Department of Biomedical Engineering

"Further development of a non-invasive infra-red (IR) system in clinical assessment of knee laxity in healthy volunteers."

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“This thesis is the result of the author‘s original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

Signed:

Date:

Abstract

Total knee arthroplasty (TKA) is a common surgical intervention for the treatment of osteoarthritis (OA), which although successful- reports significant patient dissatisfaction levels. One of the main contributing factors to this is malalignment of the tibial and femoral components.

The incorporation of computer-assisted orthopaedic surgery (CAOS) into this procedure has produced better alignment, and better functional scores post-intervention. Recently, a non-invasive navigation system, combining the intraoperative tracking system has been developed for a clinical setting.

The aim of this project was to develop an experimental methodology which would standardise the possible variations that can arise during clinician based assessment.

A validation of newly developed passive trackers was undertaken, but could not be validated to within a target repeatability of 3˚. Due to time constraints, these trackers were used throughout the study.

Angle of flexion was standardised through the creation of a flexion supporting structure, and force applied to participants was standardised. Implementing these tools into an altered laxity assessment, two measurements of varus and valgus laxity, and AP translation were taken at 5˚, 15˚, 30˚ & 45˚ intervals. Valgus measurements were repeatable (CR 3˚) between 5˚and 15˚ of flexion, varus measurements were repeatable at 5˚. The AP test for laxity was less successful, with only the assessment at 15˚ falling with the predefined limit of 3mm. When this experimental protocol was compared to the clinical assessment of an experienced surgeon, results of valgus laxity were found to be repeatable (within 3˚) at 5˚, 15˚ and 30˚, and varus laxity measurements within these limits at 5˚. These promising results show that this experimental method is capable allowing a novice to measuring laxity at a similarly repeatable level to that of an experienced surgeon at these degrees of flexion. Many of the limitations of this study can be attributed to the flaws within the experimental methodology.

Further investigation with a larger participant group is required for full validation of this technique.

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1. Introduction

The dawn of the 20th century heralded a substantial change in human lifestyle, creating a climate capable of sustaining a population comfortably into old age within wealthy, developed nations. Advancements in vaccinations and antibiotics have either eradicated or severely limited the spread of previously devastating diseases, in addition to increased access to nutritious diets and cleaner water sources allowing the development of many more children through their vulnerable years and into adulthood *(NIH, 2015).* At present, around 11 million people in the UK are over 65 years *(UK Office for National Statistics, 2014),* and this is projected to increase to 1 in 3 people by the year 2086 *(Office for National Statistics, 2013).* Such improvements in life expectancy have led to unprecedented issues affecting the quality of life of those outliving their predecessors. Elderly males and females are subject to a myriad of health problems (such as incontinence, osteoporosis and arthritis, dementia) that were not previously of concern *(Age UK, 2015).*

The aging process significantly compromises the structural integrity of the human skeleton, as the body becomes less able to maintain mineral composition of bone, leading to a decrease in mass and density. Cartilage around the joints experience considerable degeneration, and can trigger inflammatory pain and swelling, which can severely impact mobility and requires medical intervention *(NLM.NIH.GOV, 2015).* Knee joint problems are the most common ailment related to the degeneration of bone, affecting around 10% of those over 55 years of age *(Petersson, 1996).* Osteoarthritis (OA) is the most prevalent form of arthritis, where loss of cartilage leads to bone-on-bone interaction during motion, and triggering pain due to the friction within the joint. There is no definitive cure for this disease, though several treatment options are available to alleviate symptoms and to hopefully avoid the loss of physical independence *(Surgeon General, 2004).*

Total knee arthroplasty (TKA) is a common corrective procedure in cases of ongoing pain and disruption of movement within the knee, secondary to osteoarthritis. This invasive procedure resurfaces the lost regions of cartilage, and caps the femoral and tibial end of the bones to resect and replace the degenerated cartilage

(Hopkinsmedicine.org, 2015). Since the introduction of the procedure, TKA has been found to be efficient, reliable and cost effective as a treatment option for OA, with over 90,000 undertaken each year in the UK *(National Joint Registry for England and Wales, 2010)*.

Out-with the normal risks associated with surgical procedures, coronal and sagittal malalignment has a significant effect on post TKA recovery. Successful valgus/varus alignment outcomes are generally within in the 0±3˚ range, but several studies have shown that 25% of procedures result in coronal deviation greater than this accepted target *(Mahaluxmivala et al, 2001).* Although TKA is generally considered to be a successful surgical approach, 18% of patients have been reported to be dissatisfied with their outcome *(Baker et al, 2007).* The cause of this dissatisfaction is often attributed to levels of pain and discomfort experienced by the patient, which can be related to pre-operative OA severity *(Polkowski et al, 2012),* psychological factors or a result of the surgery itself, such as poor post-operative alignment *(Ali et al, 2014)*.

Navigation systems are becoming increasingly more commonplace in orthopaedic surgery, with computer-aided TKA presenting a tendency toward better alignment outcomes when using this approach *(Bäthis et al, 2004).* However, discrepancies still exist between the analysis of displacement of the lower limb as a result of variation in examination pre and post-TKA. Clinical assessment by a trained surgeon is carried out by manual examination and estimation of the angle of displacement, whereas radiographic images are used to evaluate the outcome after surgical intervention. On account of the functional and surgical benefits, development of an optical navigation system for non-invasive use has been developed over a number of year, with the hope of establishing this technology as a beneficial tool within pre-operative assessment clinics.

The key objective of this study was to adapt an infra-red optical tracking system for use in knee laxity assessment, in a non-invasive manner suitable for use in a clinic. In removing as many variables as possible, the focus of the experimental set-up is in creating a consistent, accurate and reliable protocol for registration of the anatomical parameters of the leg and recording laxity of the knee in both coronal and sagittal

planes. The development of the non-invasive infra-red system was to establish a knee-laxity assessment capable of being undertaken by a novice without any medical, or surgical training- and as such, certain restrictions required addressing.

The lack of any relevant experience suggested that standardisation of flexion angle and force applied within the assessment would be the initial point of investigation.

There are three elements to this investigation:

1. **Validation of IR trackers**
   A functional comparison of the precision of the system using active IR trackers, passive IR trackers, and the low-profile new generation IR trackers in a healthy volunteer.
2. **Assessment of knee laxity using experimental methodology**
   A group of 20 volunteers will undergo a knee laxity assessment using the new-generation IR trackers. Using the adapted, experimental set-up (standardised knee flexion, prescribed applied force), measurements of knee laxity displacement (varus/valgus & anterior Laxity) will be recorded in the hopes of investigating the repeatability of the IR system.
3. **Standard assessment of knee laxity by orthopaedic consultant**
   5 volunteers from the original group of 20 will undergo the standard clinical assessment using the new-generation IR trackers, carried out by an experienced orthopaedic consultant. No additional measures (standardised knee flexion, prescribed applied force) will be used. This section will allow the comparison of the precision of the experimental set-up, when compared with the clinical 'gold-standard'.

Results would be considered as successful in the event of a coefficient of repeatability within 3˚ for laxity assessments, and a coefficient of repeatability within 3mm for AP Laxity tests.

2. Literature Review

2.1 Anatomy of the Knee Joint

The knee joint is the largest joint in the human body, connecting the tibia and the femur at two articulations. It is classed as being a synovial hinge joint on account of the articular cartilage and lubricating synovial fluid present, which acts to absorb shock and reduce friction during normal motion *(SynovialJoints.net, 2015).* These attributes enable the knee joint to accomplish roles in weight-bearing, stability and essential mobility.

2.1.1 Structure of the Knee Joint

2.1.1.1 Bone & Cartilage Components of the Knee

The knee joint skeletal structure (Figure 2.1) centres on the concept of frictionless motion. At the juncture where the femur and the tibia meet, there are two forms of cartilage to allow unobstructed movement and reduce the chances of damage to the bones themselves, and are both essential for healthy knees *(Farah et al, 2010).*

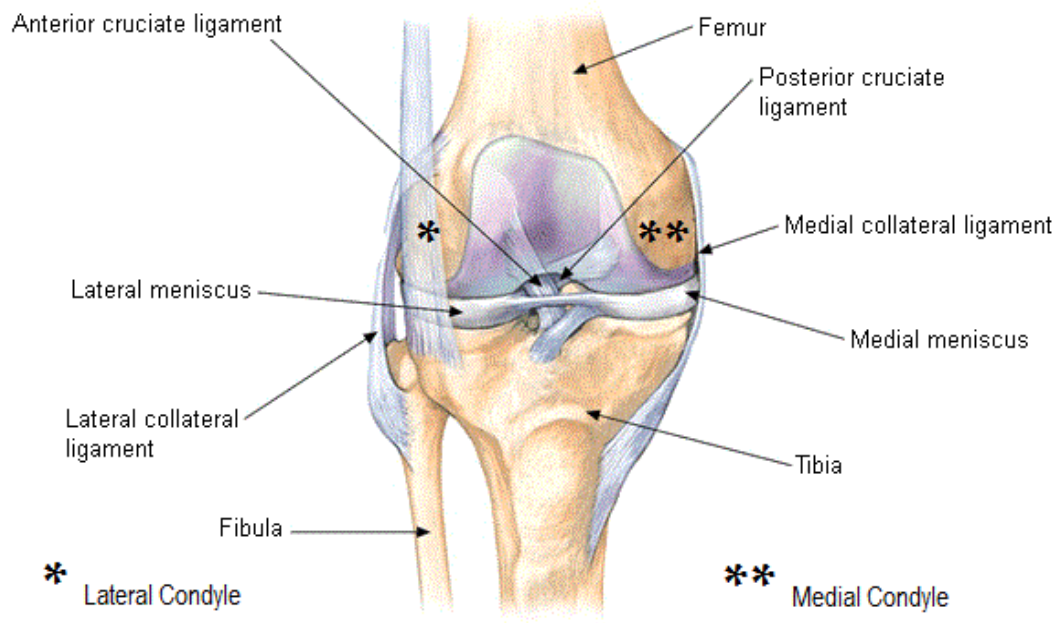

Figure 2.1- *Structure and ligamentation of the knee joint (BMJ, 2015)*

Medial and lateral condyles are rounded ‘bumps’ present at the point of articulation between the femur and tibia. The hyaline cartilage found at these articular surfaces of bone allows for ‘sliding’ interaction motion of these bones, reducing friction in conjunction with synovial fluid from the articular capsule within the joint *(InnerBody, 2015).*

The menisci of the knee joint comprises of two articular fibrous cartilage disks- the medial and lateral menisci. These act to prevent bone-on-bone rubbing and act as a shock absorber for the knee, during load-bearing and high-intensity exercise *(Tony-Gibbon.co.uk, 2015).*

The patella is a circular-triangle bone which acts as a protective component of the knee joint, and is attached across the joint by the vastus series of muscles (intermedius, lateralis and medialis) *(Rosen et al, 2015).* The patella also has a very important function in the extension of the lower limb, by displacing the quadriceps tendon – increasing the subsequent moment arm, reducing the force required for many movements *(Kaufer, 1971).*

2.1.1.2 Ligaments of the Knee

The ligaments of the knee are elastic and fibrous in nature, and are involved in connecting the bones of the femur, tibia and patella together and controlling motion of the joint. In this manner, ligaments can define the range of motion that a joint is able to undertake, in addition to increasing the stability of the joint. This is clearly demonstrated in cases of pathology or injury, when joint motion and ligament function can be significantly diminished *(Morrey, 2012).* The elasticity of these ligaments can absorb shock under stress, performing a protective function in the joint *(Buffalo.edu, 2015).*

Knee ligaments can be divided into two categories**: intracapsular** and **extracapsular** *(Weinstein, Buckwalter and Turek, 1994).*

Intracapsular ligaments include the cruciate ligaments, which cross in an ‘X’ shape to provide stability to the knee, indicated in Figure 2.1. The anterior cruciate ligament (ACL) restricts the forward movement of the tibia in reference to the femur, and is activated in hyper extension of the knee *(Bahr, 2009).* Conversely, the posterior cruciate ligament (PCL) prevents the posterior displacement of the tibia and is integral in knee flexion *(UCHU.edu, 2015).*

The transverse ligament joins the lateral and medial meniscus of the knee, and shows a high level of variation between individuals. Although its purpose is not completely known, it is thought to have a role in stability and prevention of hyper-rotation within the knee *(Messner & Gao, 1998).*

Extracapsular ligaments include the collateral ligaments, which attach across the knee joint. The medial collateral ligament (MCL) stretches from the femoral to the tibial condyle, and acts to stabilize the knee and prevent excessive rotation of the knee in the event of laterally applied stresses *(Liu et al, 2010).* The lateral collateral ligaments (LCL) attaches to the condyle of the femur and the fibula, and limits rotation of the knee following medial stress. Both the MCL & LCL restrict adductive and extensive movements around the knee joint, and are both shown in Figure 2.1 *(UCHU.edu, 2015).*

The patellar ligament shown in Figure 2.2 attaches the patella to the bony prominence of the tibia, and is strong and fibrous in order to adequately move the tibia during limb extension. This ligament attachment can be indistinguishable with that of the quadriceps tendon, and has shown tendon-like properties – as such, it can be referred to as the patellar tendon *(Rumian, Wallace & Birch, 2008).*

Two dorsal ligaments, the arcuate and oblique popliteal ligaments further aid in stability and maintaining correct movement parameters in the knee *(Morgan et al, 2010).* The arcuate popliteal originates on the fibula and has a dual attachment to the tibial condyle and the lateral femoral condyle, whereas the oblique popliteal muscle stretches in the opposite direction; originating at the lateral condyle of the femur to attach to the medial condyle of the femur *(Gray & Clemente, 1985).*

2.1.1.3 Muscles of the Knee Joint

The muscles of the knee act to move the lower limb in the following ways: extension, flexion, and medial & lateral rotation (to a lesser extent). The muscles responsible for motion can be defined by the area of attachment to the thigh to support the “hinging” action of the joint in the sagittal plane: the easiest way to categorise these muscles is by the movement that they generate.

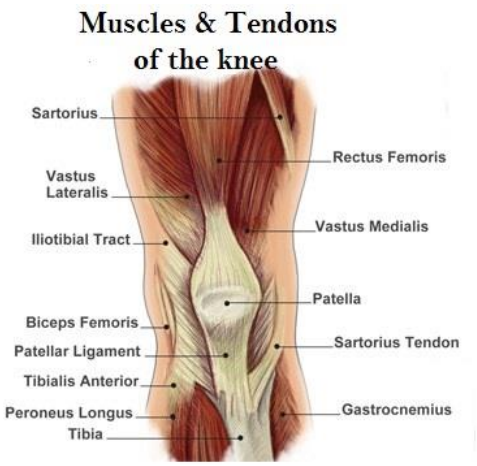

Figure 2.2*- The muscles and tendons of the knee joint (King Brand, 2015)*

Extensors: The main extensors of the knee are the large quadriceps muscle group which is mainly contained in the anterior compartment of the thigh, covering the front and sides of the femur *(Karadsheh, 2015),* as seen in Figure 2.2. Three of the heads of the quadriceps originate in the femur; vastus lateralis, vastus medialis and vastus intermedius (which is almost completely covered by the first two muscle heads). The rectus femoris is attached to the anterior inferior iliac spine and the bony ridge of the acetabulum of the hip joint. All four components of this muscle merge and join the quadriceps tendon, which lifts the patella to extend the knee and straighten the leg: the main purpose of this muscle *(Gray & Clemente, 1985).* In addition, on account of its origin, the rectus femoris is also a flexor of the hip, and the vastus lateralis aids in knee stabilisation, and as such are particularly essential in movement *(Kluwer, 2015a).*

In addition, the articularus genus muscle is related to the function carried out by the quadriceps by elevating and manoeuvring the synovial capsule to avoid compression during extension of the lower limb *(Ahmad, 1975).*

Flexors: As the flexors of the knee joint have an antagonistic action to the extensors, the muscles tend to originate in the posterior compartment of the thigh, so as to flex the knee upon contraction *(Karadsheh, 2015).* In total, there are seven muscles that act to produce flexion across the knee joint (although some of these muscle interactions can cause flexion at the hip joint simultaneously).

Unlike the quadriceps, there are three muscles that contribute to the hamstring group (Figure 2.3). All three of these muscles (long head of the biceps femoris,

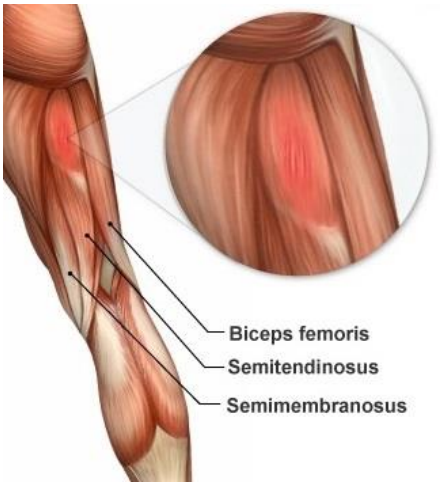

Figure 2.3 *- Posterior view of the hamstring muscle group (MendMeShop.com, 2015)*

semitendinosus and semimembranosus) originate at the ischial tuberosity of the lower hip bone – indicating that these muscle may also play a part in flexion of the hip. The semimembranosus and semitendinosus muscles both attach the medial surface of the tibia, acting to both flex the joint and control medial rotation of the knee *(Travell & Simons, 1992).* The biceps femoris is a dual-headed muscle, with the short head originating linea aspera of the femur. The muscle convolves and attaches to the lateral side of the fibular condyle, allowing for flexion and lateral rotation of the knee. The hamstrings are the antagonists to the quadriceps, and are therefore the most important group in flexion involved in movement *(WheelessOnline.com, 2015b).*

Several other muscles aid in flexion of the knee joint, and these are shown in Figure 2.4. The sartorius and gracilis muscles both originate in the pelvis, and attach to the tibia- and are the only flexors which do not originate in the posterior compartment of the thigh. They aid in flexion across the knee joint, in conjunction with the hamstring muscles *(Kluwer, 2015b).* The gastrocnemius muscle has two heads which connect to the medial and lateral heads of the femur, and extend the length of the shank and into the Achilles tendon (Figure 2.4b). As such, this muscle can produce both flexion at the knee joint, and plantar flexion of the ankle *(Merritt, 2015).* The popliteus muscle is aids flexion in an alternative manner than generating flexion via contraction of the muscle. The oblique attachment of this muscle across the knee joint from the medial surface of the tibia to the lateral condyle of the femur results in a medial rotation of the knee. This motion essentially “unlocks” the knee from full extension, and allows for further flexion and movement *(Last, 1950).*

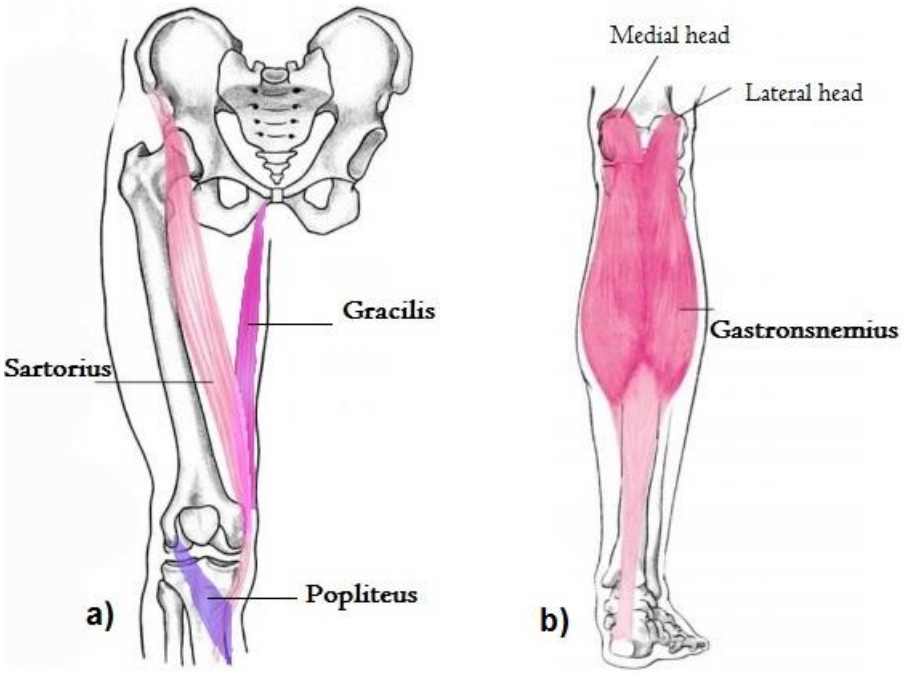

Figure 2.4 *– Additional flexing muscles of the knee joint:* ***a)*** *Anterior view of the gracilis, popliteus and sartoris muscle &* ***b)*** *Posterior view of the gastrocnemius muscle (Illinois State University, N.D)*

2.1.2 Motion of the Knee Joint

As explained in Section 2.1.1, the knee is a complex structure essential for bipedal motion. To allow for an active lifestyle, the knee must enable a great range of motion (ROM) in several planes to permit the joint articulation required for coherent movement, whilst providing stability, and durability.

2.1.2.1 Flexion-Extension

As previously outlined in Section 2.1.1.3, the muscle groups of the quadriceps and the hamstrings are the main instigators in the predominant extension and flexion of the knee joint, respectively, generating the motion in the sagittal plane.

A broad overview of the literature generally indicates that the normal ROM of the knee is 0- 135˚ flexion *(Appleton, 1993)* as depicted in Figure 2.5. This could be attributed to findings which suggest that this value of flexion can allow independent motion (manoeuvring in and out of a bath) and would not impede daily routine *(Rowe et al, 2000).* Maximum (or full) extension is normally considered to be at 0˚ of flexion (although ranges of max. flexion can vary within individuals between 5- 20˚), and at this point the LCL, MCL and to a smaller extent the anterior part of the ACL become

taut to restrict further extension *(Fuss, 1991).* Conversely, during flexion the collateral ligaments are relaxed, and the knee flexion is restricted by both the ACL and the PCL. Genu recurvatum syndrome is a term applied for 'hyperextension' of the knee joint, or where extension continues beyond 0˚ flexion *(Louden, Goist & Louden, 1998).* Hyperextension is a result of increased joint laxity, and is not considered to be problematic in healthy individuals.

The hamstrings are the most integral flexing muscles, and enable the knee joint to achieve flexion of ~150-165˚ during deep flexion experienced during activities as kneeling *(Hefzy, Kelly & Cooke, 1998).* Maximum ROM can diminish with age (caused by a myriad of reasons) and variations in maximum extension and flexion exist between sexes. The variations noted are relatively small, and have not yet been found to be of clinical importance *(Roach & Miles, 1991).*

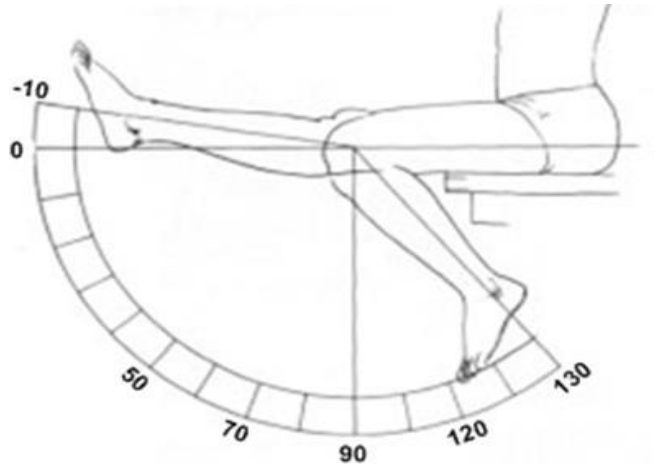

Figure 2.5 *- Normal ROM of the knee through flexion - showing hyperextension (BoneSmart.org, 2009)*

2.1.2.2 Varus-Valgus

This frontal plane motion shown in Figure 2.6, is typically related to the restrictive ligaments across the knee joint, and as such it will vary between individuals. The varus-valgus motion is dependent upon the angle of flexion of the joint, and the force applied to the lower limb during assessment. Varus and valgus deviation is at its maximum at around 30˚ of flexion, resulting in an average medial displacement of 4mm, and lateral displacement of 6mm, respectively *(Sheldon, 1994).*

The LCL is the main component in restricting varus angular displacement in all degrees of flexion, with the ACL and PCL providing auxiliary contribution. Conversely, the MCL is the main restraint in the presence of an applied valgus stress *(Miller et al, 2015).*

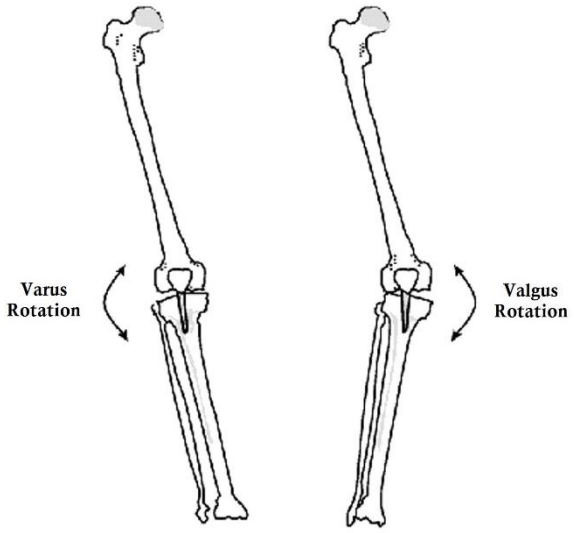

Figure 2.6 *– Varus and valgus motion in the frontal plane of motion (Sharma, 1999)*

2.1.2.3 Anterior-Posterior Translation

Anterior-Posterior translation is the 'gliding' motion of the tibia on the femur at the knee joint during flexion. Anterior translation is maximum at 30˚, and is directly related to the laxity of the ACL. Conversely, posterior translation is maximum at 90˚, and is primarily restrained by the PCL. This level of laxity is investigated using 'posterior and anterior Laxity' tests *(Muscolino, 2011).*

2.1.2.4 Internal- External Rotation

The internal-external rotation mechanism, as demonstrated in Figure 2.7 involves the rotation of the tibiofemoral joint during flexion and extension.

Internal rotation occurs early in the swing phase of walking, and is initiated by the accessory flexor muscles (i.e. not the hamstrings). These muscles cause an internal rotation of ~10˚ on account of the greater backwards motion of the lateral condyle, when the knee is flexed above 30˚ *(Sheldon, 1994).* A distinct variation in the size and geometry of the medial condyles of the femur causes the lower limb to externally

rotate by up to 30˚ at the end of knee extension *(Fuss, 1992).*

The combination of these rotating mechanisms amount to the 'screw-home' mechanism of the knee joint, which provides maximum stability across the joint at complete extension, and assists with weight-bearing undertaken by the joint *(Rajendron, 1985).*

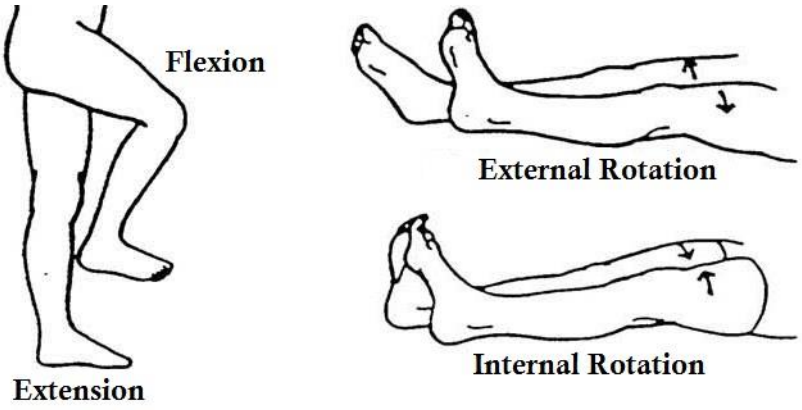

Figure 2.7- *Range of motion movements of the knee (BrooksidePress.org, 2015)*

2.2 Osteoarthritis of the Knee

Osteoarthritis (OA) of the knee is one of the largest contributors to disability in older adults and obese populations worldwide, with 18% of adults over 45 years old seeking medical intervention in the UK *(ArthritisResearchUK.org, 2014).* It is considered to be a multi-faceted musculoskeletal disorder, and although the risk factors are fairly well understood, the initiating steps of disease are yet to be underpinned.

2.2.1 Pathology of OA

OA occurs as a gradual deterioration of the 'shock absorbing' cartilage surrounding the ends of the bone, which promotes frictionless joint motion in healthy bones. The loss of this protective layer can lead to abrasive contact of the subchondral bones as a result of reduced joint space. This friction can increase bone density and cyst

formation within the bone *(Swagerty and Hellinger, 2001)*, inducing significant pain and disruption of movement in the individual. Following the characteristic loss of cartilage, inflammation triggers remodelling of the bone around the region or damage, which often results in the formation of osteophytes or 'bony spurs' *(Nagaosa, 2002)*, as shown in Figure 2.8. The bony spurs are thought to be an additional protective measure of the bone, by acting to offload pressure on the bone by increasing the surface area for load distribution *(Orthop.Washington.edu, 2015).* The cartilaginous wear within the bone ultimately results in a change of geometry within the joint. This can present itself as a narrowed joint space, or an increase in bone mass due to bone remodelling and the presence of bone spurs (Figure 2.9).

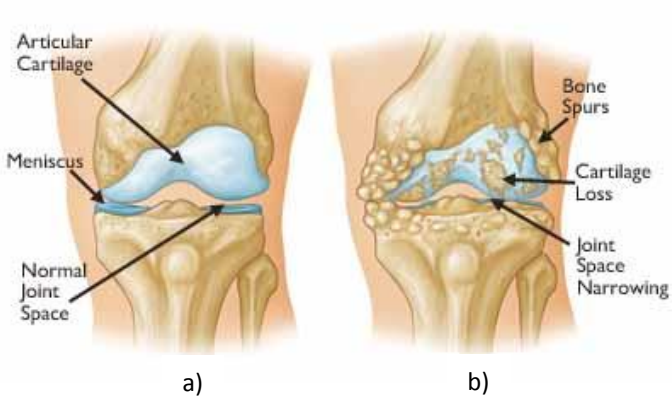

Figure 2.8*- Representation of* ***a)*** *healthy knee &* ***b)*** *osteoarthritic knee (AAOS, 2014)*

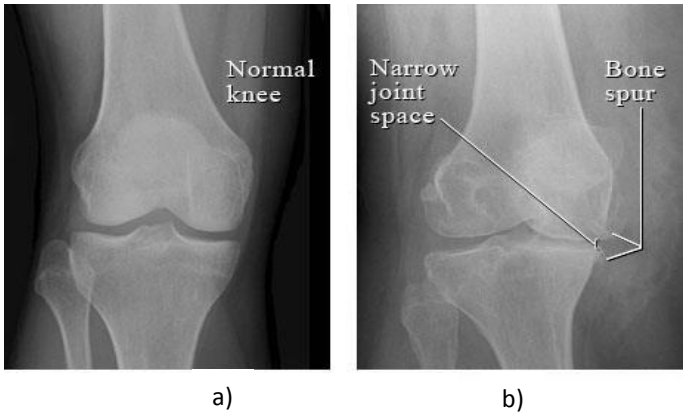

Figure 2.9*- Radiographic representation of* ***a)*** *healthy knee &* ***b)*** *osteoarthritic knee (WebMD.com, 2013)*

2.2.2 Risk Factors

Aging and obesity are consistently referred to as the main contributors, but the onset of OA is yet to be understood and there are a number of factors, outlined in Figure 2.10, which are believed to have a role in the initiation of the disease.

2.2.2.1 Systemic Factors

The prevalence of OA in the older adults is generally attributed to the 'wear and tear' of the joint over many years, as a result of the weight bearing function of the skeleton (with particular stress upon the knees).

Remarkably, adult males have a higher rate of OA in ages less than 50 years, and this changes to a higher occurrence in females, > 50 years *(Felson, 2002).* The greater prevalence of OA in older females has been linked to the depletion of oestrogen present in the body post-menopause. Oestrogen is critical in the maintenance of articular cartilage and bone, and the reduction in functional oestrogen during menopause is considered a viable trigger in increasing susceptibility of OA progression in older females *(Sniekers et al, 2010).* This has been further demonstrated in comparison studies showing the women taking oestrogen have a decreased incidence of OA, exhibiting the protective effect of the hormone *(Zhang et al., 1998).*
In concurrence with the idea of 'wear and tear' of the knee joint causing progression on OA, there is an increased relationship between physical activity levels and onset of OA.
Occupational risks such as kneeling and lifting heavy objects have demonstrated a significant relationship with increased risk of knee OA, which could be attributed to these repetitive movements in certain occupations *(Ingham et al, 2011).*

2.2.2.3 Loading of Joint

Obesity is a topic of substantial debate as to whether it is the cause or a symptom of OA, considering the immobility that can occur as a result of the disease. The relationship between overweight adults and OA is hardly surprising, with overloading of the knee joint inducing cartilaginous breakdown and other structural abnormalities *(Felson et al, 1997).*
Similarly, high-intensity repetitive joint loading sports such as football increase the likelihood of OA development, and as such preventative measures and early indications are of interest to bodies within this group *(Buckwalter & Jane, 1997).*

2.2.2.4 Intrinsic Joint Vulnerabilities

The local environment of the knee joint itself can give rise to an increase in vulnerability within the joint. For example, an alteration in joint anatomy will result in asymmetrical loading which can in turn increase focal stress on one side of the joint. The increased levels of wear can be a contributing factor in cases of both mild and severe OA.
Direct injury to either the bone or fibrous and ligamentous constituents of the joint can alter the susceptibility of the joint to progression of OA. Just as OA can increase

the likelihood of fragility and breakages within the bone, fractures to the bones of the knee can increase the risk of OA progression. Damage to the joint surface can result in avascular necrosis, resulting in a collapse of 'dead bone' on account of the restricted blood flow to the area. Subsequently, this collapse leads to an anatomical irregularity around the joint surface, producing further osteoarthritic symptoms *(Harrison et al, 2012).* Similarly, damage to the anterior-cruciate ligament (ACL) and meniscal tears can both produce premature onset of OA. The changes appear sooner in older (~5 years from injury to OA onset) than younger patients (~15 years injury to OA onset), confirming the proposed effects of aging bone in OA development *(Roos et al, 1995).*

Malalignment of the lower limb is a significant issue with OA and is a target for surgical intervention. Malalignment of the lower limb can adopt a varus or valgus deviation from the normal 'straight' alignment of the leg. The asymmetry of the lower limb causes an increase in stress application to a smaller contact area than when compared to a healthy knee – resulting in rapid cartilage degradation and consequent bone damage *(Felson et al, 2013).*

The contribution of muscle weakness to malalignment and progression of OA have been of little research interest, although muscles such as the quadriceps are integral for movement involving the knee joint *(Hurley, 1999).* Weakness of muscle groups of the lower limb have demonstrated increased levels of pain and disability, and implementation of quadricep strengthening exercises have shown possible beneficial effects on function and pain of OA patients *(O'Reilly, Jones & Doherty, 1997).*

On examination, it appears that systemic factors increase susceptibility to OA development, whereas biomechanical markers induce direct damage to the joint structure, in turn leading to OA (Figure 2.10). Investigation into preventative measures should become a precedent within the research field as the two most contributing factors (age & obesity) are population fractions that are set to increase significantly in the following years.

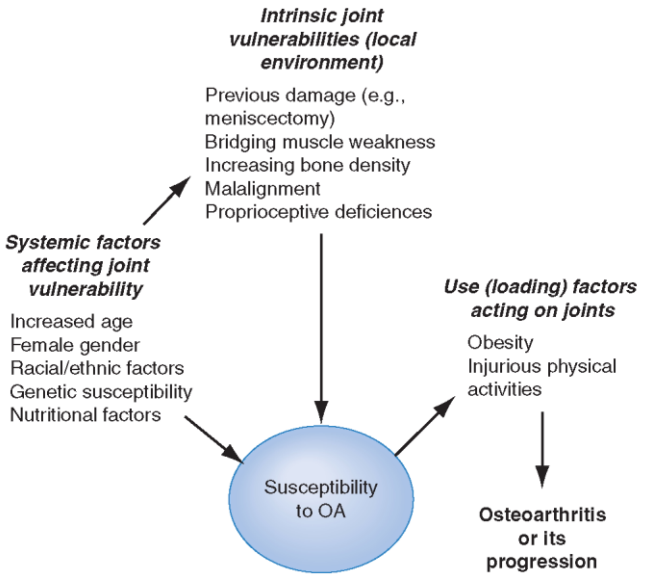

Figure 2.10- *Risk factors causing or increasing susceptibility of OA (what-when-how, 2015)*

2.2.3 Diagnosis

The multi-dimensional complexity of OA and the myriad of triggers which contribute to its initiation can impede straightforward diagnosis, and as such, in depth clinical examination is required to obtain the most complete picture of the pathology.

Joint pain is often the first indication of knee OA, characterised by increasing levels of pain during activity and relief at rest. As such, the pain often progresses throughout the day, and is therefore more intense in the evening due to activity, compared to the brief 'stiffness' experienced in the morning through inactivity *(Sinusas, 2012).* Joint range of motion and restriction of movement is a common physiological signal, and can occur as a result of changed gait due to pain behaviours or mechanical obstructions *(Hinton et al, 2002).*

Physical examination is the fundamental in the diagnosis of OA, however the subjective nature of examination can lead to levels of inter- and intra-operative variation *(Cushnaghan et al, 1990).*

Generally, standard radiographic imaging is sufficient for confirming OA in the presence of cartilage wear, narrowed joint space and osteophytes (and ruling out other conditions).The 'Kellgren & Lawerence' radiographical classification of knee OA is a recognised standard in grading severity of OA, although it is based on a subjective scale, shown in Figure 2.11. The correlation between clinical and radiographic findings is not strong *(Hannan et al, 2000),* although these images can give an indication as to the best route for management during the development of the disease.

Grade 0	Normal
Grade 1	Doubtful narrowing of joint space and possible osteophytic lipping
Grade 2	Definite osteophytes and possible narrowing of joint space
Grade 3	Moderate multiple osteophytes, definite narrowing of joint space and some sclerosis, and possible deformity of bone ends
Grade 4	Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone ends

***Figure 2.11**-K/L Radiographic Classification of Knee OA (Medscape, 2015)*

The analysis of radiographic images can be a strong indicator of malalignment of the lower limb, by visualising pathological deformations in degradation and remodelling stages of OA, and are therefore useful in diagnosing severity of the disease.

2.2.4 Malalignment of Lower Limb

The deterioration of cartilage, narrowing of joint spaces and subsequent bone remodelling can often result in asymmetrical deformations to the knee joints. This change in joint geometry can lead to the malalignment of the limb in OA in two directions in the frontal (coronal) plane. Normal alignment of the knee utilises the concept of the mechanical axis (MA) of the leg, which is visualised as a line from the femoral head, to the ankle centre, corresponding to an approximate 3˚ angle, as shown in Figure 2.12. This corresponds to the angle between the femoral and tibial components of 0˚ in neutral alignment. This is known as the mechanical femorotibial (MFT) angle. This axis can be further subdivide into the femoral and tibial mechanical axes

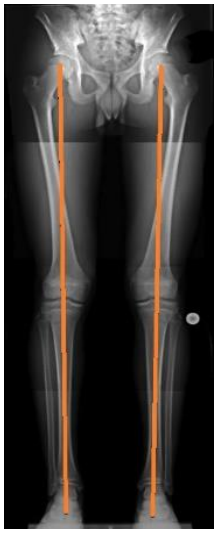

***Figure 2.12** – Mechanical axis of the leg (Kosuge & Barry, 2013)*

(Luo, 2004). Malalignment constitutes as a deviation from this MA, causing a change in MFT angle.

Varus deviation (defined as >2˚) causes the mechanical axis of the limb to pass medially to the knee centre, increasing the forces upon the medial component of the knee joint during load bearing. Conversely, valgus malalignment is attributed to the increased forces to the lateral tibiofemoral component of the knee on account of the laterally positioned mechanical axis, shown in Figure 2.13.

Sharma et al discovered that there was a significant relationship between malalignment levels in the lower limb and functional decline in mobility and an increase in pain levels experienced. The group concluded that severity of varus and valgus deformation correlated with magnitude of joint space narrowing, loss of function and pain *(Sharma et al, 2001).*

As alignment of the lower limb is a key determinant of weight-bearing capability, a shift of a few degrees can change the load at the knee. It follows that malalignment leads to increased narrowing of the joint space in occurrence of both varus and valgus malalignment (to varying degrees).

There is substantial disagreement within this field as to whether malalignment can be considered a 'risk factor' preceding OA pathology, or whether it is a consequence as to the severity and progression of the disease *(Sharma et al, 2010).*

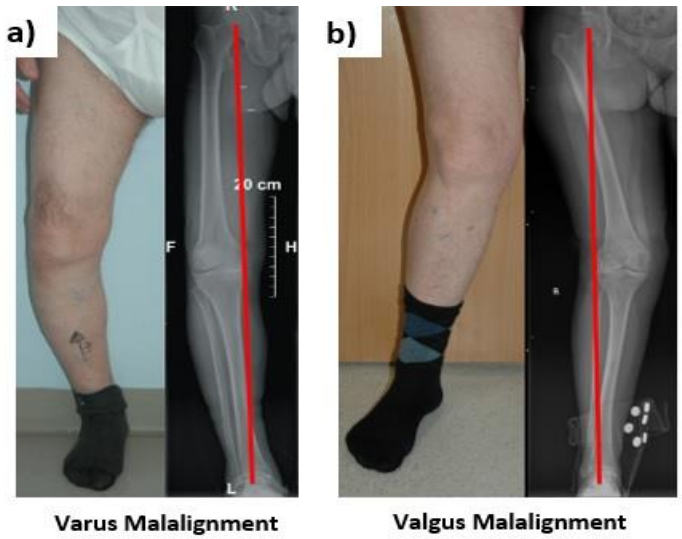

***Figure 2.13**- Clinical and radiographic imaging of **a)** varus & **b)** valgus malalignment of the lower leg (Clarke, 2012)*

2.3 Management of OA

The widespread prevalence of OA has pushed clinicians into developing patient specific 'treatment' plans, with the aim of managing the progression of the disease. To increase quality of life, steps are taken to alleviate OA related pain, improve functional mobility and restore natural knee alignment, all the while attempting to halt the advancement of the disease *(Jordan, 2003).* AAOS (American Academy of Orthopaedic Surgeons) have published a set of guidelines suggesting treatment strategies for physicians, which vary in accordance with severity of OA.

2.3.1 Non-Pharmacological Intervention

This form of treatment is mostly reliant upon lifestyle changes which can significantly affect the OA knee. Low impact aerobic exercise, defined as being exercise which promotes fitness but doesn't put extraneous strain on the musculoskeletal system is often prescribed to patients with OA as an advantageous lifestyle adaptation. Walking and swimming are excellent examples of this, promoting improved joint motion and decreased levels of pain *(Ettinger et al, 1997).* Several studies have shown positive effects during isokinetic 'muscle training' exercises, by strengthening the muscles used during normal motion *(Schilke et al, 1996).*

Promoting education about leading a healthy lifestyle is ingrained throughout the literature due to confounding evidence of the effect of obesity on the integrity of the knee joint in OA. It is unsurprising to find that weight loss reduces the effective load on the knee significantly (when considering that the knee joint experiences ~2/3 times body weight during each step), and subsequently should reduce further possible damage to the joint. One study demonstrated that a weight loss equivalent to 2 BMI points accounted for a 50% drop in OA prevalence, proving a strong correlation between these variables *(Felson et al, 1987).*

The effectiveness of stability-aiding accessories have not been as extensively researched as the previous recommendations. On account of the clear relationship between reducing load-bearing on the joint and a subsequent reduction in OA,

walking sticks are often prescribed to help redistribute the loading of the knee. The use of knee braces and orthotic insoles are subjective to individual malalignment values, but have been shown to improve stability and malalignment, although not to clinically significant levels *(Brouwer et al, 1996; Kerrigan et al, 2002).* These orthotic devices are therefore not often recommended as part of OA management strategy *(Richmond et al, 2009).*

2.3.2 Pharmacological Intervention

2.3.2.1 Oral Analgesics

The pharmacological treatment strategy acts to address the pain levels caused by OA in a various number of ways.

Painkillers such as paracetamol and NSAID's (non-steroid anti-inflammatory drugs) have been proven to be effective in the treatment of mild-to-moderate pain secondary to OA. Generally, paracetamol is initially recommended and has been shown to be as effective as ibuprofen, and almost as effective as naproxen for OA related pain. NSAIDs carry a high risk of gastrointestinal damage (as well as recurring much higher costs) in long term administration, and are therefore not generally recommended unless patients are unresponsive to paracetamol *(Abramson, 2002).*

2.3.2.2 Topical Analgesics

Topical analgesics are available and are well received by patients, demonstrating similar levels of analgesic efficiency as ibuprofen *(Dickson, 1991)* in addition to having smaller incidence of side effects. This was <1.5%, with skin irritation contributing the most of these adverse reactions *(Jordan, 2003).*

2.3.2.3 Intra-Articular Injections

Oral and topical analgesics can induce systemic side-effects, and steps have been taken to avoid these through the application of intra-articular injections.

Corticosteroids are the most widely prescribed family, and produce effective short-term pain and functional relief for up to three weeks *(Arroll, 2004)*. The hyaluronic acid injection has also demonstrated pain relief effects, but on a slightly longer timescale than its steroid partner.

Neither of these injections cause sizeable adverse effects (excusing mild discomfort

during injection), and as such can be considered a viable treatment option for OA *(Van Manen, Nace & Mont, 2012).*

2.3.3 Operative Intervention

In cases of severe pain and extremely limited mobility when pharmacological and non-pharmacological treatment routes have been exhausted, surgery may be a necessity.

Arthroscopic washing and debridement is often undertaken to relieve discomfort within the knee joint, by removing ragged cartilage and smoothing the damaged cartilage remaining in OA, reducing the further action of inflammatory cytokines *(National Joint Registry, 2010).* On account of the straightforward procedure during surgery, arthroscopic debridement can be undertaken as an outpatient procedure as the risk of complications is relatively small. However, the short-term benefits of this procedure are not widely considered to be clinically significant. A brief overview of the literature revealed studies which found marked improvements in younger patients with mild degeneration of cartilage *(Rönn et al, 2011).* Selection of patients is key in the application of this method, and cannot alter the progression of the disease state; merely offer transient pain relief in this group *(Lützner et al, 2009).*

In early OA states, triggering cartilage repair appears to be a viable clinical option in the hopes of re-invigorating cartilage production within the joint. Bone marrow stimulation is achieved by creating arthroscopic microfractures within the bone, releasing stem cells in the hope of enhancing chondrocyte production, and has been successfully used to some effect *(Steadman, Rodkey & Rodrigo, 2001).*
Osteochondral and autologous chondrocyte transplantation have demonstrated long and short-term benefits in decreasing OA symptoms, by replacing disintegrating cartilage. The cartilage tissue is either sourced from a non-weight bearing section of the joint (autograft) or from a cadaveric donor (allograft). The tissue is then used to 'plug' missing cartilage segments, and are available as treatment for both large and small cartilaginous defects. Successful outcomes of this technique are heavily reliant upon strict patient-selection criteria *(UnitedHealthcare [Ox], 2014).*

If cartilage damage is restricted to one compartment of the knee (which can cause varus or valgus malalignment, as previously explained in Section 2.2.4), osteotomy is considered to be a viable surgical option. A wedge of bone is removed from the tibia of the healthy side of the knee, causing the tibia to bend in the opposite direction of the damage, redistributing pressure within the arthritic section of the joint *(Sterett et al, 2010)*. This procedure is mostly undertaken in varus knees (as these contribute 53-76% of OA cases *(Cahue et al, 2004; Felson et al, 2004)*). Osteotomy is often considered more suitable than joint replacement for younger candidates, as it is a less dramatic alternative, and has the potential to outlast the relatively short life-span of implants in this patient group *(Wolcott, Traub and Efird, 2010)*. Initial satisfaction rates have been found to be incredibly successful at 97%, but this drops to 68% after 9 years *(Rönn et al, 2011)*. Regardless of the noted deterioration in patient satisfaction, osteotomy is regarded as being a safe and effective technique of reducing pain and increasing functionality of joints in both young and old OA patients *(Zhang et al, 2011).*

Unicompartmental knee arthroplasty (UKA) is an alternative surgical intervention for OA affecting a singular compartment, by replacing only one part of the knee (Figure 2.14). In cases of OA where the surrounding ligaments of the knee are maintained, UKA is seen as a more appealing approach. The less invasive approach allows for quicker recovery time and functionality by minimising the damage to the surrounding structures, and leaving the patella untouched. There are very specific requirements for UKA candidates, and is carried out in younger patients with less progressed arthritis and better function. This demographic of patients often leads to the implanted joint becoming worn-down more quickly than their TKA counterparts, but the less invasive approach of UKA can make revision surgery much easier than performing a second TKA *(Rönn et al, 2011)*.

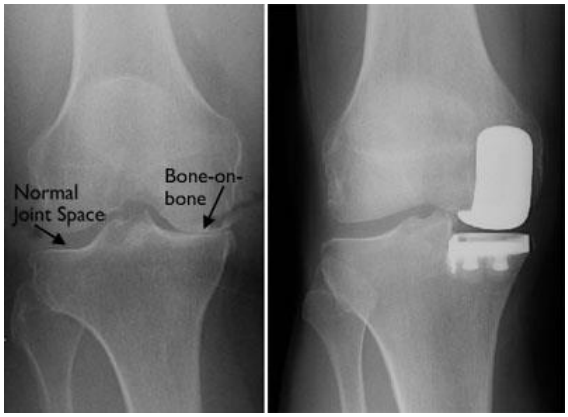

***Figure 2.14**- Unicompartmental OA before & after UKA (OrthoInfo.AAOS.org, 2015).*

2.4 Total Knee Arthroplasty (TKA)

In cases of OA where non-surgical, and non-invasive intervention is deemed to be unsuitable, TKA is a well-established and effective treatment route. Over 90,000 are undertaken in UK each year *(National Joint Registry, 2010),* and it has been proven as a safe and reproducible procedure. Like the other surgical options, TKA is primarily concerned with removing the arthritic portions of femoral and tibial bone, and using metal and plastic components to create caps on the end of these sections *(Stryker, 2015).* Unlike UKA, this process is carried out on both the medial and lateral compartments of the knee. If the knee cap is compromised, an artificial patella can be added to create the complete hinge joint, and a plastic 'spacer' is added to improve frictionless motion of the joint, as seen below in Figure 2.15 *(NHS.uk, 2014).*

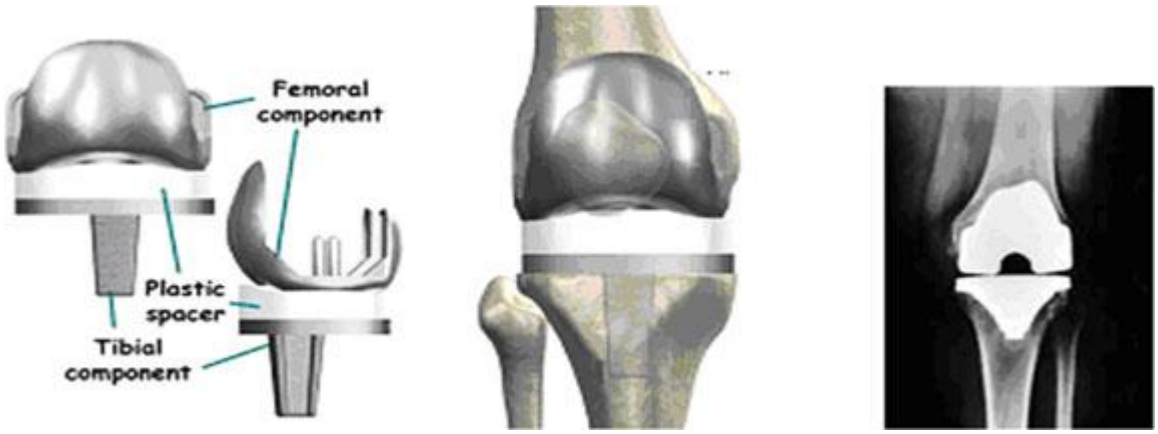

***Figure 2.15**- Artificial Knee Implant diagram & post-implant (DrMavalankar.com, 2015)*

A successful TKA procedure aims to restore knee kinematics, whilst restoring normal alignment and maintaining the integrity of the supporting ligaments. A cohort study based in the UK found that long-term results showed survival rates of implants between 81.1% (worst case) and 92.7% (best case scenario) 15 years after TKA *(Roberts, Esler & Harper, 2007).*

TKA is regarded as being a quantitatively efficient method of treatment in cases of ongoing OA, and is generally well received by patients. Although 9/10 patients regard their TKA procedure as beginning initially successful *(Woolhead, 2005),* pain

and disability often persevere following surgical intervention. However, with revision rates only around 5% after 10 years, this procedure appears to be clinically sound in achieving its aims *(Lützner et al., 2011).*

2.4.1 Indicators for TKA

As previously indicated, TKA is only recommended when other therapeutic option have been exhausted, and when other surgical measures are deemed to be inappropriate. Specific criteria for suitability of candidates for TKA centre's around the likely durability of the joint and the severity of disease progression.
The severity of the disease is often typified by the 'WOMAC' scale, which identifies the disease progression in terms of pain, stiffness and functional disability, as shown in Figure 2.16.

- **Pain (5 items):** during walking, using stairs, in bed, sitting or lying, and standing
- **Stiffness (2 items):** after first waking and later in the day
- **Physical Function (17 items):** stair use, rising from sitting, standing, bending, walking, getting in / out of a car, shopping, putting on / taking off socks, rising from bed, lying in bed, getting in / out of bath, sitting, getting on / off toilet, heavy household duties, light household duties

Figure 2.16 *- WOMAC scale of pain, stiffness and function in determining OA severity (Rheumatology.org, 2015)*

Ideally, elderly patients are suitable candidates as the joint implants are more likely to outlast the patient themselves (acceptable survival rate of joint is between 10 and 20 years). On account of the increased risk factors, and possible over-expectation of functional outcomes, younger adults are generally excluded from TKA and those that do undergo the procedures are found to be less satisfied with the post-operative recovery *(Elson & Brenkel, 2006).*

Radiographic indicators of OA- such as bony spurs and narrowed joint space- are important diagnostic criteria, though analysis showed no specific relationship between the severity of OA radiographic markers and satisfaction following TKA *(Chang et al., 2010).*

Pain and debilitating loss of function are the most definitive indicator for TKA, especially if pain perseveres following alternative, non-surgical intervention. If patients meet levels of overall mental and physical health requirements (including

age, weight and no evidence of infection) it may be appropriate to progress to TKA intervention *(Kim, Springer & Douglas, 2011)*.

2.4.2 Alignment in TKA

In considering a successful TKA procedure, it is believed that alignment between the artificial joint and the femoral and tibial components of the bone across this joint should be 0˚. If alignment is successful, the mechanical axis of the limb should pass through the centre of the knee, indicating a more natural form of load-bearing in the joint *(Werner et al, 2005).*

In cases of maintained malalignment, patients have displayed decreased functional mobility, increased wear, and ultimately implant failure due to this uneven weight-bearing across the joint. Subsequently, malalignment can cause significant discomfort for the patient, and is one of the most common complications of TKA, contributing to almost a fifth of all patients being dissatisfied with their care *(Bourne et al, 2009).*

Two main components contribute to maintaining neutral alignment of the lower limb following TKA: coronal and sagittal bone alignment, and soft-tissue balancing.

2.4.2.1 Coronal & Sagittal Alignment

Alignment of the femoral and tibial components is one of the most integral stages in a knee replacement. Standard surgical intervention aims to correct the malalignment of the lower limb to a target window of 0±3°, ensuring adequate load distribution through the prosthesis *(Werner et al, 2005).* If the lower limb is misaligned in the coronal plane, significant pressure can affect one side of the knee compartment, causing wear to the implant, in turn induces a decrease in the durability of the implant, stability of lower leg, and functional motion *(Cherian et al, 2014).*
Although 0˚ is considered the ideal mechanical alignment, post-operative targets most commonly aim to achieve varus/valgus deviation of ±3˚, with both in-vivo and in-vitro evidence reporting detrimental effects out with this range *(Ritter et al, 1994).* Achieving this relatively small ‘ideal’ value can be difficult, due to the subjectivity of assessment methods relying upon observational evaluation, as outlined previously. Incorrect positioning of implants can produce poor alignment, leading to accelerated

wear of the implant and subsequent ligament imbalance, resulting in implant failure *(Chin et al, 2005).* The propensity of human error in pre-operative planning can multiply to create significant inaccuracy in surgical alignment, even when used in conjunction with long-leg radiographs *(Willcox et al, 2012).*

The sagittal plane of malalignment has not been studied as thoroughly as the coronal plane of motion, although the majority of function of the knee is in this plane. The changing of the mechanical axis during varying flexion and extension has led to disagreement within the field as to what the reference axis in sagittal analysis would actually be. However, it is understood that levels of over-flexion can lead to wear *(Puloski et al, 2001),* and over-extension can eventually result in increased levels of fracture within the bone *(Ritter et al, 2005).*

2.4.2.2 Balancing Soft Tissues

On account of the stability and the structural importance that the ligaments of the knee give to the joint, soft tissues are essential in maintaining neutral lower limb alignment. The progression of OA can lead to restricted ligament function across the knee joint, in addition to an intrusion of osteophytes into the knee joint space, restricting the motion of the joint.

In addition to alignment values, soft tissue ligament balancing is just as (if not possibly more) important in optimal joint restoration following TKA *(Jerry & Dounchis, 2013).*The surgical goal of balancing ligaments is to create uniformed tension around the knee, in both extension and flexion. Similar to the effects of neutral alignment, better balance of force across the knee joint is related to a better functional outcome and reduction in patient perceived pain *(Takahashi, Wada & Yamamoto, 1997).* However, management of soft tissue balance during surgery is not defined by quantitative measures, and are conditional to the subjectivity of clinical assessment. Soft tissue balancing is undertaken to create and maintain equal tension in all ligaments across the knee, during both flexion and extension, and is well recognised as an essential component of a successful TKA procedure *(Griffin, Insall & Scuderi, 2000).* Several methods are actively used to assess the balance of tissues, including tibiofemoral spacers, loaded tensors and laminar spreaders – which all rely upon the surgical 'intuition' to determine when balance is achieved *(Matsumoto et al, 2012).*

To achieve optimal soft tissue balance, a proportionate gap between the femoral and tibial components in extension and flexion is related to a greater functional outcome following surgery *(Mihalko et al, 2009).* There are two main approaches to achieving a balanced gap: altering the tension in the tissues, and altering the rotational axis by removing portions of the bone.

Resection of bone can allow alteration of rotational axis of the femur independent of the tissues to realign the mechanical axis, but is related to levels of inaccuracy due to natural variation in femoral anatomy between patients *(Daines & Dennis, 2014).* Soft tissue release involves making incisions in muscles and ligaments which are causing joint deformity by being too 'tight'. There is a fine line for acceptable soft tissue release, as knees that are considered tight may be related to an increased level of patient dissatisfaction following surgery, and excessive release leads to a number of complications, such as higher levels of post-operative bleeding, infection *(Kumar & Dorr, 1997)* and increased instability *(Zalzal et al, 2004).* Gradual release of tissues is an effective and common technique to correct inherent deformities of the knee and subsequent malalignment. A comprehensive overview presented to the AAOS, determined that 66.5% of TKA's undertaken required at least one release *(Peters et al, 2013).*

2.5 Clinical Assessment of the knee

2.5.1 Varus Valgus Stress Test

Pre-operative clinical assessment of laxity preceding TKA is often undertaken by means of a manual knee examination by the operating surgeon, to establish levels of medial and lateral collateral ligament laxity. This can be executed by supporting the knee and applying force to the ankle in varying degrees of flexion, and at hyperextension (Figure 2.17). In applying a valgus stress, the medial instability of the limb was examined in both locked (hyperextension) and unlocked (flexion) positions. An applied varus stress produces lateral movement, accounting for instability *(Magee,*

2008). The result is deviation from the neutral axis, and allowing the varus/valgus angle of displacement to be calculated *(Consultant360.com).*

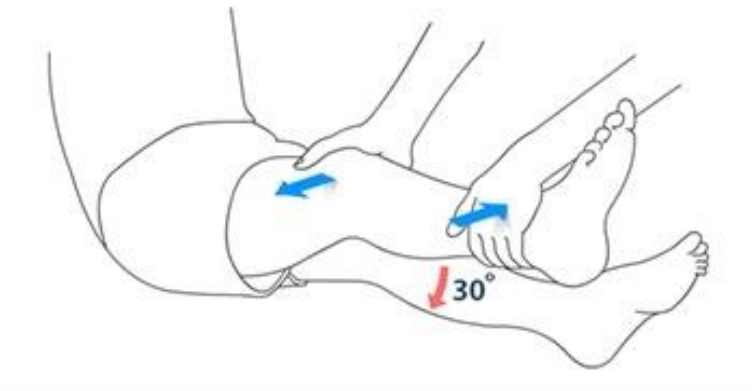

***Figure 2.17** – Diagram of a varus stress test carried out at 30˚ (Hip Knee Specialist, 2015).*

The level of displacement can guide the surgeon as to the need for, and extent of any surgical release. However, this form of assessment is highly subjective and can generate high volumes of inter- and intra-observer variation *(Edwards et al, 2004).* It is most likely this observer variation which has caused post-operative laxity results of ±3˚ in almost 30% of cases *(Petersen & Engh, 1988).*

2.5.2 Anterior Laxity Test

The anterior Laxity test is clinically applied to establish the presence of anterior cruciate ligament injury, which could indicate the need for surgical intervention. The patient's foot should rest upon the examination couch, with the knee flexed at 90˚ and the hamstrings relaxed. The clinician places the hands around the tibia (with thumbs around the joint line), which is then drawn forward from the femur in short, sharp motions *(WheelessOnline.com, 2015a),* as demonstrated in Figure 2.15. The 'normal' value of displacement for this motion should be approximately within 6mm, with deviations indicating a 'positive' result, and therefore the presence of injury *(PT Haven, 2015).*

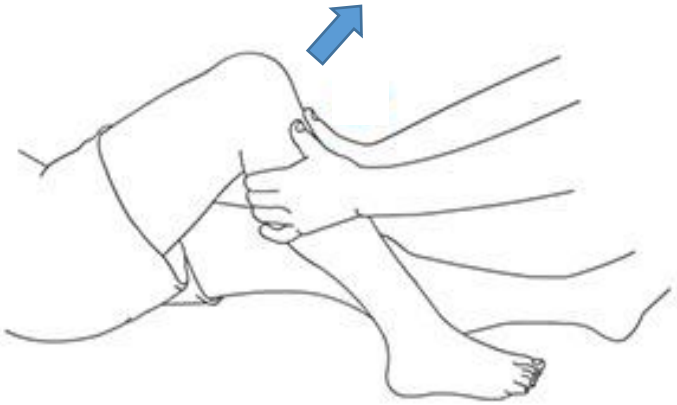

***Figure 2.15**- Diagram of anterior Laxity test carried out at 90˚ (Hip Knee Specialist, 2015).*

A firm endpoint to this motion suggests an intact ACL, whereas a ruptured ligament produces a softer, less distinct endpoint. If the increased displacement occurs anteriorly, injury to the ACL is suspected. Conversely, if the displacement occurs posteriorly, this indicates possible damage to the PCL *(ClinicalAdvisor.com, 2015).* If this test is carried out between 20-30˚, it is termed as the Lachman Test.

2.5.3 Issues with clinician based assessment

The analysis of laxity is based on the estimation of the surgeon, with understanding being based upon what "feels right" at levels of flexion. When estimating the ligament laxity, there is no set protocol in terms of angles of flexion and extension, and methods of recording axial displacement can be imprecise *(Bäthis et al, 2004).* There will be significant variations between clinicians as no uniformed applied force target exists, and the greater the level of force applied, the greater the volume of perceived displacement *(Sekiya et al, 2009).* Measurements of laxity are undertaken when the candidate is in the supine position, and therefore no load-bearing is experienced upon the joint, potentially leading to an incorrect assessment of ligament laxity on account of an alteration in mechanical axis in weight-bearing *(Krackow et al, 1990).*

Additionally, there are inconsistencies within pre- and post-operative imaging for gathering information for surgery, as radiographic imaging can be inconsistent on account of possible patient-positioning errors and clinical interpretation.

The subjectivity of clinical laxity assessments of the lower limb preceding TKA can create a real problem in achieving a clinically neutral alignment following surgery. The above factors, in conjunction with a necessary learning curve for newly qualified surgeons *(Cheng, Cheng & Chen, 2011)* as they gain the skills necessary to assess levels of displacement manually, may contribute to the ~30% of patients which suffer from malalignment following surgical intervention *(Petersen & Engh, 1988).*

2.6 Computer-Assisted Orthopaedic Surgery (CAOS)

Computer-assisted surgery is a discipline utilising technology combining engineering, computing and robotics to aid in simulation, planning and implementation of surgical tasks in the hope of improving clinical and operative outcomes *(DiGioia, Jaramaz & Colgan, 1998).*

Originally, computer-assisted surgery (CAS) was developed to locate tumours in neurosurgery *(Knake, 1980),* but has since been incorporated into many surgical fields. Orthopaedics has been shown to be an excellent candidate for CAS, and as such there has been significantly progress in this field since its inception. Bones and the related soft-tissues can be accurately evaluated by fluoroscopy, CT, MRI and radiographic imaging, allowing for gathering of precise information for 3D rendering of the imaged body segment. Additionally, the solid nature of bones does not allow for significant deformation of their structure, and therefore information gathered pre-operatively can be applied during surgery *(Sugano, 2003).*

The introduction of CAOS has raised the standards of modern orthopaedic surgery, by increasing the expected levels of precision and accuracy within procedures and to positively impact in clinical and surgical outcomes. The fine motion control which is afforded with the use of robotics has the potential to improve minimally invasive surgical intervention *(Ulrich et al, 2007),* allowing the application of this technology to explore new concepts. The creation of simulations of surgery available with the use of CAS has opened up a new avenue for the training and education for surgeons, providing repeatable and safe scenarios to hone technical skill *(Kneebone, 2003).* This technology has provided accomplishments in optimal positioning of prostheses

during joint replacement surgery, and ensure optimal ligament balance whilst maintaining the stability of the artificial joint *(Nizzard et al, 2002).*

Guiding systems for CAS are generally considered to be defined as three distinct groups: passive, active and semi-active guiding systems, and classification is related to the ratio of operator and device control of the system *(Troccaz, Peshkin & Davies, 1998).*

Passive systems are reliant upon the surgeon, or operator controlling and executing the steps of the procedure. These systems can take the form of relaying kinematic information regarding location of markers in 3D space, or stabilising movements undertaken by the surgeon *(Schneider & Troccaz, 2001).* Active systems take on a specific task during the procedure, which can extend to holding and controlling tools, to making surgical incisions and manoeuvring through complex geometry. These systems are often used to compensate for tasks where extremely high levels of precision and accuracy are required *(Vendittelli, 2013).* Semi-active systems combines pre-positional aspects to translate complex and accurate surgical plans and implement them during the operating procedure. This type of system can involve mechanical constraints restricting the effective field open to the human operator (for example, retracting saw when the tool goes out with the planned surgical field). The combination of operator interaction and system programming has restricted this approach to fairly straight-forward surgical techniques *(Lemke et al, 2002).*

Passive systems are becoming widely adopted as the preferred method CAS for orthopaedic procedures, as it refers detailed information to the surgeon who can use this to achieve more accurate alignment values and allows more freedom to achieve the pre-surgical plan than when compared to active and semi-active systems *(Lang et al, 2011).* These systems use a series of cameras to track surgical instruments, and body segment geometry and alignment to monitor progress in real time *(Davies et al, 2007).* The use of CAOS in UKR has demonstrated significant increases in alignment and soft-tissue balance compared with standard approaches *(Cobb, 2006),* although these findings have not been unanimous across the literature.
Malalignment of the lower limb and ligament loosening, as well as the longevity and survivability of orthopaedic implants are issues still affecting the long-term success

of joint replacement related to inaccuracy of surgical procedures. The implementation and growing popularity of computer-assisted surgery in orthopaedic procedures is both increasing the precision and accuracy possible, as well as improving the success of minimally invasive surgery *(NUS.com.sg, 2010).*

2.6.1 Navigation in CAOS

To ensure a successful procedure using CAOS, there are three essential components of surgical navigation: data acquisition, registration and tracking technology *(Kanlić, DeLaRosa & Pirela-Cruz, 2006).*

2.6.1.1 Data Acquisition

Collecting data for use in navigation is normally considered to be a two-tiered approach, to ultimately provide the surgeon with a visualisation of the bones and surgical instruments used during the procedure. Pre-operative imaging is delivered in the form of CT or MRI scans, to gain a radiographic map of the musculoskeletal system which forms the basis of the surgical plan *(Radermacher et al, 1998).* Intraoperative imaging is also integral to the implementing this plan during surgery, with fluoroscopic imaging able to illustrate bones and soft tissues in real time *(Parikh et al, 2014).* Image-free data collection relies upon the anatomical landmarks and kinematic geometry of the skeletal frame (using mathematical joint centre calculations and trackers) to recreate a model of the bones throughout the duration of the operation *(Jolesz, 2014).*

2.6.1.2 Registration

Registration is the essential process wherein the pre-operative surgical plan is applied to the patient's physical anatomy, removing spatial inconsistencies that could arise between the data collection and tracking stages of navigation. This is known as 'spatial transformation' *(Simon, 1997a).* In addition to the trackers attached to bone to establish the position of the patient's anatomy within the surgical field, the surgical instruments must also be registered to relate their position to the anatomy. This is especially important in terms of semi-active CAS procedures where the surgical area has precise boundaries (*Kanlić, DeLaRosa & Pirela-Cruz, 2006).* Using the information gathered during data acquisition and registration, systems can often calculate optimal

orthopaedic implant positioning and has been credited with improving component alignment, and implant survivability *(Rosenberger et al, 2007).*

By tracking the body segments during surgery, the CAOS system is able to fully realise the motion of the bones, by communicating via infra-red (IR) trackers to signal the position of these trackers to IR cameras. As these trackers are attached to the bone, and rely upon the use of anatomical landmarks, the rendered model of bones reflects the patient specifically, and ultimately results in a patient specific 3D intra-operative model *(Radermacher et al, 1998).*

2.6.1.3 Image-Based Navigation

2.6.1.3.1 CT Based Imaging

Image-guided navigation systems heavily rely upon extensive pre-operative imaging in order to create the surgical plan. CT- based navigation was developed for use in lumbar-spinal surgery, and recreates a complex 3D model of the skeleton. However, this system is related to a lengthy registration process, focusing on paired anatomical bony structures and correlating these with landmarks on the CT images *(Lavallée, 1996).* This form of navigation has been investigated into its impact in TKA surgery, but has generally been found to be a costly addendum. Subsequently, other navigation techniques are more often used in orthopaedic knee surgery *(Delp et al, 1998).* Alternatively, intra-operative CT guided systems are available, which allows for real-time imaging without need for registration. This technology is also not widely used, due to its cost and the additional space required for these machines in the operating theatre *(Hüfner et al, 2004).*

2.6.1.3.2 Fluoroscopic Imaging

As fluoroscopic imaging is such an integral component of pre-operative assessment, it is unsurprising that this technology has been amended to allow for intra-operative use. Fluoroscopic navigation allows for continuous feedback of the bone components and surgical tools, and is well-suited for tracking the placement of the implant *(Joskowicz, 2000).* Both 2D and 3D fluoroscopy provides surgical guiding in up to 4 planes, however, the radiation involved can be detrimental to both patients and clinical staff *(Nolte & Beutler, 2004).*

2.6.1.4 Image-free Navigation

Image-free navigation systems are the simplest and most widely used guiding systems for use during TKA surgical procedures. As previously outlined, these systems involve calculation of the ankle, hip and knee centres twinned with anatomical registration of bony landmarks to create a kinematic surgical model, and was pioneered by Picard in 1997 (*Pimpalnerkar and Haritinian, 2013).* Precise registration is essential, as small errors in anatomical surface registration can be magnified in reference frames, meaning measurements could be incorrect to the tune of a few degrees *(Siston et al, 2007).*

Optical tracking of bone segments and surgical instruments is utilized as an alternative to the CT or fluoroscopy options used in image-guided systems. Infra-red (IR) camera and tracker systems have become a popular option for use during image-free navigation as the system is not affected by interference of metal objects, which is a significant problem in electromagnetic systems which renders it undesirable for use in operating theatres *(DiGioia et al, 2005*). A number of functional requirements are expected of an 'ideal' optical tracking systems in terms of viability. Trackers should be small and self-contained, and able to track position and orientation accurately, with resilience to any environmental interference *(Welch & Foxlin, 2002).* IR systems have been well adopted in this respect as measurements have demonstrated fast and accurate responses *(Sugano, 2003).* Development of image-free CAOS has resulted in a multi-component system to optimise data acquisition and real-time informational processing *(Picard et al, 2000).*

2.6.2 Infra-Red (IR) Image-free Navigation

Image-free navigation comprises of several components involved in collecting and processing kinematic information. This technology has been pioneered in almost exclusively in TKA procedures, and hip arthroplasty procedures to a much smaller extent *(Walker, Monda & Chauhan, 2010.)*

2.6.2.1 Infra-Red Trackers

Intra-operative trackers make computer software aware of their position, and their kinematic positioning is then used to build the surgical model *(Simon, 1997b).* Trackers must be visible to the IR camera at all times, or the signal is lost and components are

not tracked. During navigated TKA, the trackers are attached to pins which are drilled into the bone, (one in the femur, and one in the tibia) in an effort to increase stability and remove signal interference that could be caused by motion of the soft-tissues.

Active trackers: Active trackers emit infra-red light via LEDs which is recognised by an IR camera. This type of tracker demonstrates a strong signal despite its generally small size, but relies upon an additional power source (such as battery packs or mains power) to function. This is not ideal in surgery, as heavy battery packs can result in unnecessary movement of the trackers and additional wiring within the surgical area could complicate matters further *(Mehling, 2006).*

Passive trackers: Conversely, passive trackers are retro-reflective, and therefore do not act as a light source. By reflecting IR light back to a camera, the markers are visualised, albeit creating a weaker signal that their active counterparts. As this method does not require an additional power supply, stability can be improved but signals from passive trackers can be affected by handling of the trackers themselves, as a build-up of dirt can occlude some of the signal *(AR-Tracking.com, 2015).* Passive trackers are more often used in orthopaedic surgery due to their usability and reduced cost profile, compared to active trackers.

2.6.2.2 Localiser

The localiser of the system uses a series of camera's (usually two or three) to determine spatial positioning of trackers within the surgical field. By arranging these cameras in a binocular arrangement (like the NDI Spectra IR camera), there is a defined field of measurement- leading to increased accuracy of positional calculations *(Picard, 2007).*

The IR camera of an image-free navigation systems acts as the input device, by calculating the position of the IR trackers in the surgical field and transfers the data to the computational unit. The type of camera used varies with the capability of the trackers within the system. Active trackers are used in conjunction with simple IR-sensing cameras, whereas passive systems require IR-emitting cameras to provide a light source for the reflection of IR light which indicated their position *(Biswas, 2013).*

2.6.2.3 Registration Stylus

In addition to the two segment trackers which are attached to the bone segments, the system uses a tracked stylus, or pointer. This instrument is used during registration of anatomical landmarks to quantify their position in reference to the thigh and shank segments, and calibrate the lower leg model used during surgery *(Siston et al, 2007).*

2.6.2.4 Computer System

The computer system is involved in determining the position in space of each IR tracker, and can then monitor the movement of the generated body segments in space.

The software of the computational component visualises the bones of the joint, and allows clinicians to track the movement of the lower limb in real time, establishing and achieving functional targets. Data can then be saved, and stored for further analysis, if required.

2.6.3 Outcomes of Image-free Navigated TKA

The optimal 'end-game' of CAOS is in delivering safe, accurate integration of pre-operative imaging and planning into surgical intervention. It has been shown that the implementation of CAOS can improve precision in surgical outcomes, but the relationship between successful surgical intervention and functional outcome has yet to be strictly defined *(DiGioia, 2003).* Generally, for a successful TKA both knee-alignment and soft-tissue balancing are integral factors, and are the two main focal points for investigative studies into the outcome of CAOS *(Huten, 2002).*

2.6.3.1 Mechanical Axis Alignment

The introduction of CAOS in TKA procedures has been shown to improve lower limb mechanical alignment and implant positioning *(Bäthis et al, 2004; Decking et al, 2005; Ensini et al, 2007; Johnson et al, 2013)* and improved accuracy *(Pitto, 2006)* in both the coronal and sagittal planes. Standard computer navigated approaches have not been found to improve rotational alignment in TKA procedures *(Matziolis et al, 2007)*, however, alternative land-marking techniques have provided increased accuracy for rotational alignment *(Lützner et al, 2008).*

Studies have demonstrated that there is a clear discrepancy between CAOS and manual alignment techniques, with computer navigation displaying much less

variation. Attainment of ideal mechanical alignment (0±3°) can be as high as 96% for CAOS procedures, compared to 78% in standard TKA procedures *(Bäthis et al, 2004).* However, a multi-centre study consisting of a greater number of TKA assessments reported that mechanical alignment of the lower limb within 0±3° was achieved in 88% of computer-guided surgeries, compared to the manual standard procedure obtaining ideal alignment in only 72% of cases *(Jenny & Boeri, 2003).*

Studies into the outcomes of CAOS produced improved alignment results and a reduction in statistical outliers following TKA *(Dyrhovden et al, 2013)*, but demonstrate their own limitations. Radiographs cannot accurately depict rotational components, and thus the anatomical landmark identification carried out by surgical staff is important in definition of alignment of the mechanical axis *(Lonner, Laird & Stuchin, 1996).*

As previously outlined, standard assessment of knee laxity and alignment is often subjective. It would therefore follow that clinical assessment would become more fine-tuned as clinicians gain more experience, and complete more surgeries. Increased levels of accuracy supported by CAOS could allow inexperienced clinicians to benefit from the real-time feedback during surgery, leading to reduced learning curve and improved operative outcome *(Seyler, 2008).*

2.6.3.2 Soft Tissue Management

Investigation into the use of navigated technology in relation to soft-tissue release has been validated to produce repeatable and reliable results and have aided in the quantification of release required, as opposed to the conventional subjective approach currently utilised *(Picard et al, 2007).*

The implementation of CAOS to the process of soft tissue balancing allows for the surgeon to gauge alignment, whilst measuring flexion-extension gaps throughout the patient ROM *(Babazadeh, 2009).* The use of navigation during flexion and extension of the knee demonstrates ligamentation balance throughout this motion, which can aid the surgeon in pinpointing position of soft-tissue balance *(Klein et al, 2004).* This benefit shows extreme promise in the field of surgical training, by improving alignment perception; invaluable for improving surgical outcomes with or without computer-navigation systems.

The real-time feedback features of CAOS systems can allow surgeons the freedom to undertake sequential, selective release of tissues and monitor the alignment and balance step by step, therefore limiting the release that may be undertaken. Ritter et al demonstrated that less soft-tissue release was preferable, as although excessive laxity returned a greater ROM, it was also related to a greater pain profile in patients, as well as increased levels of implant dysfunction and wear *(Ritter et al, 2007).* However, excessive tension of the joint can lead to a reduced range of motion and deviation from the MFT angle by >4˚- indicating the very delicate nature of this tissue-balancing procedure *(Pang et al, 2011).*

CAOS systems have shown both improved alignment, and reduced levels of soft-tissue release in TKA, compared to conventional techniques. Picard et al developed an algorithm using data collected during CAOS, which reduced the requirement for soft-tissue release in navigated patients (25%), compared to conventional techniques (46%) *(Picard et al, 2007).* Enhanced predictors for identifying the need for tissue-release have been developed, and resulted in an even lower level of navigated release in only 10.75% *(Haikki, 2009).* Remarkably, a group have demonstrated a release rate of 2.2% in CAOS groups following a slightly altered surgical approach, by analysing the need for tissue-release following bone cuts and osteophyte excision *(Goudie & Deep, 2014).*

Using a combination of gap balancing, alignment values and functional scoring systems, CAOS has demonstrated an improved outcome compared to conventional methods. At 90˚ of flexion and at extension, there was a reduced level of outliers (determined as >3mm between medial and lateral sides), and this can possibly be attributed with the more accurate achievement of a rectangular joint gap with CAOS *(Lee et al, 2009).*

A combined approach of infra-red landmark data and kinematic data referring to soft-tissue should be able to produce accurate and repeatable results in reference to both mechanical alignment and tissue-balancing values.

3. Validation of the new-generation passive IR trackers

This chapter describes the non-invasive optical IR tracking system used throughout the study, and describes the registration process that will be used in Chapters 4 & 5 in detail.
It reports the functional comparison of the precision of the system using active IR trackers, passive IR trackers, and the low-profile new generation IR trackers in a healthy volunteer.

3.1 Description of Optical Tracking System

The image-free optical tracking system used in study was adapted from the OrthoPilot® Navigation System (Aesculap, Tuttlingen, Germany), which is the most popular CAOS system currently used in Scotland. The OrthoPilot system shown in Figure 3.1 has been comprehensively analysed, and demonstrated accuracy in surgical measurements within 1˚ of ideal alignment values *(Skowroński et al, 2005)*, well within the 0±3° operative target. This system does not require pre-operative images (CT/MRI) and as such, eliminates the need for intraoperative data matching or planning- streamlining the pre-operative process, in addition to removing operative radiation exposure *(Clemens et al, 2004).*

Figure 3.1*- OrthoPilot® Navigation System (BBraun, 2015).*

The ‘PhysioPilot v1.0’ software is derived from the ‘Knee Suite’ protocols of the OrthoPilot system, and was used on a laptop, to make the system more portable than that used in surgery. The NDI Spectra IR optical camera **(**Figure 3.2**)** was mounted to a tripod, and was used in conjunction with the PhysioPilot software to simulate the OrthoPilot stacks used intraoperatively.

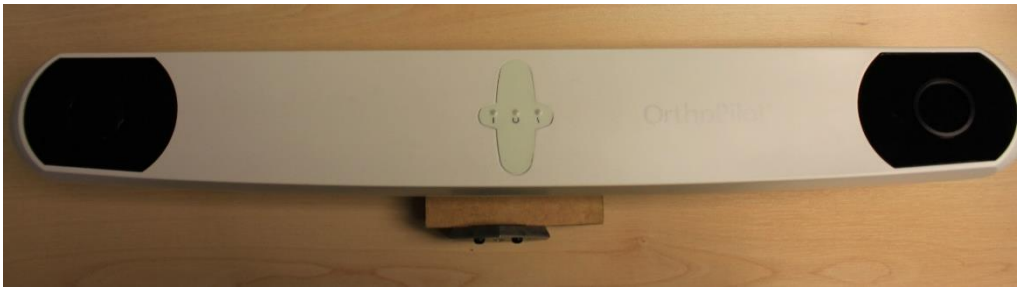

Figure 3.2*- NDI Spectra 'OrthoPilot' IR camera*

This imageless IR navigation system has been clinically validated for measurement of mechanical alignment in supine extension and early flexion *(Clarke et al, 2012).* Further investigation demonstrated that the PhysioPilot software provided accurate and reliable measurements for anterior-posterior laxity *(Alho et al, 2015)* and coronal laxity following force application across the knee joint *(Clarke et al, 2012).* Reflective, passive trackers are most commonly the IR markers of choice in CAOS, thus they were chosen to be used as the markers within this study. Furthermore, following on from his 2012 study, Clarke developed a new-generation of lower-profile passive IR trackers, to increase stability of fixation.

3.2 Description of Trackers

The PhysioPilot system has been used to record knee laxity before, firstly using active IR trackers that were with the OrthoPilot system intraoperatively *(Clarke, 2012)* and secondly with a passive IR reflective trackers. *(Alho et al, 2015; Henderson et al, 2015)* shown in Figure 3.3.

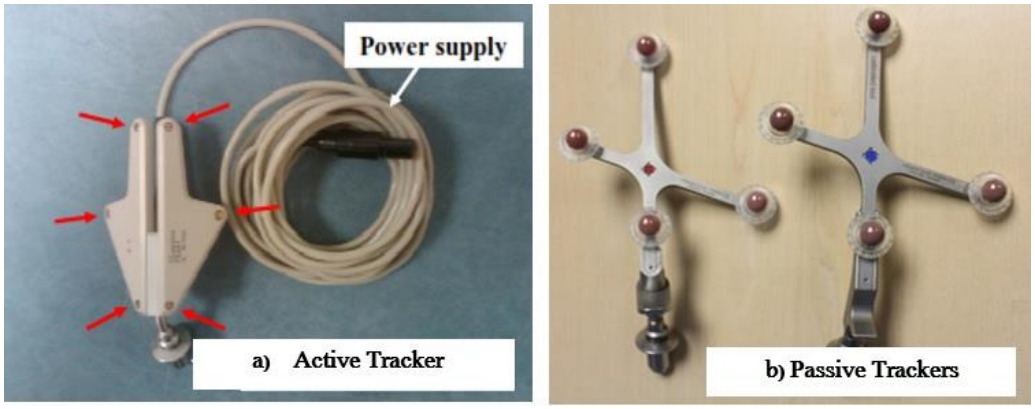

Figure 3.3 – a) *Active IR tracker and power supply and* ***b)*** *Passive IR tracker set (blue for the femur, red for the tibia)*

Accuracy and precision of both the previous active and passive reiterations of the IR tracking systems has been demonstrated in femorotibial alignment in extension and slight flexion *(Clarke, 2012; Alho et al, 2015)*. However, Henderson et al found that measurements varied out-with the acceptable target range as flexion was increased from zero, and proposed that the issues were on account of the navigation trackers.

To combat the variation given by the passive trackers, new low-profile IR passive trackers were developed. These new-generation trackers (Figure 3.4) were mounted on elasticated strapping on metallic base plates, and were designed to reduce extraneous motion of the trackers.

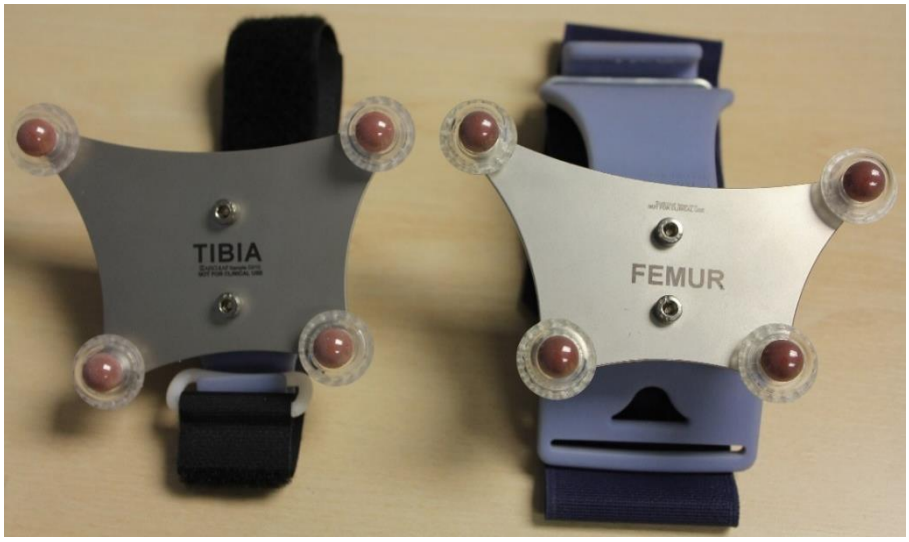

Figure 3.4 *– New-generation low profile IR tibial and femoral*

These trackers were attached to the participant at the same position. The femoral tracker was attached at the musculo-tendonous junction of the quadriceps femoris muscle (~10cm proximal to the patella) and the tibial tracker was attached slightly distal to the tibial tuberosity (~10cm distal from the patella), as demonstrated in Figure 3.5.

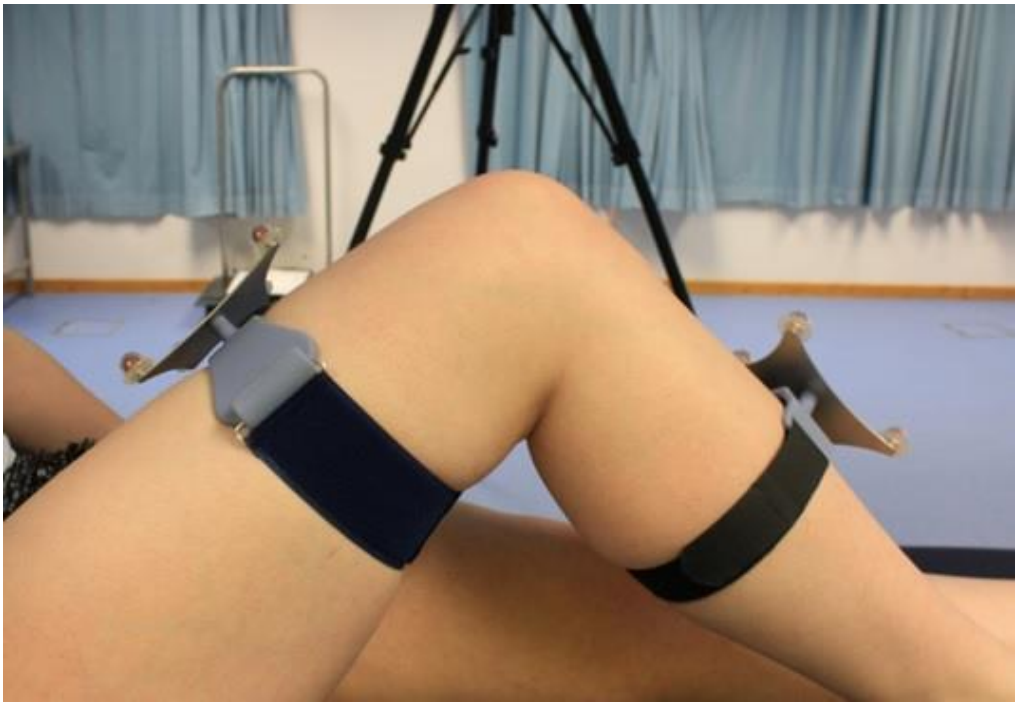

Figure 3.5 *– Positioning of the new-generation (femoral and tibial) IR trackers attached to a participant*

3.3 Validation Methodology

To investigate whether these new-generation passive trackers were as accurate and reliable as the previous incarnations, multiple registration processes were undertaken. To eliminate any likelihood of skewed results on account of the inexperience of the investigator, these registrations were undertaken by Mr Clarke, an experienced orthopaedic surgeon based at the Golden Jubilee National Hospital.

Five repetitions of each registration were undertaken to demonstrate the accuracy and reliability of each tracking system (active, passive, new-generation passive). The registration process is as follows:

3.3.1 Registration Process

3.3.1.1 Registration of Anatomical Landmarks

The first steps of the registration are involved with using the IR tracked registration stylus shown in Figure 3.6, which when held steadily to the anatomical position requested will register the location of the bony landmark- noting its position in 3D space in relation to the femoral and tibial trackers. This procedure will generate a 3D

model of the lower limb to use later on when recording displacement due to force administration.

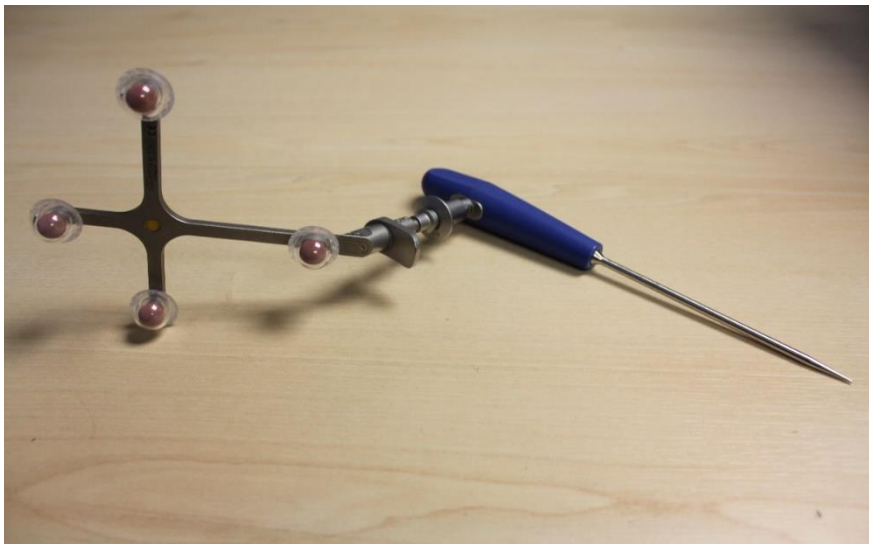

Figure 3.6 *– Registration stylus*

The participant lay relaxed in a supine position on an examination couch for the duration of the registration assessment. The right leg of the participant was positioned at 90˚ of flexion.

To register the geometry of the knee, the stylus was placed at the medial epicondyle, where the data was saved using a foot pedal, to allow for the use of both hands for registration (which aids in keeping the registration stylus steady for accurate data registration). This was followed by registration of the lateral epicondyle (Figure 3.7).

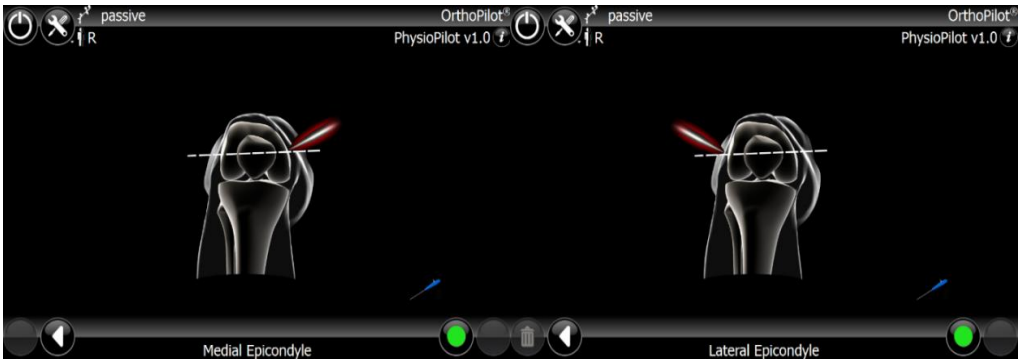

Figure 3.7 – *Anatomical registration of the medial and lateral epicondyle*

Using these two points as reference, the stylus was placed in the anatomical centre of the knee, shown in Figure 3.8. The interface guided the stylus to aid with approximating the position.

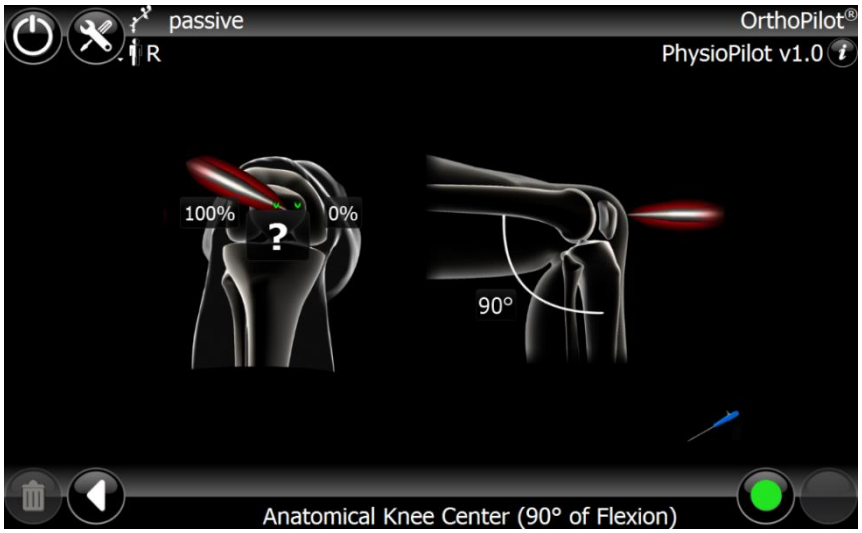

Figure 3.8 *– Anatomical registration of the anatomical knee centre in flexion*

The same procedure was undertaken to fully register the geometry of the ankle, and the participant's leg remained at 90˚ of flexion. The medial and lateral malleolus were both registered (Figure 3.9) and the anatomical ankle centre was registered (Figure 3.10).

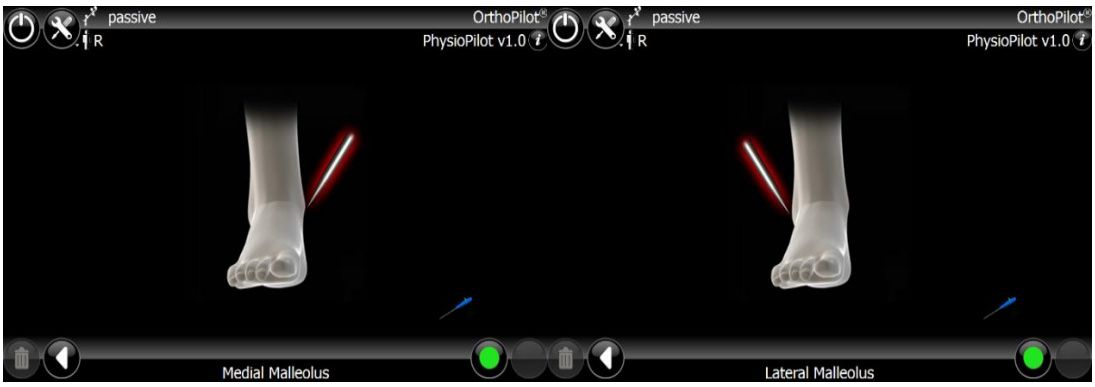

Figure 3.9 *– Anatomical registration of the medial and lateral malleolus of the ankle*

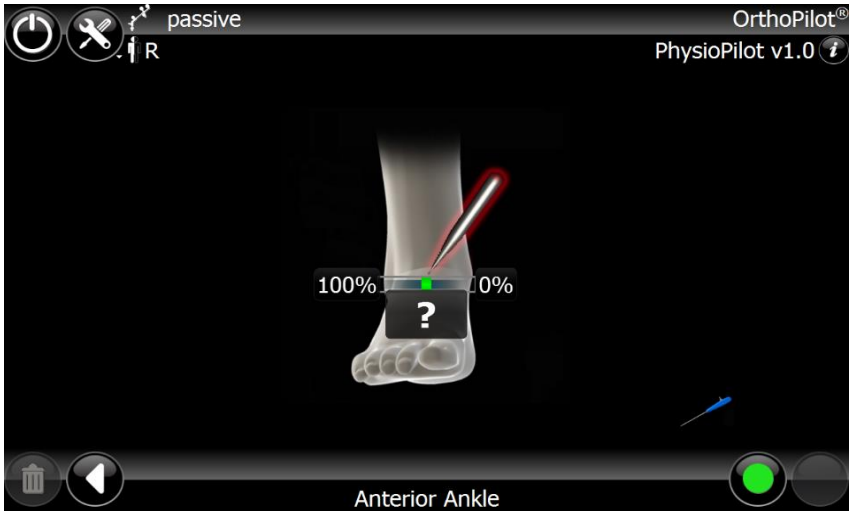

Figure 3.10 – *Anatomical registration of the ankle centre*

The anatomical ankle centre is harder to accurately identify than the knee centre, so the participant was asked to raise their big toe, thus activating the extensor hallucis longus muscle which is an effective indicator of the anatomical ankle centre.

3.3.1.2 Registration of Functional Joint Centres

Taking the positional data gathered in Section 3.3.1.1, the true centre of the hip and knee joint was calibrated by recording the position of the leg through prescribed motion. The centre of the hip was assessed through rotation of the participant's extended, relaxed leg (Figure 3.11).

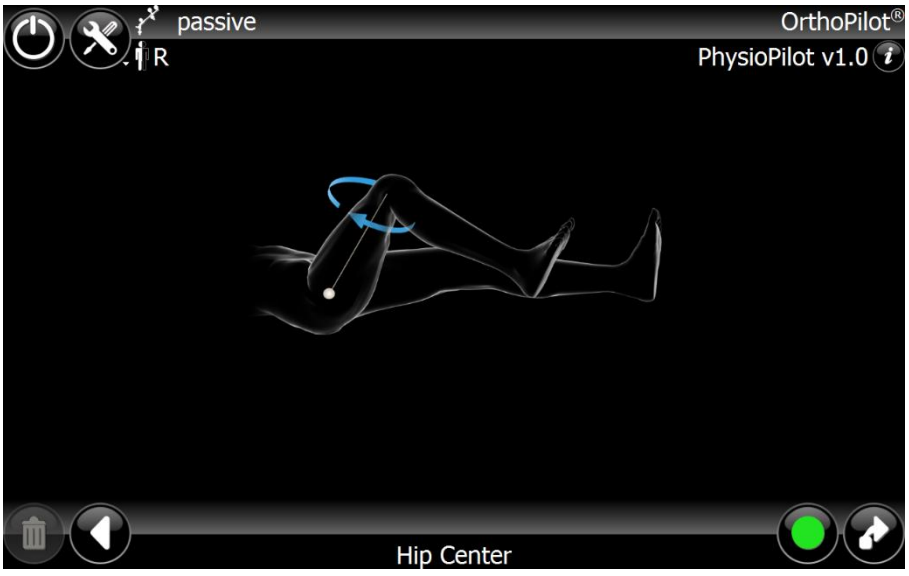

Figure 3.11 *– Prescribed motion for recording functional hip centre*

The heel of the foot was supported and the leg was slowly moved in a small circle, corresponding to the designated instruction of the PhysioPilot software (Figure 3.12). It was essential that the participant was completely relaxed, as any voluntary contraction of the leg muscles resulted in motion which is not recognised by the software, and registration would be rejected. By tracking the movement of the IR trackers in relation to the anatomical landmark positions and following the PhysioPilot path, it was possible to calculate the point of rotation, and therefore the hip centre.

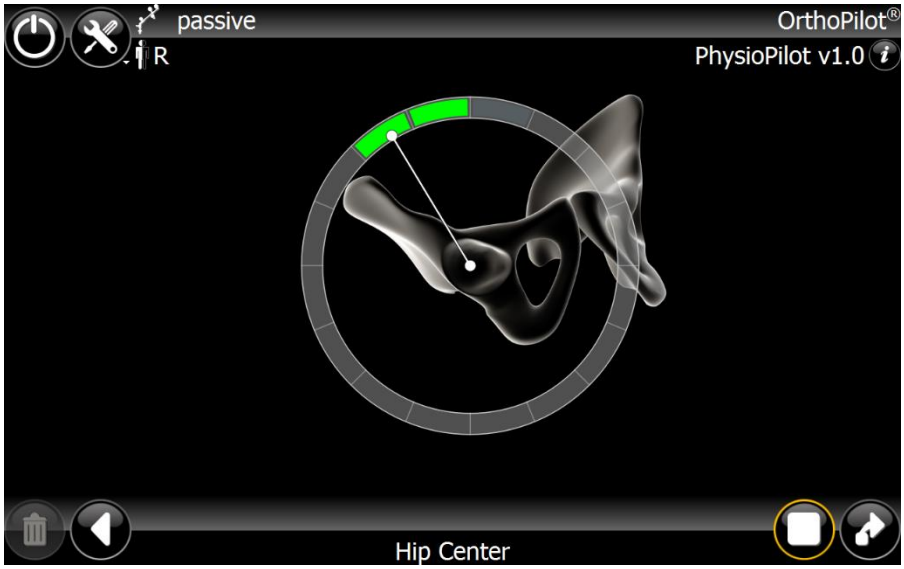

Figure 3.12 *– The path of rotation, for calculation of the functional hip centre*

To calculate the functional knee centre, the relaxed leg was flexed from full extension to approximately 90˚, following the designated path (Figure 3.13), with care being taken to keep the foot in the neutral position. At maximum flexion, the tibia was rotated medially and laterally by holding the foot, completing calculation of the functional knee centre.

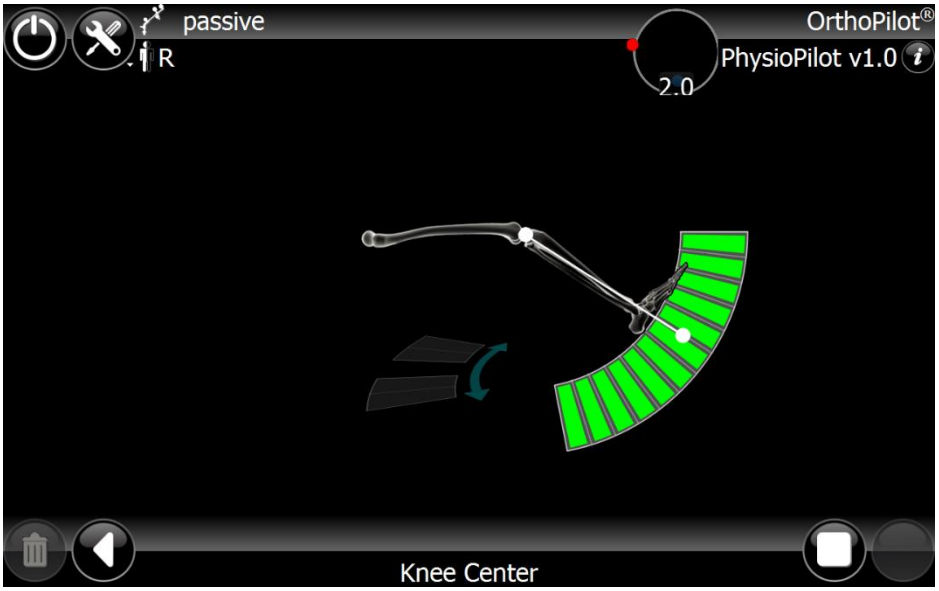

Figure 3.13 *– The path of flexion, and medial and lateral rotation for calculation of the functional knee centre*

This completed the registration process, and a virtual model of the participant's leg was then generated (Figure 3.14), as the participant's leg was extended and supported by the heel. The mechanical axis of the leg demonstrated the natural alignment of the participant in coronal and sagittal planes in terms of angular varus/valgus and extension values, using the data collected in the previous registrative steps. An additional recording of the supine mechanical alignment was also taken at 0° of flexion, for reference.

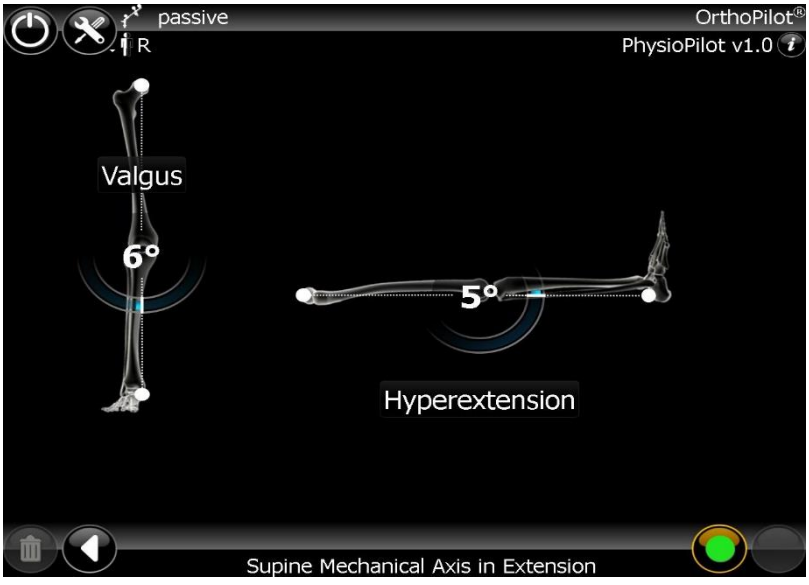

Figure 3.14 *– Natural mechanical alignment of participant following registration*

The registration process was repeated five times for each tracker type, and results were analysed for accuracy and repeatability. The original active trackers have shown accuracy within ˚±1˚ *(Clarke, 2012),* and it is this level of precision that is hoped to be replicated (or bested) by the new generation passive trackers.

3.4 Statistical Tests

Statistical analysis was completed using MedCalc software, and Microsoft Excel. Agreement between measurements was assessed using Bland-Altman analysis *(Bland & Altman, 1986),* with mean differences, standard deviation (SD) and limits of agreement calculated. Coefficients of repeatability (CR), which show the range of which 95% of the data points lie were calculated to further confirm the agreement shown in these Bland-Altman plots, to demonstrate repeatability of the tracker sets.

The widely referenced intra-operative target of alignment is ±3˚, and is used in comparing conventional and navigated surgical outcomes *(Mahaluxmivala et al, 2001).* As the levels of precision required for navigation are high, repeatability coefficients of 3˚ were deemed to be acceptable (demonstrating that 95% of measurements fell within a ±1.5˚ range).

3.5 Results

Five registration procedures were carried out on the right leg of one healthy participant, to obtain the supine MFT angle at extension. This was repeated for the active, passive and new-generation passive IR trackers detailed in Section 3.2. Taking the active tracker set to be the ‘gold standard’, this method was compared to the passive and new-generation passive trackers individually to investigate the repeatability.

The mean angles of MFT angle in alignment was 3˚ for the active trackers, 3.7˚ for the passive trackers and 3.3˚ for the new-generation tracker set. The results of the

registrations all returned a valgus alignment, and the corresponding repeatability statistics are shown in Table 3.1.

Tracker Type	Mean difference (˚) ± SD	Repeatability Coefficient (CR)
Passive	-0.7 ± 1.5	3.0
New-Passive	-0.3 ± 2	3.9

Table 3.1 *- Mean difference and repeatability coefficients for MFT angle following multiple registrations, comparing Active and Passive IR trackers, and Active and New Passive IR trackers*

Table 3.1 demonstrates that only recordings from the passive trackers were demonstrated to be more repeatable than that of the new-generation passive trackers when directly compared to the active trackers.
The corresponding Bland-Altman *(Bland & Altman, 1986)* plots are shown for comparison of active and passive trackers (Figure 3.15), and active and new-passive trackers (Figure 3.16).

Each plot shows the inter-registration recording repeatability, although the Bland-Altman plot in Figure 3.15 confirms that only the passive trackers fell within the accepted limits of agreement of 3˚.

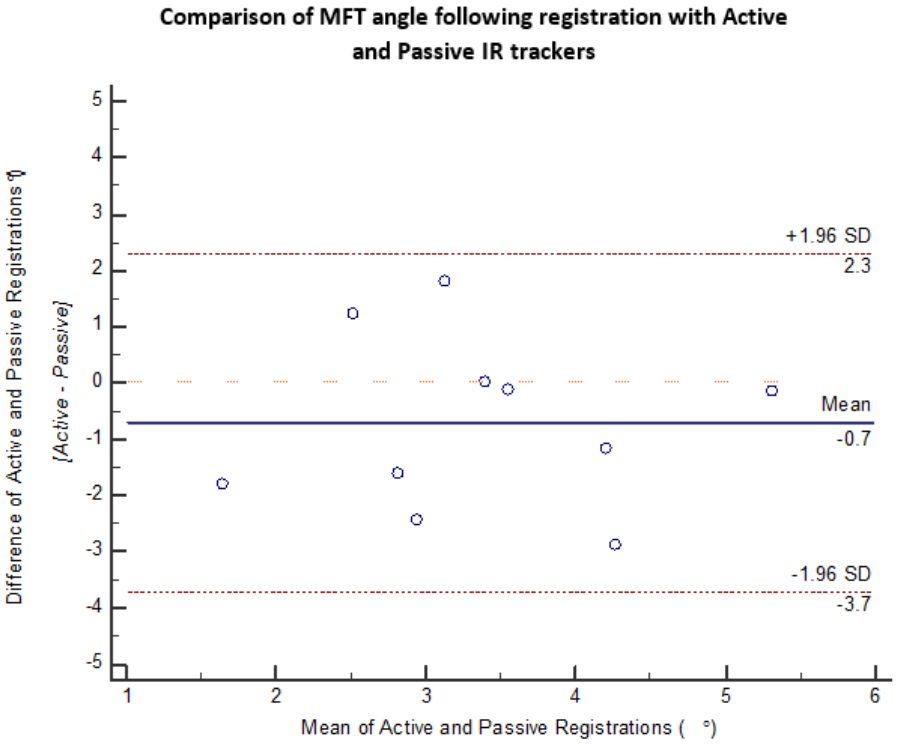

Figure 3.15 *- Comparison of MFT angle following registration with Active and Passive trackers*

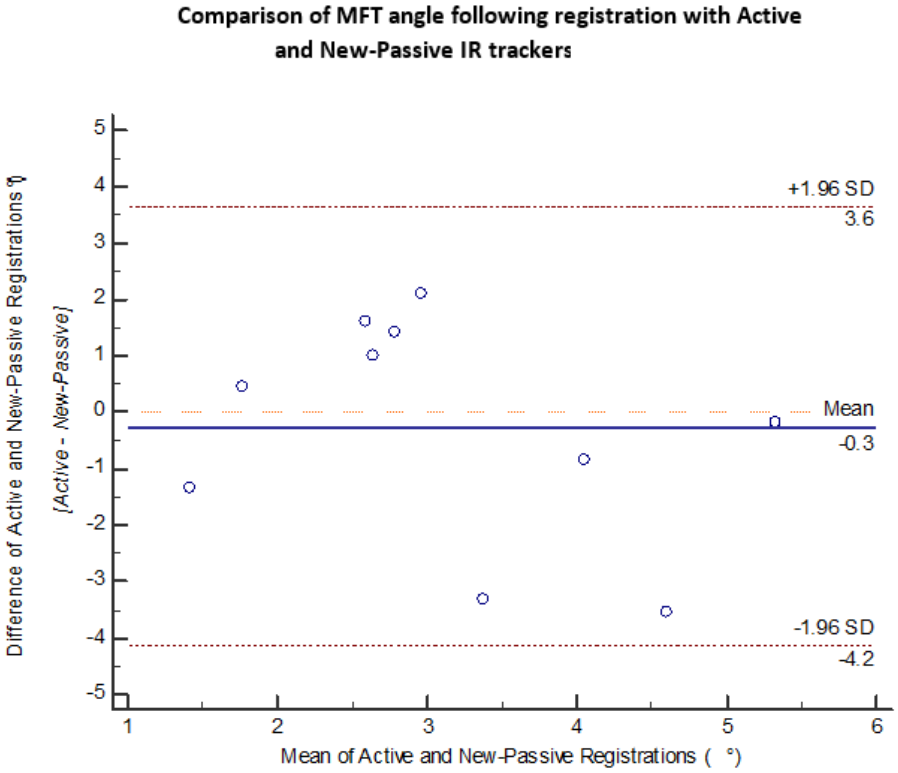

Figure 3.16 *– Comparison of MFT angle following registration with Active and New-Passive trackers*

3.6 Discussion

To evaluate the repeatability of the new-generation passive IR trackers and standard passive IR trackers, five registration procedures were carried out to obtain the supine MFT angle. These tracker types were compared to the 'gold standard' technique using active IR emitting trackers.

The use of the non-invasive tracking system has been validated to a precision of approximately ±1˚ in a similar non-invasive clinical assessment *(Clarke, 2012),* and the new-generation trackers were hoped to demonstrate a similar level of accuracy. Table 3.1 demonstrates that only passive markers demonstrated an accuracy within the prescribed limits of agreement of 3˚. The new-generation trackers demonstrated a wider distribution of 3.9˚.

On account of the level of variation demonstrated within the data, it is assumed that it cannot be entirely attributed to the operator, as an experienced orthopaedic consultant carried out the multiple registration consecutively on a single individual. This step was undertaken to remove significant variability that could be introduced by the inexperience of the investigator. However, the results of these assessments found that these methods weren't repeatable within the ±1˚ range. However, repeatability coefficients of both tracker types fell well within the intra-operative target of alignment (±3˚). The variation in results could possibly be attributed to a relatively low number of registrations; a lack of repeatability could be determined by the small volume of data.

Due to time constraints, and the limited availability of Mr Clarke, these new-generation passive IR trackers were not assessed for repeatability compared with the active and passive trackers until after participant testing had begun. The new-generation trackers were used for the subsequent laxity assessments in varus and valgus directions and AP tests detailed in Chapters 4 and 5, despite the fact that accuracy and precision fell short of their expectations. On account of this, it is suggested that further validation should be undertaken with a larger number of registration repetitions.

3.7 Conclusion

Validation of the new-generation passive trackers was not successful with the ±1˚ range previously achieved by Clarke in 2012. However, both the new-generation passive and standard passive trackers fell well within the surgical target of ±3˚.

The small pool of data collected could have contributed to the unexpected result, and as such, further investigation including a repeat trial with more registrations is suggested.

4. Assessment of knee laxity using experimental methodology

An experimental methodology was designed to eliminate variables surrounding standard clinical assessments of laxity, this included designing a wooden supporting structure to maintain angle of knee flexion.

Using the optical tracking system from Section 3.1, a cohort of 20 participants underwent two varus/valgus laxity assessments, and two AP Laxity tests.

4.1 Surgical Observation

To better understand the application of IR optical tracking approach in orthopaedic knee surgery, the Golden Jubilee National Hospital permitted access to both a conventional TKA surgery, and an IR navigated unicompartmental knee replacement. In observing the differences in procedure and surgical approach with manual and CAOS, the disparities between surgical set-up and required experimental simulation of the system became clear. The technique exhibited by surgeons in aligning and assessing the laxity of the knee joint highlighted the variables which would require standardisation of this process in a clinic environment. This information determined the design process for the experimental procedure.

4.2 Standardisation of Possible Variables

In observing assessment of knee laxity by a trained clinician, it was noted that there were no defined angles of flexion, nor specific prescription of force applied during examination. These were the two variables that this study set out to standardise.

4.2.1 Flexion Angle Supporting Structure

This study focuses on the laxity of the knee joint in varus/valgus, and in anterior/posterior directions under the application of force. Guidelines for these assessments suggest an angle of flexion between 20-30˚ for varus/valgus testing, and 90˚ for AP testing *(University of California (SF), 2015),* but as previously stated, clinicians flex the knee until they get a response that ‘feels right’. On account of previous

positive findings of IR recordings of laxity at extension, the range of investigation for this study was at 5˚, 15˚, 30˚ and 45˚ of flexion.

A simple, adjustable wooden structure was proposed to create these four angles, so as to support the knee joint across this range of angles, and is shown in Figure 4.1, below. In maintaining this support, variation in angles of flexion which could be introduced by the investigator would be essentially eliminated.

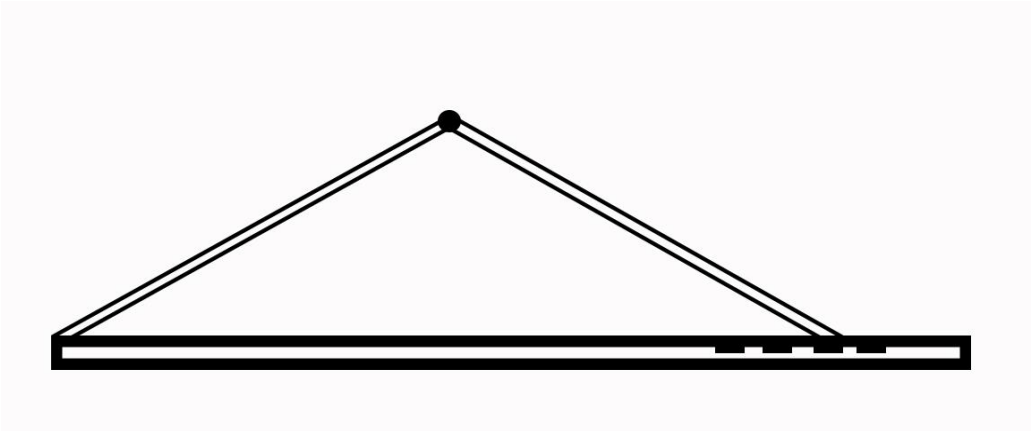

Figure 4.1 *– Simple draft of the wooden supporting structure*

This rationale of the support was to create a hinged wooden 'bridge' that could be fixed at the desired angles of flexion, ensuring ease of use and portability of design. This diagram was passed to Mr Stephan Murray, who created the support shown in Figure 4.2, and Figure 4.3.

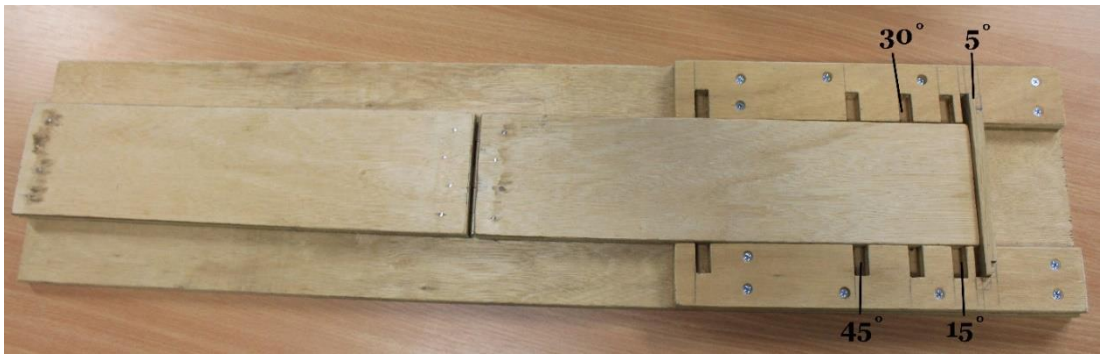

Figure 4.2 *– Wooden supporting structure, showing the design and mechanism for angle support.*

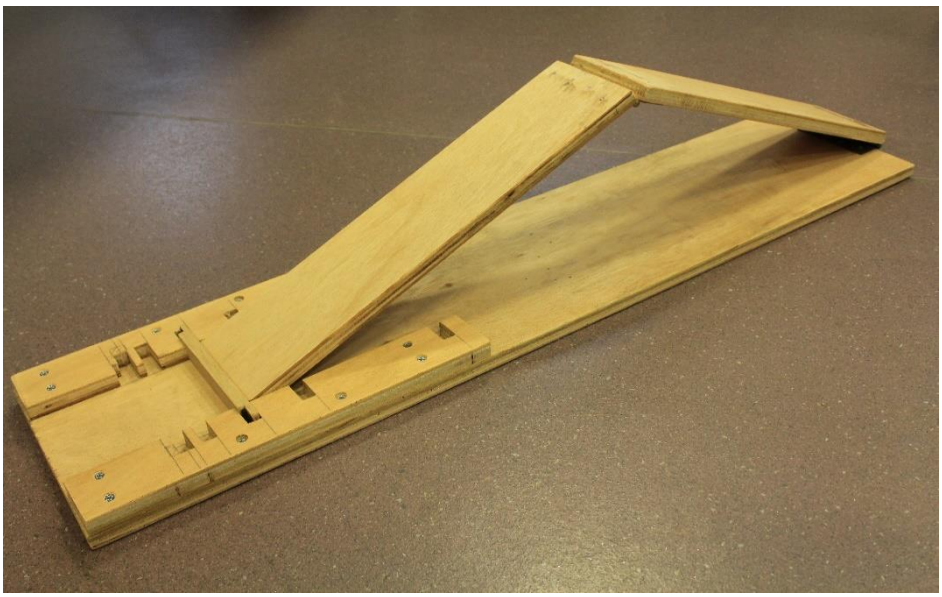

Figure 4.3- *Wooden supporting structure at 30˚*

4.2.2 Standardisation of Force Application

It was established that in the interest of viable results, that the force applied to all participants should also be standardised. A moment of 18Nm was proposed on account of it being well-tolerated in clinical practice, and should not cause any levels of pain or discomfort to participants *(Clarke, 2012).*

The force was be applied via a 'Salter SuperSamson' 10kg spring balance to the

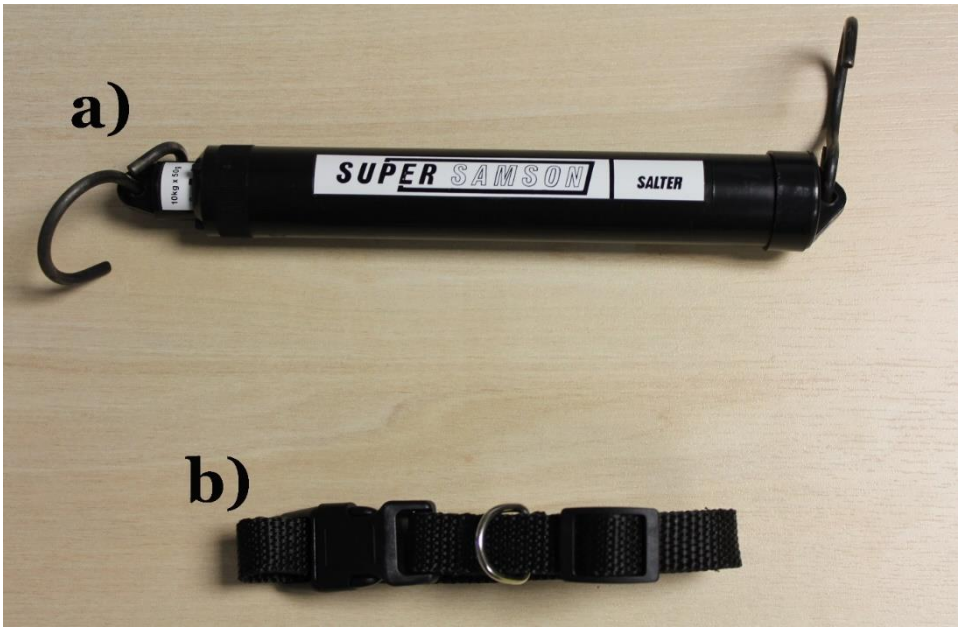

Figure 4.4- a) *Salter 'SuperSamson' 10kg spring balance and* ***b)*** *woven strapping*

ankle via a woven strap (Figure 4.4) when applying varus & valgus forces, and to the top of the tibia (just underneath the patella) when AP force was applied. This arrangement acted to simulate the hands-on force applied by a clinician.

To standardise the application of force for each participant, the length of the tibia was measured by recording the distance from the knee centre to the ankle centre, and the calculation shown below was used to ensure force was relative to each individual.

$$18Nm \div Tibial\ length\ (m) \div 9.81$$
$$= Applied\ Force\ (kg/force)$$

4.3 Participant Selection

4.3.1 Ethical Approval & Consent

This study was granted approval by the University of Strathclyde Biomedical Engineering Departmental Ethics Committee on the 26/06/15.

In adherence with this approval, all volunteers were provided with a patient information sheet (PIS) outlining the stages of participation throughout the study, alerting them to any possible risks. Each participant was required to sign a declaration of consent before participation within the study, to acknowledge the potential risks of the study and that it is understood that participation and collected data can be withdrawn at any stage without consequence.

4.3.2 Selection of Participants

4.3.2.1 Recruitment of Volunteers

This study required a cohort of 20 healthy volunteers from within the University of Strathclyde Biomedical Engineering department. Informative emails were circulated throughout the department outlining the stages involved in participation, in addition to exclusion and inclusion criteria. No incentive of any kind was offered in return for participation within the study.

4.3.2.2 Exclusion and Inclusion Criteria

The parameters of this study required healthy participants, and as such there were specific criteria required to allow participation.

Inclusion Criteria: Participants were required to be:

- **i.** Generally healthy university individuals (staff & students)
- **ii.** Age range of 18-70
- **iii.** Able to mobilise independently

Exclusion Criteria: The following self- declared variables would discount volunteers from participating:

- **i.** A history of knee-replacement
- **ii.** No indications of previous knee injury
- **iii.** Abnormal lower-limb alignment

4.4 Methodology - Experimental Laxity Assessment

20 participants (9 female, 11 male) were recruited with a mean age of 26.3 (range 22-55) and a mean BMI (body mass index) of 25.4 (range 17.9-31.8). These participants fell within the inclusion criteria set out in Section 4.3.2.2, and consented to all steps in the assessment process.

4.4.1 Volunteer Repeatability

Each volunteer lay relaxed on an examination couch, with the new-generation passive IR trackers attached as demonstrated in Figure 3.5. Participants underwent two kinematic registrations of the right leg as outlined in Section 3.5.2, and the resultant supine mechanical alignment values were recorded. If the values for the coronal and sagittal alignment were within 2˚, registrations were said to be repeatable, and varus/valgus and AP stress testing was initiated- this was the accepted agreement limit between registrations. In some cases, a third registration process was undertaken before proceeding to the assessment of laxity.

4.4.2 Experimental Laxity Assessment

Once repeatability of the IR markers was completed with each participant, experimental assessment of laxity was undertaken. The experimental set up was as shown in Figure 4.5.

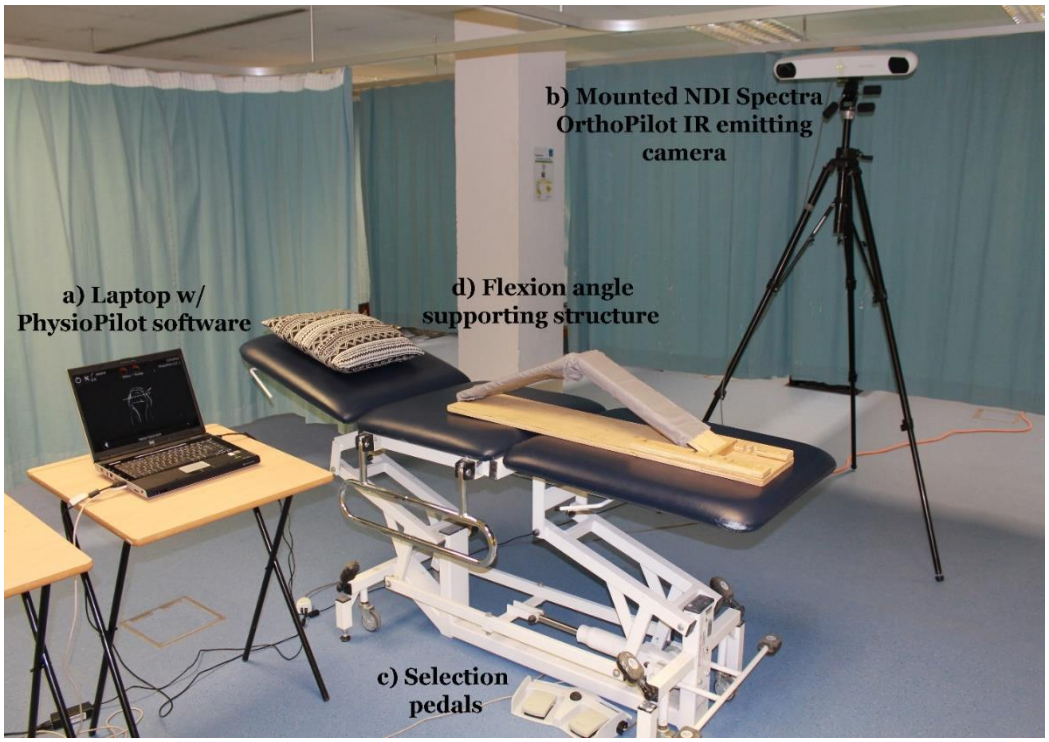

Figure 4.5 *– Experimental set-up for assessment of laxity, featuring:* ***a)*** *PhysioPilot software interface;* ***b)*** *OrthoPilot IR camera;* ***c)*** *USB Selection pedals;* ***d)*** *Developed flexion angle supporting structure*

4.4.2.1 Varus Valgus Assessment

The wooden supporting structure outlined in Section 3.3.3 a) was placed underneath the participant's right leg, so that the knee joint aligns with the point of flexion between the two planks of the structure. The wood was covered in a soft cotton fabric to improve the comfort to the participant, and to reduce the likelihood of pinching the skin when adjusting the angle.

The support was first positioned at 5˚, and the ankle strap and spring balance were attached to the participant. The investigator placed a hand on the knee to restrict the motion of the upper leg, and the spring balance was pulled in a controlled manner to the pre-calculated applied force value in both varus and valgus directions to record displacement of the lower limb, in the manner shown in Figure 4.6. This data was

saved by use of the foot pedal, allowing for both hands to be free for applying laxity and supporting the knee.

The support was first positioned at 5˚, in the manner shown in Figure 4.6, and the ankle strap and spring balance were attached to the participant.

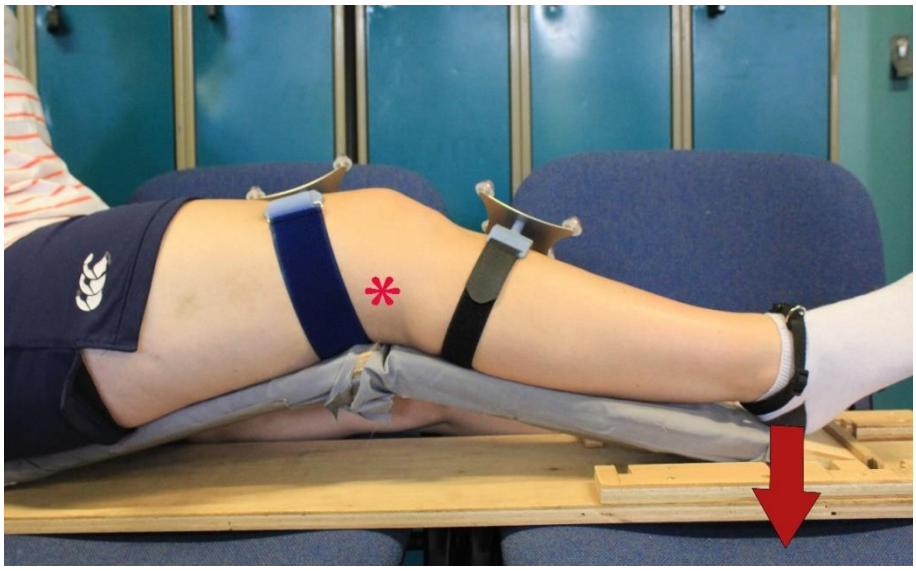

Figure 4.6 *– Experimental set-up with participant for varus valgus laxity assessment, supported at 15˚. The* ******* *indicates the placement of the hand to restrict motion, and the arrow indicates the perpendicular motion in valgus assessment.*

The investigator placed a hand on the knee to restrict the motion of the upper leg, and the spring balance was pulled in a controlled motion to the pre-calculated applied force value in both varus and valgus directions to record displacement of the lower limb. An example of the PhysioPilot recording screen is show in Figure 4.7.

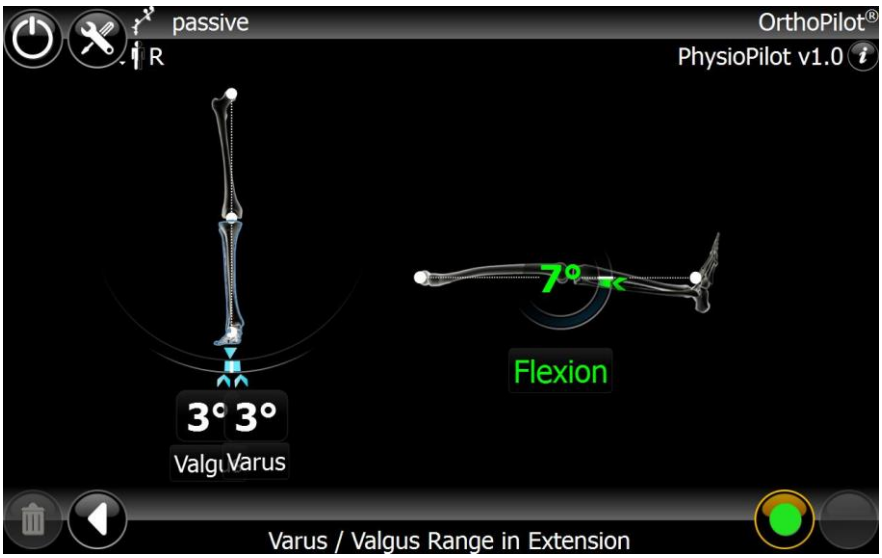

Figure 4.7 *– PhysioPilot screen for recording varus/valgus laxity at 5˚ flexion*

This data was saved by use of the foot pedal, allowing for both hands to be free for applying laxity and supporting the knee. The process was repeated for angles of 15˚, 30˚ and 45˚ angles of knee flexion

4.4.2.2 AP Laxity Test

To investigate the displacement of the tibia from the femur in the anterior plane, the strapping was applied to the upper tibia, just below the patella as show in Figure 4.8. The investigator restricted motion of the femur by applying force to the patella.

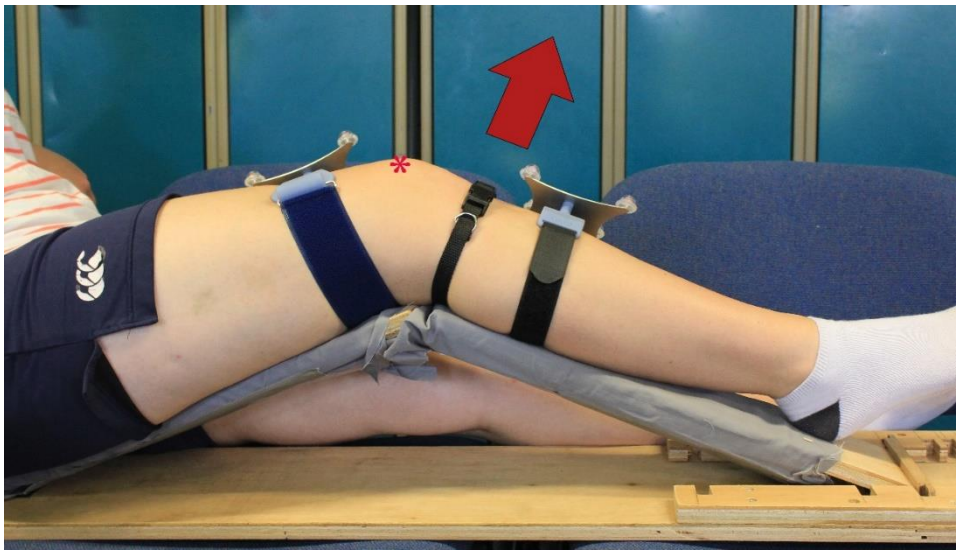

Figure 4.8 *- Experimental set-up with participant for AP Laxity assessment, supported at 30˚. The * indicates the placement of the hand to restrict motion, and the arrow indicates the perpendicular motion in AP assessment.*

The spring balance was pulled perpendicular to the tibia in short, sharp jerks to the standardised force which was calculated, producing anterior displacement of the tibia- the motion is demonstrated in the PhysioPilot recording screen (Figure 4.9). This process was undertaken at 5˚, 15˚, 30˚ and 45˚ angles of flexion.

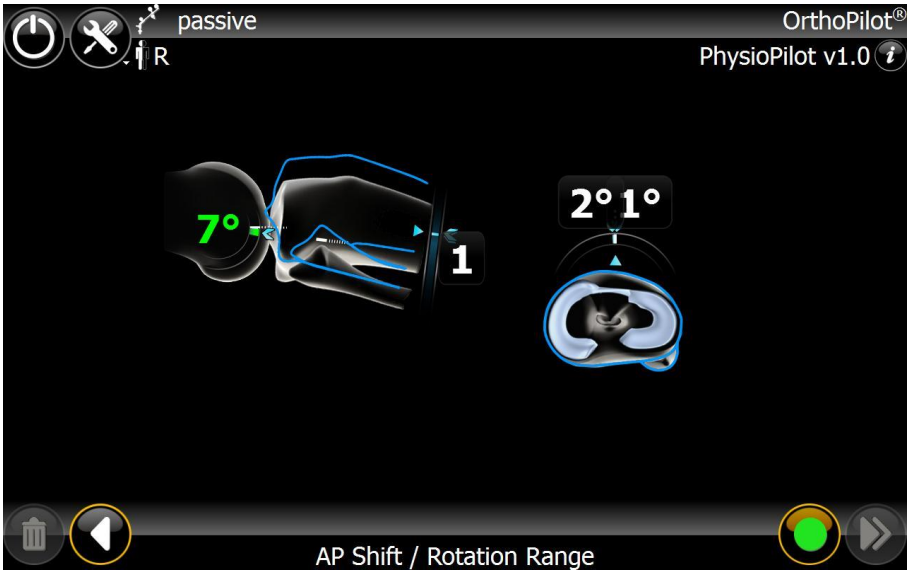

Figure 4.9 – *PhysioPilot recording screen for anterior translation of the tibia during AP Laxity test*

Once the varus valgus and anterior Laxity assessment was completed the participant underwent a third registration process, followed by another laxity assessment and subsequent data collection.

4.5 Statistical Tests

Statistical analysis was completed using MedCalc software, and Microsoft Excel. Agreement between the two measurements was assessed using Bland-Altman analysis *(Bland & Altman, 1986),* with mean differences, standard deviation (SD) and limits of agreement calculated. Coefficients of repeatability (CR), which show the range of which 95% of the data points lie were calculated to further confirm the agreement shown in these Bland-Altman plots, to demonstrate repeatability of the system.

For the varus valgus laxity assessments, the acceptable limits of agreement remained as 3˚ as explained in Section 3.4.

For AP testing, anterior translation of the tibia is considered poor if the measurement is found to be >3mm, in comparison to the normal knee *(Arneja & Leith, 2009).* As such, the acceptable limit for AP shall be considered to be 3mm.

4.6 Results – *Varus Valgus Assessment*

Of the 20 participants recruited for the assessment of knee laxity through the range of motion, 5 participants did not progress to the knee laxity assessment on account of failed hip joint centre calculations. The remaining 15 participants (6 female, 9 male) continued onto the laxity assessment, with a mean age of 28.9 (range: 23-55) and a mean BMI of 24.5 (range: 17.9- 31.8).

Two recordings of varus and valgus displacement as a result of the applied stress were recorded at each angle of flexion, once two consecutively similar registration values were achieved for each participant (it was decided that values within ±2˚ would be considered suitable).

Repeatability results for varus and valgus displacement angles at differing degrees of flexion are shown in Table 4.1.

Angle of flexion	***Varus Stress*** **Mean difference (˚) ± SD**	***Varus Stress*** **Repeatability Coefficient (CR)**	***Valgus Stress*** **Mean difference (˚) ± SD**	***Valgus Stress*** **Repeatability Coefficient (CR)**
5˚	0.3 ± 2.0	4.0	0.0 ± 1.3	2.2
15˚	-0.3 ± 1.4	2.8	-0.3 ± 1.4	2.7
30˚	-1.0 ± 2.6	5.0	-1.0 ± 2.6	7.3
45˚	1.0 ± 4.7	9.2	-1.5 ± 3.2	6.3

Table 4.1 *- Mean difference and repeatability coefficients for two recordings of varus and valgus stress displacement angles following force application at 5˚, 15˚, 30˚ and 45˚.*

Bland-Altman plots were generated to visualise the limits of agreement for each measurement. The valgus stress measurement at 5˚ (Figure 4.10) and both the varus

and valgus recordings at 15˚ (Figure 4.11 and Figure 4.12), were within 3˚ limits of agreement. All other measurements were out with these limits of agreement, showing similar distribution as varus stress at 30˚ flexion, shown in Figure 4.13. The mean differences of all recordings are small, and therefore no systematic errors are present within the optical navigation system. All additional Bland-Altman graphs not shown in this section can be found in the appendices in Section 9.2.

Analysis of the Bland-Altman plots and CR demonstrated that valgus recordings were overall more repeatable than their varus counterparts (limits of agreement were closer to clinically relevant figures). As the angle of flexion increased, there was less agreement between the measurements and Bland-Altman plot distribution varied widely.

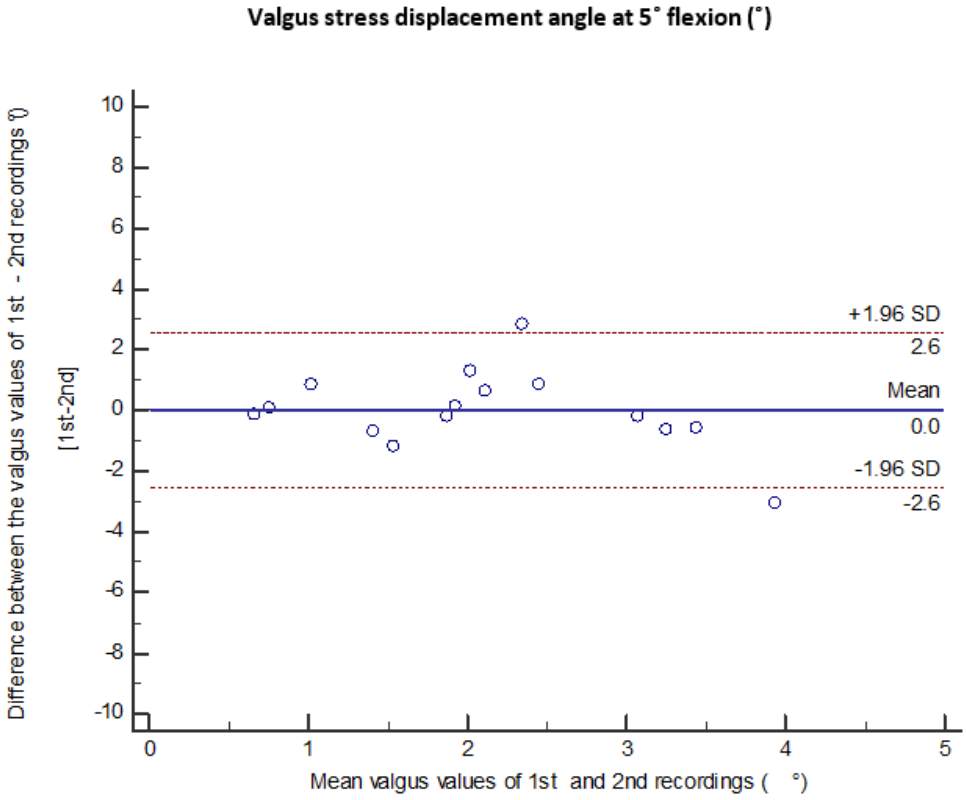

Figure 4.10 *– Average of valgus stress displacement angles at 5˚ flexion (˚)*

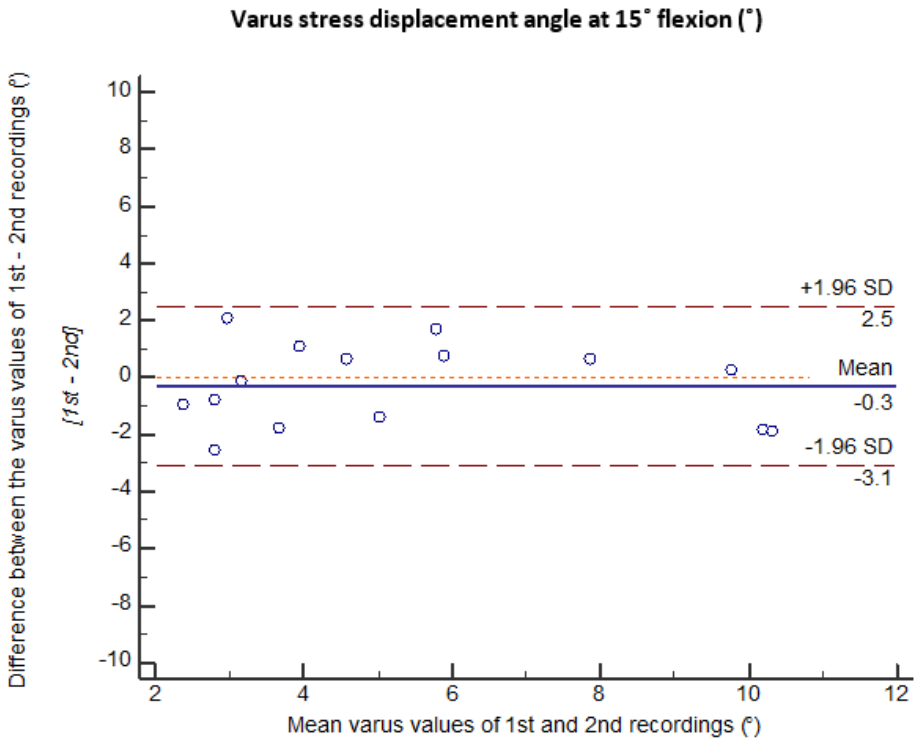

Figure 4.11 - *Average of varus stress displacement angles at 15˚ flexion (˚)*

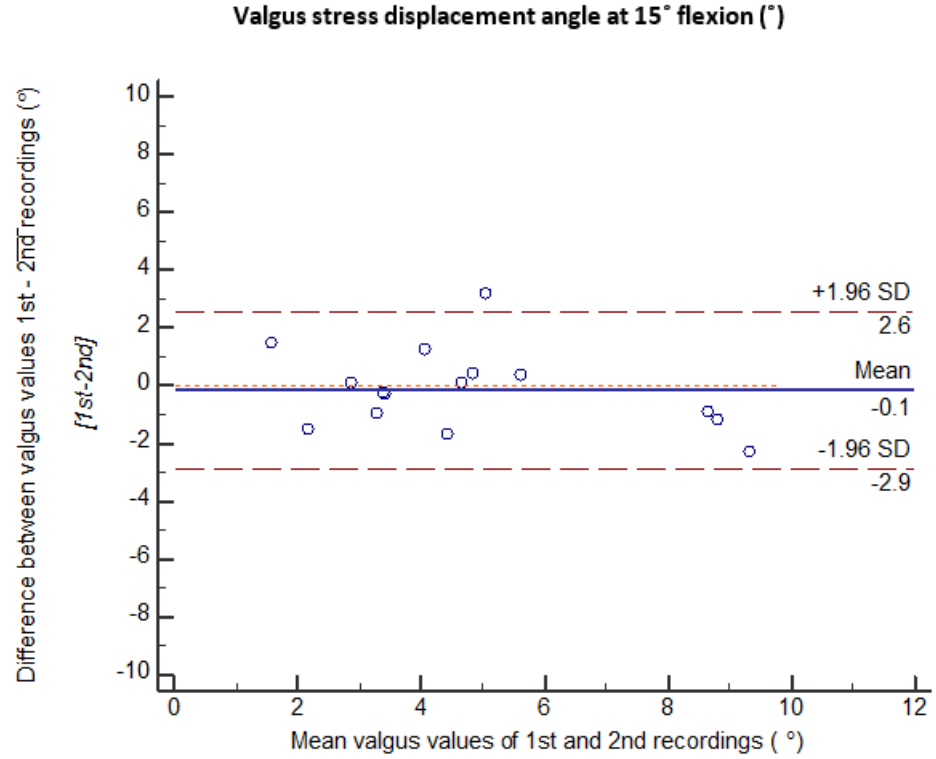

Figure 4.12 *- Average of valgus stress displacement angles at 15˚ flexion (˚)*

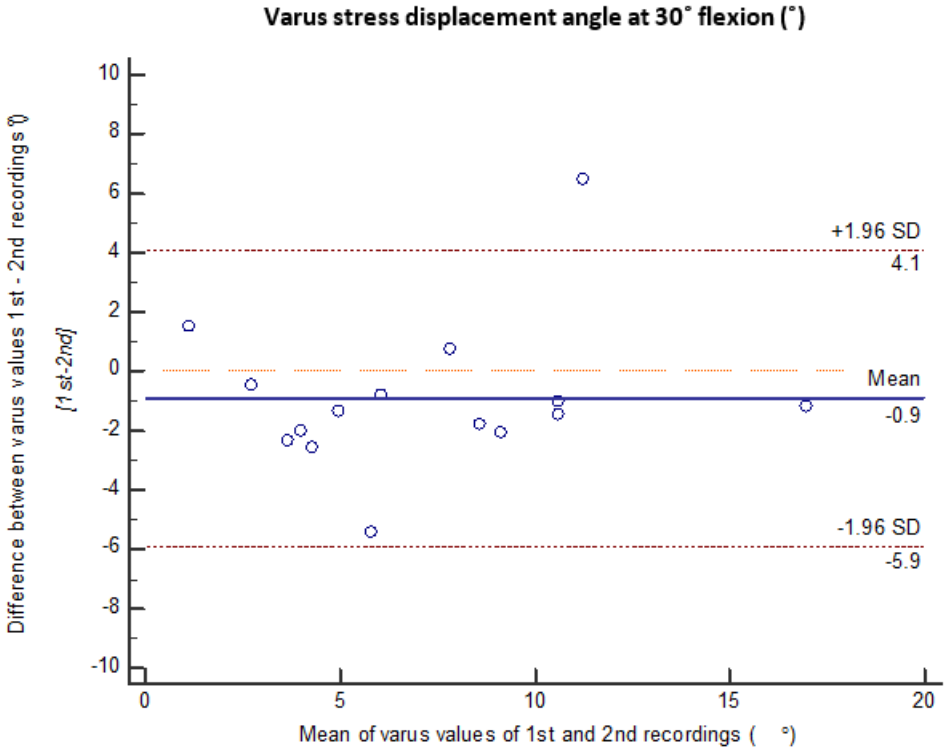

Figure 4.13 *- Average of varus stress displacement angles at 30˚ flexion (˚)*

4.7 Discussion - *Varus Valgus Assessment*

The assessment of laxity is an important clinical step in both the diagnosis of knee injury, and as a pre-operative step in orthopaedic management of soft-tissues. As previously outlined, the use of this non-invasive tracking system has been validated for repeatable recordings of supine MFT angle of within ±1˚ *(Clarke, 2012).* This work was followed up by an attempt to standardise the assessment for coronal laxity with the aim of providing repeatable laxity measurements using this system. The use of standardised force application of 18Nm during laxity assessment resulted in mean valgus laxity of 3˚, and a mean varus laxity of 4-5˚ *(Clarke et al, 2012a).*

Adopting the same level of standardised force, laxity assessment resulted in a valgus laxity within approximately ±2.5˚ at 5˚ and 15˚ flexion, and a varus laxity of approximately ±2.5˚ at 15˚ flexion. Above these flexion angles, repeatability coefficients fall out with the acceptable limits previously proposed. Although the laxity values recorded were out with the ±1˚ target achieved by Clarke, all recordings

were more accurate than ±5˚ window which is associated with human error through standard methods of visualisation *(Markolf, Mensch & Amstutz, 1976).*

Russell demonstrated repeatability of a non-invasive system up to 40˚ flexion, and complete lack of agreement above this angle, similar to the trend seen with varus and valgus laxity in this study. It was proposed that the reduction in repeatability over this degree of flexion could be on account of soft-tissue artefact, and the movement of the soft tissue through flexion could contribute to an increase in this artefact *(Russell et al, 2014).*

It is hugely important to maintain the degree of flexion throughout assessment, as it is this angle with determines the orientation of the ligaments, and subsequently their level of restraint, or how 'tight' they are *(Kweon, Lederman & Chhabra, 2013).* The development of the wooden supporting structure to maintain flexion angle did not take into account the inherent variation of soft tissue volume between participants. Therefore, the alignment of the participant's leg did not correspond directly to the alignment of the structure. This resulted in the knee not being supported at the exact prescribed angle. The implications of this divergence at small angles of flexion (ie. 5˚) did not result in huge deviations. However, at the larger angles of flexion such as 45˚, there were huge variation between angles recorded between participants, which ranged from 37˚ to 59˚. The increased levels of variation in agreement at higher angles of flexion could be in part attributed to this oversight in the methodology. However, the use of the wooden supporting structure did reduce the variability in set flexion angles, as measurement error in human estimation has been demonstrated to be up to 20˚ *(Cushnaghan et al, 1990).*

Additionally, the PhysioPilot software prevented the recording of laxity in the 'Varus/Valgus Range in Extension' if the angle of flexion was >30˚. The configuration of the software meant that for recording laxity at 30˚, the leg must be manually positioned at this angle (regardless of the angle that the leg is naturally positioned at by the wooden flexion supporting structure). Further to this, collection of varus and valgus laxity at 45˚ had to be recorded separately via the 'Load Line' recording screen, introducing variability in the angle of flexion that was truly being recorded. The discrepancies that could arise due to the deviation in data collection

could be partly responsible for the wide limits of agreement and subsequent CR for 30˚ and 45˚ assessments.

As outlined in Section 4.2.2, mean valgus laxity values were overall more repeatable than varus laxity values when analysed via Bland-Altman plots and CR (a trend also notable in the standardised assessment of coronal laxity *(Clarke et al, 2012a)*). In the case of this experimental methodology, the disparity between accuracy could be attributed to the positioning of the investigator during application of varus and valgus stress. The applied valgus stress involved pulling the spring balance toward the investigator in a smooth, controlled manner. In applying a varus force, the investigator remained in the same position, and pulled the spring balance away from the participant. As this involved leaning across the volunteer, the movement was noticeably less smooth and controlled, and was more susceptible to deviation from a perpendicular path.

Results showing similar poor agreement have been attributed to the lack of standardised force application incorporated into the methodology, leading to subjective assessment *(Henderson et al, 2015).* The standardisation of force device utilised in this study was much more rudimentary than the force application device (FAD) used by Clarke et al. On account of the manual 'Salter SuperSamson' 10kg spring balance, it is very possible that the applied force was not as precise as required, introducing an element of variability into the assessment.

4.8 Results – *AP Laxity Test*

Following the assessment of laxity, participants underwent two AP Laxity tests to quantify the anterior displacement of the tibia from the femur. The repeatability values of AP displacement (mm) for varying degrees of flexion are shown in Table 4.2.

Angle of Flexion (˚)	Mean difference (mm) ± SD	Repeatability Coefficient (CR)
5˚	0.2 ± 2.5	5.0
15˚	-1.3 ± 1.8	3.6
30˚	-0.7 ± 2.2	4.2
45˚	0.5 ± 2.6	5.1

Table 4.2 - *Mean difference and repeatability coefficients for two recordings of anterior displacement of the tibia (mm) following force application at 5˚, 15˚, 30˚ and 45˚.*

Both the repeatability coefficients and the Bland-Altman plots of AP displacement demonstrate that all of the recordings were outside the acceptable limits of agreement (3mm). AP displacement repeatability was poor, and both the CR and the Bland-Altman plot distribution demonstrate this. An example of the Bland-Altman plots of AP translation at 15˚ flexion is seen in Figure 4.14, and the plots of AP translation at other degrees of flexion are seen in the appendices (Section 9.3).

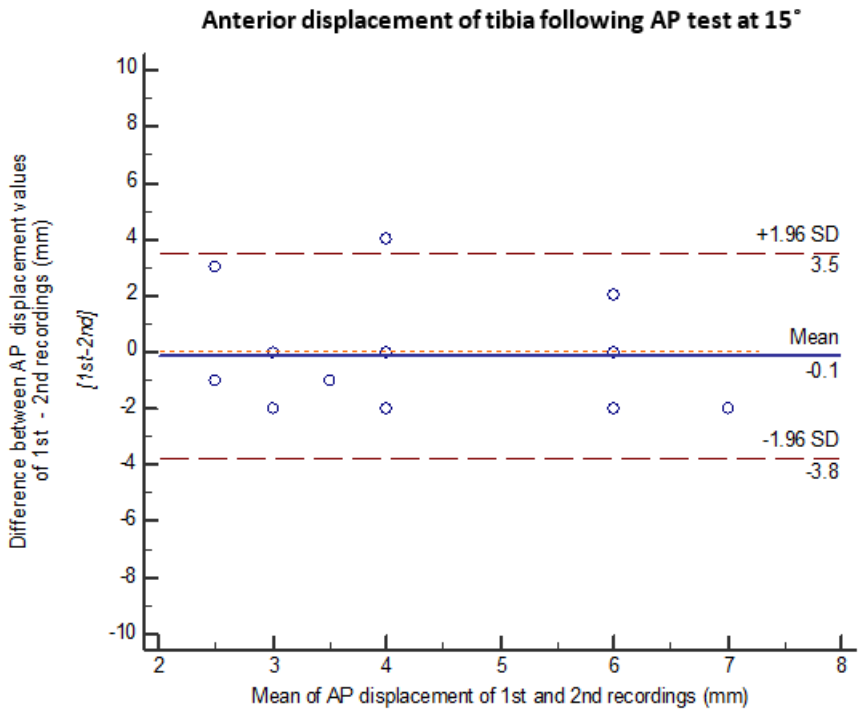

Figure 4.14 *– Average AP displacement values at 15˚ flexion (mm)*

4.9 Discussion - *AP Laxity Test*

The AP Laxity test is seen as being one of the most important indicators of cruciate ligament injury by documenting the anterior displacement of the tibia from the femur. In a normal knee, this displacement should fall with 6mm- with values outside this range considered abnormal, and a warning sign of potential injury *(PT Haven, 2015).*

Non-invasive AP displacement assessments were undertaken in cadaveric specimens by Russell, and the clinical assessment compared favourably within the commercial CAS systems, within an agreement level of 3mm up to 40˚ flexion *(Russell et al, 2013).* Conversely, this study found that agreement between AP displacement values demonstrated poor repeatability, with recordings at every angle of flexion being >3mm.

A contributing factor within the AP assessment could be the positioning of the limb following varus/valgus laxity assessment – as the woven strapping had to be transferred from the ankle to just beneath the patella. It has been previously noted that repeatability of knee Laxity tests can be unduly affected by deviations in positioning of the limb during assessment *(Edixhoven et al, 1987)*, which is entirely possible during this assessment.

Alho et al carried out a similar non-invasive study to quantify and measure AP laxity throughout a range of flexion angles, but found that without standardisation of force, only laxity at 30˚and 45˚ fell within the suitable limits of agreement of 3mm *(Alho et al, 2015).* The failure of this study to obtain relevant AP laxity values could possibly be attributed to the methodological shortcomings outlined in Section 4.7 in regards to possible inconsistent application of force via the spring balance.

It is also proposed that in AP laxity assessment, the use of woven strapping has demonstrated potential implications. Even with the strapping tightly fastened to the tibia, both participants and the investigator reported movement was mostly within the soft tissue itself as opposed to moving of the tibial component of the limb. This could possibly result in a either a false reading of anterior tibial displacement, or create higher levels of soft tissue artefacts. Similar findings were demonstrated in a pilot

study comparing fabric and rubber strapping non-invasive fastening techniques to bone screws, and it was found that the rubber strapping produced less reliable results, introducing the concept that fastening material could detrimentally influence results *(Russell, 2015).*

The force applied to the tibia during AP testing remained 18N throughout assessment between participants. Russell, when further investigating AP laxity in cadavers used 100N anterior force on the tibia – sizeably more than applied in this study. This force was not replicated in this study due to the equipment available for testing. It is possible that the size of the force is a contributing factor in experimentally recreating the standard AP laxity assessment performed clinically *(Russell, 2015).*

4.10 Conclusion

The subjective nature of laxity assessment is one of the main possible contributing factors to poor surgical outcomes, such as malalignment. Navigated optical tracking systems provide an assistive role intra-operatively in terms of aiding in correcting alignment, but lack of consistent assessment methods of laxity can lead to errors in translation from planning to surgery. This system was previously developed with clinical application in mind, and as such, it is a non-invasive, portable method for assessment of alignment. When compared to standard radiographic assessment, the use of IR navigated systems removes exposure to harmful ionising radiation, whilst instantaneously feeding information back to the clinician at time of assessment.

This study aimed to further improve this system, by developing an experimental protocol which would remove the two main variables within assessment – maintained angle of flexion and standardised force applied during assessment. Although the experimental design contained integral flaws, valgus displacement angles were found to be repeatable at 5˚ and 15˚ of flexion, and varus displacement angles were repeatable at 15˚. For the AP Laxity test of laxity, measurements were out with the acceptable limits of displacement at all degrees of flexion.

Although this system did not demonstrate excellent precision and repeatability across the board, the positive results found in this study could mean that a more refined

experimental protocol could increase the levels of precision measured by the system. Further design suggestions are made in Chapter 6.

5. Standard assessment of knee laxity by an orthopaedic consultant

Five participants from the original group were asked to return to undergo a standard clinical assessment of knee laxity (as described in Section 2.5) by Mr Clarke, using the new-generation passive IR trackers. Their mean age was 24 (range: 23-25) and the mean BMI was 23.4 (range: 17.9- 30.9). As this assessment does not include the experimental additions of the supporting structure or standardised force applied by the spring balance, only one assessment was done with each individual, under the assumption that due to Mr Clarke's considerable experience, no repetition to prove accuracy of assessment would be required. The data collected from these participants can be compared to the results gathered from the experimental laxity assessments in Section 4.6 and Section 4.8. This analysis will give some indication as to how accurate and reliable results from the experimental protocol are in comparison with the gold standard of clinician based testing.

5.1 Methodology – Standard Clinical Laxity Assessment

The new-generation passive trackers were attached to participants as shown in Figure 3.7, and the registration process described in Section 3.3.1 was completed. Mr Clarke performed a standard clinical varus valgus, and AP laxity assessment, without the use of the experimental measures used in Chapter 4.

5.2 Statistical Tests

Statistical analysis was completed using MedCalc software, and Microsoft Excel. Agreement between the mean laxity assessments of participants with the experimental methodology, and the measurements obtained during clinical assessment were assessed using Bland-Altman analysis *(Bland & Altman, 1986).* The mean differences, standard deviation (SD) and limits of agreement calculated were all calculated. Coefficients of repeatability (CR), which show the range of

which 95% of the data points lie were calculated to further confirm the agreement shown in these Bland-Altman plots, to demonstrate repeatability of the experimental methodology, compared to the standard clinical assessment.

As in Section 4.5, acceptable limits for varus valgus laxity was 3˚and the acceptable limit for AP were considered to be 3mm.

5.3 Results – *Varus Valgus Assessment*

Comparison of experimental and clinical assessment of laxity using the IR tracking system was undertaken in the randomly assigned group of 5 participants. However, due to a storage error, data for only 4 participants was available for analysis in this section. The mean age was 23.75 (range: 23-25) and the mean BMI was 21.48 (range: 17.9-26.3).

The repeatability values between the experimental and clinical assessment methodology are demonstrated in Table 5.1.

Angle of flexion	***Varus Stress*** **Mean difference (˚) ± SD**	***Varus Stress*** **Repeatability Coefficient (CR)**	***Valgus Stress*** **Mean difference (˚) ± SD**	***Valgus Stress*** **Repeatability Coefficient (CR)**
5˚	-1.5 ± 0.8	1.5	-1.5 ± 0.8	1.6
15˚	-0.7 ± 2.6	5.1	-0.9 ± 1.4	2.8
30˚	1.8 ± 6.7	13.1	-3.7 ± 1.1	2.2
45˚	-1.8 ± 3.6	7.1	-1.7 ± 3.3	6.6

Table 5.1 *- Mean difference and repeatability coefficients for experimental and clinical recordings of varus and valgus stress displacement angles following force application at 5˚, 15˚, 30˚ and 45˚.*

The repeatability coefficients for varus and valgus laxity at 5˚ fall well within the limits or agreement previously proposed. The measurements of 1.5˚ for varus and 1.6˚ or valgus indicate a very similar result. The corresponding Bland-Altman plots

are shown as Figure 5.1 and Figure 5.2, respectively and show good repeatability between experimental and clinical assessment. Additionally, valgus displacement angles at 15˚ (Figure 5.3) and 30˚ demonstrated, similar levels of agreement within 3˚ limits. All other measurements fell out with these limits, as demonstrated in by the Bland-Altman plot of varus stress at 45˚ in Figure 5.4.

As seen in Section 4.2.2, Bland-Altman plots and CR both demonstrated that valgus recordings were again more repeatable throughout the angles of flexion than the varus recordings, and limits of agreement were more conservative and nearer clinically relevant values. As the angle of flexion was increased, the laxity values for both varus and valgus directions increased.

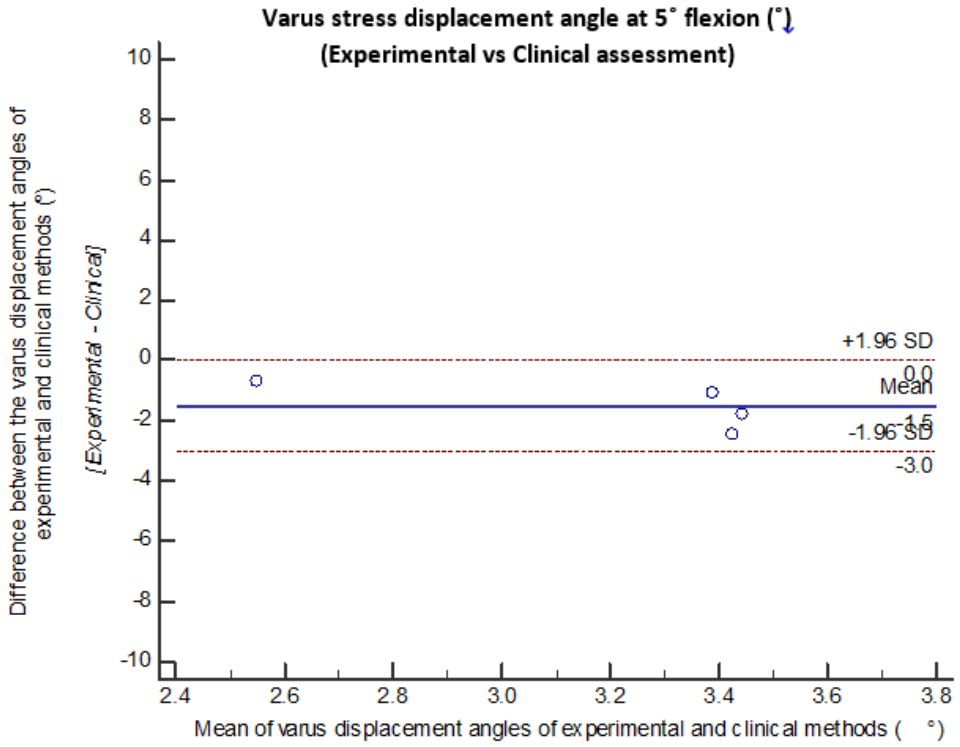

Figure 5.1 *– Average varus stress displacement angles in experimental and clinical methods at 5˚ flexion (˚)*

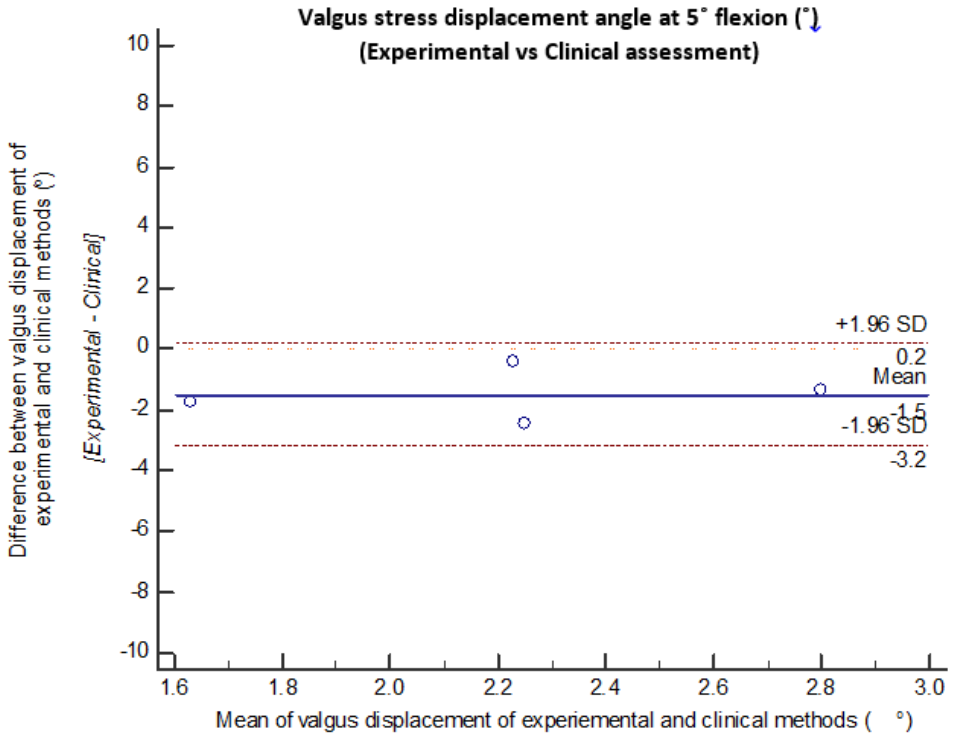

Figure 5.2 – *Average valgus stress displacement angles in experimental and clinical methods at 5˚ flexion (˚)*

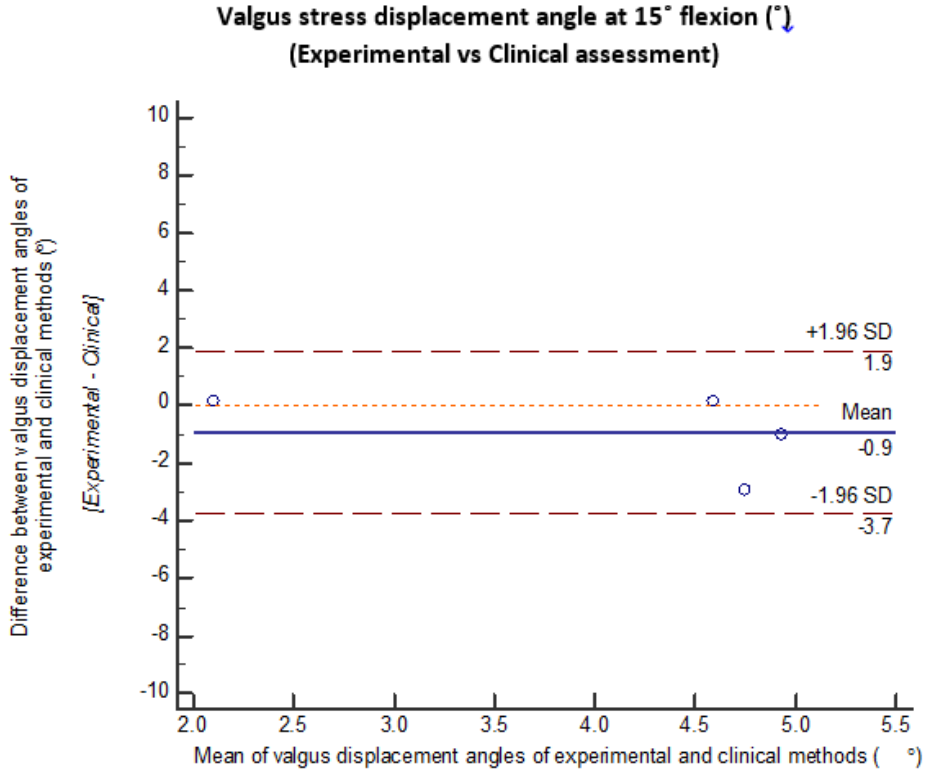

Figure 5.3 – *Average valgus stress displacement angles in experimental and clinical methods at 15˚ flexion (˚)*

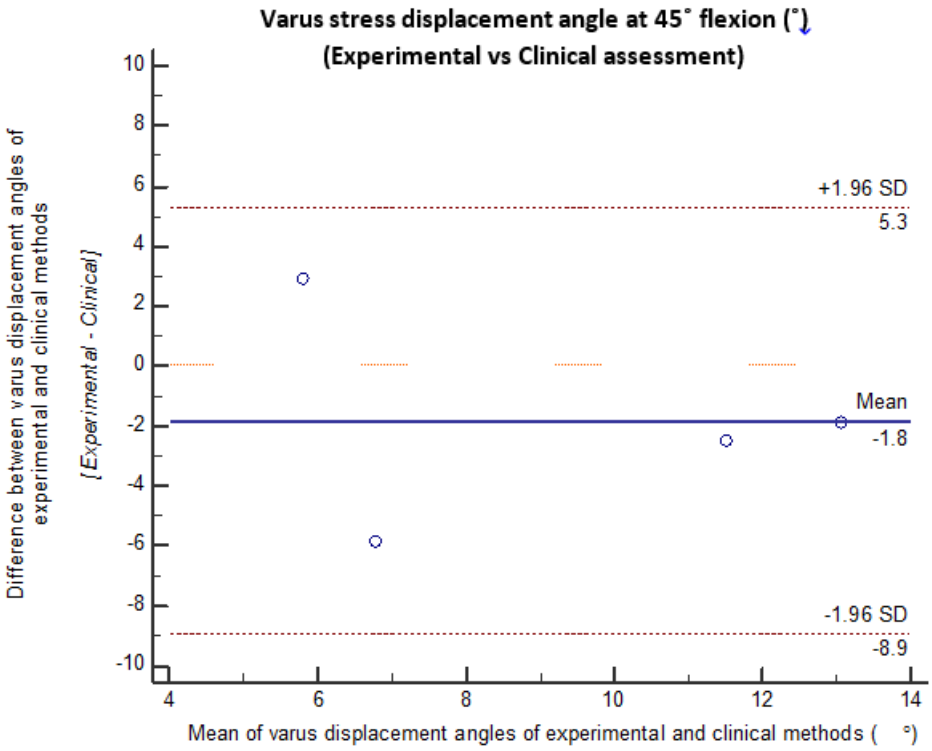

Figure 5.4 – *Average varus stress displacement angles in experimental and clinical methods at 45˚ flexion (˚)*

5.4 Discussion – *Varus Valgus Assessment*

The main objective in standardising clinical assessment of laxity is to improve upon the current standard assessment, which relies upon visual cues and meeting subjective 'end-points' of joint laxity. To establish the accuracy of the experimental protocol, laxity assessments for 4 participants were compared to the standard manual laxity assessment carried out by Mr Clarke- an experienced orthopaedic consultant.

The repeatability of the experimental protocol at 5˚ flexion for both varus and valgus laxity values (1.5˚ and 1.6˚ respectively) fell well within the 3˚ limits of agreement. These values were just outside the limits of agreement of laxity previously reported by Mr Clarke, following varus (±1 ˚) and valgus (±1.5˚) stresses in extension *(Clarke, 2012).* In addition, valgus displacement angles at 15˚ and 30˚ were also within the pre-defined limits of agreement. Comparatively, varus stress displacement measurements at 45˚ (Figure 5.4) showed significantly larger limits of agreement than varus stress displacement recordings at 5˚ (Figure 5.1).

This is a very positive result, indicating that with the use of the experimental

methodology, an inexperienced novice can obtain repeatable results at small degrees of flexion, when compared to an experienced consultant.

As seen in Section 4.2.2, valgus laxity assessment proved to be more repeatable than varus assessment overall, and can possibly be attributed to the factors outlined in that section (ie. difficulty in applying smooth, steady force).

The limits of agreement of both varus and valgus laxity values grew wider as the angle of flexion increased in comparison with the clinical assessment. This could be attributed to the fine control of flexion angle available to the clinician, as opposed to the pre-determined angles of the wooden supporting structure (and the subsequent deviation that it can cause at higher levels of flexion).

5.5 Results –*AP Laxity Test*

The repeatability values of the comparison of the experimental to the clinical assessment of anterior displacement of the tibia from the femur during an AP Laxity test are shown in Table 5.2.

Angle of Flexion (˚)	Mean difference (mm) ± SD	Repeatability Coefficient (CR)
5˚	-0.3 ± 2.8	5.6
15˚	-0.38 ± 1.5	2.9
30˚	0 ± 2.3	4.6
45˚	-0.1 ± 2.6	5.1

Table 5.2 *- Mean difference and repeatability coefficients for experimental and clinical recordings of anterior displacement of the tibia (mm) following force application at 5˚, 15˚, 30˚ and 45˚.*

Table 5.2 shows that only the AP displacement at 15˚ falls just within the acceptable limits of agreement 3mm, confirming the Bland-Altman plot in Figure 5.5. The corresponding Bland-Altman plot for AP translation at 30˚ in Figure 5.6 is an example of the same trend of poor agreement and wide distribution at 5˚, 30˚ 45˚ flexion, as all measurements are >4.6mm.

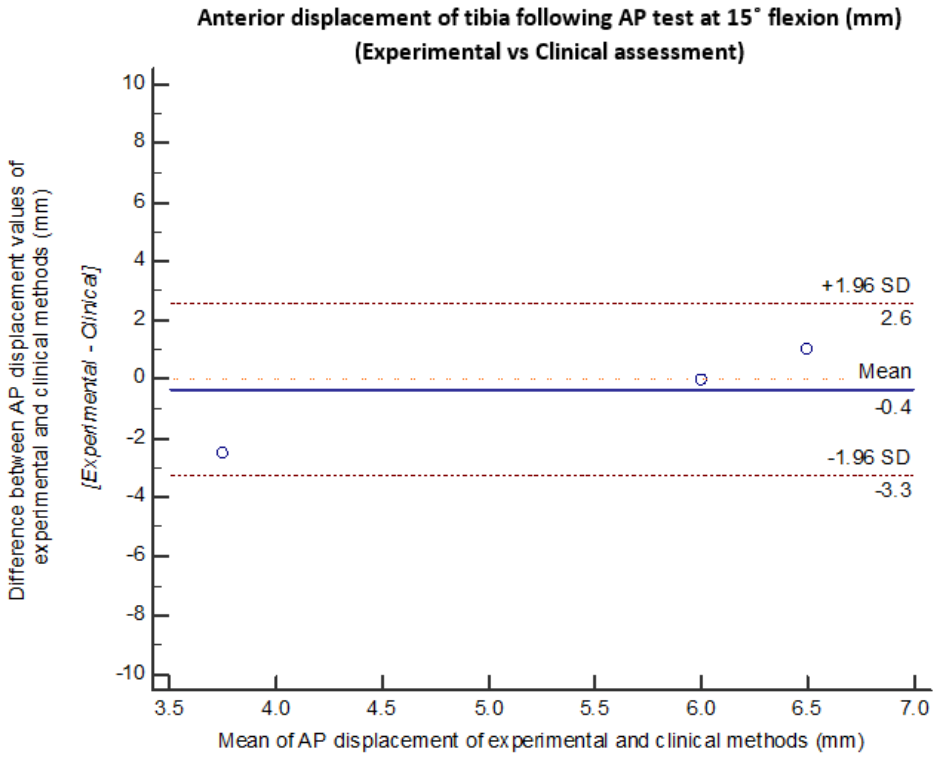

Figure 5.5 *- Average AP displacement values of experimental and clinical methods at 15˚ flexion (mm)*

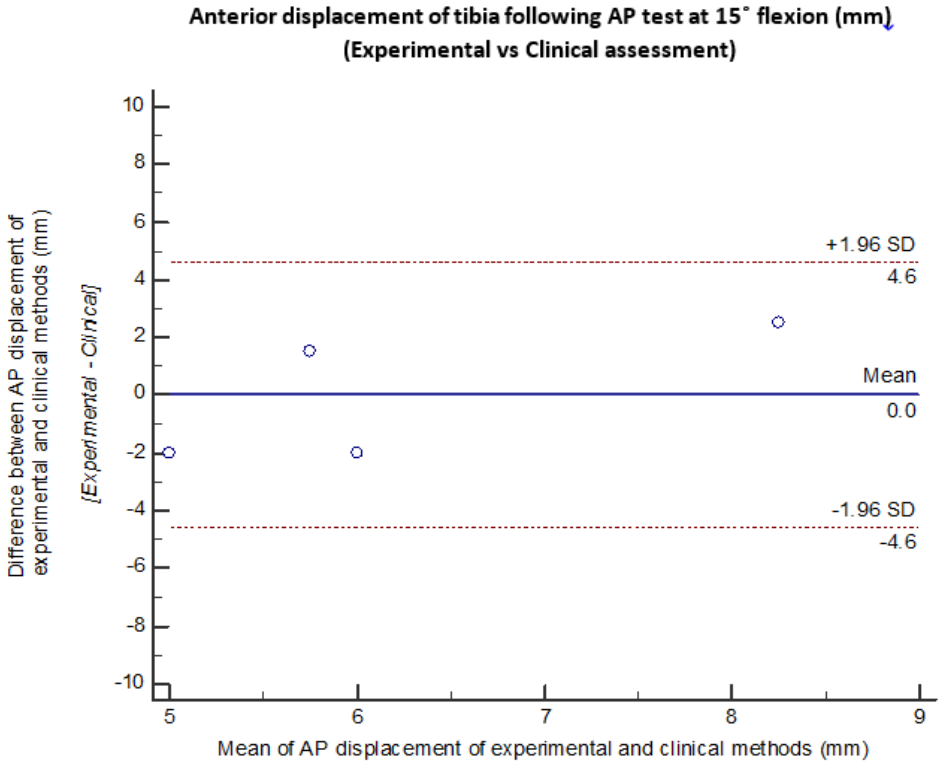

Figure 5.6 *- Average AP displacement values of experimental and clinical methods at 30˚ flexion (mm)*

5.6 Discussion – *AP Laxity Test*

The repeatability of the experimental methodology just falls within the 3mm limits of agreement an angle of 15˚ flexion (3mm). The lack of corroboration between experimental and clinical assessment of AP laxity is possibly related to the difference in application of force. Whereas a clinician can physically wrap their hands just below the tibiofemoral joint line and translate the tibia, the experimentally applied force is delivered via a spring balance and woven strapping. This was discussed in Section 4.9, and this motion is hypothesised to most induce soft tissue movement and create increased levels of soft tissue artefact.

AP laxity assessments undertaken by Russell have also documented much higher levels of force application than the 18Nm used within this study, and this level of force may be closer to that practiced in standard clinical assessments *(Russell, 2015).*As previously stated, this force was not attempted due to the devices available.

5.7 Conclusion

Considering the inherent flaws within the experimental methodology and the reduced level of precision than expected from the new-generation passive trackers, several measurements were shown to be repeatable when compared to the standard assessment of an experienced orthopaedic consultant. Valgus laxity assessments fall within acceptable limits at 5˚, 15˚ and 30˚, and varus laxity assessments were found to be agreeable at 5˚.

Similar to the previous results in Section 4.8, the AP Laxity tests were much less successful. However, measurements between experimental and clinical assessments did agree at 15˚- providing a promising baseline for further investigation into repeatability of this system.

6. Further development of experimental protocol

Many aspects of variation within the results of this study have been attributed to possible errors introduced by the design of the experimental methodology.

On account of the strict time constraints imposed on this study, it was impossible to physically further develop the wooden support prototype, or to repeat assessments with modified experimental methodology. However, careful consideration has been given to the failings of the experimental design, and the following sections contain future recommendations for further development.

6.1 Alteration to force application

Following varus valgus, and AP laxity assessments, the spring balance used was found to be highly variable and rather inconsistent. In order to maintain the portability of the system, an electronic dynamometer *(Sharma et al, 1999)* would be more suitable. An additional feature of 'limiting' the amount of force would be favourable- in order to restrict any extraneous force being applied and aid in keeping force within standardised limits. A tracked force device, such as that investigated by Clarke would be even more advantageous *(Clarke, 2012)* – by enabling clinicians to ensure that force is being applied perpendicular to the tibia.

The woven strapping that was used in conjunction with the spring balance introduced a degree of error during AP assessment. Both participants and the investigation noted that the AP Laxity test results were mostly attributed to the movement of soft tissue, regardless of how tightly the strap was fastened. If elasticated strapping was used, this variation could be restricted, by tightly containing the soft tissue and reducing the motion. This would hopefully result in a noticeable AP translation.

These alterations, in conjunction with the higher force application suggested for AP Laxity tests could beneficially alter the experimental results.

6.2 Alteration to flexion supporting structure

The concept for this structure was taken from that of cadaveric work into varus laxity assessments by LaPrade, in his work investigating collateral ligament injuries *(LaPrade, 2008).* During the design phase, it wasn't taken into consideration that the specimen in LaPrade's study were fixed to the supporting structure. This oversight led to the problems in controlling the limb during participant assessment.

Although the knee was restricted by the investigator, the lower limb showed the tendency to rotate as the angle of flexion increased no matter what alterations were made to hand positioning during assessment. If the structure were to have two sections to restrict the leg, it would prevent rotational motion and reduce variation within laxity measurements. This has been quickly demonstrated in Figure 6.1.

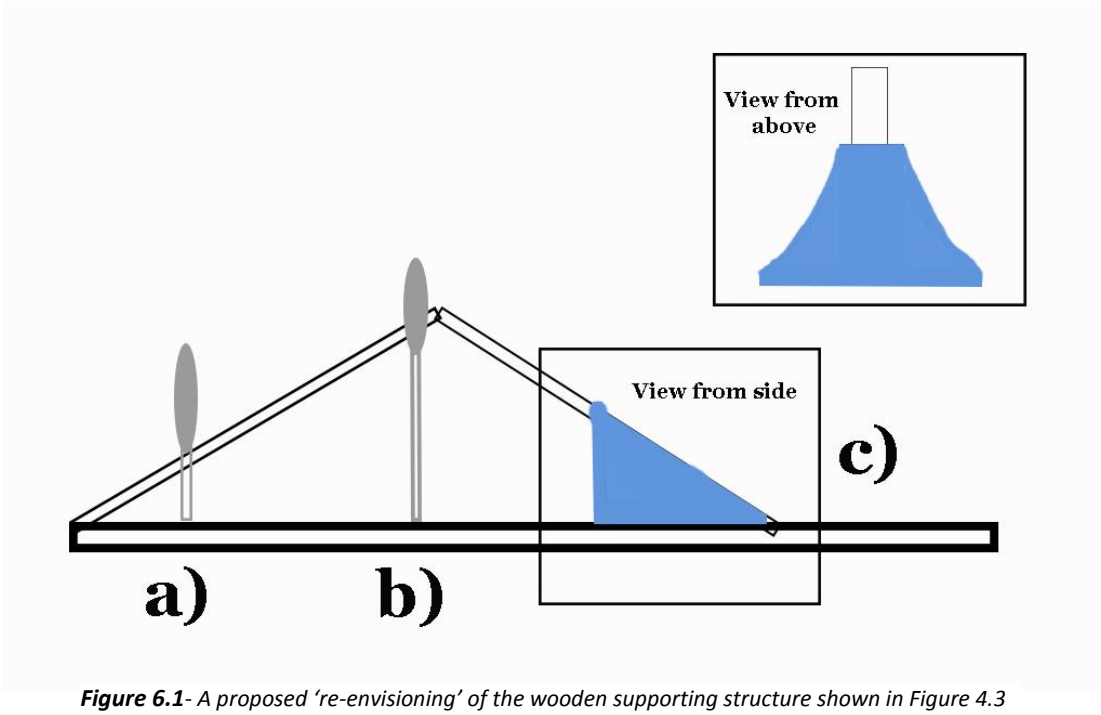

Figure 6.1*- A proposed 're-envisioning' of the wooden supporting structure shown in Figure 4.3*

In Figure 6.1, wooden slats are present at either side of the support and would act to restrict the motion of the thigh (**a)**), and the knee (**b)**) during varus and valgus laxity assessments.

Additionally, as the degree of flexion (and therefore envelope of laxity) increased, the displaced lower limb moved along the surface of the supporting structure when force was applied. As the structure was rather narrow (12cm width), the displaced limb often moved beyond the borders of this structure. This occasionally occurred as a noticeable 'jerk' in motion, twinned with an increase in displacement recorded. Without the support directly underneath the ankle, it was difficult to ensure that the force was being applied directly perpendicularly to the limb. Part c) of Figure 6.1 could be a possible improvement to the original design. This represents the supporting structure adopting a bell-shape, to ensure that the structure will be beneath the ankle for the whole range of laxity measurements recorded. This would (in theory), improve repeatability of the procedure, as well as increasing the stability of the limb throughout motion.

Another path of investigation could include the development of the method of fixing flexion angle. On account of the varying soft tissue volume between participants, there was a great deal of variation within the angle of the knee, compared to the 4 increments of flexion the device was capable of. The creation of a completely flexible structure, able to maintain any angle of flexion between 0-90˚ for example, would result in the operator being able to use the true flexion angle reading of the participant from the navigation software to set the angle of flexion of the structure to produce the true angle of flexion wanted.

As this experimental methodology has shown limited success on account of flaws in its design, further design ideas have been suggested in the hope that they address some of the variable discovered throughout testing.

7. Conclusions

Measurement and standardisation of knee laxity in coronal and saggital planes has been established as a valid clinical research avenue, in the hope of creating an accurate and reliable non-invasive method of quantitatively analysing knee kinematics in a pre-operative setting *(Picard, 2007).* The possible benefits of a IR tracking system for pre-operative assessment are numerous. As well as investigating several parameters throughout the patient ROM, it could possibly allow for further analysis of fundamental variables not currently accounted for, such as dynamic and weight bearing alignment. On account of the increase in precision possible, further reductions in morbidity and improvements in standard of living is possible *(Chauhan et al, 2004).* In addition to the benefit of the patient, this type of system could provide important training for junior surgeons, in providing them with guides of alignment as they develop their skill at the beginning of their career. In terms of the over-burdened NHS, an increase in the precision and accuracy of TKA could have a positive effect of current revision rates, which are ~6% after 5 years, increasing to ~12% after 10 years *(Labek et al, 2011).*

This study, utilising an optical tracking technology system developed for non-invasive *(Clarke, 2012),* use has demonstrated some level success in assessing varus and valgus laxity in early flexion (5˚ and 15˚). These measurement values came well within the surgically acceptable limits of ±3˚, and as such can be considered as a favourable result. The most promising results of this study were the high levels of repeatability using this experimental methodology, when compared to an experienced orthopaedic surgeon. The ability to prove repeatability at small angles of flexion is a small step in the development of quantifying knee laxity, both to improve surgical and (hopefully) functional outcomes.

The future work of this study should focus on re-developing the standardisation methods, which were found to create errors during the process of assessment.

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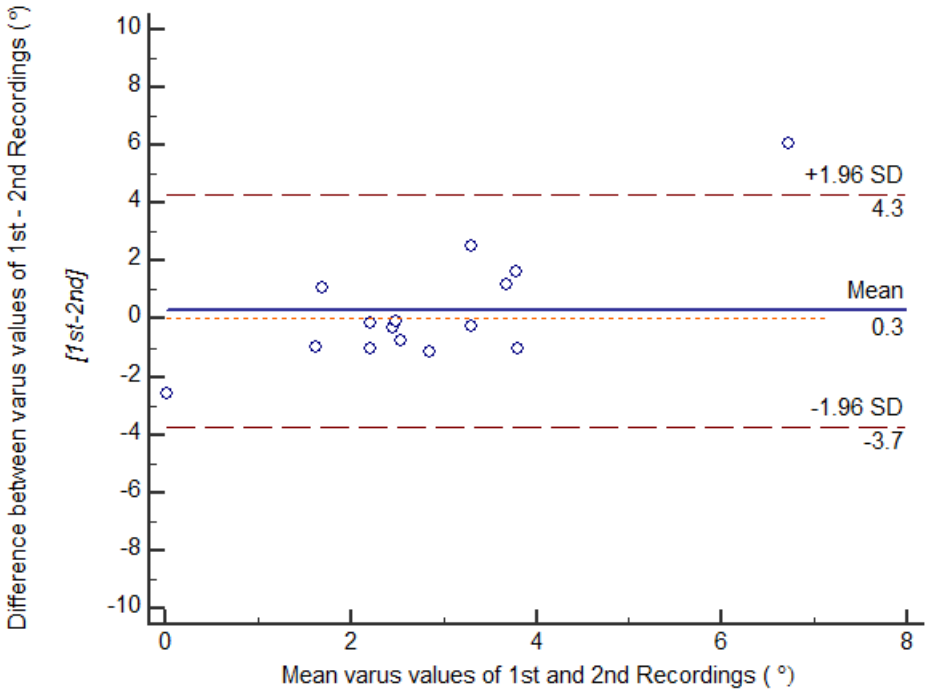
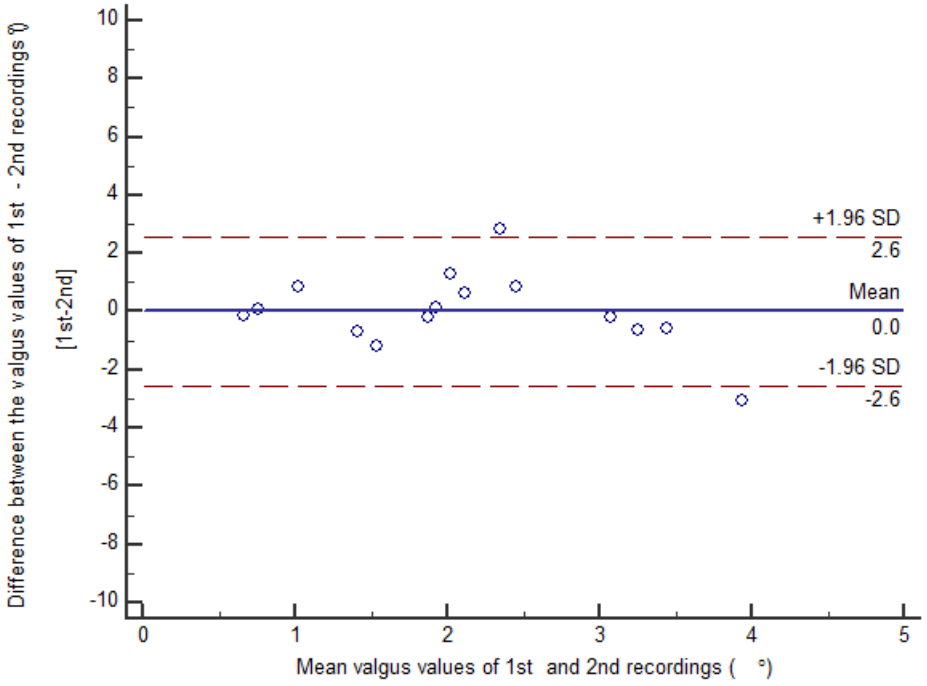
9. Appendices

9.1 Bland Altman Plots of Varus Valgus Laxity

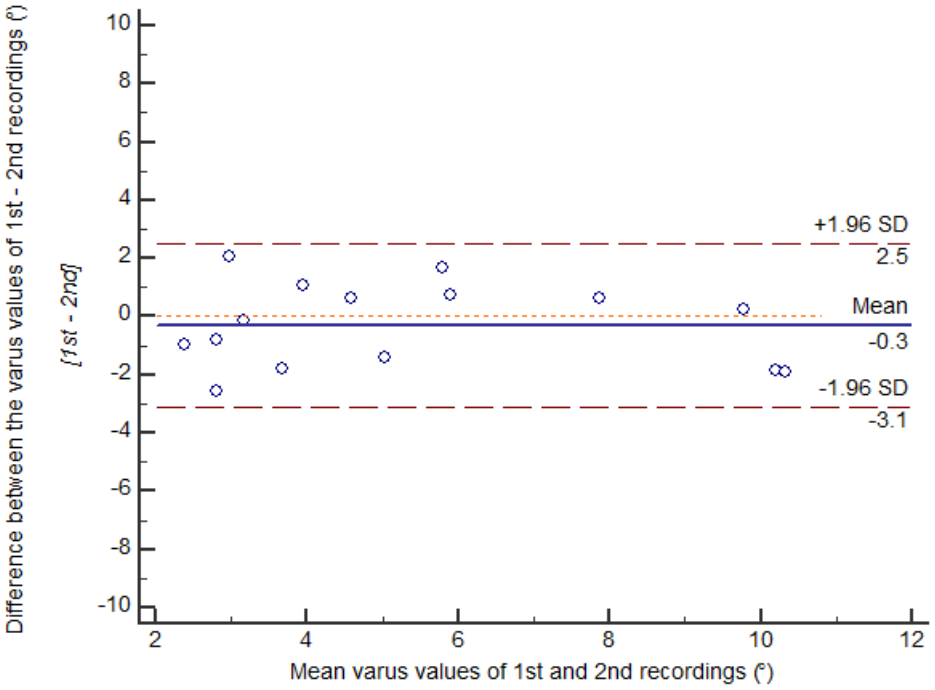
Varus laxity - 5˚



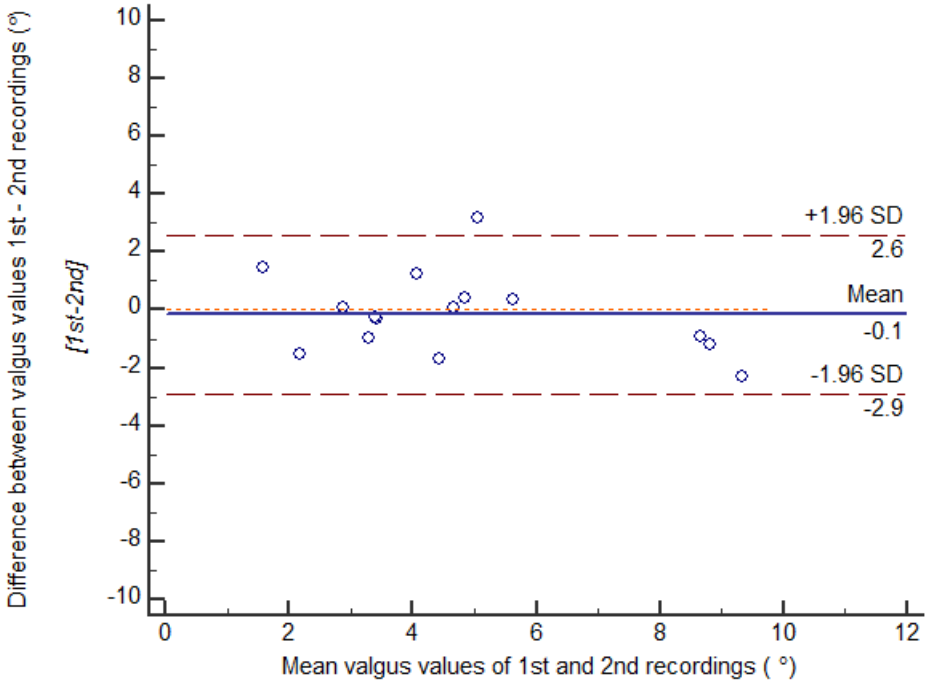
Valgus laxity - 5˚



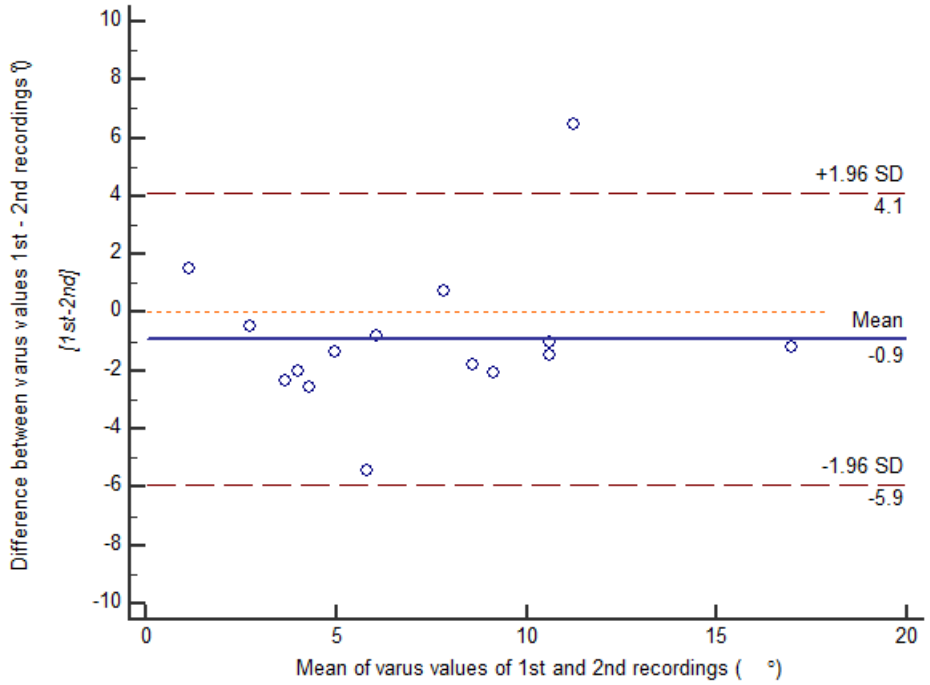
Varus laxity - 15˚



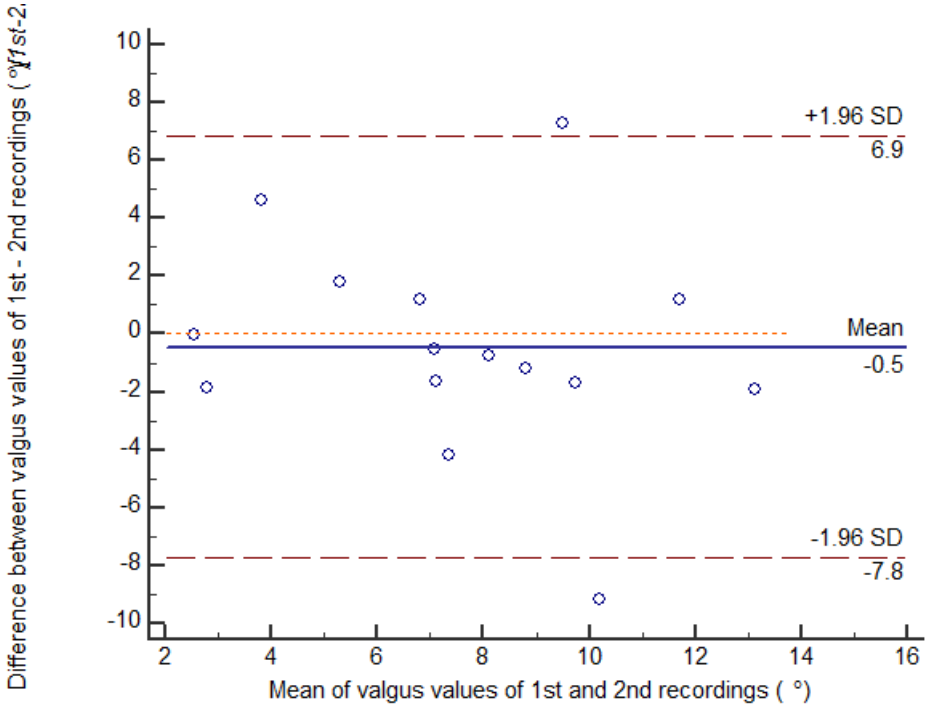
Valgus laxity - 15˚



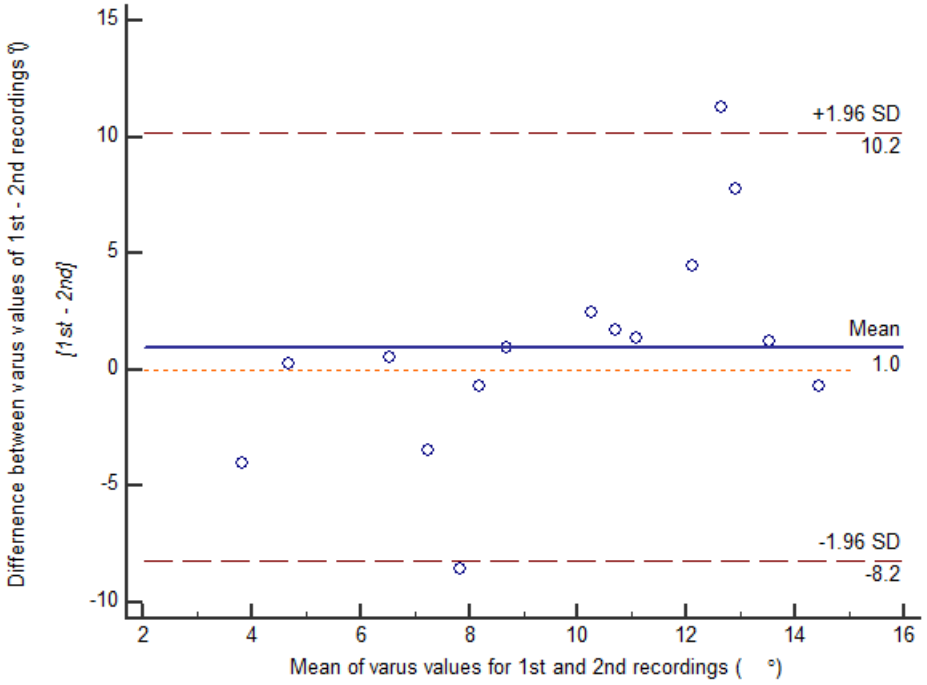
Varus laxity - 30˚



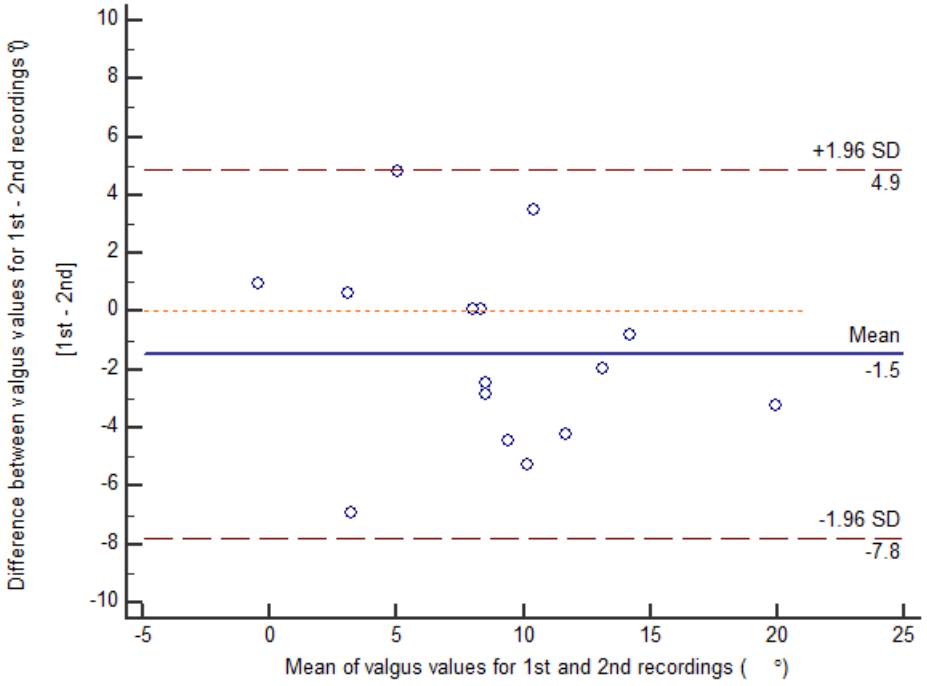
Valgus laxity - 30˚



Varus laxity - 45˚

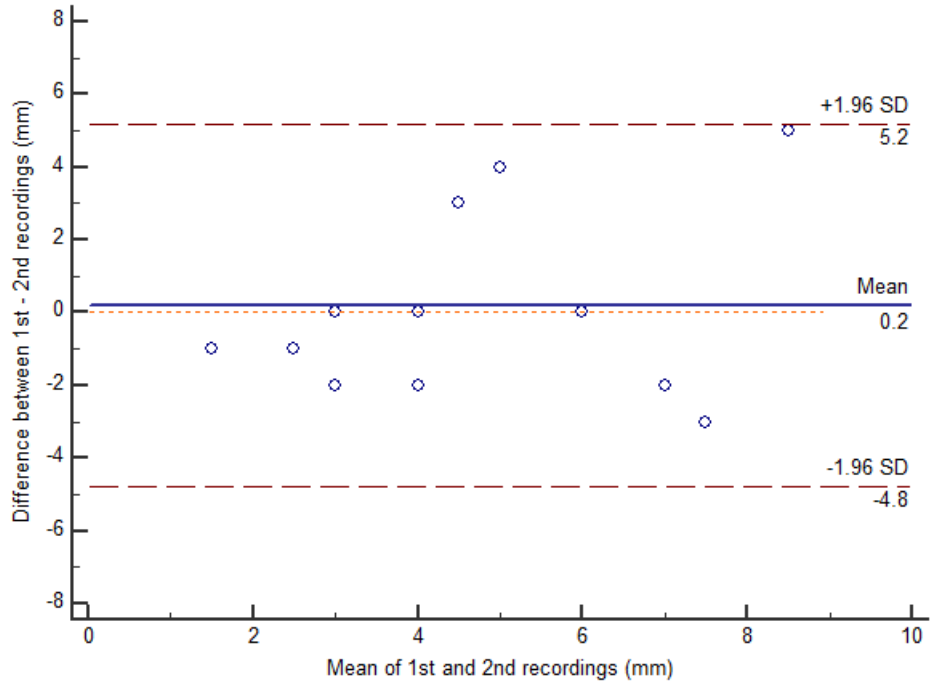


Valgus laxity - 45˚



9.2 Bland Altman plots of AP Laxity

AP Translation - 5˚



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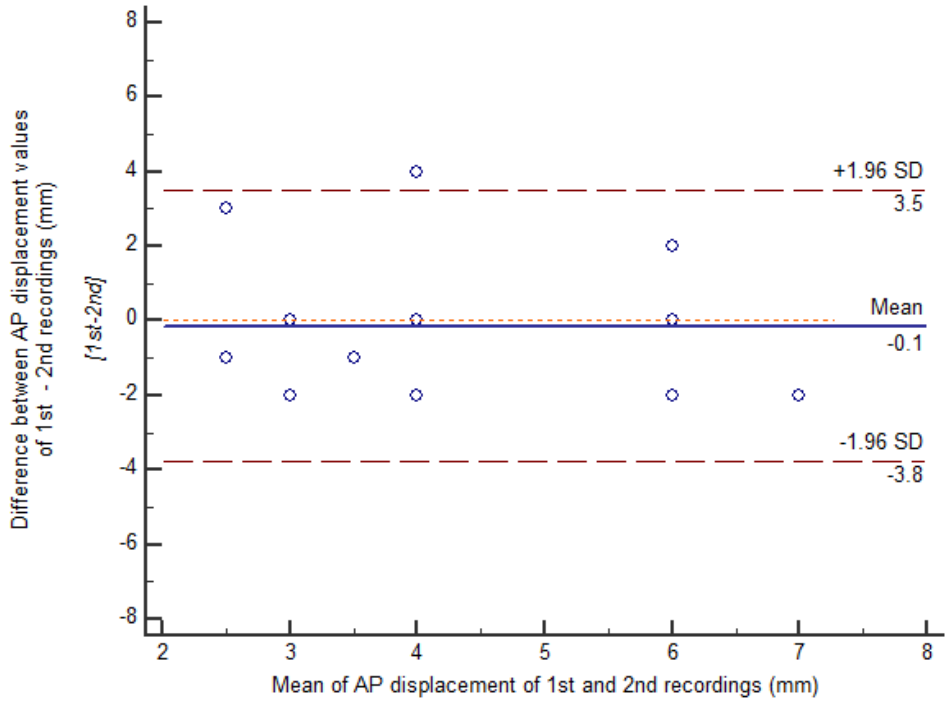
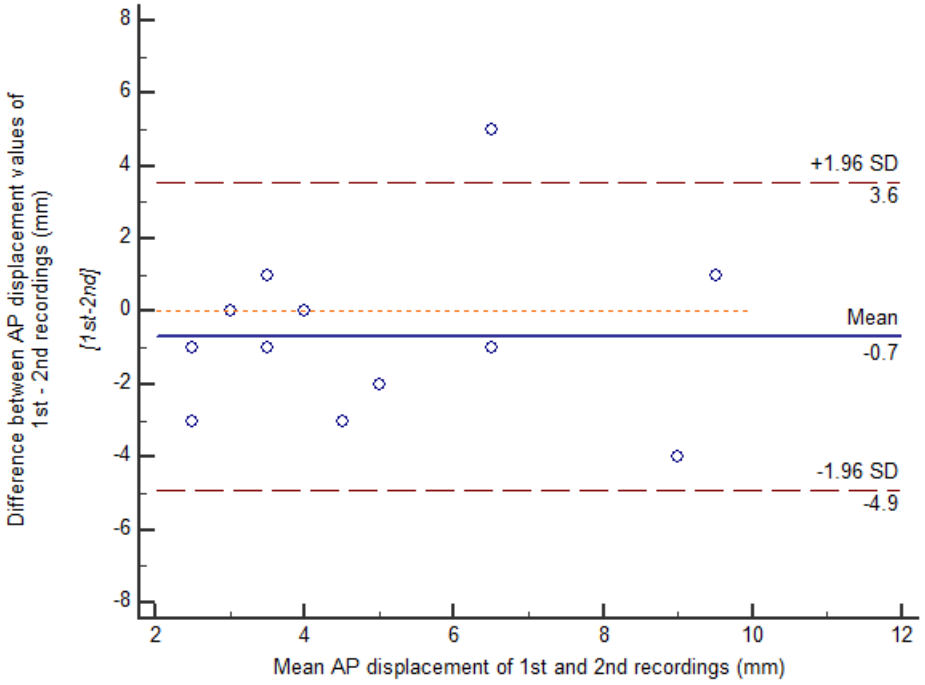
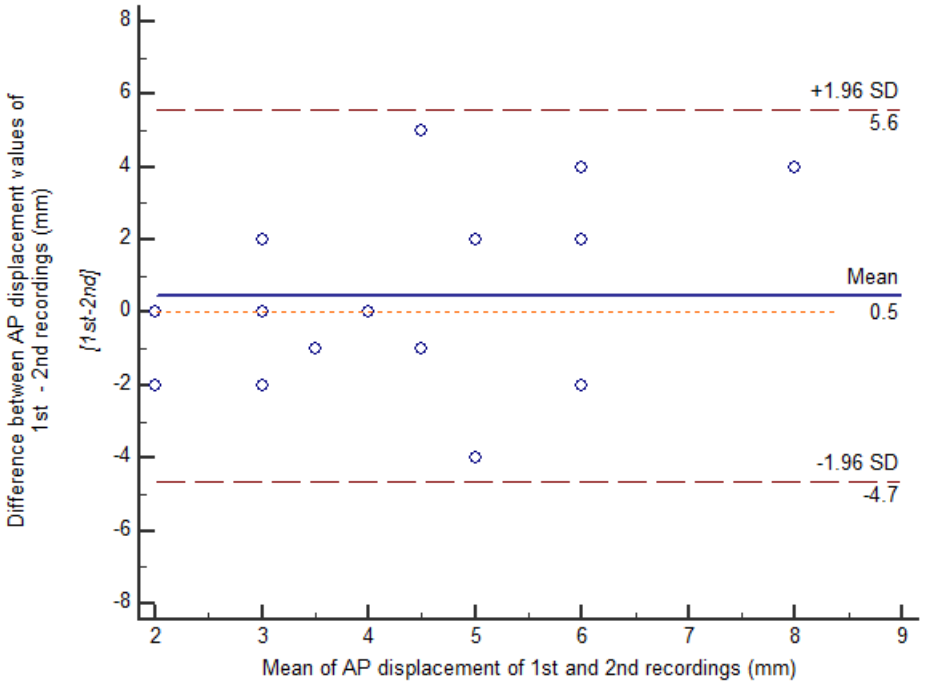


AP Translation - 30˚

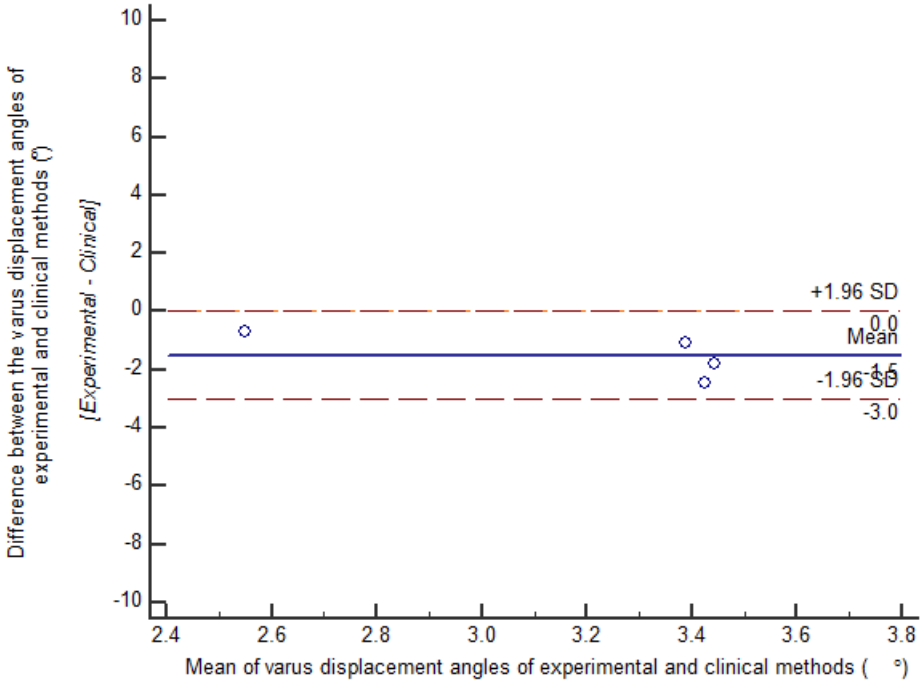


AP Translation - 45˚

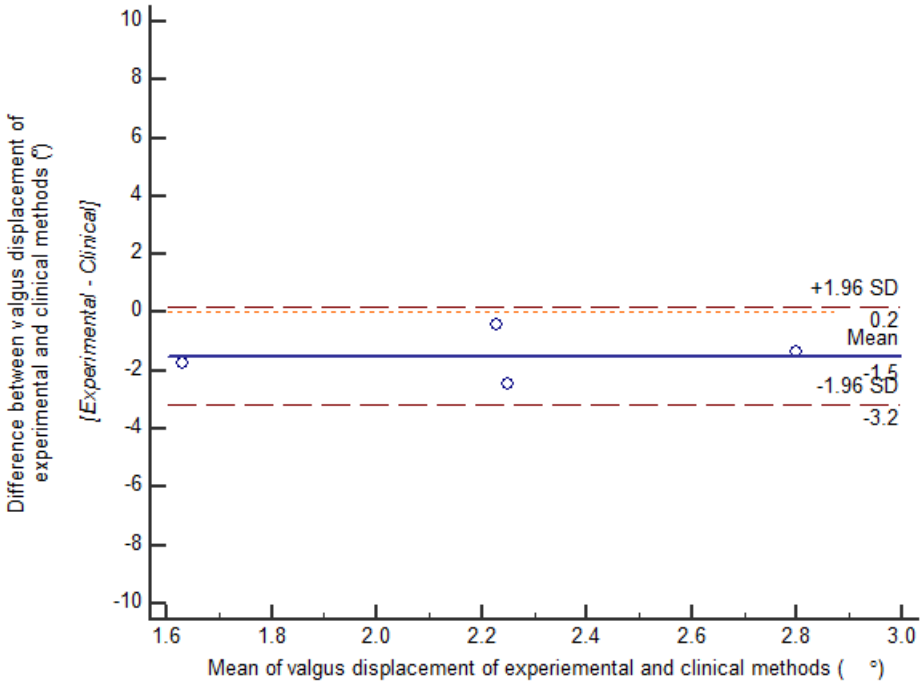


9.3 – Varus Valgus laxity (Experimental vs Clinical)

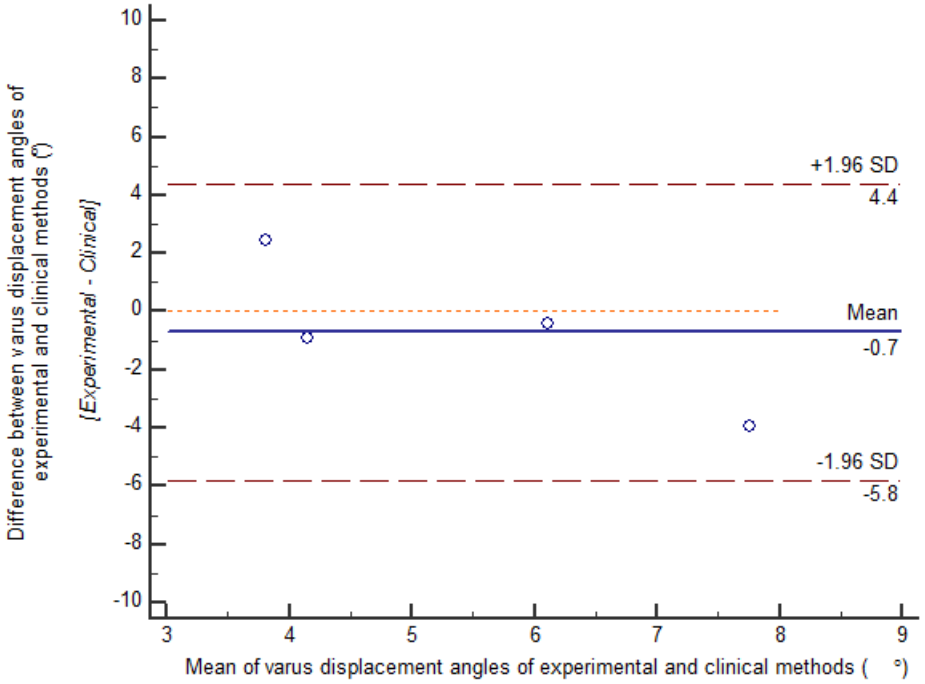
Varus laxity - 5˚



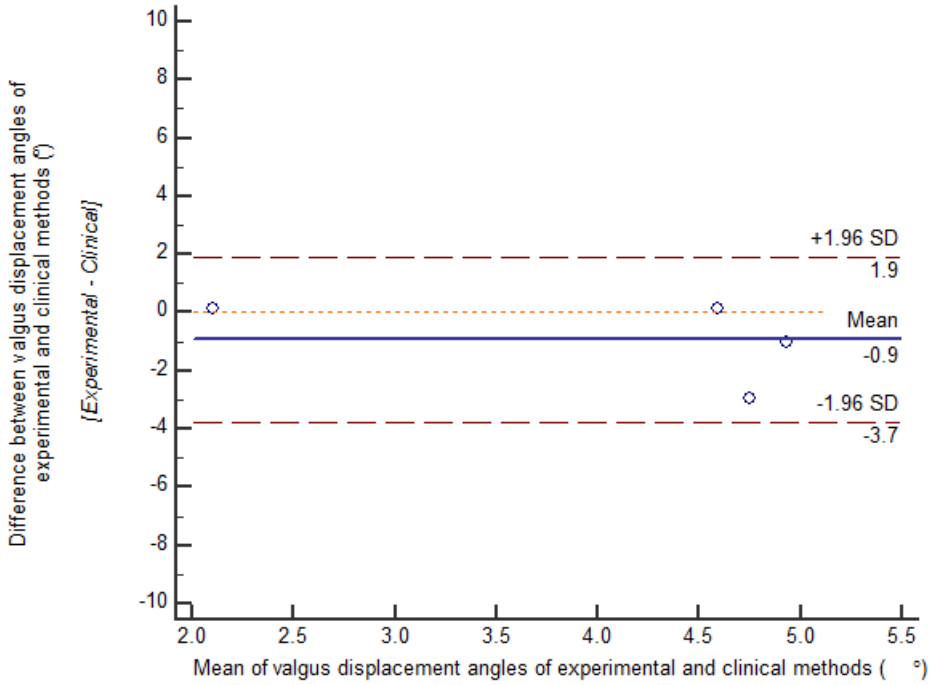
Valgus laxity - 5˚



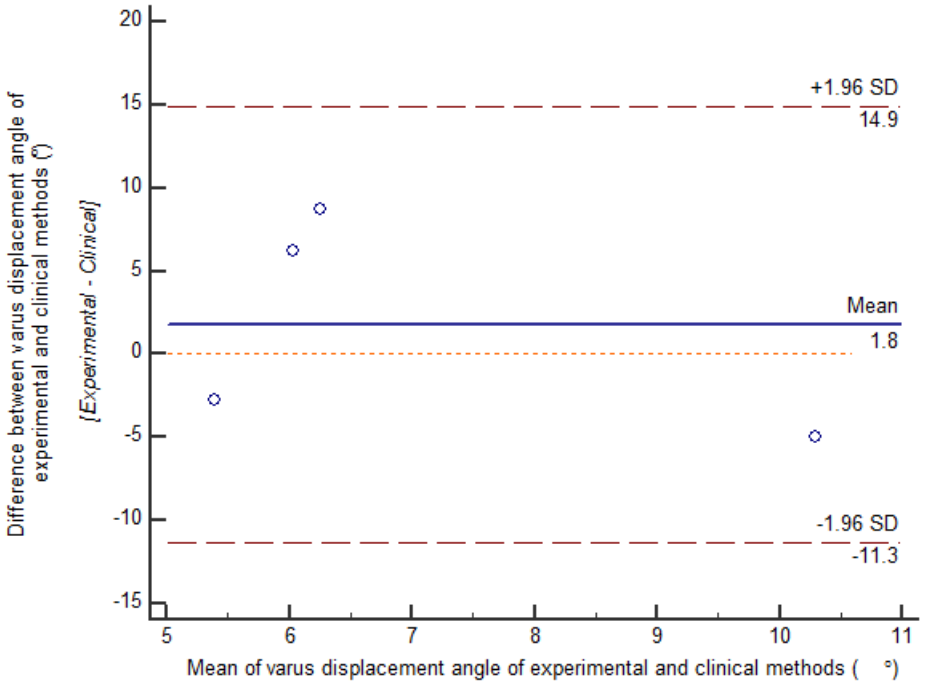
Varus laxity - 15˚



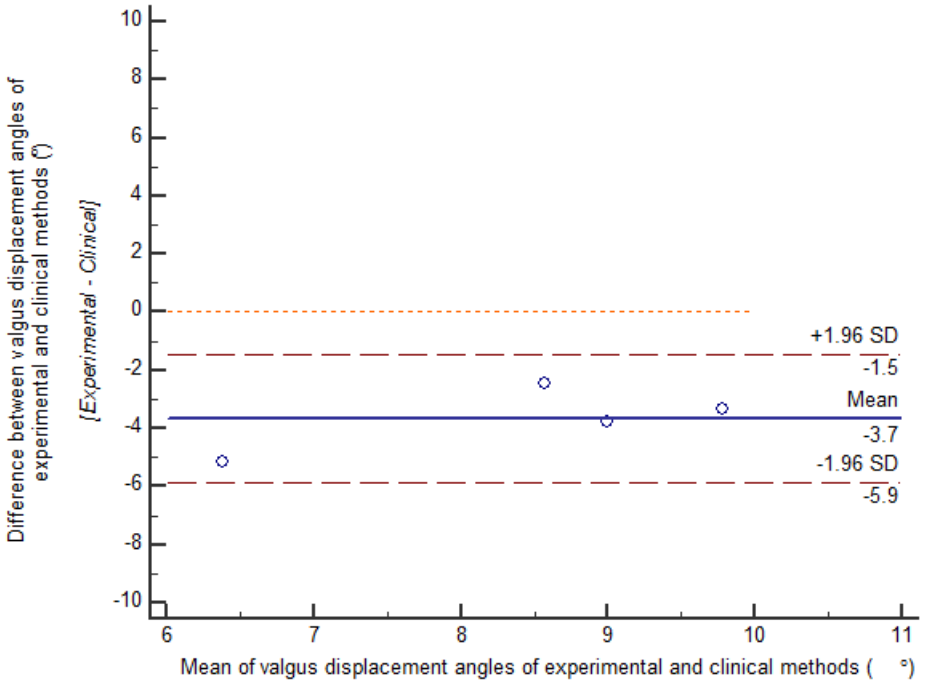
Valgus laxity - 15˚



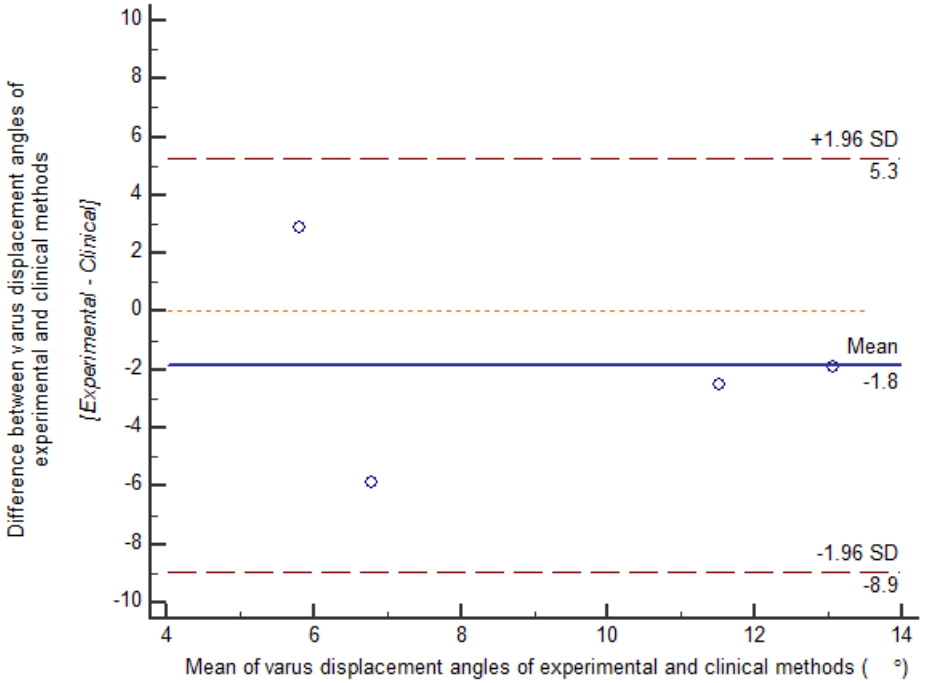
Varus laxity - 30˚



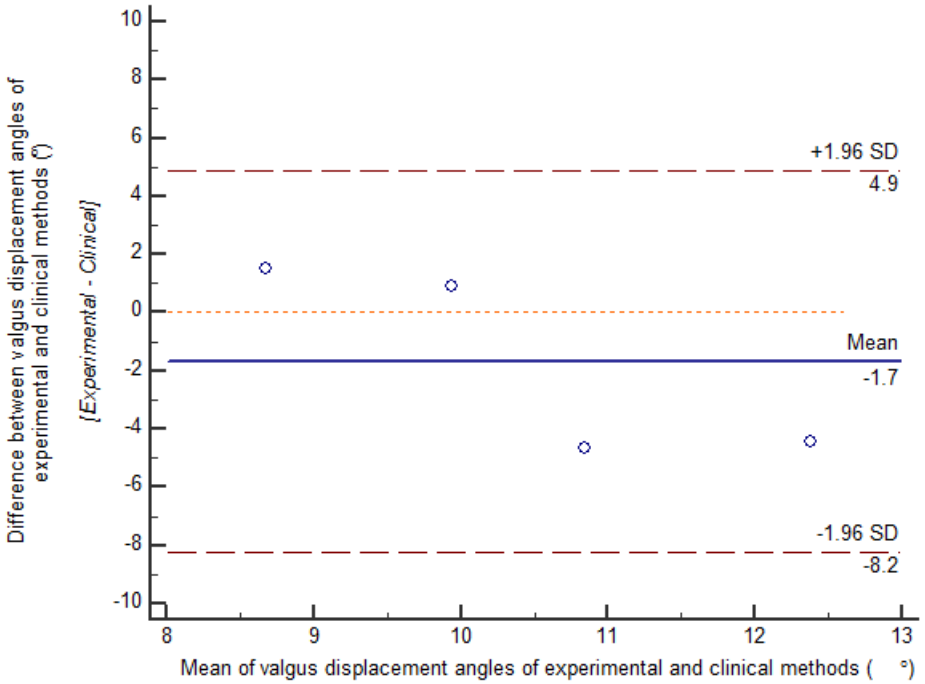
Valgus laxity - 30˚



Varus laxity - 45˚

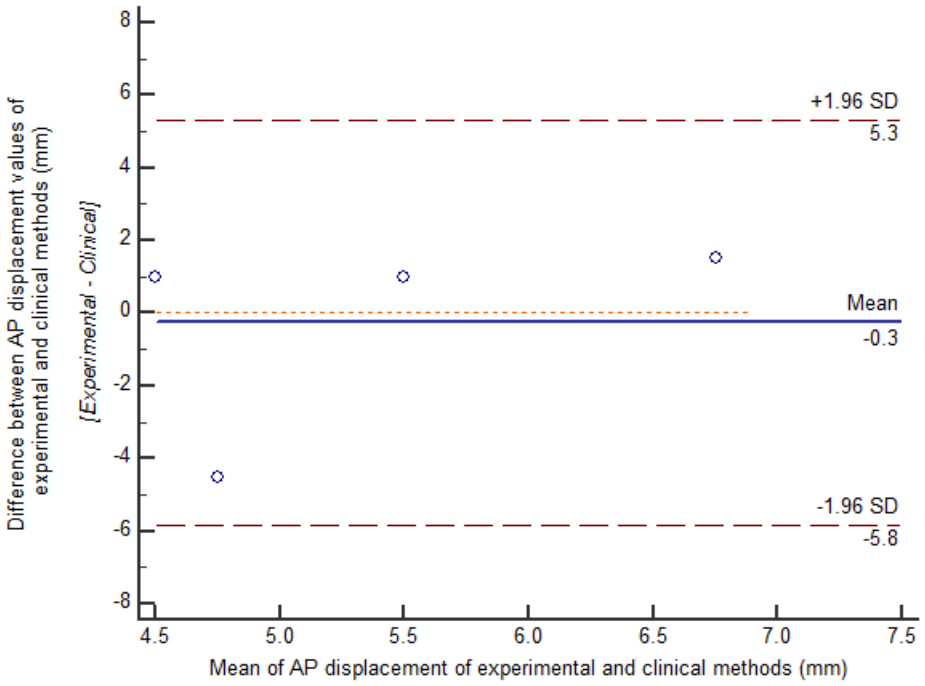


Valgus laxity - 45˚

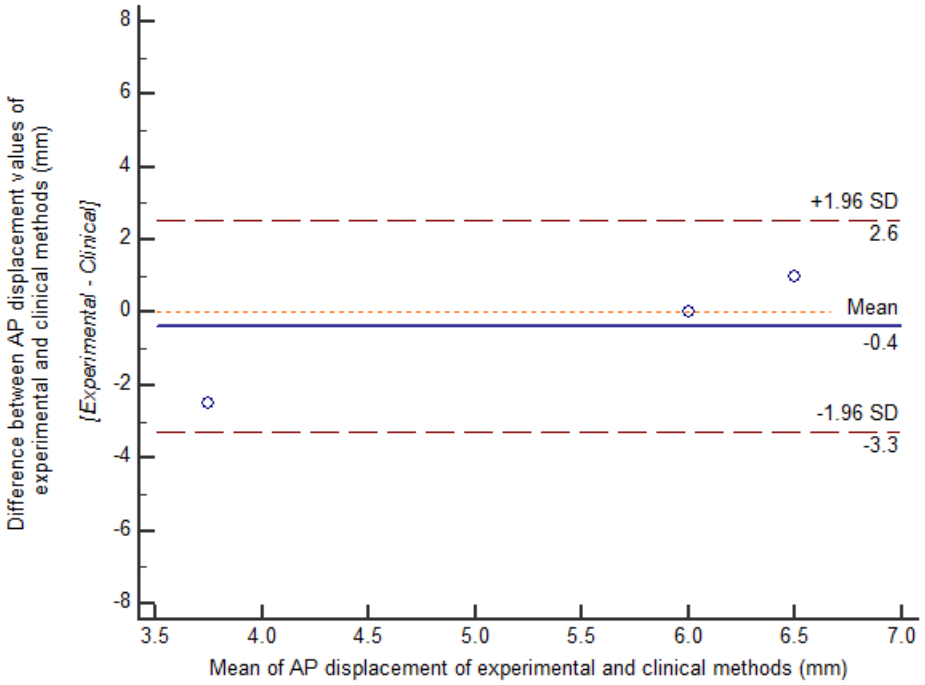


9.4 – AP Laxity (Experimental vs Clinical)

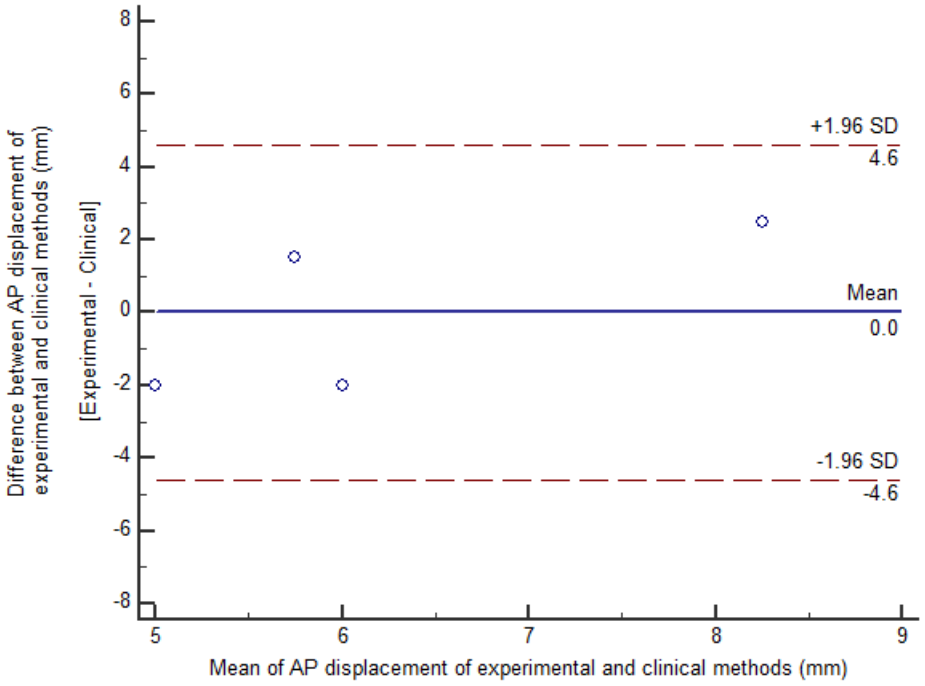
AP Laxity - 5˚



AP Laxity - 15˚



AP Laxity - 30˚



AP Laxity - 45˚