), rotational stability was consistent with these secondary rotations observed during the AP stability tests. At full extension, the tibial component of the fixed bearing Saiph rotated internally at a very low torque, while the MRK was much more stable (Figure 5.11). The rotational stability also depended on flexion angle: the MRK could rotate further before instability at 90° flexion than at full extension, while the Saiph rotated much more at 0° flexion (Figure 5.12). When the devices were tested in deep flexion (120° and 135°), the Saiph maintained low internal rotation stability, while the MRK remained more stable (Figure 5.13). During these rotation tests, the tibial component of both devices underwent coupled AP and ML translations of approximately  $\pm 5$  mm. The mobile bearing Saiph, unsurprisingly, had very different IE stability characteristics compared to the fixed bearing TKRs, rotating at very low torque in both directions until the “stop point” of the mobile bearing where the torque then increased until the 20° rotation limit, stipulated by the standard, was reached (Figure 5.14). This device behaved very similarly at 90° flexion.



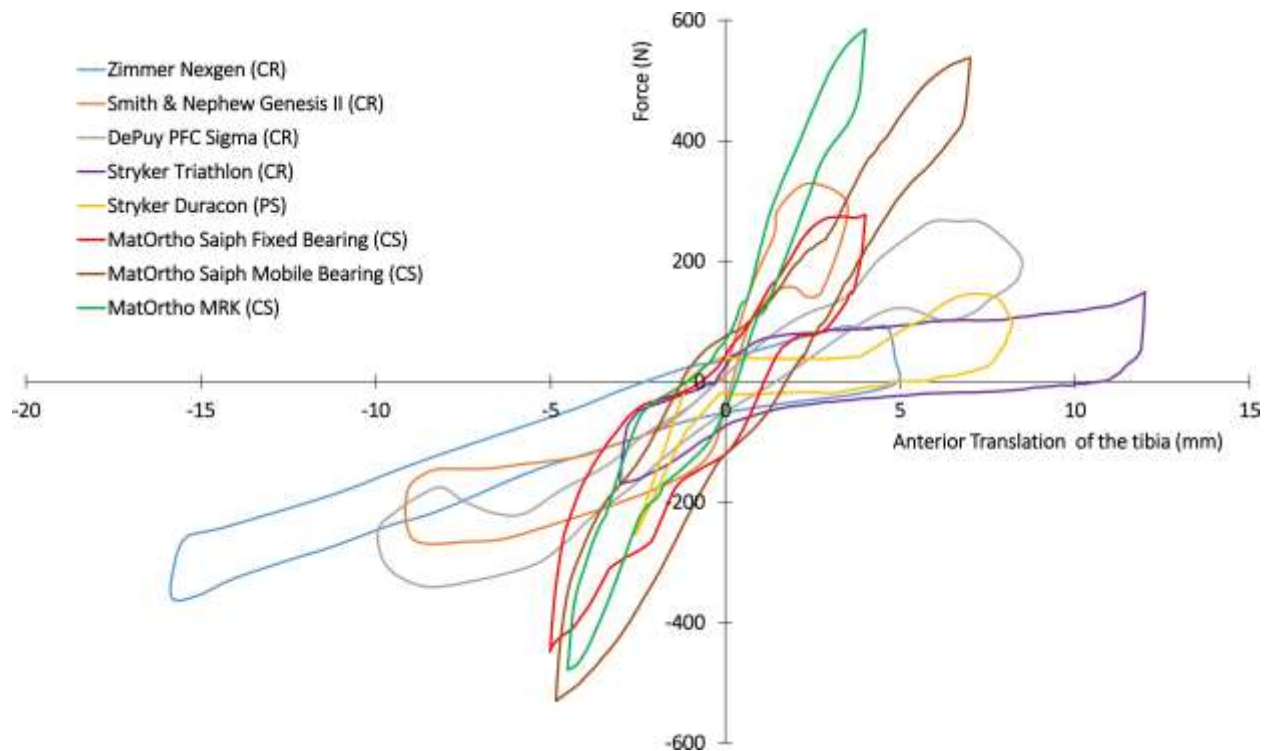
**Fig: 5.11 IE rotational stability at 0° flexion for 3 TKRs at 50:50 M:L loading and 710 N axial compression.**



**Fig: 5.12 IE rotational stability at 0° and 90° flexion for the fixed bearing Saiph and the MRK at 50:50 M:Lloading and 710 N axial compression.**



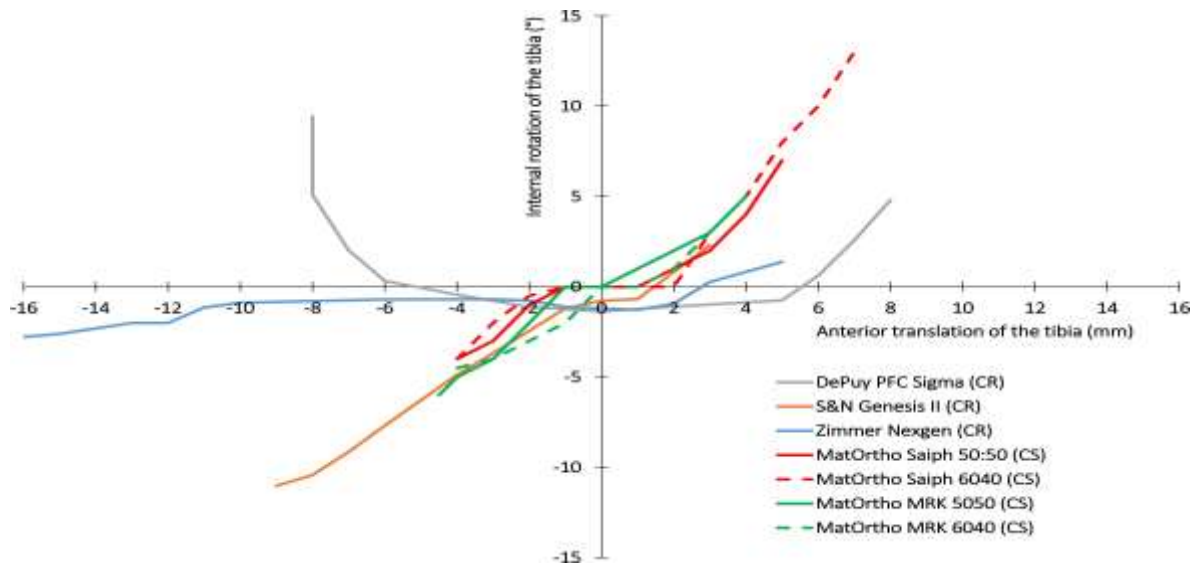
**Fig: 5.13 IE rotational stability for the MRK at a range of flexion angles, 710 N axial loading and 50:50 M:Lloading distribution.**



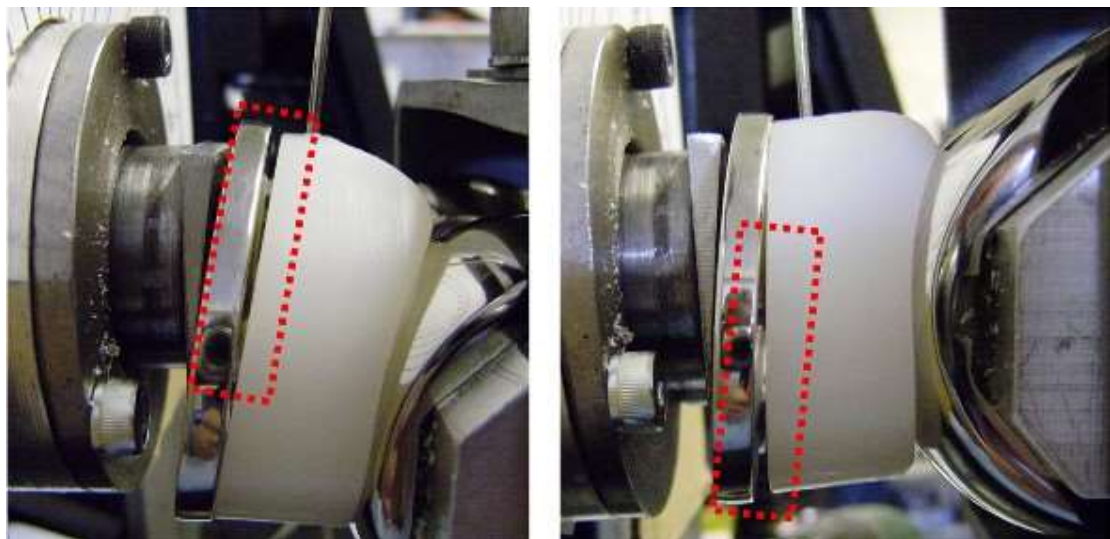
**Fig: 5.14 AP stability of 8 different TKRs. The devices were tested at 0°flexion, 710 N axial load and 50:50 M:L loading.**

Coupled tibial IE rotation, a secondary motion in the AP translation tests, was found to be sensitive to the M:L loading distribution, confirming the initial hypothesis. The MRK and the fixed bearing Saiph demonstrated similar rotational behaviour to each other and to the Smith & Nephew Genesis II (Figure 5.15). It was surprising that the mobile bearing version of the Saiph TKR did not rotate more than it did during testing (in fact, it rotated less than the fixed bearing Saiph). This may have been due to the “rocking” that was observed during testing; instead of rotating internally and externally as expected, the tibial bearing would start to tilt away from the tibial tray as the tibia was translated away from the neutral point (Figure 5.16). It is not clear why this occurred but it may have been a result of higher than expected frictional forces between the femoral and tibial components or between the UHMWPE bearing and the tibia tray. The coupled tibial rotations, in response to AP translations, were particularly sensitive to the M:L load distribution with the Triathlon TKR; this author believes that this will be common in other

symmetrical TKR designs. Taken together with these recent results, it implies that secondary rotational instabilities may occur with these symmetrical, non-congruent TKR designs, which do not appear to have considered variations of M:L loading in their designs.



**Fig: 5.15 Coupled tibial rotation during AP stability testing. The devices were tested at 0° flexion, 710 N axial load and 50:50 M:L loading unless indicated.**



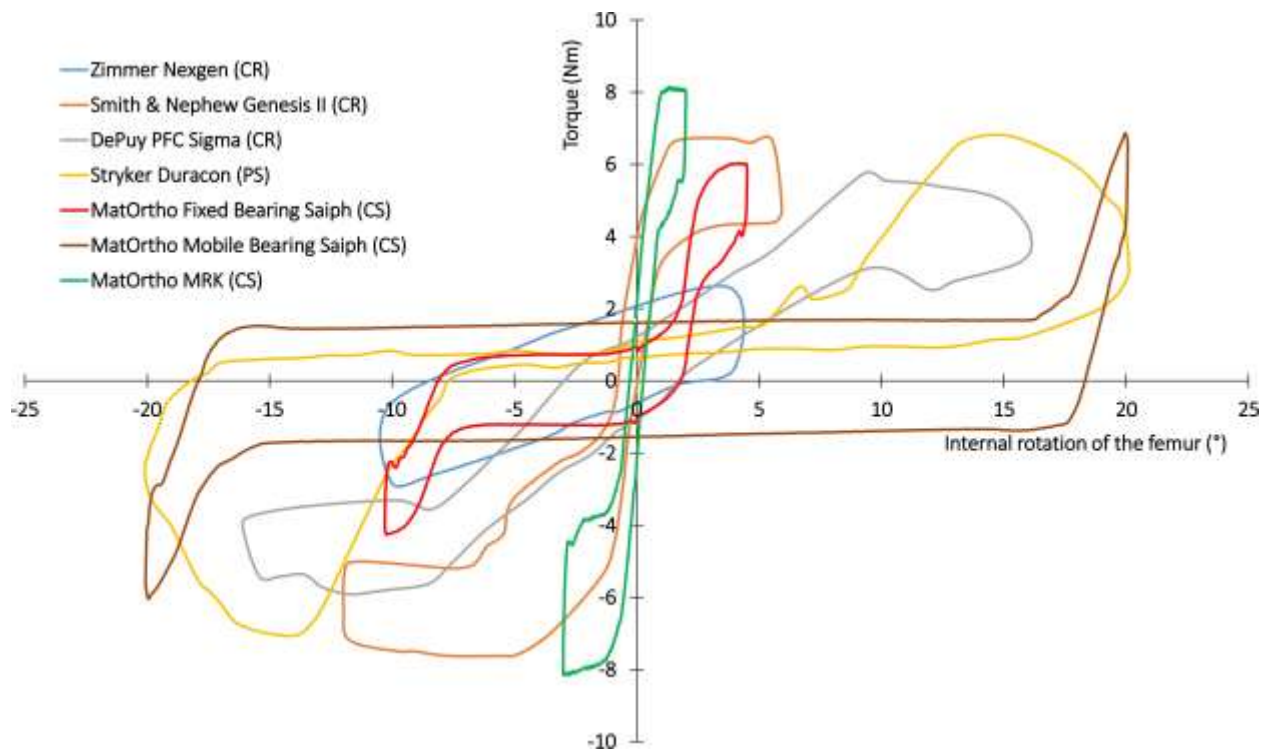
**Fig: 5.16 Mobile bearing “rocking” during AP testing, the red dashed boxes indicate where the UHMWPE bearing has separated from the polished CoCr tibial tray. Left: anterior translation of the tibia.**

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

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

The three medial-sphere type devices were also assessed in IE rotation. The reduced stability in flexion reflected the transition from a congruent fit of the articular surfaces in extension, becoming progressively less congruent as the knee flexed. This may be a general finding that will also occur in implants with a smaller femoral condylar radius posteriorly than distally. The results confirmed that the medial pivot worked as intended,

with rotation being more apparent when the joint load was at the 60:40 M:L distribution, freeing the lateral compartment. With the rotation occurring about the centre of the medial condyle, the centre of the tibial tray underwent a secondary coupled translation of approximately  $\pm 5$  mm. It may be useful to more precisely measure these secondary motions, which may have implications for how the implant “feels” to the patient. These results were also compared to those in the literature (Figure 5.17). It is interesting to note how constrained the MRK and Genesis II devices are at full extension.



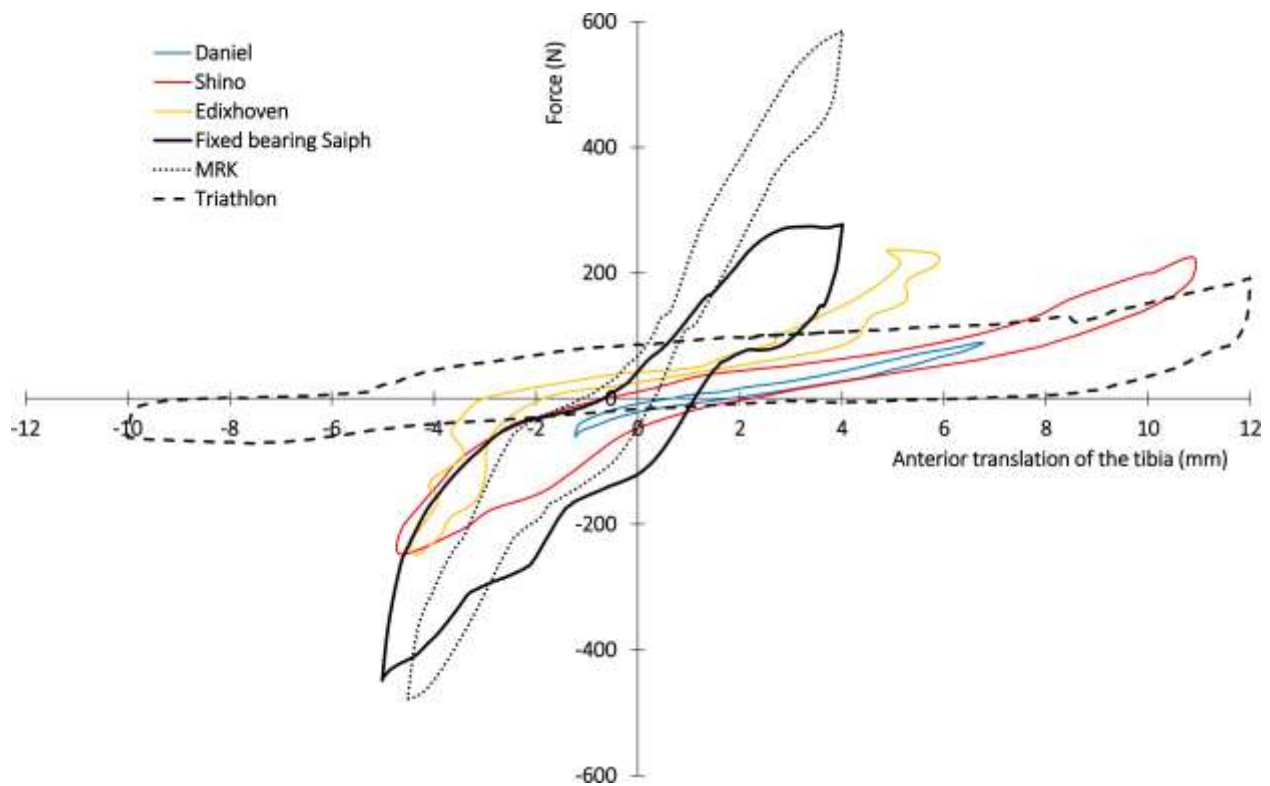
**Fig: 5.17 IE stability of 7 different TKRs. The devices were tested at 0° flexion, 710 N axial load and 50:50 M:L loading.**

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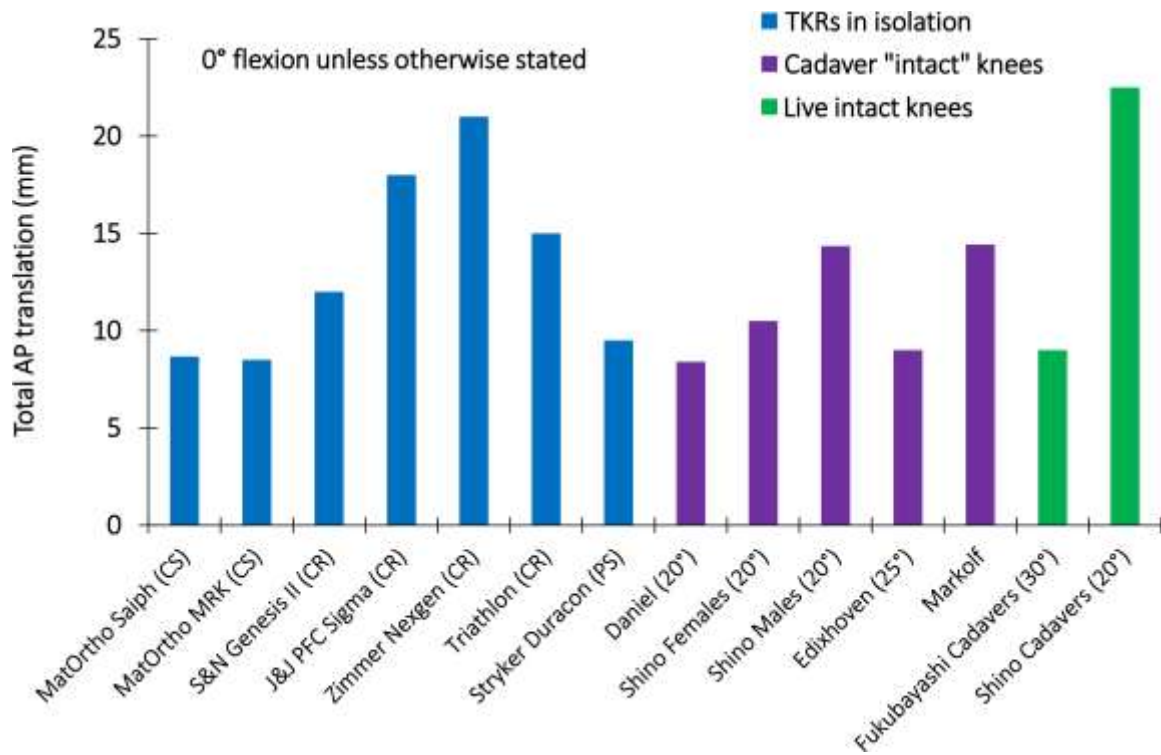
## 5.5 COMPARISON TO THE STABILITY OF HUMAN KNEES

If these results are compared to data from normal knees the MRK tended to be over constrained in the anterior drawer direction, whereas the Triathlon's stability in that direction appeared to match quite closely the behaviour of normal knees (Figures 5.18 & 5.19). In the posterior direction, however, the Triathlon was much less stable than the human knees and the other TKRs, which makes sense as it is a CR device and the

other TKRs (the Saiph and the MRK) are CS implants. Of course, it is not only the cruciate ligaments that contribute to anteroposterior translational stability in the human knee, but also the collateral ligaments and muscles surrounding the knee joint, so these implant-only test results should be considered with that in mind.



**Fig: 5.18 TKR and human knee stability at or near full extension.**



**Fig: 5.19 Total AP laxity of a range of TKRs and real human knees.**



**Fig:5.20 Fabrication of Knee stimulator**



***Fig:5.21 Assembly view of Knee stimulator***

## **5.6 DISCUSSION**

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

A graph of all these results, together with those from this study, for 0° flexion at 710 N axial load and 50:50 M:L loading distribution, can be seen in Figure 5.14. The variation in AP stability among the different kinds of TKR is evident. It is obviously not reasonable to directly compare the stability results between the CR/CS devices and the PS devices. But these differences demonstrate that these tests do work as a measure of the intrinsic stability of a device, without the influences of soft tissues and other patient variables and therefore represent a common sense check of the methods. The reduced stability in the

posterior drawer direction for the CR devices is an obvious and predictable example (Figure 5.14). The lack of anterior stability demonstrated by the Stryker Triathlon, Stryker Duracon and Zimmer Nexgen was more surprising, however, as all of these TKRs are designed to be ACL sacrificing, with the articulating geometry of the devices playing the role of stabilising the knee in anterior drawer.

## **CHAPTER 6**

### **CONCLUSION AND FUTURE WORK**

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

The ASTM standard testing has been made mandatory for all new TKRs in order for the device to be CE marked. Every manufacturer therefore has these stability data on file. Unfortunately, there is almost no data made publicly available by them, in published peer-reviewed journal articles. Therefore, this is a lost opportunity to learn about the effect of the stability characteristics on patient outcome. Ideally, the results from these tests could be used by surgeons alongside patient specific variables, such as the condition of the PCL and collateral ligaments, in selecting the most appropriate device for each patient. Whether or not this is possible in practice is debatable, and even if it were, it does not seem to be ideal for surgeons to be using lots of different devices routinely as each are quite different in terms of instrumentation and operative technique and each time a new device is introduced into practice there is a learning curve to overcome. In addition, the condition of the ligaments might be difficult to properly assess prior to the operation by which time it would be too late because the implant needs to be chosen before the arthrotomy is made (and therefore before knowing the condition of the soft tissues).

Stability results such as these may also be viewed with potential implant loosening in mind; inherent stability of a device suggests that the implant has a greater ability to

transfer shear forces or torques (in translational and rotational modes, respectively) to the underlying bone, and this may have implications for the efficacy of the fixation of the device. It is difficult to scrutinise this theory any further from large datasets such as the joint registries, because although they contain failure mechanisms for all primary TKRs that need revising, and revision rates for individual TKR designs, they do not combine the two.

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

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**ANNEXURE:**

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# KNEE SIMULATOR TESTING MACHINE

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**KEYWORDS:** Knee simulator, osteosarcoma, prosthetic, knee joint, degrees of freedom.

## ABSTRACT:

Recent statistics show that big bones in the lower extremities are affected by more than 70% of osteosarcoma cases (femur and tibia). Most instances are documented in youngsters under the age of 20, and they all call for prosthetic reconstructive surgery. As a result, the creation of artificial prosthetics is the clear-cut solution to this important problem. A mesenchymal-derived primitive altered cell that exhibits osteoblastic differentiation and produces malignant osteoid is an aggressive malignant tumour known as osteosarcoma. The histological kind of primary bone cancer that is most prevalent is this one and needs to be replaced by prosthetic devices. To sustain 10 years of prosthetic life in the human body, the prosthesis needs undergo testing that amounts to roughly 10 million cycles before being implanted. This artificial prosthesis is tested using a machine called a "knee simulator" that produces a variety of movements.

## 1. INTRODUCTION:

Numerous millions of individuals throughout the world suffer from the crippling, painful condition known as osteoarthritis (OA) of the knee, which has a significant socioeconomic impact. In the vast majority of patients with severe OA of the knee, total knee replacement (TKR) is an effective treatment that reduces pain and restores function. Despite the fact that the device provides them with pain relief, the clinical

# **FABRICATION OF KNEE SIMULATOR TESTING MACHINE**

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## **ABSTRACT:**

Recent statistics show that big bones in the lower extremities are affected by more than 70% of osteosarcoma cases (femur and tibia). Most instances are documented in youngsters under the age of 20, and they all call for prosthetic reconstructive surgery. As a result, the creation of artificial prosthetics is the clear-cut solution to this important problem. A mesenchymal-derived primitive altered cell that exhibits osteoblastic differentiation and produces malignant osteoid is an aggressive malignant tumour known as osteosarcoma. The histological kind of primary bone cancer that is most prevalent is this one and needs to be replaced by prosthetic devices. To sustain 10 years of prosthetic life in the human body, the prosthesis needs undergo testing that amounts to roughly 10 million cycles before being implanted. This artificial prosthesis is tested using a machine called a "knee simulator" that produces a variety of movements.

**KEYWORDS:** Knee simulator, osteosarcoma, prosthetic, knee joint, degrees of freedom.

## **Introduction:**

Numerous millions of individuals throughout the world suffer from the crippling, painful condition known as osteoarthritis (OA) of the knee, which has a significant socioeconomic impact. In the vast majority of patients with severe OA of the knee, total knee replacement (TKR) is an effective treatment that reduces pain and restores function. Despite the fact that the device provides them with pain relief, the clinical outcome of TKR surgery is uneven, and a sizable minority of patients who are pain-free following surgery continue to be dissatisfied. This discontent is thought to be partially caused by functional shortcomings that patients encounter with their prosthetic devices, and that these, in turn, are caused by a number of reasons, including: the design of the TKR; removal of one or both of the cruciate ligaments, modification to the other soft tissues in the knee joint, including ligaments. Over time, there have been a variety of TKR designs developed in an effort to address issues that have been



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THIS IS TO CERTIFY THAT

Mr. PONMUTHU P

*Student, School of Mechanical Engineering, Sathyabama Institute of Science and Technology, Chennai, India* has presented a paper entitled "*Knee Simulator Testing Machine*", in the second International conference on "Advancements in Materials Science and Technology – iCAM 2022", organized by Sathyabama Institute of Science and Technology, Chennai, India in association with Alexander Dubček University of Trenčín, Slovakia, during November 02–04, 2022.

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