University of Strathclyde.

Department of Bioengineering

Functional and clinical outcome 3 months post partial knee arthroplasty, comparing MAKOplasty® to conventional surgery.

Miranda Asher

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Abstract

Osteoarthritis of the knee is becoming a more prominent issue in modern society. The pain caused by the disorder and limitation in knee movement impedes the patient's ability to complete daily activities in an independent manner.

The Oxford unicompartmental knee arthroplasty was developed over thirty years ago. It is a successful procedure which relies heavily on the surgeon's accuracy and uses conventional cutting guides.

Recently the FDA approved the first robotic arm interactive orthopaedic surgery, the MAKO RIO™. The Glasgow royal infirmary has embarked on a ten-year study into the long and short-term possible merits of the system.

This study looked at the early functional and clinical results up to 3 months post operation. The first 20 subjects were randomised into Oxford (n=10) and MAKO (n=10) unicompartmental knee arthroplasty groups.

Questionnaires such as the Oxford Knee Score and American Knee Society Score, passive ROM and pain scores showed that there was significant improvement after surgery in both patient groups ($p>0.05$). There were significantly greater angles of flexion recorded ($p = 0.006$) for the MAKO group compared to conventional group.

Alignment post surgery within the MAKO group was varied, but showed no significant difference to the equivalent scores for conventional UKA. The average surgery time was found to be significantly longer for the MAKO group, 111 mins (standard deviation 12.78 mins) compared to 67.3 min (standard deviation of 4.27 mins) for the Oxford group.

Declaration of Authenticity and Author's Rights:

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 lead to the award of a degree.

Signed: Date:

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Chapter 1: Origins of project

As we will discover below, the Oxford unicompartmental surgery has been available for more than 30 years. Knee arthroplasty is an effective method of surgery, which has evolved over the years to allow the option of total knee arthroplasty (TKA) as well as unicompartmental knee arthroplasty (UKA). Unicompartmental knee arthoplasty is less invasive than the TKA and is therefore preferred in suitable cases. The early Oxford UKA had problems of high failure rates, as discussed by Kort et al (2011). However, recent development of the prosthesis itself has resulted in improved outcomes. One study commissioned by the Swedish government (Knutson, et al. 1994) shows a high percentage of poor results in patients with UKAs, speculating chronic inflammatory arthritis, use of inferiorly designed implants and misalignment of the leg postoperatively. Although this report was commissioned in 1992 (and published in 1994), the issue of misalignment remains a factor, which may be attributable to human error.

The MAKO RIO™ is a robotically assisted guidance system, which has been developed with an aim to decreasing the possible influence of human error.

This study looks at clinical outcomes recorded up to and including 3 months post surgery. Patients were randomly assigned to receive either a MAKOplasty® or a conventional UKA, and the results from the groups were compared. The statistical comparison investigates the possible advantages and disadvantages of the MAKOplasty® compared to the conventional method.

Chapter 2: Anatomy of the knee

Human Anatomy has been extensively described from variable sources; reference was drawn from various anatomy and physiology textbooks (Magee 2002),(Putz and Pabst 2000),(Gray 1981).

2.1: Bony landmarks

The human leg consists of three long bones – the femur (thigh bone) and the calf bones of the tibia and the fibula.

The bony landmarks of the femur are shown in **Figure 1.** These structures are important as these are the points of origin and insertion of tendons and ligaments, as well as the articulating surfaces, which dictate the function and ROM (Range of Motion) of the knee.

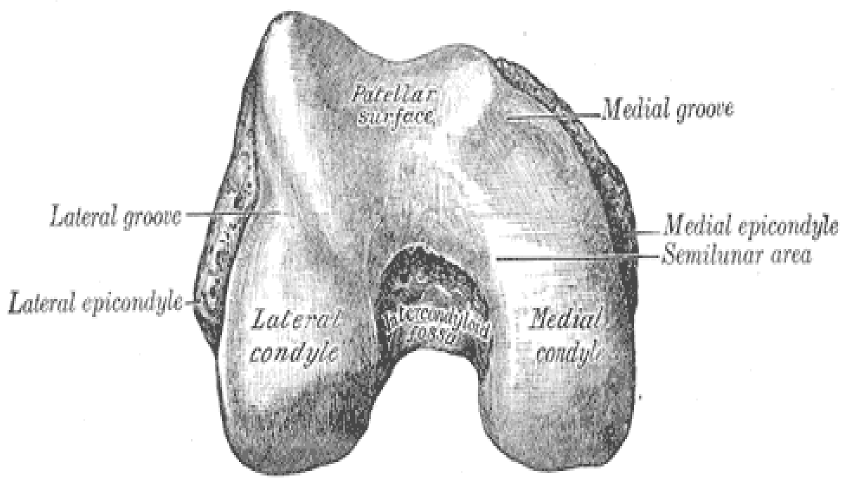


Figure 1: posterior and inferior aspect of the femur bone with relevant landmarks (Gray 1981)

The femur is the longest and strongest bone in the body. The main shaft is considered to be almost entirely cylindrical. Relevant to the function of the knee is the distal end of the femur. The femur has two bulbous outcrops, which are more prominent on anterior side of the bone (condyles) and slightly less on the posterior (epicondyles). In between the epicondyles there is a deep notch (the fossa intercondylaris). As seen in **Figure 2** the anterior surface of the distal femur there is also a smooth and shallow articular depression referred to as the facies patellaris (for articulation with the patellar). The shaft of the femur has a prominent longitudinal ridge on the middle third of the bone, which is the linea aspera. This ridge is the attachment for many muscles and is formed due to the tension generated by these muscles.

Figure 2 shows the bony landmarks of the tibia and fibula. Both bones are shaft bones. The tibia is the larger of the two 'calf bones.' The proximal end of the tibia (**Figure 3)** is most relevant to the knee architecture and consists of medial and lateral condyles. The medial facet of the proximal tibia is oval in shape and concave in the medial-lateral direction. A long oblong elevation on the anterior surface forms the tibia tuberosity. In between the fossas of the condyles there are rough depressions, which create the connecting surface for the cruciate ligaments and the menisci.

Figure 2:Posterior view of tibia and fibula (Netter 2010)

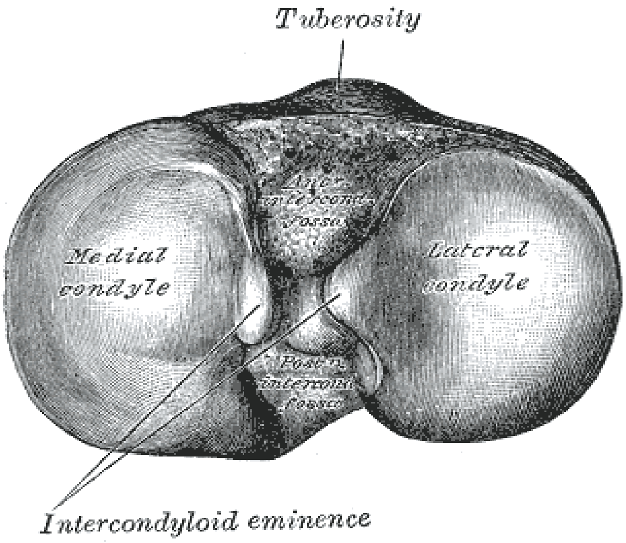


Figure 3: Proximal end tibia (Gray 1981)

The patella bone, (**Figure 4)** often referred to as the kneecap, is a relatively smooth bone with few landmarks. The posterior surface forms the articulating surface. It is vaguely triangular in shape with the longer edge, referred to as the base, being the most proximal part of the bone and the Apex being the point and most distal part of the bone.

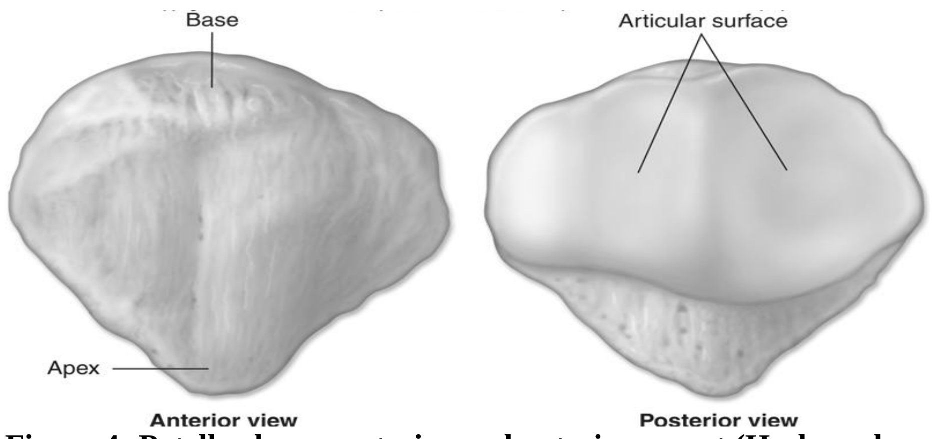


Figure 4: Patellar bone posterior and anterior aspect (Herbrandson 2005)

A number of muscles of the knee have their origin at the os coaxae, at the hip. The os coxae are constructed by the pubis, Ischium and Ilium. The two os coxae are mirror images of each other and, combined with the sacrum and coccyx, form the pelvic girdle. The superior aspect of the Ilium forms a wing like shape, tipped with a ridge, which forms the iliac crest. The crest stretches posteriorly from the spina iliaca superior anterior (SIAS) to the spina iliaca posterior superior (SIPS). Inferiorly to the Ilium is the Ischium, the superior ramus of the ischium forms a large swelling posteriorly, and this is the ischial tuberosity.

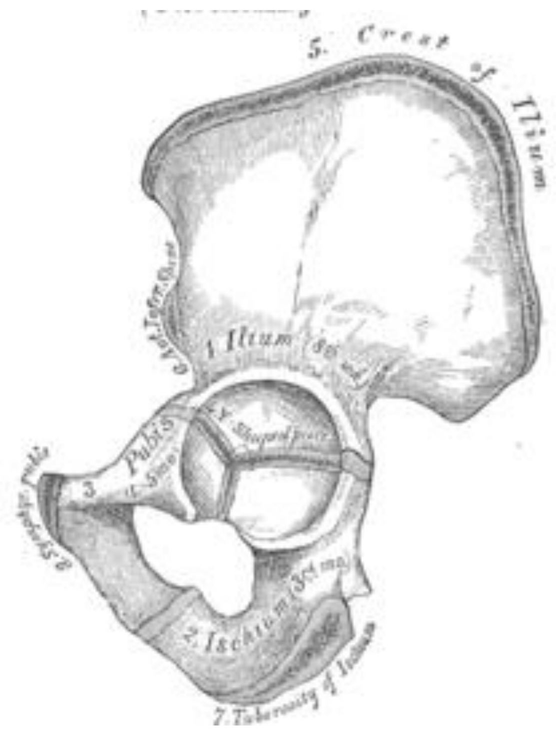


Figure 5: Os coxae (Gray 1981)

2.2 The articulation

The articulatio genus is a complex system as it consists of three articulations in the one joint, where each of the distal condyles of the femur and the proximal condyles of the tibia articulate as well as the patella articulating with the femur. The posterior aspect of the joint is a bowl shaped space, the popliteal fossa also referred to as the knee pit.

Due to the three articulations of the joint, there are three points of high wear. These constitute the knee's three compartments, the medial and lateral tibiofemoral and the patellofemoral compartment.

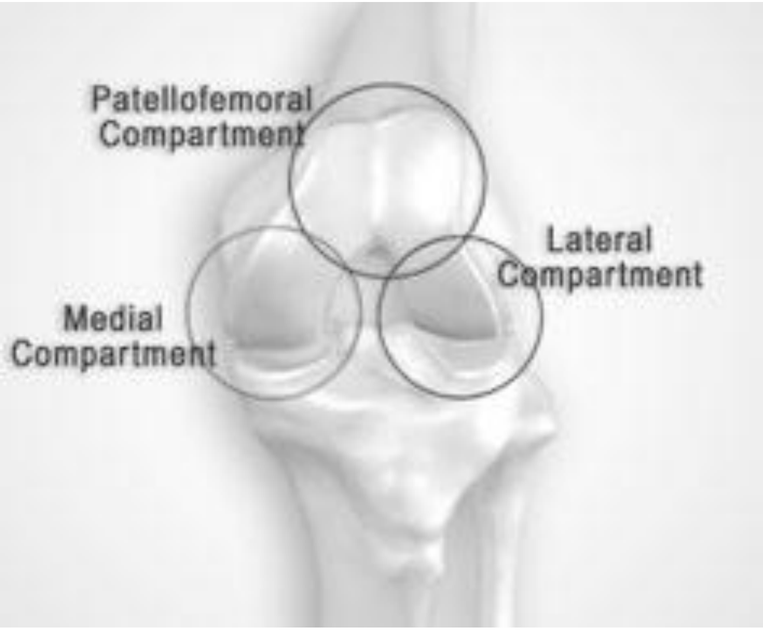


Figure 6 Compartments of the knee (keepingyouwell.com)

The lateral and medial compartments represent the point where the condyles of the femur make contact with the tibia bone. The final compartment is where the patella and femur bone make contact. These compartments are highly relevant to the course and progress of ostheoarthritis.

2.3: Ligaments and tendons

The bony landmarks of the knee are connected with tendons and ligaments (**Figure 7**).

The patellar tendon connects the patella distally to the tuberoses tibialis and middle portion of the tendon of the quadratus medialis (the quadriceps tendon) connects the patella proximally to the bones of the leg. The posterior surface is separated from the synovial membrane by the infrapatella fat pad.

Either side of the articulation are the collateral ligaments. These ligaments run from the proximal part of the femur epicondyles. The lateral collateral ligament is a thick cord, which attaches to the caput fibularis. The medial collateral ligament is, however, a flat band and consists of two layers: the superficial layer attaches to the tibial epcondyle, whilst the deep layer attaches to the menisci medialis. These ligaments limit medial and lateral deviation of the knee especially when the knee is flexed.

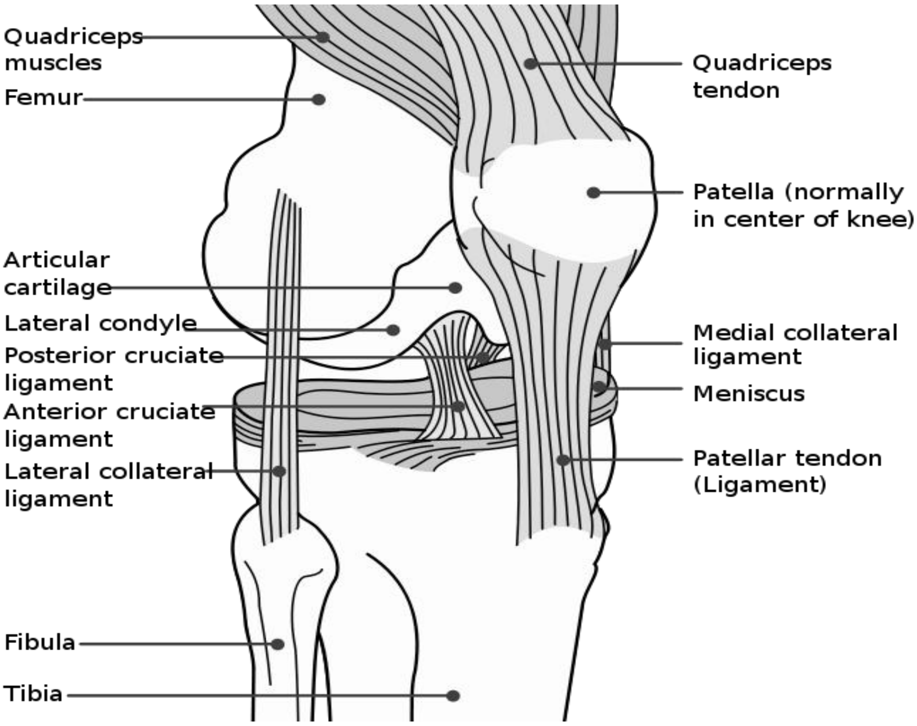


Figure 7: Ligaments of the knee visible from the anterior-lateral perspective. (ConforMIS 2011)

Two further ligaments critical to the stability of the knee are the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL). The ACL sits on the lateral side and the PCL on the medial. From a sagittal view they are seen to form an X, both originating in the intercondyloid notch and inserting into the head of the tibia. They are both contained in individual synovial sheaths and the stop the tibia displacing anteriorly (ACL) or posteriorly (PCL) relative to the femur.

2.4: Muscles

Many of the muscles, which influence the knee, are bipennate, having influence on more than one articulation.

The following musculature functions as synergists to extend the knee:

- The Quadriceps Femoris is the large bulk muscle on the anterior of the thigh and the main extender of the knee. The quadriceps are believed to aid in the tracking of the patella (Doucette and Goble 1992) and although vital in gait and strong stepping activities (such as stair climbing) shows little action whilst standing still. It is composed of four muscles;
    - Rectus Femoris; originating at the SIAS of the pelvic bone and inserting into the patella tendon.
    - Vastus Lateralis and Vastus Medialis originating from the lateral and medial aspects respectively of linea aspera and inserting into common quadriceps tendon of the patella. The medialis is more obviously active in the final stage of extension.
    - Vastus intermedialis lies deep to the rectus femoralis originating from the anterior, lateral aspect of the femur and inserting into the tendons of the rectus femoris.
- The Tensor fascia lata originates at the iliac crest of the pelvis and inserts into the tibial lateral condyle. This muscles action in normal gait is weak and limited; its function is more as a stabiliser when the joint is weight bearing, although there is some debate about this (Goldfuss, Morehouse and LeVeau 1973).

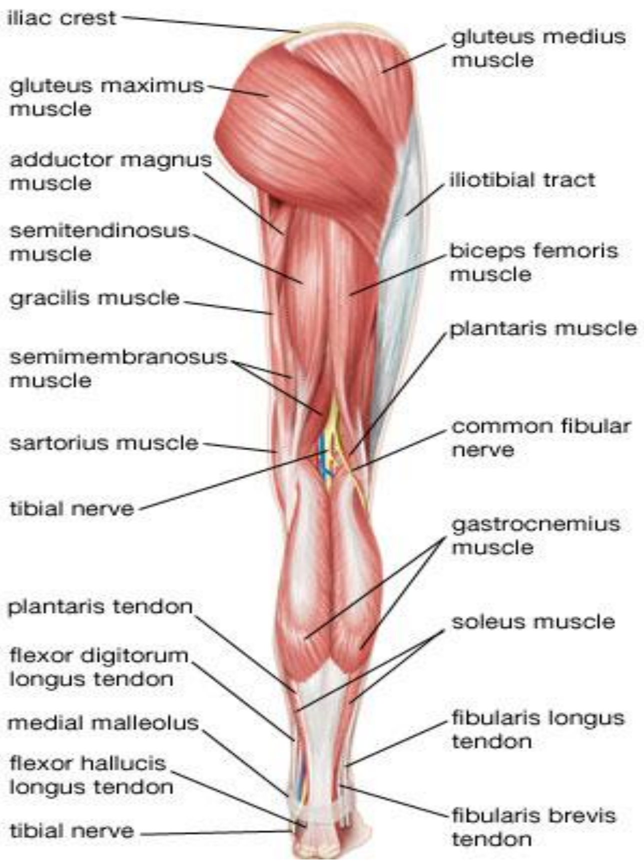


Figure 8: Posterior and anterior muscles of thigh, passing over knee joint. (EncyclopediaBritannica 2011)

The following muscles are antagonists to the knee extensors and function to flex the knee:

- The hamstrings consisting of
    - Semitendinosis
    - Semimembranosis (deeper),
    - Biceps femoris (2 heads; caput longus and breves.)

  The principal distinction between the semitendinosis and semimembranosis is the rounded tendon shape of the former in contrast to the flat membrane of the latter. All three muscles originate from the pelvis (ischial tuberosity) with the first two forming insertion into the medial condyle of the tibia whilst the biceps insert into head of the fibula.
- The Triceps surea, the three muscles of the calf, all inserting into the calcaneus;
- The gastrocnemius constitutes the muscles that form the shape of the calf, with two bellies (see **Figure 8**.) The heads of the muscle originate at the medial and lateral condyles of the femur and insert into the calcaneus bone of the heel of the foot, via the Achilles tendon. The gastrocnemius provides a great deal of the propulsion needed for gait.
- The Soleus is a very powerful muscle, but has little or no influence on the knee.
- The Plantaris is a very weak flexor of the knee from lateral supracondylar ridge to the Achilles tendon.
- The Gracillis, the longest, thinnest adductor muscle originates at the ramus of the pelvis and inserts onto the medial tibia. It is a crucial muscle at the beginning of swing phase of gait.
- The Sartorius has a limited role in flexing the knee when the hip is also flexed. Originating from the superior pelvis and inserting into the medial tibia.
- The Popliteus is a small, triangular muscle that sits in the fossa popliteus. It originates from a long tendon, which attaches to the lateral surface of the lateral condyle of the femur. It is connected to the lateral meniscus and inserts

into the posterior aspect of the tibia. This muscle is speculated to be mainly for proprioception. However, it also functions to laterally rotate the knee when in closed chain (foot on ground) as well as aiding when strong knee flexion is necessary in open chain (foot off floor)(Palastanga, Field and Soames 2002).

2.5: Meniscus

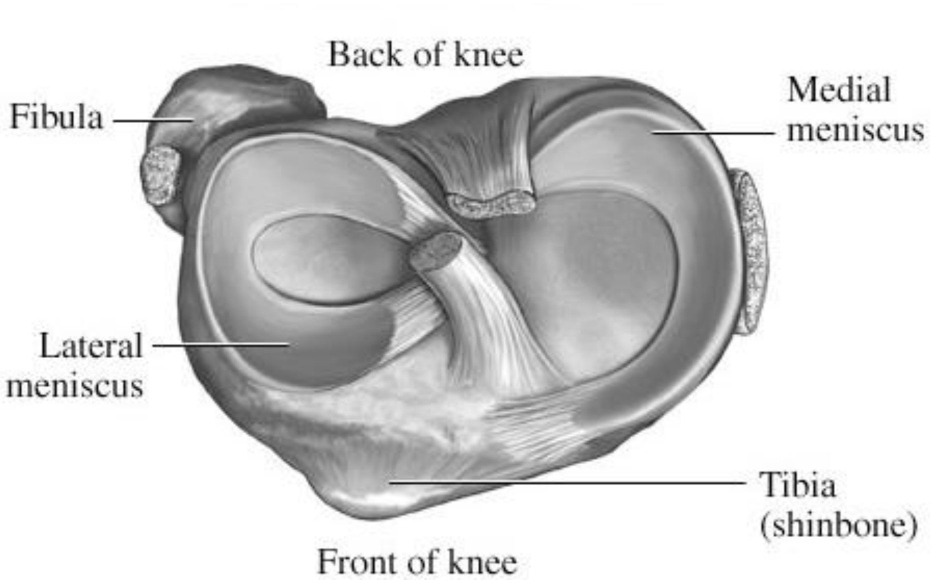


Figure 9: The Meniscus of the human knee, superior aspect of right knee(Blahd and Fu 2011)

A meniscus is a fibro cartilaginous structure; due to its crescent shape it only partially divides the cavity of the joints in which it is found.

In the case of the knee there are two menisci, lateral and medial. Its presence is essential in maintaining the structural integrity of the joint when it undergoes torsion and tension, as well as dispersing the weight and friction caused in the knee. It is attached to the fossae between the condyles and thinning out towards the centre of the crescent. Due to the changing contact surfaces of the knee the weight of the body can be dispersed.

2.6: Bursae

Another point of anatomical interest in the knee is the bursae of the knee, synovial sacs. They provide cushioning for weaker parts of the joint as well as enlarging the joint space. The knee has 13 bursae, 5 of which are found on the anterior of the knee.

- The prepatellar bursa is the most superficial of the anterior bursae and commonly the first to suffer inflammation from trauma. Due to its location, it is a thin layer of synovial fluid.
- Infrapatella bursa, between the patella ligament and the skin.
- Deep patella bursa, between the upper tibia and the patella ligament.
- Suprapatellar bursa between the distal femur and deep surface of the quadriceps femoris, allowing the tendon of the quadriceps to move freely over the tibia.
- The pretibial bursa between the tibial tuberosity and the skin, limiting the friction as the skin moves over the tuberosity.

Generally there are four further bursae found on the lateral and four on the medial of the knee.

- The lateral and medial subtendinous bursea of the gastrocnemius sit between the lateral or medial head of the gastrocnemius and the joint capsule.
- Laterally the fibular bursa and Fibulopopliteal bursa both sit between the LCL and the adjacent tendons. The Subpopliteal bursa separated the popliteus tendon and the lateral condyle of the femur
- Medially the Pes anserine bursa and Bursa semimembranosa sit between the MCL and adjacent tendons.
- There is also a bursa, which separates the head of the tibia and the semimembranosus.

The pes anserine bursa is linked to chronic knee pain and weakness if it becomes inflamed. This can be due to injury or overuse leading to swelling which limits the joint. The pes anserinus itself is the point at which the three tendons of the Sartorius, gracilis and semitendinosus muscles meet.

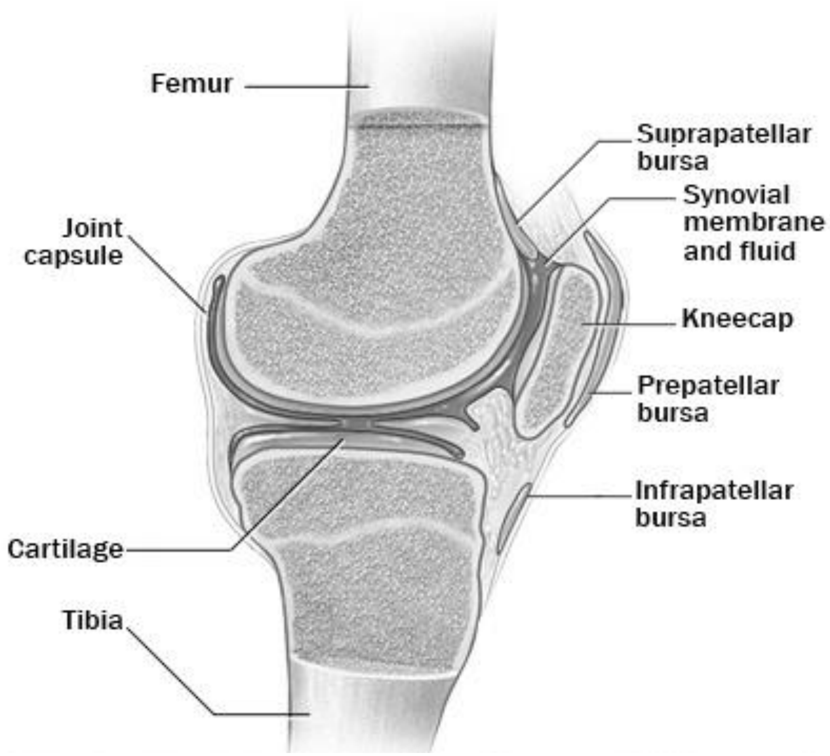


Figure 10 Lateral view of knee showing some key bursae (Mayofoundation 2011)

2.7: Arteries, Veins and Nerves

The main arteries, which supply the knee area, are the femoral, popliteal, anterior tibial and posterior tibial arterties. The popliteal artery can be used to palpate the pulse deep in the fossa popliteal when the knee is in flexion. The deep veins, which accompany these arteries, are referred to by the same names. There are two superficial veins of note, the greater and lesser saphenous veins. The greater has a thick wall and is often harvested for use in coronary bypass surgeries, due to the large number of deeper veins, its removal does not limit Venus return.

One of the most important nerves around the knee is the popliteal nerve (or common fibular nerve), which is located at the back of the knee. Deriving from the dorsal branches of level L4-S2 of the spine. It extends along the lateral side of the popliteal fossa, close to the medial margin of the biceps femoris and wraps around the neck of the fibula. It then divides into the superficial fibular nerve and deep fibular nerve. This nerve serves to innovate the Peroneus longus and brevis. Myotome distribution means that the spinal nerve L3 straightens the knee whilst L5 causes extension. The dermatomes are distributed such that L4 and L5 supply the skin on the front of the knee and S1 and S2 the knee pit area.

Figure 11: Dermatome distribution legs. (Norman 1999)

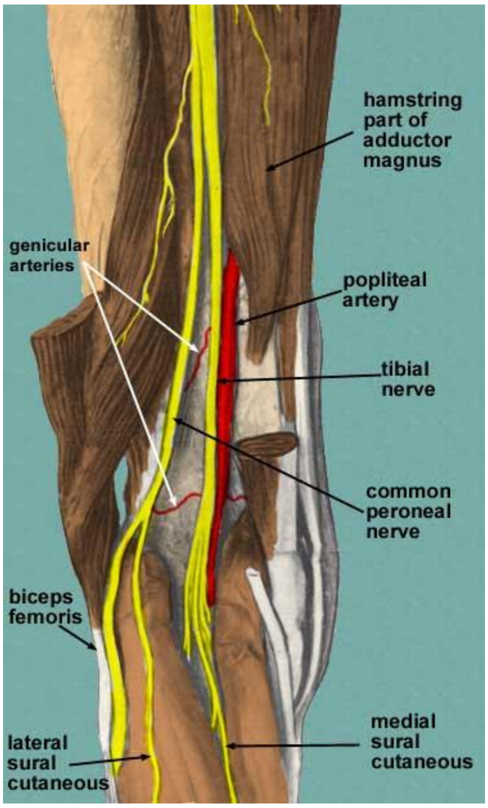


Figure 12: The major artery & nerves of knee (Netter 2011)

Chapter 3: Biomechanics of knee

3.1: Quadriceps angle

The Quadriceps angle is formed when a straight line is drawn from the ASIS to the centre of the patella and a second line from the centre of the patella to the tibial tubercle. In adults this is reported by Horton and Hall (1987) to be 15.8 ± 4.5 degrees for women and 11.2 ± 3 degrees for men. It is seen as an important predictor of biomechanical abnormality in the lower limb due to the correlation with the angle between the rectus femoris and patella tendon. Women have larger Q angles than men and this is, believed to be, linked to a higher rate of knee pathologies. However, there is some debate as to the cause of this difference and the true influence of the Q angle on wear on the knee (Livingston L 1998).

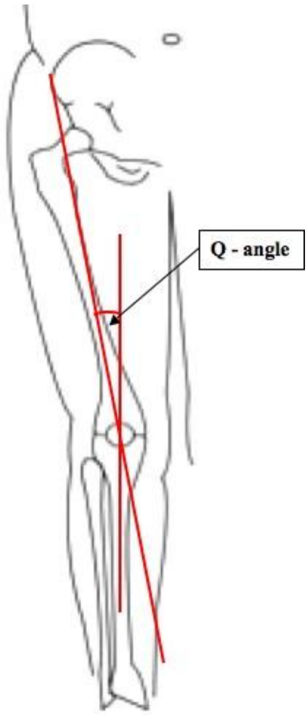


Figure 13: The Q angle of the leg (coreconcepts 2011)

3.2: ROM of the knee,

The knee is designed to have only 2 active degrees of freedom (DOF), that is to say it should only move in the sagittal plane. It is functionally a hinge joint with a complex roll and glide motion allowing the recognised extension from neutral (antiflexion) of up to 10°, and maximal flexion of between 135 and 150°.

Due to the three joint construction of the articulation however, the passive knee has 6 DOF. Normal active ROM is given to include 20-30° of medial rotation (tibia on femur) and 30-40° of lateral rotation(Magee 2002). This is necessary to avoid locking of the knee in stance phase of gait.

Deviation of the knee from neutral in the coronal plane is known as varus (medial deviation of the knee joint from midline) and valgus (lateral deviation of the knee joint towards the midline.) The knee is designed to have some 'give' provided by the ligaments to help avoid injury. However, excessive rotation or deviation is considered pathological.

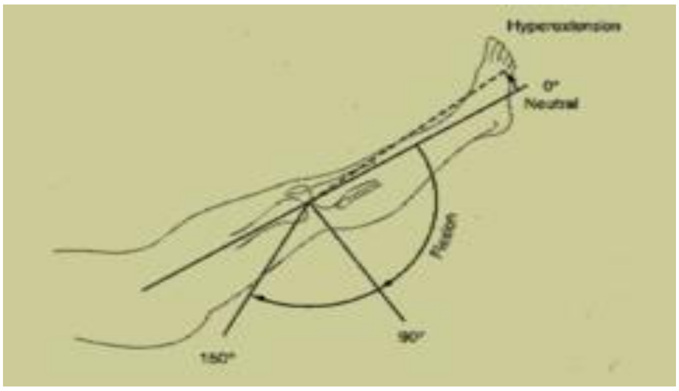


Figure 14, ROM of a healthy knee.(Quiznet 2005)

A study by Rowe et al (2000) discusses necessary ROMs for daily activities include >90° for gait and slopes, 90-120° for stair climbing and rising from a seat. This is totalled to equal approximately 135° full ROM for daily activities. The same paper is recommended that functional rehabilitation should aim at a ROM of 110°

3.3: Gait analysis.

Many articles (Ganeddula 2009), (Messier 1992), (Mündermann, Dyrby and Andriacchi 2005) have shown that osteoarthritis has a significant impact on the gait pattern, decreasing cadence and stride length, therefore reducing speed of gait.

During closed chain flexion of the knee the tibia rolls posteriorly on the femur, elongating the ACL, which pulls on the tibia and causes posterior glide of tibia. In an open chain motion the femur rolls posteriorly on tibia.

By 25° of flexion in the lateral compartment, roll is accompanied by anterior glide of femur (again due to ACL pull) which encompasses both compartments in late to maximum. Posterior roll of femur is eventually limited by the tension of the PCL (Palastanga, Field and Soames 2002).

The movement from extension to flexion causes both menisci to move posteriorly, both undergo great deformity and the lateral menisci receding twice as far as the medial.

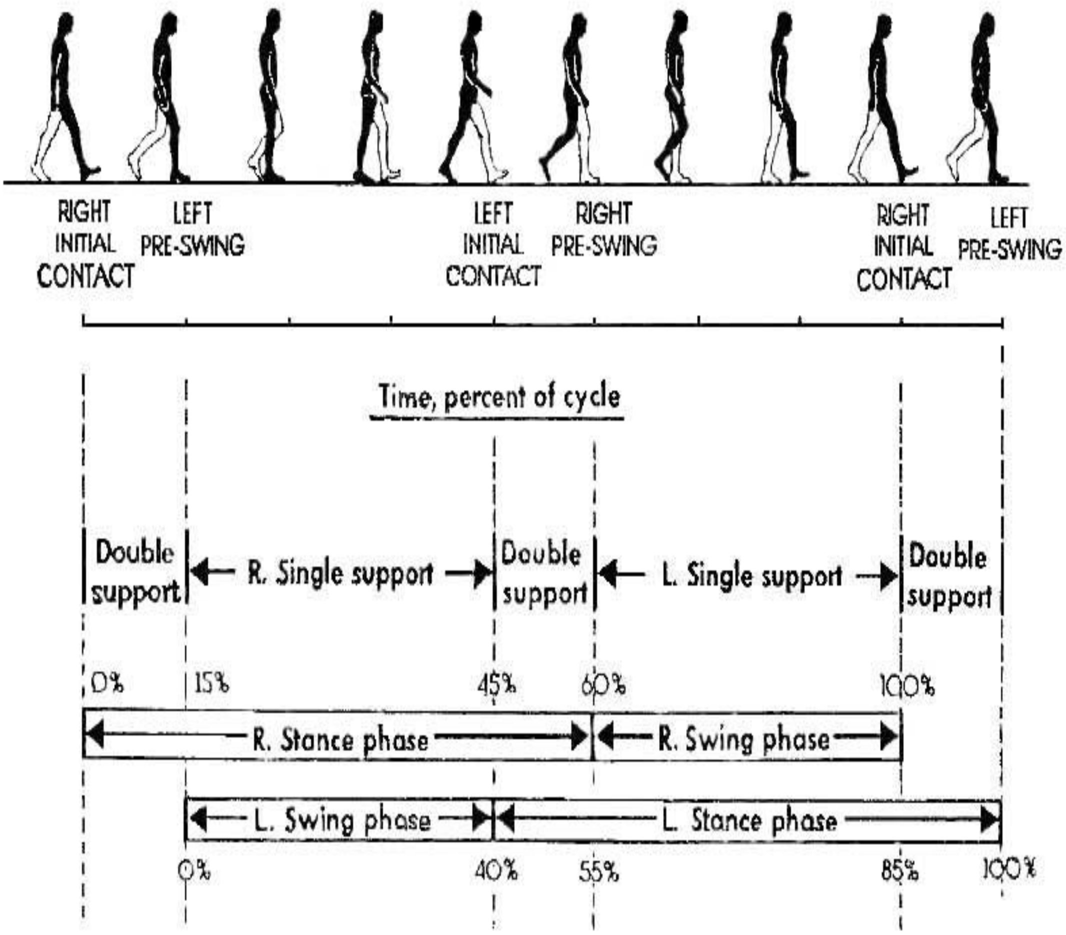


Figure 15 Gait cycle and support phases (Todd)

In gait the forces on the knee increase rapidly from heel strike, reaching a peak when the foot has made full ground contact (**Figure 15**). The exact force is dictated by the body weight and the muscle activity across the knee to prevent knee collapse. The second peak vertical force is at the point of propulsion in stance phase. These vertical forces are three to six times greater in stair climbing when compared to walking on an even surface (Costigan, Deluzio and Wyss 2002). Conversely, the mediolateral forces are only about a quarter of the body weight if the tibio-femoral alignment is neutral (0±3°). Any varus or valgus deviation is considered to have a profound effect on the loading pattern and therefore the pattern of wear in the knee joint.

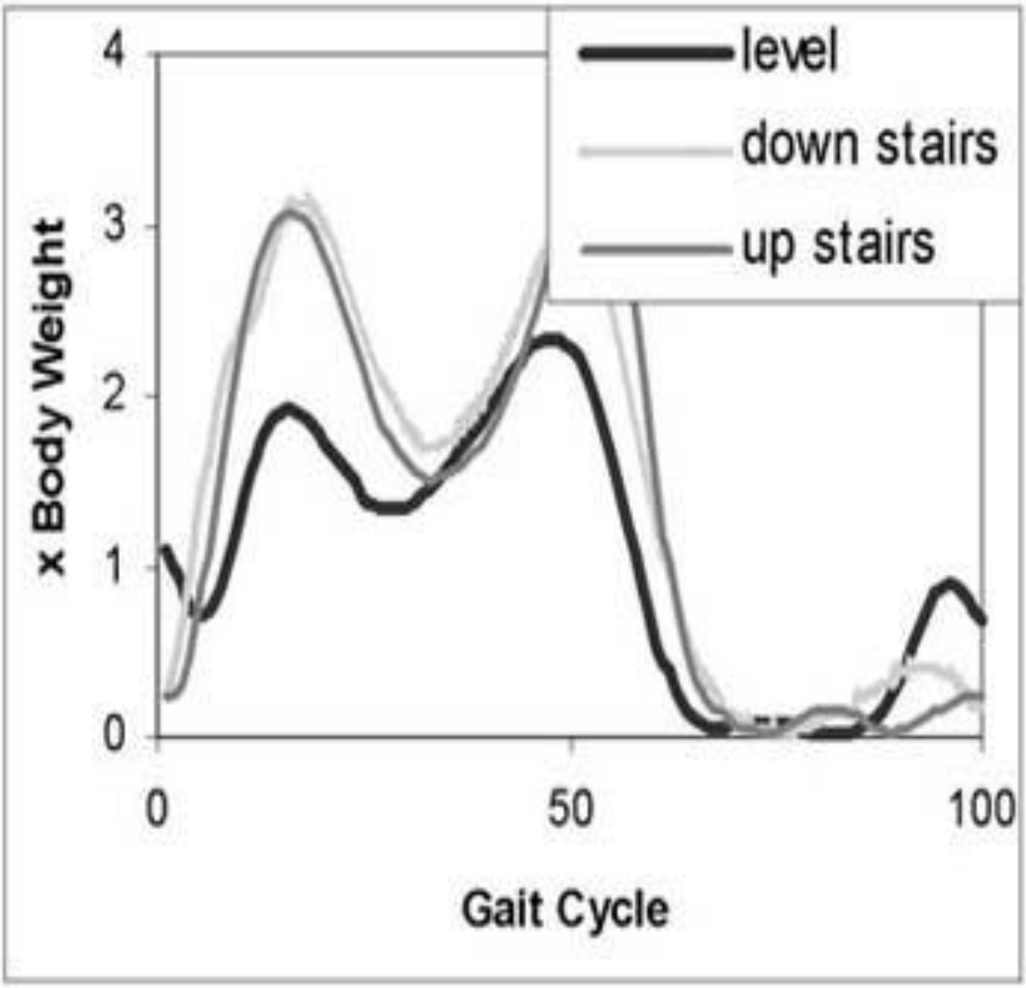


Figure 16 multiple of body weight felt as force through knee joint at different stages of gait cycle, comparing level walking to descending and ascending stairs.(Kaufman 2011)

Chapter 4: Arthritis
4.1: Definition of disorder

Arthritis is defined as acute or chronic joint inflammation; this can cause the onset of pain and structural changes. There are 3 mains types of arthritis which effect the knee joint (American Academy of Orthopedic 2007); Osteoarthritis, rheumatoid arthritis and posttraumatic. For the purpose of this paper we will focus on Osteoarthritis, the most common form of arthritis in the western world.(Lawerence, et al. 2008)

Osteoarthritis effects synovial joints and is caused by the breakdown and eventual loss of the cartilage of the joint. The aging process is strongly linked to the disease progression(Felson, et al. 1988), as the water content of the cartilage increases and the protein content decreases. Healthy cartilage absorbs the mechanical shock of movement and allows joints to glide over one another. As the cartilage degenerates and flakes the cushioning effect decreases and years of wear cause inflammation and swelling of the joint. Bone spurs can start to grow at the edge of the joint space (United states department of health 2011). These can also break off and float into the joint space, causing further pain. Eventually joint movement is impeded.

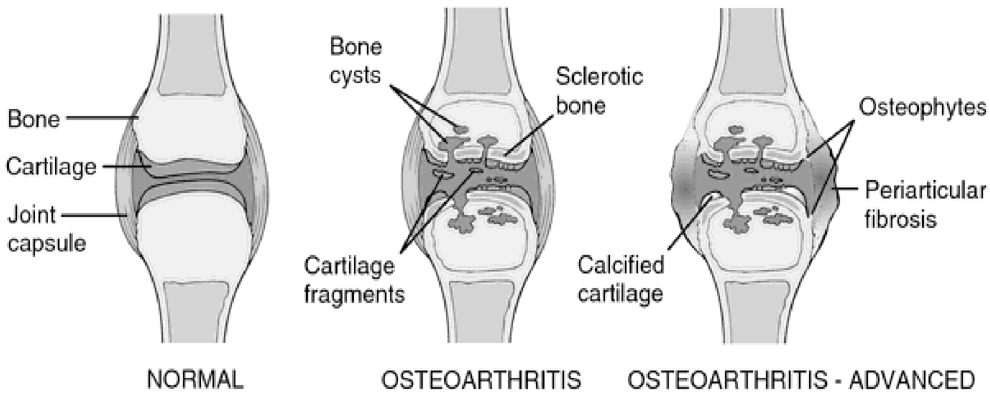


Figure 17 progression of osteoarthritis in the knee joint.(O'Toole 2003)

Although particular cartilage has poor innervations defect in cartilage themselves are not, in themselves, symptomatic. They may however, evolve into further symptoms and later, into arthritis.

4.2: Risk factors

Some of the causes of osteoarthritis include factors such as excessive body weight, leading to damage due to the increased forces on the knee. Overuse and injury can also stimulate osteoarthritis. Further factors include possible hereditary links.

Prevalence is higher in Native Americans than in the general American population and generally OA is more common in Caucasians than other ethnicities. Conversely it has been seen that knee osteoarthritis is more common in African American women (Hoaglund, Yau and Wong 1973)

The disorder is so prevalent in the elderly that it is believed to be evident in 80-90% of persons over 65 years in the United States. However, due to its often-asymptomatic nature patients will not notice symptoms until after age 50, therefore implying there is a high prevalence in younger persons (Burch 1966)

Women are also more susceptible to osteoarthritis of the knee joint, one possible theory is that due to the hormones produced by the female body to allow the pelvis to widen for birth, the laxity of the female tendons is higher. This causes the joints to move more and creates more wear. After menopause the levels of the hormone estrogen drop, this hormone has been shown to protect cartilage from inflammation and as levels reduce this protection is lost.

There are two common lifestyle factors, which attribute to the prevalence of osteoarthritis, the first factor being smoking. Smoking has been shown to have a significant effect on the cartilage loss and therefore increases the risk of OA. In fact, studies show that smokers are more than twice as likely to develop OA as non-smokers (Eustice 2011). The reasons behind this link include; the increase carbon monoxide levels in the blood which impedes cartilage repair by impeding blood oxygenation, possible disordering of the deter cell production in cartilage and increased blood toxicity, therefore increasing cartilage loss.

Also, on the rise in modern society is obesity. The more weight a person carries the more pressure on the joints. If it is consider that the knee can be subject to 3 times the body weight in certain activities, the effect of obesity on the knee joint is magnified (Felson, et al. 1988). As the number of people suffering from obesity is increasing, so therefore is the link to OA becomes more apparent.

Researchers interviewed by B. Hendrick for WebMD Health News (2010) expect the number of adults with arthritis will hit 67 million world wide by 2030.

4.3 Biomechanical impact of arthritis

As seen in the anatomy section, the knee has three compartments. This paper focuses on the most common compartmental osteoarthritis, the medial tibiafemoral joint. The centre of mass of the body falls between the legs; this creates a greater force on the medial side or compartment of the knee. During normal gait, a load of approximately 2-4 times the body weight crosses the knee and 2/3 (Palastanga, Field and Soames 2002) of this is transmitted on the medial side (**Figure 18**). It can therefore be conceived that the wear of cartilage is more prevalent on the medial compartment of the knee

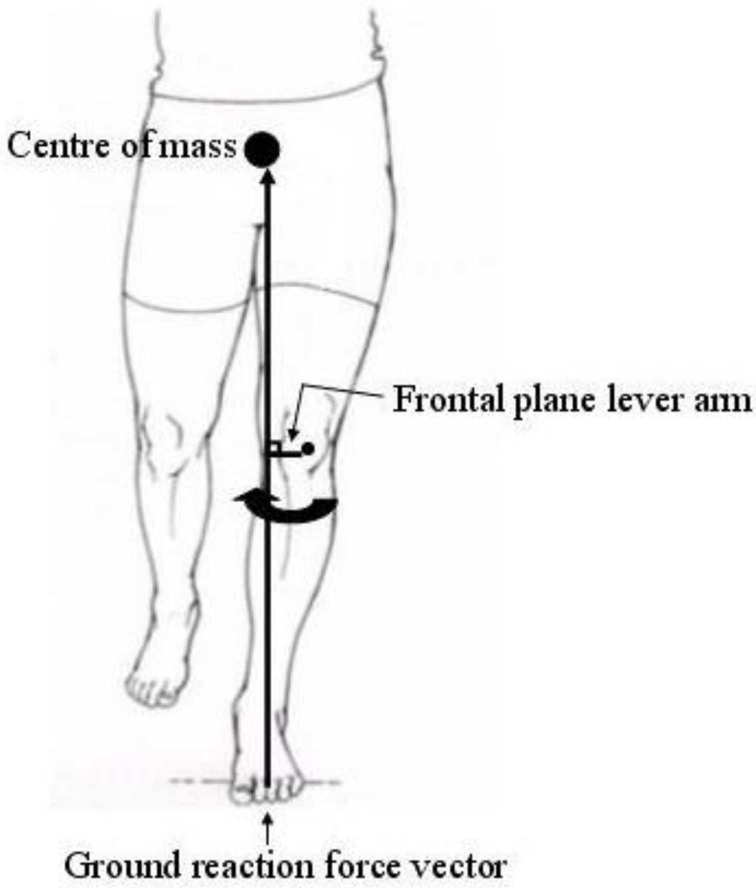


Figure 18: Line of force through knee midstance (Ganeddula 2009)

As a result of these changes the gait pattern of individuals is significantly altered (Bejek, et al. 2006). Knee extension and flexion is significantly reduced. This, in turn caused changes in the overall gait pattern, cadence increases to compensate for a decrease in step length. This results in a longer double support phase and a reduced swing phase. The base of support is also widened as stability is reduced. The difference in ROM and moments in gait is also affected by the severity of disorder. The graphs from **Figure 19** show the important difference between asymptomatic and symptomatic OA in regards to gait.

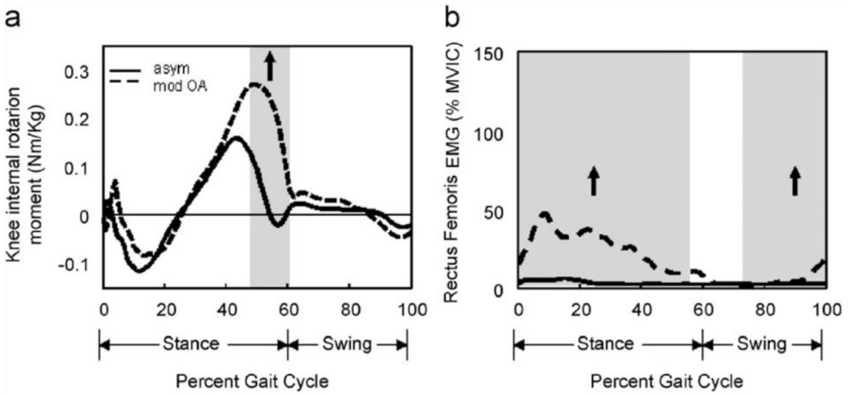


Figure 19 Dotted line representing moderate OA and full line representing asymptomatic OA. (Astephen, et al. 2008).

A: Internal knee rotation moment (moment y), B: Rectus femoris activation pattern,

These graphs show that the forces and moments experienced by the knee and surrounding musculature are severely altered by osteoarthritis. In early swing sufferers of sever arthritis produce a small hip extension while moderate sufferers produce a hip flexion moment.

Chapter 5:Surgery

5.1: Oxford UKA

Much of the information about the oxford procedure and pictures in this section are sourced from the Manual of Surgical Technique (BIOMET 2007)

The oxford partial knee arthroplasty was first conceived in 1974 and first implanted in 1976. According to Biomet ™, who own the design patent, over those 30 years the 20 year survival rate of the prosthesis has been 98%.(BIOMET, Oxford® Partial Knee 2011). However, some early studies showed that the components used were prone to early failure (Kort, Romanowski and van Raay 2011), so by late 1980's interest and therefore use of the oxford partial knee had reduced.

For a partial knee replacement, 75% less bone and cartilage is removed than in a total knee arthroplasty, this means the operation is less painful and recovery is generally more rapid than with a TKA and patients can be released from hospital within 48 hours.

The planning stage involves the selection of the correct component to implant; there are currently 5 different sizes of each of the 3 components to fit the patients' anatomy and all femoral and tibial bearings are interchangeable

Figure 20: Implant conventional UKA (BIOMET 2011)

Three components make up the oxford prosthetic; femoral, tibial and polyethylene tray (meniscal bearing.) These consist of (BIOMET, Oxford® Partial Knee 2011);

Twin peg femoral component, two pegs for additional rotational stability. Spherical design minimizes the contact stress through the entire ROM, with curved inners to minimise bone removal.

Anatomically shaped tibial component, for excellent bone coverage. Made of cast colbalt chromium molybdenum alloy.

Mobile meniscal bearing, free floating to remain fully congruent with femoral component thought ROM

ArCom® Direct Compression Molded polyethylene is the material used to reduce the effects of wear.

The surgery is performed through a minimally invasive incision, across the middle of the patella, of approximately 3-4 inches (Figure 21). A surgical saw is then used to remove the affected part of the tibia and femur. A reamer forms a hole through the femur for attachment of the prosthesis. The components can then be cemented into location.

A thigh tourniquet is applied and the thigh supported at 30° flexion and slight abduction but with full ROM up to 120°. At a flexion of 90° an incision is created across the patella and some of the retro patellar fat pad is exci**se**d.

Figure 21: Skin incision made (BIOMET 2007)

The shaft of the saw guide for the tibia is placed parallel to the long axis of the bone itself. It is designed such that the horizontal saw cut will slop back wards and downwards. The upper end should lies against the exposed bone, then pushed laterally to accomidate the patellar tendon.

Figure 22: Tibial saw guide. (BIOMET 2007)

Large osteophytes must first be excised to improve access around the joint.

Figure 23: Oseophytes removed. (BIOMET 2007)

Figure 24: Saw guide (BIOMET 2007) blade points towards head of femur.

The saw guide **Figure** is applied to the exposed tibial area from the tibial tubercle to plateau rim. The level at which the tibia must be sawn is dictated by the extent of erosion. A reciprocating saw is used to make the cut. The blade must reach to the back of the tibial plateau, and a retractor is placed to separate the collateral ligament from the tibia. The vertical cut is made down to the guide and then horizontally along the guide.

Figure 25: Retractor used while vertical cut made. (BIOMET 2007)

The vibrations of the saw allow the plateau to be easily excised. A as the feeler gauge (used to measure the gap width is sufficient, i.e. enough bone has been removed)

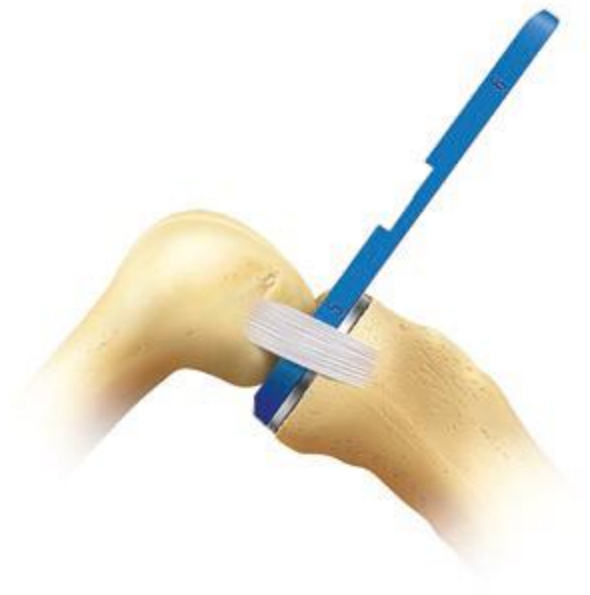


Figure 26: Feeler gauge used to asses if enough bone has been removed. (BIOMET 2007)

The femoral hole of 5mm is drilled with the knee at 45°. The exact location of the hole is 1cm anterior to the anteromedial corner of intercondylar crotch, directed towards the ASIS of the pelvis.

The femoral drill guide is aligned by resting on the tibial template. This is stated as a common point of error. If this is not touching the vertical wall (which may be obstructed by cartilage or osteophytes) then the alignment will be affected.

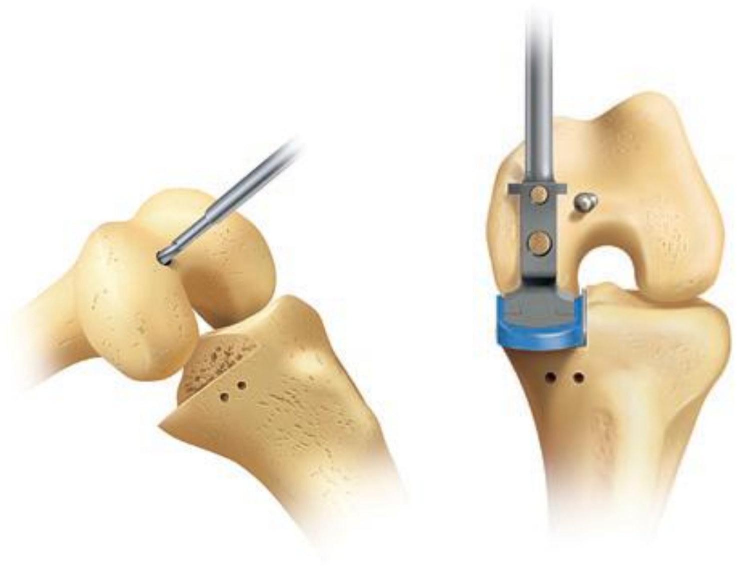


Figure 27: Femoral drill guide aligned (BIOMET 2007)

By changing the degree of flexion and internal/ external rotation the drill guide is made to lie parallel with the IM rod before a rod is drilled in to hold the guide in place. All instruments are removed and the femoral saw block is inserted into the drilled holes and tapped in. The posterior femoral condyle is excised along the block base (slotted or unslotted guide)

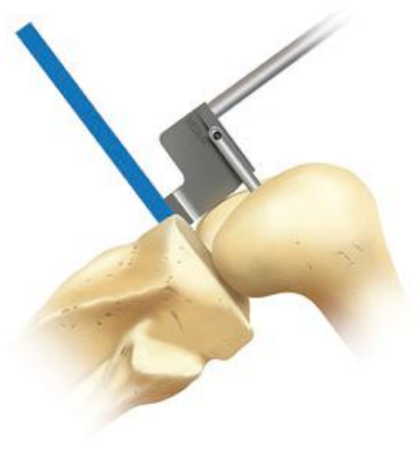


Figure 28: drill guide lies parallel with IM rod (BIOMET 2007)

Internal and external rotations of the tibia is used to align the drill guide parallerl with the intramedullary rod. (viewed in the transverse plane.)

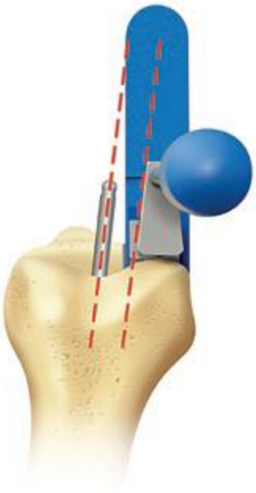


Figure 29: Alignment in transverse plane (BIOMET 2007)

All alignments are confirmed and the 4mm drill is passed through the upper hole and the the 6mm drill through the lower. All instruments are removed, the rods are removed with hooks. The femoral saw guide can then be inserted into these holes.

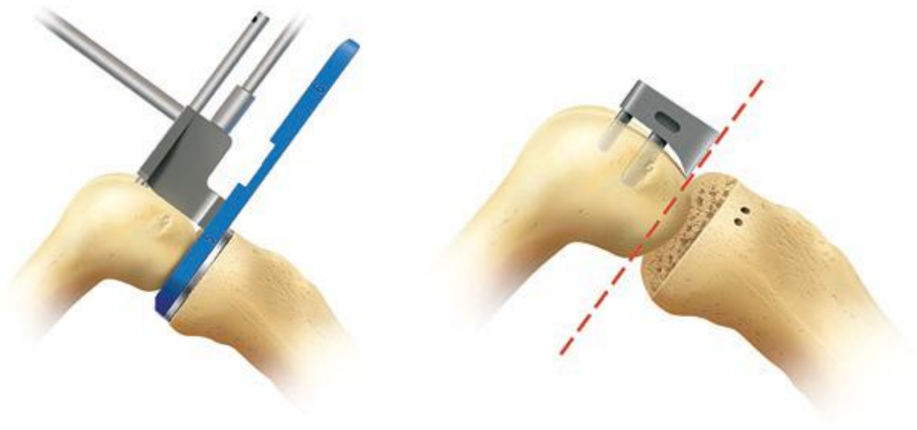


Figure 30: Final alignment and drilling and insertion of femoral saw guide. (BIOMET 2007)

The posterior facet of femoral condyle is removed, attention is drawn to avoiding the collateral ligament and ACL. It is now possible to remove any remnants of the medial meniscus.

A spigot can be inserted into the large drill hole and tapped into place.

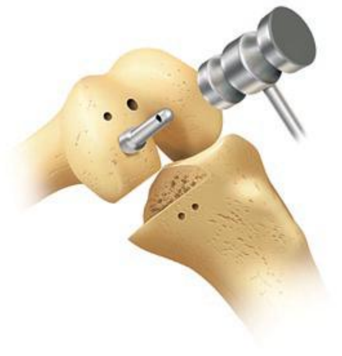


Figure 31: Spigot tapped into largest drill hole (BIOMET 2007)

The knee is flexed to 60°, a spherical mill can be guided onto the bone. The spigot limits the depth of drilling.

Figure 21: Drill and spigot (BIOMET 2007)

All instruments are removed and the protruding bony corners produced at the periphery of the cutting edge and the area that was under the flagor are trimmed off.

Figure 33: Bony corners trimmed. (BIOMET 2007)

Templates are inserted and the gap present at 90° and 20° of flexion is used to calculate further milling needed. The femoral condyles must be trimmed (both posteriorly and anteriorly) with the implementation of another guide, to limit possibility of impingement.

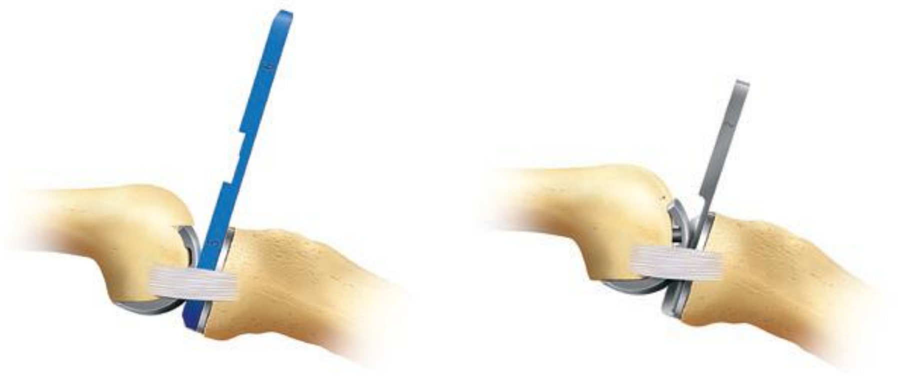


Figure 34: Equalizing the 20° and 90° flexion gaps. (BIOMET 2007)

The tiibial condyles are trimmed anteriorly and posteriorly. Anteriorly using a chisel

Figure 35: Anterior tibial condyles removed(BIOMET 2007)

And posteriorly the guide is attached directly to the chisel to detach all the oseophytes. Before a finger is inserted to check complete clearance.

Figure 36: Posterior tibial guide and chisel. (BIOMET 2007)

The final preparation of the tibia plateau, involves the use of a template to make out the area in which the grove should be excavated. The full excavation is done with a groove gouge to allow the tibia component a good attachment.

Figure 37: Saw template for groove gouge and gouge. (BIOMET 2007)

Trial components are inserted and the ROM of the knee is tested.

Figure 38: Trial Tibial component inserted and tapped into place. (BIOMET 2007)

Once the correct alignment is confirmed the cement key drill is used to make small drill holes and the surfaces cleaned with pulse lavage. Two separate cements are used to fix the components in place. Once it is set the feeler gauge is removed, as is excess cement. The chosen bearing are snapped into place to complete the placement and then the wound is sealed.

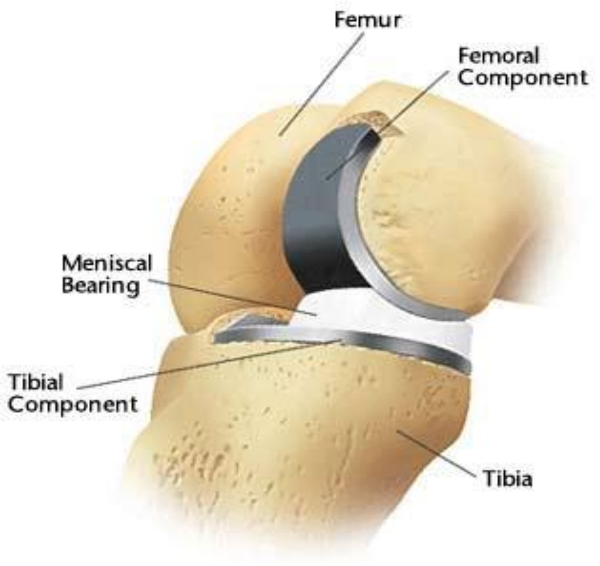


Figure 39: Final placement of implants (BIOMET 2007)

This method of alignment involves burrowing holes into the bones, which will affect the healing process. For a patient to be suitable for oxford partial knee arthroplasty, they must meet certain criteria. This criteria will be discussed in the methods section.

5.2: MAKO UKA

The basic principels of the resurfacing remain the same, in the MAKO procedure, as for the oxford method. Including inclusion and exclusion criteria. The difference between the two methods is mainly in the surgical procedure. The MAKO RIO™ is described as a robotic arm interactive orthopaedic surgery. It is the first FDA approved apparatus of this kind.

Figure 40 The MAKO RIO™'s robotic arm (Ferré 2010)

The suggested advantage of this method of surgery is the accuracy in cutting, implant and post operative alignment of the bones. A vital part of this accuracy is the planning process.

Firstly a CT scan is taken of the affected knee; this is then digitized and aligned with 3d renderings of the implant components.

Figure 41 The MAKO RIO™ machine(Ferré 2010)

The machine itself is the MAKO RIO™ , (robotic arm interactive orthopaedic system, 41.)

The robot consists of;

1. Tactile robotic arm with substantial dexterity as well as ROM, the arm helps provide a tactile resistance to maintain the safety zone of the cutting area.

2. The controller is the hardware of the system and interacts with the other systems. It controls the low level functions of the operation, including the tactile markers and the tactile constrains and safety circuit. They follow an array of marker attached with bone pins to the bones of the limb.

3. Stereo tracking system camera an instruments- an infrared tracking system relays constantly during the operation to convey the relative position of the limb to that of the machine. The refresh rate is so great that the feedback can be taken as live.

4. End effector- This is the mechanical component connecting the drill burr or bone cutting instrument, to the arm itself.

5. Bone cutting instrument- This composes of a disposable cutting time and a high speed motor. It is shaped like a standard pen, allowing the surgeon to grasp it in and manoeuvre easily.

6. Portable Base Console- Housing the controller and base components which power the arm, the base allows the whole console to be placed next to the patients in the most convenient position.

The second component of this system consists of the screen, **Figure 26,** which the surgeon focuses his attention onto.

An integral benefit of this system is the software used to navigate and map the progress of the operation.

This complex system has many components (Figure 42);

1. Surgical Planning Software – Used both pre operatively and inter-operatively. The alignment is pre planned using 3d renderings of the implants and the joint. The image is then used as guidance for the surgeons.

2. Tactile Safety Zone- the image gives a visual representation of the area to be drilled, beginning with a green overlay of the bone to be drilled; once the required amount is removed the image will show the area as white. This increases accuracy and allows surgeons to stop before feeling the physical barrier. The image will turn red if the physical barrier is reached, this is such a small deviation beyond the barrier that it is insignificant, but will be discussed later.

3. Instrumental Locator- shows the position of the bone-cutting instrument relative to the anatomy.

4. Monitor- Pre-surgery CT scans are taken of the knee joint. This image is used as a 3d rendering for the surgery. The viewpoint and level of zoom can be altered by the user throughout surgery.

5. Mobile Base- The screen system is also attached to a base, which allows it to be moved and positioned in whichever location is most appropriate.

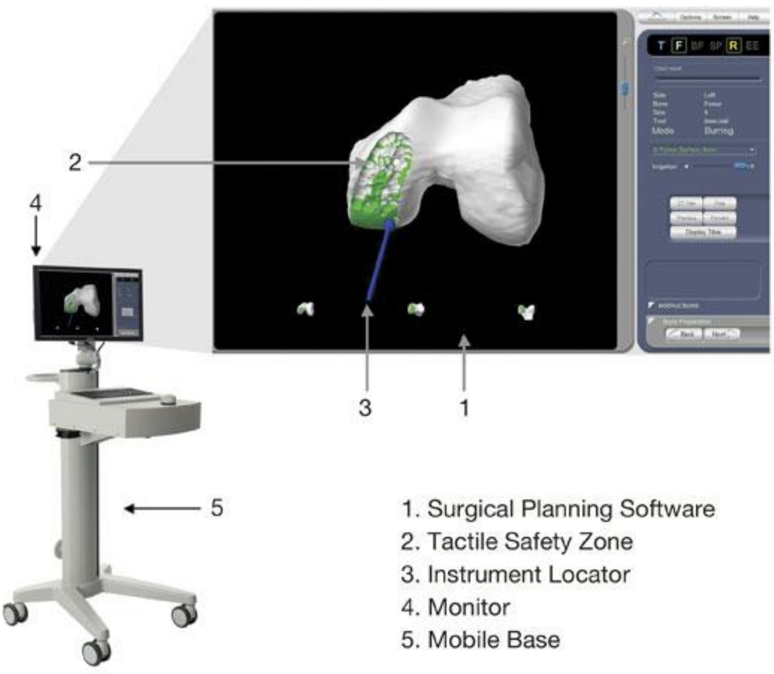


Figure 42, The Operation display (Ferré 2010)

Figure 43 The Restoris MCK (Chow 2011)

MAKO, on their website (MAKOplasty® 2011), claims that the design of the implant allows the resulting knee to be more natural feeling, with a quicker recovery due to the less invasive and tissue sparing surgical (MAKOplasty® 2011). The implant used is a Restoris MCK (multi compartmental knee system) specifically designed for the RIO. There are 2 components, available in variable sizes:

The femoral component has

1. A high flex design, allowing up to 155° of flexion.
2. Dual pegs to optimise the alignment and fixation
3. Anterior region, which is curved to allow for a more natural fit, which avoids patella impingement.
4. The patello femoral component is design for optimal smooth tracking,
5. The overall shape is designed to secure fluid movement of the patella from the trochial groove to femoral condyles.

6. The proximal flange is designed to capture the patella when at full extension and allows it to track smoothly.

7. Trochlear notch was designed to curl into the femur, therefore avoiding ACL impingement.

The Tibial components is available is two designs, either may be used:

1. Onlay: This consists of two separate parts with a base plate approximately 2mm thin, allowing a periosteum-friendlier resection and reduce post-operative pain. The base plate is also designed for ease of insertion to self-align polyethylene.

Figure 44, The Tibial component Onlay design (Ferré 2010)

2. Inlay-, which requires less bone removal than onlay design.

Figure 45, The Tibial component Inlay design (Ferré 2010)

The process undertaken for MAKOplasty® has one additional factor. Prior to the surgery a full leg CT scan must be taken for the planning process. This image is then converted by a MAKO specialist into a 3D rendering, which can be aligned with pre programming. During the procedure, standard navigation markers are placed in both the femur and tibia, as well as mounting on a robotic arm. The centre of rotation of the hip and various bony landmarks are determined in the registration process. These are correlated with the previously reconstructed model, allowing for real time monitoring of relative position of bones, joint and robot through out the process.

Impeding osteophytes are removed and any capsular adhesions are relieved. The system maps the position of the femur and tibia as they are manipulated through the full ROM of extension/ flexion with an induced varus deviation. This ensures mapping of the 3D positioning, representing appropriate spacing within the joint. The mapping is fine tuned to fill the gap left by the disease with the appropriate implant, to ensure good articulation through the full ROM. Finally the volume of bone to resects is defined by the final planned position(Conditt and Van Vorhis 2009).

It is proposed that the surgeon's accuracy will be improved by the use of the machine. The area to be altered is pictured on the screen in green, and once the required amount of bone has been removed the images on the screen converts to a white colour. Whilst inside the defined area for resection, the burr offers no resistance. As it approaches the boundaries the robotic arm resists movement outside of these boundaries.

It would be detrimental to the procedure to have a hard end resistance of the arm, thus there is soft end resistance which means the arm can not be pushed further and thereby drill further than an 'over drilling' of an insignificant amount (1mm). If this happens the area on screen will turn red, to indicate to the surgeon but the robot will resist any deeper drilling.

Chapter 6: Literature review

For the study to be relevant and progressive it is important to look at what data is already available in the area of arthroplasty and particularly the criteria that defines a successful operation and recovery. Five areas of interest were identified and investigated.

6.1: Previous information on the MAKO

J.H. Lonner (2009) Robotic Arm-Assisted Unicompartmental Arthroplasty, Seminars in Arthroplasty, doi:10.1053.

The MAKO RIO™ has been developed as a progression from early models of the MAKO robotic arm, in 2009 it became the first FDA-cleared robotic arm system for orthopaedic surgery (MedGadget 2009). Since its conception there have only been a limited number of studies conducted looking at the influence the MAKOplasty® may have on clinical outcomes.

One such paper, published in 2009 by J.H. Lonner looked at the first 400 UKA MAKOplasty®s, which had been performed in the United States. A matched group of conventionally implanted UKA's was compared at 3, 6, and 12 weeks.

All patients were requested to start physical therapy on the same day as surgery and to start immediate ambulation with a cane and to perform ROM exercises.

The patients were generally discharged within 24 hours and most were able to ambulate without a cane within 1-2 weeks.

The general procedure is outlined in the article and is the same as described in section 5.2 MAKO UKA.

Although the results recorded using the AKSS questionnaire where not significantly different between the two groups, the post-operative limb alignment was significantly improved by the use of the tactile guidance system. Lonner also observes that these results come as part of the early learning curve period of both use and development of the MAKO system. The surgeons have more experience using the conventional method.

This is the most important factor to take into account in this study, as these are the first surgeons to use the new device and although they have several years of experience performing conventional UKAs, they are newly acquainted with the MAKOplasty® system. This study does show the MAKOplasty® to be equally as effective as the conventional method yet does not review the possible extra surgery time needed for the MAKOplasty®s.

6.2: Oxford unicompartmental knee arthroplasty:

The J.W. Goodfellow, C.J. Kershaw. M.K.D'A. Benson, and J.J.O'Conner (1988) The Oxford Knee for Unicompartmental Osteoarthritis (The First 103 Cases), The Journal of Bone & Joint Surgery: 70-B:692-701.

As previously discussed, the conventional method for unicompartmental knee arthroplasty was developed more than 30 years ago, as such there are many studies exploring the effectiveness and efficiency of the method. The study by Goodfellow et al(1988) looks at the suitability of UKAs for osteoarthritis sufferers. The results collected look at the effects on different areas of recovery including pain, stability, ROM and functional improvement.

As part of the inclusion criteria, all participants were sufferers of osteoarthritis with complete loss of cartilage in the affected compartment and 'full thickness' (no cartilage damage) in the unaffected compartment.

103 UKAs of 85 consecutive patients (some having bilateral operations) were included in the study. This included both lateral and medial compartments, 77 in women and 26 in men, with a mean age of participant of 70 years.

Postoperatively the patients were asked to keep the leg immobilised for 6 days before flexion is started and then crutches used to assist gait for the following 6 weeks.

A histographic representation was given of the pain experienced by the patients on a four-point scale (none, mild, moderate or severe). The majority of patients reported their pain on activity to be intense before the operation, with a majority reporting no pain postoperatively. This improvement was shown to be significant ($p<0.001$), as was the same rating taken at rest both pre and post operatively ($p<0.001$).

Due to the fact that not all patients pain was reduced, the hypothesis was addressed that residual pain may be a product of patellofemoral arthritis. However, a square table comparing level of pain on activity to the state of the patellofemoral joint at operation found no correlation.

The ROM improvement was also addressed by method of a histogram plotting maximum flexion in degrees pre and post operatively. In this case there was no significant difference as the mean result of 104° preoperatively only increased to a mean of 105° after surgery. Other planes of motion were improved, the axial rotation was seen to improve significantly from a mean of 14° to 20°, as the flexion deformity decreased from a mean of 6.5° to 5.4°, ($p<0.03$).

Preoperatively a majority of 62% of knees were in varus (deformity) with only 32% within 5° of the coronal plane normal. The operation brought 85% of the knees back into the correct alignment. Stability in the sagittal plane was not improved; in the coronal plane there is significant improvement when tested with the knee in slight flexion.

Finally specific activities were addressed. Highly significant improvement was seen in walking distance. 85% of the knees showed walking distance improvement. The number of patients requiring a walking aid was also reduced to only 8% from a prior percentage of 46%. Stair climbing was assessed using a set of stairs, with no handrail, with 1.5cm risers; prior to the operation only 2 patients were able to perform the task, compared to 60% post operatively. However, it is not clearly defined as to what percentage are walking one step at a time.

Goodfellow et al addressed complications and failures post operatively; as 9 revisions (7 for medial components) were performed in the time between operations and publication, although there have been no failures of the components due to creep, wear or fracture. The failures occurred due to 1 knee showing degeneration in the lateral tibiofemoral compartment, 3 knees suffering aseptic loosening, 1 case bearing dislocation and 2 knees showing rapid loosening on one side which later lead to collapse of the lateral femoral condyle.

Of note in the outcomes a significant link was found between the failure of the arthroplasty and the state of health of the anterior cruciate ligament ($p<0.019$) showing the importance of the health of this ligament prior to operation. This correlates with an earlier paper published by the same authors (O'Connor, Shercliff and Goodellow 1988).

The paper goes on to state that the question arises as to whether the intake criteria for the patient was stringent enough, as perhaps some of the failures were predictable. They also state that this has lead them to revise their intake criteria as well as the age limit for patients, proposing an exclusion criteria for patients under 65 years, as the short period of invalidity is justifiable. However, there is currently no minimum age limit for the current procedure.

This paper outlines the effectiveness of the conventional method of surgery; the improvement seen in patients post surgery indicates that replacing only one compartment is still an effective method of surgery. However, the study does not compare the surgery to any other method and there remains possible room for improvement, which may be achieved by the MAKOplasty®.

6.3: Computer assisted surgery

H. Bathis, L. Perlick, M. Tingart, C. Luring, D. Zurkowski, J. Grifka (2004) Alignment in Total Knee Arthroplasty (A comparison of computer-assisted surgery with the conventional technique.) The Journal of Bone & Joint Surgery: 86-B:682-7.

The MAKO RIO™ was developed in the anticipation of improving the current method of surgery; previously developed robotic arms have not made it through the approval process. However, computer navigation systems have been examined before. In the paper by Bathis et al (2004), the 80 patients received TKA using a computer-assisted ct-free navigation system and the outcomes recorded were compared to an equal sized group receiving a conventional TKA. No exclusion criteria were defined for the study for age, sex, previous surgery or deviation of axis of the leg. This gave a broad range of participants form age 31 to 88.The same team with experience in both methods were used in all surgeries having preformed at least 120 of the computer assisted procedures and numerous conventional.

The computer-assisted technique used was the VectorVision CT-free knee from BrainLAB in Munich. Using an optical tracking unit, detecting reflections, from maker spheres rigidly attached to the patient, with an infrared camera. A draped touch-screen monitor function as the controller. An initial registration procedure defines the specific landmarks of the leg and digitises the important structures of the knee.

Before the bone is resected; the axes of the leg, ROM and laxity of the ligaments can be assessed and documented. The navigation system determines the orientation of the cutting blocks. Axial alignment both pre and postoperatively are measured by use of a radiograph and two independent observers (at three different times) the axial alignments were measured.

The Kolmogorov-Smirno test were used to asses if alignment followed a normal distribution, Levene’s test was used to assess the constant variance, the role of gender was assessed with the Fisher's exact test, length of the operations are compared by use of the t-test and box and whisker plots were used to analyse post operative alignment.

Before discussing the results the author reported that the interobserver reliability for the study was high.

Frontal plane alignment was shown to be significantly better in the computer assisted group (t-test $P<0.01$.) It was also seen that the varus/ valgus deviation was also improved by use of the computer assistance with a lower occurrence of deviation over 3° and a smaller range of deviation (maximum of 4° compared to 8°.) An even greater difference was seen in the sagittal plane ($P<0.001$).

With the opposite bias is seen when the length of the operation was assessed, in this area a significant difference ($P<0.01$) was reported with the conventional method taking and average of 64 mins (plus/minus 11 mins) compared to the computer assisted taking 78mins (plus/minus 12 mins) This constitutes 11-18 minutes longer for the operation using the navigation system due to initial alignment. This also means that the patient must be under the influence of general anaesthetic for a longer period of time. This is considered acceptable in clinical practice.

6.4: Validation Outcome scores

To validate the successful outcome of surgery, different measurements are necessary. There are many different measurement scales employed for this, some of which have been specially developed for knee arthroplasty.

6.4.1: AKSS

R. Y. L. Liow, K. Walker, M. A. Wajid, G. Bedi, C. M. E. Lennox (2010) The Reliability of the American Knee Society Score, Acta Orthopaedica Scandinavica: 71(6):603-608

The knee society recognise the importance of evidence based practice and as such have developed scales that can be used as tools to allow researchers and clinicians to evaluate outcomes.

A total of 29 patients were randomly evaluated by 6 observers, with variable experience in examination of the knee joint, (consisting of a consultant, junior doctor, 2 residents and 2 arthroplasty nurse practitioners.) All participants were either awaiting knee arthroplasty (primary or revision) or those who had received knee replacements in the last 6 months.

The observers scored the same patient twice with an interval of at least 2 hours. The ROM was measured by the observers by using a goniometer and recorded in a standardized chart; all answers to the AKSS were then converted into points. For each patient the standard deviation of the observer's scores was squared to obtain a set of variances, the average of this was given as the interobserver variance and the square root was given as the standard deviation. A multiple of 1.96 gave the "95% confidence interval" which was used throughout the paper. The intra observer variance was calculated in a similar fashion, and all calculations were verified by use of Single factor ANOVA. The F test variance test was used to test for significance between the variance. Finally unweighted Kappa statistic was applied to assess the intraobserver agreement for each component of the AKSS.

The results showed that there was a 95% chance that any single observer would obtain a score within 16 points of the true value for any given patient, and within 21 points for the functional score. Intra observer differences were much smaller, that is to say for a single observation from a single assessor is likely to lie within 11 points of the true value, this is 13 points for the functional score.

True values are defined as the score that is considered to be correct for a given patient.

This raises many issues, as the paper does not outline how the ‘true values’ were calculated.

The patients were stratified according to the multiplicity of joints affected by arthrosis and general infirmity. Although the author fails to define these groups and give a true definition of which patients are included in-group A etc. so the data from this section cannot be fully assessed. It was observed that experience in this type of assessment was relevant to intraobserver variance. The highest occurring with the junior doctors (3 months experience of assessment) and their scores were seen to be significantly different to those of all other observers. The nurses however, had the highest intraobserver difference for function score, but not to a level of significance. If the nurses and junior doctors results were excluded and only the results of the more experienced residents (with a least 3 years experience) and consultant were included, then flexion contracture, alignment and mediolateral stability measurements resulted in increased agreement. Although the nurses showed good intraobserver coherence between the two of them, they generally failed to spot many instabilities and falsely categorised patients. Variation in ROM, as expressed by the variance of the points (each point representing 5° of motion,) a single observer taking a single reading is 95% likely to be within 3.9 points of 20° of the true value, for the intra observe value this was 13°.

Reference is drawn to a study by Ryd et al (1997) where the interobserver SD was seen to be twice that of the study under discussion. The root of this problem is not fully investigated or explained, However, it is postulated that unless the observers are “trained assessors” it is hard to confidently attribute any discrepancies in scoring to the scale, as the observers may be the cause. This is the reason that it has become increasingly undertaken by arthoplasty outcome teams.

The paper concludes by stating that if a patient is seen by 2 different observers at 2 different visits it can not be confidently stated that a change is real unless the change in score exceeds 23 points. If the patient is seen by the same observer on two different occasions the change in score can only be considered real if it exceeds 16 points. Although the principals of the study are sound, the sample of observers was very low, a total of 6 observers from 4 different experience backgrounds. Therefore the influence of the 3 less experienced observers is highly influential on the outcome. Trials by Boone et al(1978) show, that this is method of observation gives easily repeatable results. For our trial we will use the same, highly experienced clinical nurse for every observation using the AKSS. This should largely negate the need for a 16-23 point difference in order for changes to be taken into account. The use of the goniometer is also a skill that must be learned and practiced, this has great influence on the observers ability to record ROM to an accurate degree, again our observer is highly trained and experienced in this.

6.4.2: HADs

A. Montazeri, M. Vahdaninia, M. Ebrahimi and s. Jarvandi (2003) The Hospital Anxiety and Depression Scale (HADS): translation and validation stuffy of the Iranian version. Health and quality Life outcomes: 1:14

It is often the case that these outcome scores are validated in order to justify and assisted in the translation into another language.

The questionnaire was translated from English to Persian; some problematic terms such as ‘butterflies in the stomach’ were adapted culturally. The new translation was administrated to newly diagnosed breast cancer patients in Tehran. In a one-year period a trained female nurse collected data in face-to-face interviews. The Cronbach’s alpha coefficient was used to test the reliability of the scale. The validation of the scale was performed using the known groups comparison and convergent analysis, this outlined the scores ability to recognise the subgroups defined by the stage of the disease.

The results were displayed in a table and showed a mean age of 47.2 years and 45% had loco-regional disease. An impressive 99% found the score acceptable. The Cronbach's alpha coefficient showed that the depression and anxiety scores were highly reliable in sub grouping. However, item 7 (I can sit ease and feel relaxed), item 11 (I feel restless if I have to be on the move) and item 10 (I have lost interest in my appearance) showed a weak correlation with the anxiety score. The discussion covers the point that face-to-face interviews may carry a bias in the results as the interviewer may influence the patient. Also the question was raised as to whether the correlation seen between the anxiety and depression scores make the questionnaire more relevant as a general scale of discomfort. For the purpose of our study, the total score maybe more relevant to use as an indication of the patients emotional progression post surgery.

The nature of this trial was to make the questionnaire understandable for the native speakers therefore the role of its acceptability is the articles main area of concentration. The influence of the interview may be relevant, but may also allow the patient a better understanding of the question being asked and, with the same interviewer being used, should have a limited impact. Other than these points, the HAD scale is seen to be a valuable scale to monitor the general 'mood' of the patient any changes in this mood over a given period or event.

6.5: Effects of alignment on failure rate in total knee replacement

D.M. Fang, M.A. Ritter, K.E. Davis (2009) Coronal Alignment in Total Knee Arthroplasty (How important is it?) Journal of arthroplasty,6, 1

This paper explores the fact that, in many papers, it is cited as a fact that the long leg alignment of the femur on the tibia postoperatively affects the success of the implant. By use of radiograph we will measure this postoperative alignment. To validate the influences this alignment may have on the long and short-term functional outcome of the prosthetic, Fang's paper 'Coronal Alignment in Total Knee Arthroplasty' is referenced.

This paper addresses the fact that there is little evidence to support, what is referred to as an assumption that improved coronal alignment in TKA leads to improved function and longevity. The article goes on to state that the early research done on this factor was influenced by the use of historic prosthetic designs.

Between 1983 and 2006 a total of 6070 primary TKAs were performed on 3992 patients. The same metal-backed, non-modular tibial implant with compression-moulded polyethylene is used in each case.

Radiographs were obtained preoperatively and at 2, 6 and 12 months postoperatively and every 2-3 years thereafter. Patients were stratified into groups based on the long leg alignment preoperatively; varus, valgus and neutral.

28% of patients died within the follow up period (6.6 year plus/minus 3.5). 0.84% of knees failure with an average time to failure of 5.5 years (plus/minus 3.7.) Of these failures 78% were on the tibial side, 14% on the femoral side and 8% from both sides.

The revision rate for the neural group was significantly lower (0.5%) compared to Varus and Valgus groups (1.8% and 1.5% respectively.) At 20 years the survival rate for the neutral alignment group was 99% compared to 95% for the Varus group and 97% for the valgus.

The results correspond to a 6.9 times increased task of failure by medial tibial collapse in varus knees, compared to those which are properly aligned ($p<0.0001$) and a 3.7 times increased risk with valgus alignment compared to neutral.

Older age is shown to be a highly significant factor, improving the prosthetic survival ($p<0.0001$).

The paper can be summarised as displaying that long leg alignment has a significant effect on the longevity of the prosthesis, tibial alignment alone does not affect the life of the implant. Also confirming the notion that valgus deviation has more of a negative impact on the failure rate of the implant. However, this paper does not take into account any reasons for the varus or valgus alignment, such as natural deviation due to anatomy. One paper (Ridgeway 2002) performs a retrospective assessment of UKAs in the United Kingdom, as well as reviewing other article, which have found no correlation between alignment and failure rate. The surgeons in this study have aimed not to return the knee to neutral, but to a less extreme deviation that is still inline with patients anatomy.

Chapter 7:Methodology

Currently underway at the Glasgow Royal infirmary is an in-depth investigation into both the long and short-term outcomes of UKA using MAKOplasty® (with restoris inlay) implanted by use of the MAKO RIO™ tactile guidance system compared to the Oxford partial knee.

7.1: Patient group

The total number of patients to be included in the study will amount to 150 patients (75 in each group) this is over the entire period of the study, to include long-term follow up. For the purpose of this thesis the results from the initial 20 patients (10 in each group) will be analysed. For inclusion in the study patients must adhere to the following criteria:

- Both of the cruciate ligaments must be intact
- BMI of 40 or less
- OA confined to one compartment only
- Any flexion deformity must be less than 10° and correctable
- Opposite component must have full cartilage thickness
- The effected side must have full cartilage thickness loss
- The arthritis must not be an inflammatory kind
- No indications of ACL damage (med-lat subluxation or tibia bone loss.)

Ethics and group distribution

This study has been approved by Glasgow Royal Infirmary local ethics committee and the University of Strathclyde's ethical committee. To ensure the study complies with standard of ethics, the patients are informed of the investigation and the difference between the two procedures before they give consent.

The patients are randomly distributed between the two groups and are entitled to ask which method of arthroplasty they are being assigned. The study is voluntary, so patients may withdraw at any time.

7.2: Pre surgery interviews

Once the patient has been assigned a group, the preliminary questionnaires are addressed.

1. The first section was completed by the researcher; the number of consultation and patient's mobility aids as well as systemic disorders and their medication are noted. It is also important to at this point calculate the BMI value of the patient, (varus/ valgus) according to the x-ray.

2. AKSS (appendix 1): The researcher also completes the American Knee Society Scores for the patient.

This score looks at two areas of importance:

Functionality (score out of 100)

Knee score : Pain, stability and ROM (score out of 100)

The system is devised to encompass many of the scales currently in place whilst remaining simple. Many of the scales that incorporate all components into one score do not compensate for age related functional degradation. Therefore the score may decrease (due to lowering general functional ability) when the knee itself is unchanged(Insall, et al. 1989)

The first section involves a grading on pain on walking and climb stairs (from Severe at 0 points to none at 35 points.)

A goniometer is then used to measure the ROM of extension, flexion and excursion (lateral/ medial deviation) with one point awarded for every 5°.

Extension lag (number of degrees which lower leg deviates from full extension when quadriceps are fully contracted.)

Degree of flexion contracture (abnormal shortening of muscle tissue, rendering muscle highly resistant to passive stretching)

Malalignment (abnormal forces through the kneecap tending to pull it laterally/ medially) 2 points deducted for every 5° of malalignment

Pain at rest (from 0 to 15 points deducted)

All points are totalled to create a score out of 100.

The functional score is created from reviewing

- How far the patient can walk
- How well the patient can walk up and down stairs
- The walking aid needed for walking
- This score is also added up to create a total out of 100.

The following scales are completed by the patient, reducing the bias but also the experience of the assessor (the patient):

HAD (appendix 2)- the hospital anxiety and depression score is a fourteen-question scale used to determine the levels of anxiety and depression patients are experiencing. They call upon the patient to reference feelings experienced in the last week. Patients were asked to give one response out of four to each of the questions in the Scale. They are asked to give an immediate response without considering their answers for too long. The questions related to depression and anxiety are not separated or specifically identified to the patient.

VAS : Two visual analogue scales:

The Visual Analogue Pain Scale is often considered by clinicians as more beneficial than a descriptive version(Price, et al. 1994), which would involve the patient giving comments such as “I feel awful”, “everything’s fine”, because it aids the patient in rating their pain without distractions. It also allows a specific numerical scale that can be statistically analyzed. The line is exactly 10 cm long and, the score is determined by the distances, in mm of the line marked by the patients from the left hand end of the line, giving a maximum score of 100 and minimum of 0.

Figure 29: the VAS for pain (adapted from Diary)

A very similar scale is used for the patient to notate the level of their stiffness, with labelling from "no stiffness" to "extremely stiff".

OKS (appendix 3): The Oxford Knee score was devised specifically for patient assessment after TKA, the oxford knee scale is a twelve-item assessment of function and pain. This is a self-assessment form that would generally be filled in by the patients themselves it is a simple 1-5 point scale (Dawson, Fitzpatrick and Murray 1998). Its simplicity and shortness make it easily reproducible and sensitive to change. 12 questions in the OKS cover; pain on rest, walking, sitting, at night and how this interference with daily activity or activities you are unable to perform.

PCS (appendix 4): The Pain catastrophising scale is a 13-point scale looking at the thoughts and feelings appreciated by the patient post operatively. There are 13 questions covering; rumination, magnification and helplessness. Each question can be scored from 0-4 on how often these feelings are experienced. This is also relevant to how each patient copes with and emotionalises the pain they experience.

7.3: Operation, Surgeons and research assistant

Patients who will receive the MAKOplasty® receive a CT scan prior to surgery. This difference in the two procedures makes it impossible to make this a blind trial. As it would be unethical to perform an unnecessary CT scan on the patients receiving the oxford partial knee.

There are three surgeons performing the operations. All three surgeons will perform both types of surgery. All surgeons are experienced using the Oxford partial knee method. They have also performed 10-15 MAKOplastys® prior to the trial.

The patients receive an operation date and undergo surgery; during the first days they are observed in the hospital until ready for discharge. Both groups receive identical standards of care whilst in the hospital.

To ensure a high level of consistency, the measurements will all be taken by the same research nurse. This ensures a higher significance in score changes pre and post operatively. All other scores are recorded by the patients themselves.

7.4: Patient diary and 10 day follow up

Patients are given a dairy outlining rehabilitation exercises (appendix 5) and explaining the scales they will have to use. They are given responsibility to fill these in themselves everyday.

From the first day after the operation patients are asked to fill in their Perceived Pain, using the VAS. A new 'clean' scale is filled in everyday. As well as noting any need to use painkillers.

They are also then asked to complete tick boxes indicating the exercises they have performed that day to enable us to monitor any possible external influence on the rate of rehabilitation and pain reduction.

Finally they are instructed to complete another tick box section with functional questions, which have been taken from the AKSS. This is done daily for the first 7 days and then once a week up to eight weeks post operatively.

After 10 days the patient is contacted by telephone to assess the status of the wound (dry/ spotting/ serious DC/ bleeding / purulent)

Also any visits to the Physiotherapist, Orthopaedic outcome centre of GP are noted along with current walking aid used.

This consultation looks at any complications that have arisen post –operatively and the measures taken to control them or action necessary.

7.5: 3-month follow up

The 3-month postoperative assessment is performed at the hospital in line with the clinical check up.

Alignment: A full leg x-ray is also performed at this appointment and the angle of Varus/ Valgus of the postoperative knee is calculated on the long leg xray after surgery.

The following scores are repeated:

- Pain and stiffness
- AKSS.
- OKS
- HAD

The following factors are also carefully notated:

- ROM – flexion and extension
- Tenderness of wound
- Length of wound
- Number of visits to GP and Orthopaedic Outcomes service and hospital post operatively
- Use of painkillers post operatively.
- Complications
- EQ-5d (similar to pain scale)

7.6: Aims of the study

1. As postulated in some of the literature, the alignment of the prosthetic is a critical influence in the longevity of the implant. We will compare the alignment of limbs in the two groups from varus/ valgus. Alignment will be calculated from long leg x-rays taken post operatively.

2. We will compare average ROM from each group and scoring ROM according to improvement in flexion and extension angles, from pre-op to post op. We can look for significant difference in the two outcomes.

3. Changes in function and pain will be assessed. For the OKS, AKSS and both VAS scores, the pre-operative and 3-month post-operative scores will be assessed for improvement in the score.

The OKS and AKSS can be further broken down to evaluate the average score received for each question, to identify any obvious areas of discrepancy.

4. Length of surgery. The MAKO company claim(Corp, MAKOplasty® Partial knee resurfacing 2011) that the MAKOplasty® will give improved results, with consistently reproducible precision, more accurate implant alignment, However, the general length of the procedure including set up may mean longer time under anaesthetics. Surgery time for the two groups will be compared.

5. The diary results for both the VAS and the AKSS will be compared, giving an average score for each day post operation.

6. PCS and HAD will compared for the two groups. Both these scales deal with the patient's emotional perception of events, these emotional responses may effect or be effected by the outcome of the operation. Again, the HAD score can be broken-down to view the mode response for each question.

Chapter 8: Results

All results will be tested for significance using the Student t-tests (paired and unpaired as relevant) alpha is set at 0.05 (5%) and the null hypothesis is stated such that for denominal factors Ho = no difference between the two methods of surgery.

For continuity the conventional surgery group will be referred to as group C and the MAKO as group M in text. Averages given are the mean, unless otherwise stated.

Nominal results will be assessed for significance using the Mann-Whitney Utest. Again $p<0.05$ is set as alpha. The null hypotheses for these tests differ from that stated above and are documented with results. The Mann-Whitney Utest (Utest) is used because of the sample size. As the values are nominal they must first be ranked and the ranking order is stated in the text each time this test is used. For the test to be valid the nul hypothesis can not be stated as M=C, therefore both of the other possibilities must be explored (in our case group C's outcomes ranking higher or group M's outcomes ranking hire.) if p value exceeds 0.05 this stated hypothesis is accepted. In the case that the stated hypothesis must be rejected the opposite hypothesis must then be tested, if both hypothesis are rejected it can be assumed that the two groups are not statistically different.

8.1: Preoperative patient demographic

The test population comprises of twenty patients, due to their random distribution they is no assurance that the two groups have similar population.

Table 1 outlines the mean and standard deviation of the preoperative measurements for each group. Also listed is the p-value calculated using the unpaired student t-test.

BMI is limited, by the inclusion criteria, to a maximum of 40, with no minimum. All other scores are limited by the individual outcome scales used.

Table 1: preoperative mean score

	MAKO		Conventional		**Ttest p-values**
	Mean	Standard deviation	Mean	Standard deviation	
BMI	32.70	5.43	33.45	5.06	**0.75**
Extension (deg)	4	3.94	5	4.71	**0.61**
Flexion (deg)	114.5	15.39	113.5	7.84	**0.86**
OKS	40.1	9.49	40.3	7.09	**0.96**
AKSS: Function	60	18.1	53.5	20.28	**0.46**
AKSS: Knee	54	16.17	52.3	13.86	**0.80**
AKSS: Total	114.0	29.7	105.8	24.4	**0.51**
VAS	44.2	27.6	52.3	15.88	**0.43**
PCS	14.6	13.38	7.6	12.71	**0.46**
HAD: Anxiety	7.7	5.08	7.1	4.2	**0.78**
HAD: Depression	6.1	4.91	4.9	3.73	**0.55**

There is no significant difference, in the BMI or preoperative clinical and functional scores, between the two groups.

Table 2 shows pre operative alignment of the leg, this was measured using the long leg x-rays taken in session prior to surgery. (All results are in degrees). This is the mechanical axis of the lower limb (Hip-Knee-Ankle angle).

Table 2: Alignment post operation

	Pre op	
	Conventional	**MAKO**
	-1	-4
	-9	-3
	-2	-8
	-2	-8
	-4	-5
	-6	-4
	-7	-14
	-1	-9
	-5	-9
	-8	-2
Average	-4.5	-6.6
StDev	2.95	3.66
Ttest p-value		0.17

There is again, no statistical difference between the alignment values pre-operatively. The range for group C was -9 to -1 degrees. The range for group M was -14 to -2 degrees.

The intake formula also includes some nominal values of interest such as, the gender of the patient. Group C has 8 men and 2 women, while group M has 5 men and 5 women.

Employment status is also notated, as this may have bearing on a patient's ability to rest or undergo rehabilitation after surgery. The possible categories include: Employed, Employed on sick leave, Unemployed and Retired. (For the benefit of statistical analysis the type of employment was raked in this order.)

Table 3 outlines nominal factors; Gender and employment status. The Mann-Whitney U test is used to calculate the p-value for each of these factors. The relevant hypothesis is labelled

Table 3:Nominal preoperative values (Mann-Whitney U test)

Gender			
	Null Hypothesis	Significantly more men in MAKO group	Significantly more men in Conventional group
	Z value	-3.02	-0.98
	Utest p-value	0.003	*0.33*
	Outcome	Ho REJECTED	*Ho not rejected*
Employment status			
	Null Hypothesis	Significantly greater rates of employment MAKO group	Signifcantly greater rates of employment Conventional group
	Z value	3.02	-3.02
	Utest p-value	0.003	0.003
	Outcome	Ho REJECTED	Ho REJECTED

For employment status, all p-values are well below alpha and thus both null hypothesis can be rejected, this shows that there is no statistical difference between the two groups. However, due to the italic p-value for the category of sex, the hypothsis is accepted that there are significantly more men in group C than M. This means the distribution of gender across the groups is unequal.

8.2: Alignment post operatively

Table 4 shows the mechanical axis angle of each patient as measured postoperatively from weight bearing long leg x-rays. The results are presented in degrees where varus alignment is noted as negative and valgus as positive. Also in the tables are p-values obtained by the student t-test.

Table 4: Leg alignment deviation pre and post surgery.

	Post op	
	Conventional	**MAKO**
	-0.5	4
	4	0
	0	0
	-3	-1
	-5	-3
	-4	0
	0	-7
	-1	-8
	0	-9
	-2	-2
Average	-1.15	-2.6
StDev	2.54	4.17
Ttest p-value		0.31

Prior to surgery group M had an alignment further from neutral than group C. The resultant postoperative mean of group C (-1.15°) was nearer to neutral (0°) than that of group M (-2.6°).

The range of mechanical axis alignments for group M was -9 to +4 and group C from 0 to -5.

Figure 46 depicts the data from Table 4 in a box plot format, showing the mean and standard alignment for varus/valgus

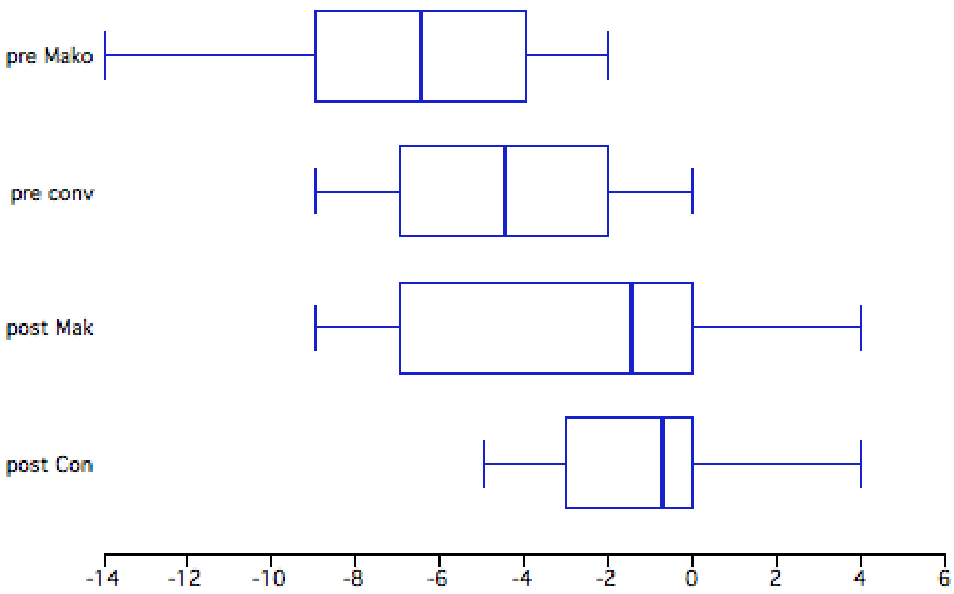


Figure 46: Box plot showing Leg alignment distribution pre and post operatively.

Although there is a much larger range of alignments in group M, figure 46 shows that this range decreases post operatively. Also seen is that the range of group C reduces dramatically post surgery, whilst both groups show a distinct shift towards neutral alignment.

The aim of UKA is to restore patients natural lower limb alignment, which is varied within the population. Neutral alignment is not the natural alignment for the everybody.

Table 5 shows this distribution for the postoperative mechanical axis alignment (varus/ valgus.)

Table 5: Postoperative alignment knee

Alignment group	Conventional	MAKO
0< to +4	1	1
0	3	3
<0 to -5	6	3
<-5 to -10	0	3

Table 5 clearly demonstrates the greater distribution of alignments in group M with more patients in a more extreme varus category. This distribution remains post operatively.

Mechanical axis alignment (varus/ valgus) information from Table 5 is statistically assessed in Table 6 with the Mann-Whitney U test. The null hypothesis is constructed from the observation that group C has more patients in higher ranks (if the ranking is taken in order alignment groups are shown in Table 5.)

Table 6: Mann-Whitney U outcomes alignment

Null Hypothesis	**The outcome for conventional is significantly higher than for MAKO**
Z value	-1.06
Utest **p-value**	0.3
Outcome	Ho REJECTED

The results show that difference in alignment is not significant (p = 0.3 from both T-test and Mann-Whitney U test.)

8.3: Range Of Motion

Table 7 shows the mean flexion and extension angles post operatively, as well as the change in angle, with the relevant t-test, p-value outcomes (comparing group C to group M).

Negative score for extension indicate hyperextension whilst positive values indicate that the patient can not fully extend the knee. Full extension of the knee will be indicated with 0. In the Change column, negative extension scores show improvement and flexion improvement is shown with a positive score.

Table 7: Flexion and extension

		Post operatively		**Change**	
		MAKO	**Con**	**MAKO**	**Con**
Extens	**Mean**	1	3.5	-3	-1.5
	STdev	2.11	4.74	2.58	4.11
	Ttest p-value		0.15		0.34
Flexion	**Mean**	128.3	116.36	13.8	3.5
	Stdev	5.77	13.25	12.29	15.28
	Ttest p-value		***0.03***		0.11

The average outcome for both groups showed an improvement in both flexion and extension.

Also seen from Table 7 is the much larger range of flexion results (standard deviation 12.29 for M and 15.28 for C) compared to extension (standard deviation 2.58 for M and 4.11 for C.)

Table 8 shows the p-values calculated to indicate the significance of the change in flexion and extension from pre to post operatively.

Table 8: Paired Ttest for pre operative to postoperative flexion and extension angles

Paired t-test	**MAKO**	**Conventional**
Extension p-value	0.005	0.28
Flexion p-value	0.006	0.49

This table shows that there was a significant improvement in maximum flexion angle for group M. The extension angle was also improved in group M but it did not reach significance improvement. However, there in no significant change in flexion or extension for group C.

Figure 47 :shows the frequency distribution post operatively for flexion (a) and extension (b).

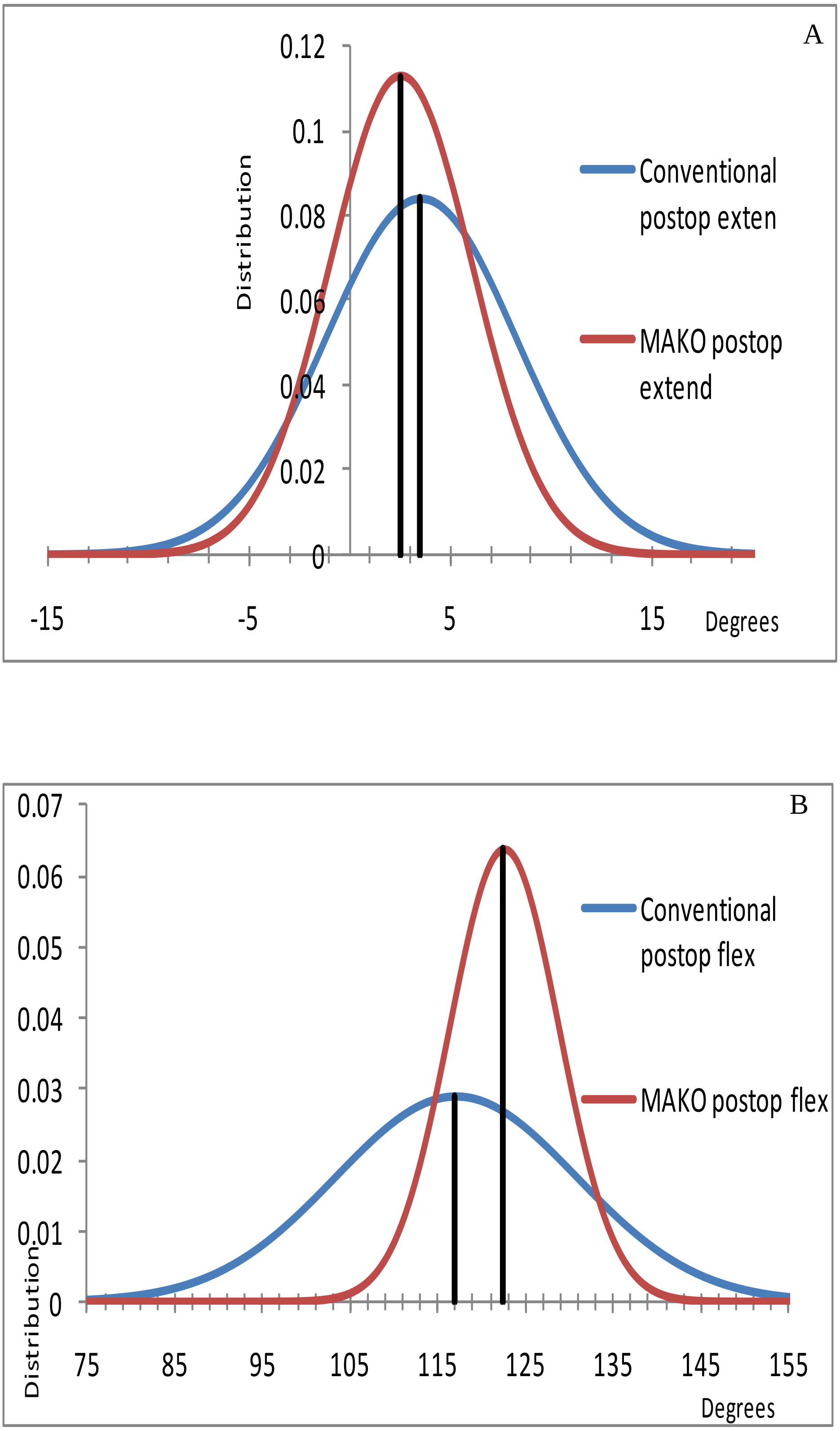


Figure 47: frequency distribution of (a) Flexion & (b) Extension

Figure 47 shows a very similar range of distribution for the two groups in flexion, whilst for extension there is clearly a greater range of outcomes for group M.

Also apparent is the very similar mean angle of extension for the two groups, with a more distinct difference in mean score for flexion for group M compared to group C.

The ROM is defined as the angle cover from maximum flexion to maximum extension

The mean total ROM prior to surgery is :110.5 degrees for the group M and 108.5 degrees for group C. After surgery this range has improved to 127.3 degrees for group M and 113.5 degrees for group C.

8.4: OKS

Table 9 shows the average scores from the OKS postoperatively and the change in score. The paired t-test results compare the scores post operatively for each group as well as comparing the change in scores and a p-value is given for each outcome.

Lower scores correspond to superior functional outcome, with possible scoring from 12-60 (for postoperative and preoperative averages.)

Table 9: Mean scores

	Post op		**Change**	
	Mako	**Con**	**Mako**	**Con**
Average	26.1	27.5	14	12.8
Stdev	6.81	7.17	11.16	5.35
T-test p-value		0.66		0.76

There is no statistically significant difference between the two groups post-operatively (p = 0.66).This table highlights the very small difference in the mean OKS score of the two groups, this differences is statistically insignificant.

Table 10 shows the p values when the preoperative scores are compaired to the postoperative scores for the same group.

Table 10 T-test pre to post op

	Mako	**Con**
Paired Ttest p-value	0.003	3.45E-05

Of note is highly significant change in score in both groups ($p<0.05$.) Showing that the unicompartmental arthroplasty itself is of benefit to the patients in terms of OKS.

However, noted from the results is the range of improvements in the scores of group M, with fewer patients in the mean category for this group.

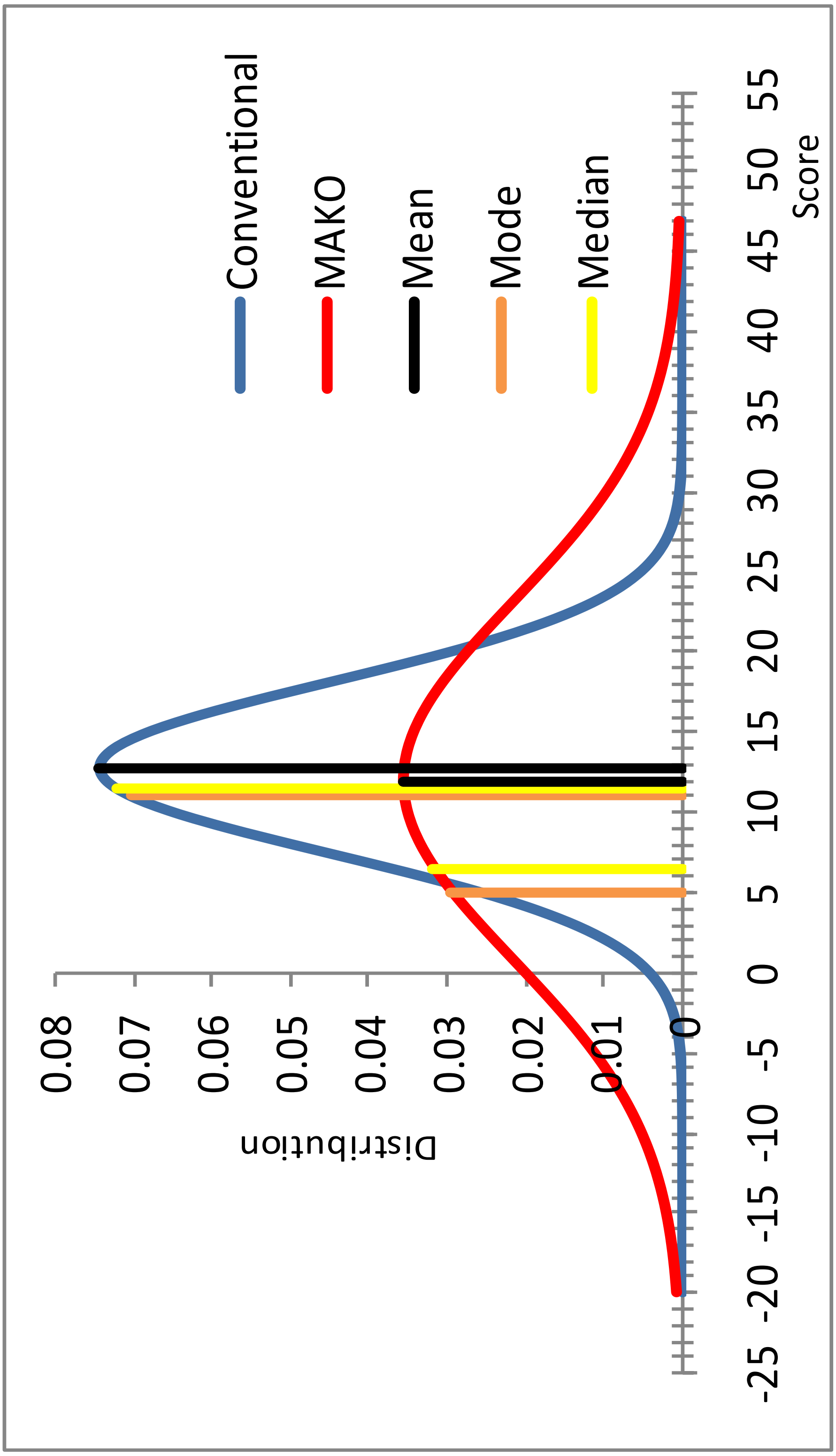
Table 11 shows the mode, mean and median averages for both groups .

Table 11: Average Scores OKS

	Pre-Op Score	3 Month Score	Change
Mean MAKO	38.1	26.1	12
Mean Conv	40.3	27.5	12.8
Mode MAKO	36	31	5
Mode Conv	39	33	11
Median MAKO	39.5	27.5	12
Median Conv	39.5	29	11.5

Although the mean OKS scores are very similar, the mode shows a much larger discrepancy between the groups when examining the changes in the scores. This shows that there is a great diffence in the most common score seen for each group. To fully explore the implications of this it would be necessary to take a larger sample size to demonstrate which values fall within the normal range of group M scores, compaired to outliners.

Figure 48 shows the frequency distribution graphs for both groups, when comparing the change in score; the mean, mode and median scores are marked.


Distribution
Score
Conventional
MAKO
Mean
Mode
Median
0.08
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0
-25 -20 -15 -10 -5 0 5 10 15 20 25 30 35 40 45 50 55

8.5: AKSS

8.5.a. Total score

Table 12 shows the mean post-operativly and mean change in score for both the functional and knee scores of the AKSS, as well as the total score.

The Function and Knee scores ranges from 0- 100 points (therefore, the total ranges from 0-200 points), any negative values indicate that the score was worse after surgery.Also shown are the P-values, derived using the student T-test

Table 12: AKSS Scores

AKSS scores		**Post**		**Change**	
		M	**C**	**M**	**C**
Func	**Mean**	80.00	67.00	20.00	11.00
	Stdev	17.48	17.83	22.11	16.12
	Ttest p-value		0.12		0.31
Knee	**Mean**	82.90	73.60	28.90	17.70
	Stdev	11.10	10.94	19.63	18.97
	Ttest p-value		***0.08***		0.15
Total	**Mean**	162.90	140.60	48.90	28.70
	Stdev	23.97	26.57	30.42	30.41
	Ttest p-value		***0.06***		0.15

The table above shows that the P-value for postoperative totals is higher than alpha by only a small margin (p = 0.06). This is of interest, as it is noted previously that prior to surgery these scores were not significantly different (p = 0.51.) It is reasonable to assume there is a markedly higher scored in the knee scores and total score for group M. The functional scores are significantly similar.

As shown, the difference in average score for the two groups is 8 points prior to surgery compaired to 23 after the surgery.

There is no significant difference between the 2 groups in terms of AKSS scores however, with increased numbers in the two groups the difference may reach significance.

Figure 49 shows a boxplot which, depicts the improvement in the functional and knee scores of the AKSS (between preoperative and 3-month post op) for both the groups.

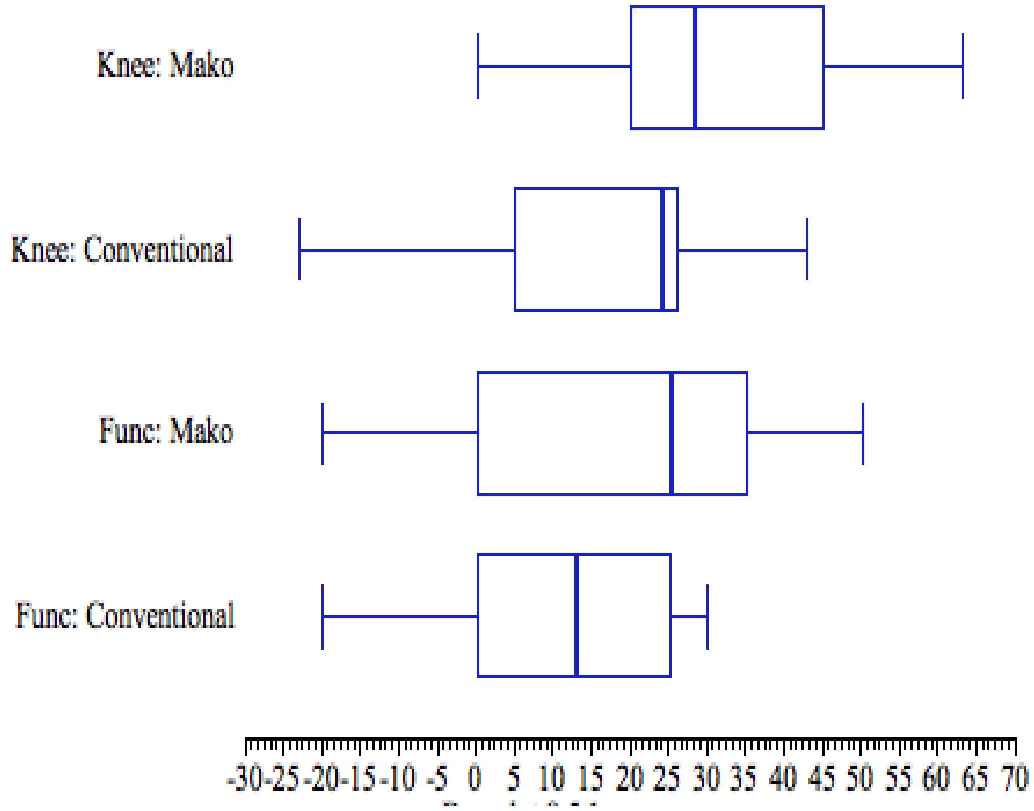
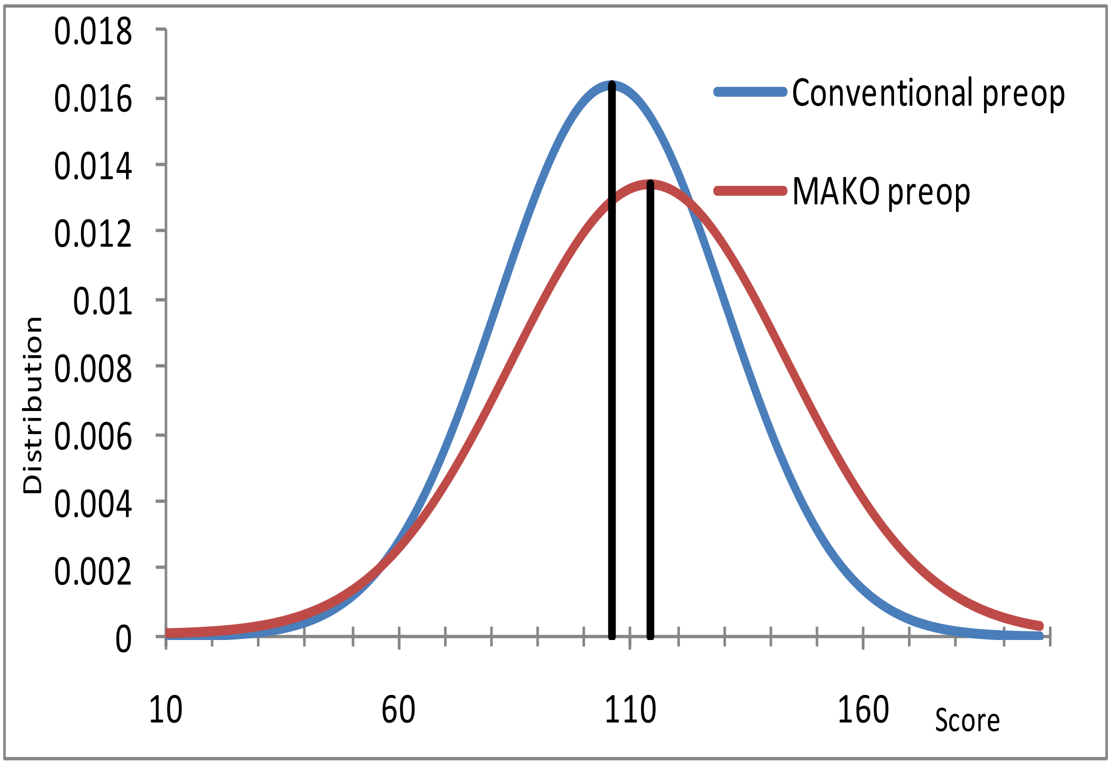


Figure 49: Boxplot of function and knee scores AKSS

This Box plot shows the range for each category is very similar. Also showing a similar score distribution for the functional section of the questionnaire , yet not for the knee scores. Group M has a very large distribution range of function scores.

Figure 50 shows the frequency distribution graphs of the Pre (a) and Post operatively (b) of scores for the two groups. The central line depicts the mean score for each group

A



B

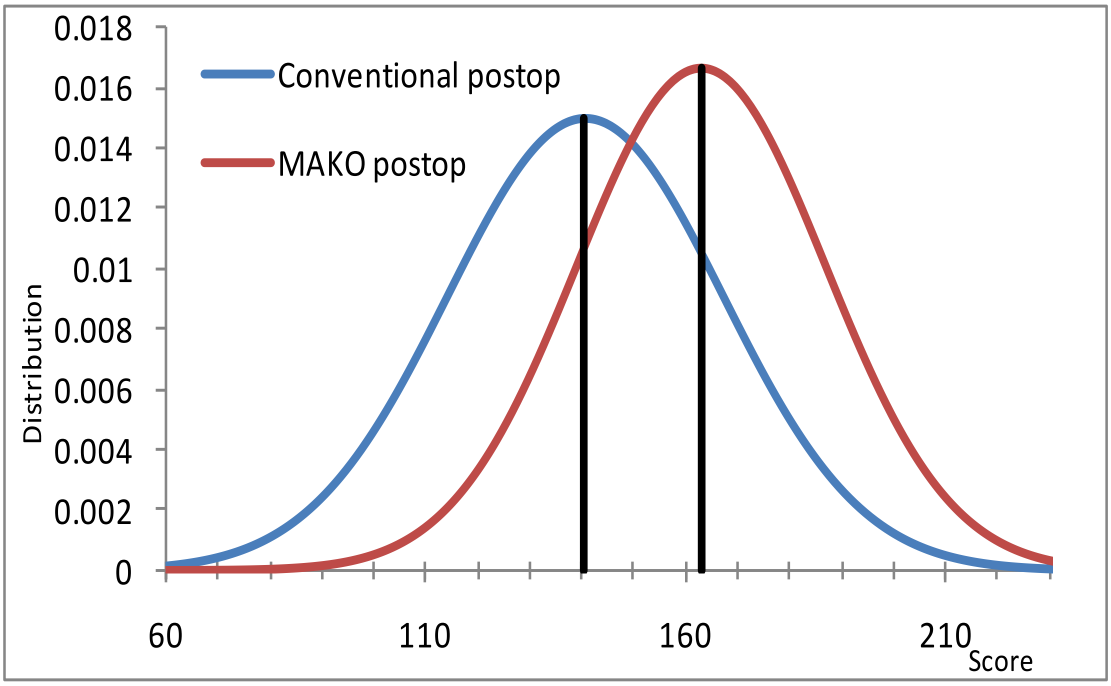


Figure 50: Frequency distribution graphs of Pre (a) and Post (b) operative AKSS scores

AKSS mean scored are reduced post operativily for both groups. Also postoperativly the two mean scores are similar with an increased range for group C.

8.5b: AKSS Breakdown

Figure 51 shows the responses of the patients to the individul questions in the function section of the AKSS. As each group contains 10 patients , the maximum possible result for any variable is 10 and the minimum is 0.

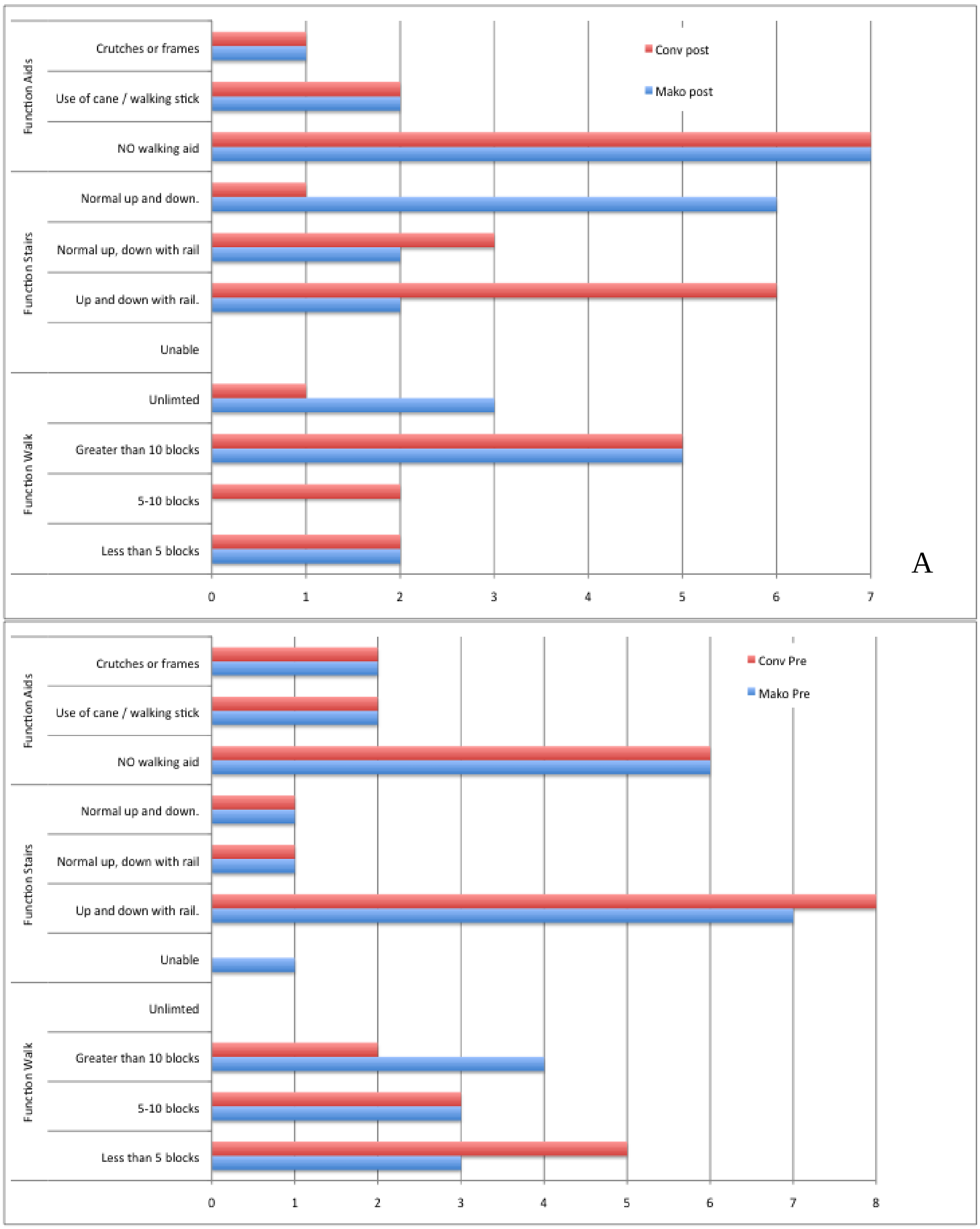


Figure 51: Responses to AKSS function prior to (a) and post(b) operation.

The bar graph shows that prior to surgery there were some differences in responses in the two groups. Post surgery however, there is a great similarity in responses for each question. Corresponding to the significantly similar scores for the functional outcome, shown in section 8.5a.

Table 13 looks at group M and C comparatively to each other, while Table 4 shows the comparative of pre to post op significance. Walking aid outcome is identical both post and preoperatively in the two groups, therefore is not assessed.

M>C is taken to mean that the group M has a significantly higher ranking than group C, while M<C signifies the opposite. The ranking of responses is based on the scoring system for points awarded. Pre>Post signifies a higher ranking in postoperative scores compared to preoperative scores and Post> Pre, the opposite.

P-values were derived using the Mann-Whitney Utest.

Table 13: p-values AKSS function M:C (Mann-Whitney U test)

H0	**M>C**		**M<C**	
	Preop	**Postop**	**Preop**	**Postop**
Walking				
Z value	**-2.34**	**-2.12**	**-0.23**	**-0.23**
Utest p-value	**0.02**	**0.034**	**0.82**	**0.82**
Outcome	*Ho not rejected*	*Ho not rejected*	**Ho REJECTED**	**Ho REJECTED**
Stairs				
Z value	**-1.89**	**-3.48**	**-2.49**	**-1.06**
Utest p-value	**0.06**	**0.0005**	**0.01**	**0.29**
Outcome	**Ho REJECTED**	*Ho not rejected*	*Ho not rejected*	**Ho REJECTED**

Table 14: p-values AKSS knee Pre:Post (Mann-Whitney U test)

H0	**Pre>Post**		**Post>Pre**	
	MAKO	**Conv**	**MAKO**	**Conv**
Walking				
Z value	**-1.66**	**-1.29**	**-3.17**	**-1.29**
Utest **p-value**	**0.097**	**0.197**	**0.002**	**0.197**
Outcome	Ho REJECTED	Ho REJECTED	*Ho not rejected*	Ho REJECTED
Stairs				
Z value	**-0.76**	**-0.76**	**-2.72**	**-2.72**
Utest **p-value**	**0.45**	**0.45**	**0.07**	**0.07**
Outcome	Ho REJECTED	Ho REJECTED	Ho REJECTED	Ho REJECTED

Table 13 indicates that there is no significant similarity between the groups, with walking distance higher for group M both pre and post operatively. For stair climbing, group C is shown to be at a higher level preoperatively, whilst group M ranks higher postoperatively. This is of particular note, as none of the scores for stair climbing changed significantly from pre to post op. Showing both groups to be significantly different in outcome scores for walking, with group M showing a higher ranking both pre and post operatively.

Table 14 shows that there is no significant difference in rankings from pre-op to post, except for group M walking distances. This is indicated to have improved post operatively.

Figure 52 shows the responses of the patients to the individul questions in the knee section of the AKSS. As each group contains 10 patients , the maximum possible result for any variable is 10 and the minimum is 0.

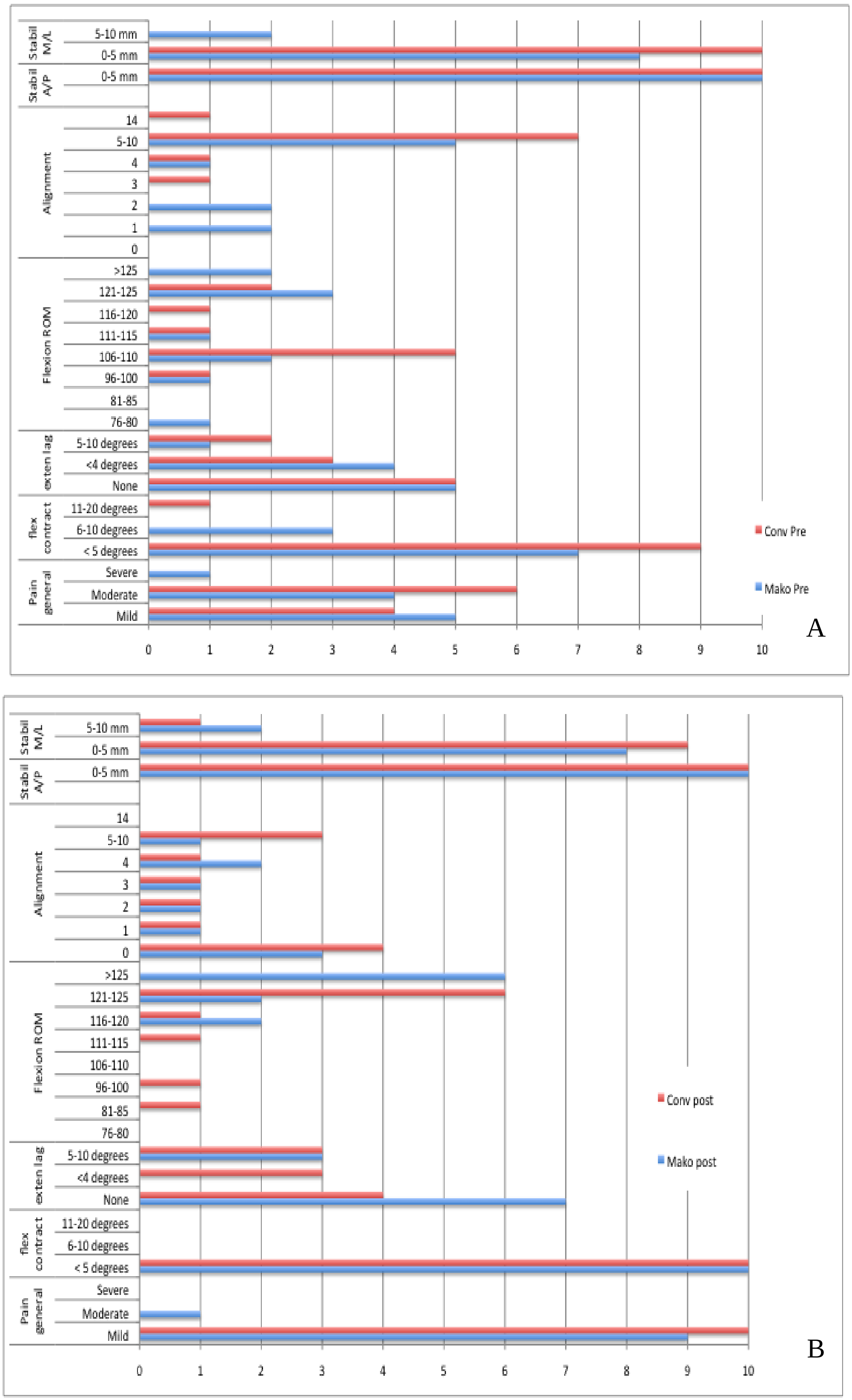


Figure 52: Reponses to AKSS knee questions Prior to (a) and 3-month post (b) surgery.

The bar charts show differing results, for each knee question, from the two groups.

ROM and Alignment are dealt with in sections 8.3 and 8.2. Also, stability A/P is identical for both. Therefore, these questions are not explored further in this section. The other questions from the functional score are assessed in Tables 15 and 16, using the Mann-Whitney U test for statistical diversity.

Table 15 looks at group M and C compairitivly to each other ,while Table 16 shows the comparative of pre to post op significance.

Table 15: p-values AKSS knee M:C (Mann-Whitney U test)

H0	**M>C Pre**	**M>C Post**	**M<C Pre**	**M<C Post**
Pain				
Z value	-1.81	-3	-1.51	-3.78
Utest p-value	0.07	0.13	0.13	**0.0002**
Outcome	*Ho not rejected*	*Ho not rejected*	*Ho not rejected*	Ho REJECTED
Flex cont				
Z value	-1.74	-3.78	-3	-3.78
Utest p-value	0.08	**0.0002**	**0.003**	**0.0002**
Outcome	*Ho not rejected*	Ho REJECTED	Ho REJECTED	Ho REJECTED
Exten lag				
Z value	-1.66	-2.19	-1.29	-3.02
Utest p-value	0.097	**0.03**	0.2	**0.003**
Outcome	*Ho not rejected*	Ho REJECTED	*Ho not rejected*	Ho REJECTED
Align M/L				
Z value	-3.78	-3.1	-2.27	-2.42
Utest p-value	**0.0002**	**0.002**	**0.02**	**0.02**
Outcome	Ho REJECTED	Ho REJECTED	Ho REJECTED	Ho REJECTED

Table 16 p-values AKSS Knee Pre:Post (Mann-Whitney U test)

Ho	**Pre>Post**		**Post>Pre**	
	MAKO	**Conv**	**MAKO**	**Conv**
Pain				
Z value	-0.76	-0.3	-3.78	-2.72
Utest p-value	0.45	0.77	0.0002	0.01
Outcome	*Ho not rejected*	*Ho not rejected*	Ho REJECTED	Ho REJECTED
Flex cont				
Z value	-1.51	-3	-3.78	-3.78
Utest p-value	0.13	0.003	0.0002	0.0002
Outcome	*Ho not rejected*	Ho REJECTED	Ho REJECTED	Ho REJECTED
Exten lag				
Z value	-1.13	-1.81	-1.74	-0.83
Utest p-value	0.26	0.07	0.08	0.4
Outcome	*Ho not rejected*	*Ho not rejected*	*Ho not rejected*	Ho REJECTED
Align M/L				
Z value	-3.78	-2.57	-3.02	-2.57
Utest p-value	0.0002	0.01	0.003	0.01
Outcome	Ho REJECTED	Ho REJECTED	Ho REJECTED	Ho REJECTED

Tables 15 and 16 give very specific information about the following factors:

- Pain;
  - Post-operatively pain is significantly greater in group M
  - Postoperative pain for group M is significantly increases three-month post surgery, when compared to prior to surgery.
- Flexion contracture
  - As both null hypothesis are rejected it can be seen that post operatively the scores for both groups are significantly similar.
  - Pre-operatively Group M has a significantly better outcome scores than group C
  - Group M's preoperative scores are significantly higher than those post-operatively
  - Group C's scores do not change significantly from pre to post op.
- Extension lag
  - Post op scores are significantly similar for the two groups
- Stability M/L
  - No significant difference is recorded for any of the parameters.

8.6: Pain scale

Table 17 shows the average, standard deviation and P-values for both group post operatively and the change in score. The maximum score is 100 and minimum 0 (0 indicates no pain, the higher the score the more pain perceived.)

A negative change in score indicates that pain decreased postoperativly.

Table 17 Scores VAS

	MAKO	**Conve**	**MAKO**	**Conve**
	Post-op	**Post-op**	**Change**	**Change**
Average	16.3	22.4	-27.9	-29.9
StDev	13.4	19.18	19.18	19.18
Ttest P-value		0.42		0.86

This table shows a slightly greater mean improvement in group C, with a wider range of results in group M (standard deviation 17.45 and 29.49 respectively.) Again these results are not significantly different (P=0.86). The mean score post operatively is lower for group M than group C and therefore less pain is experienced by this group.

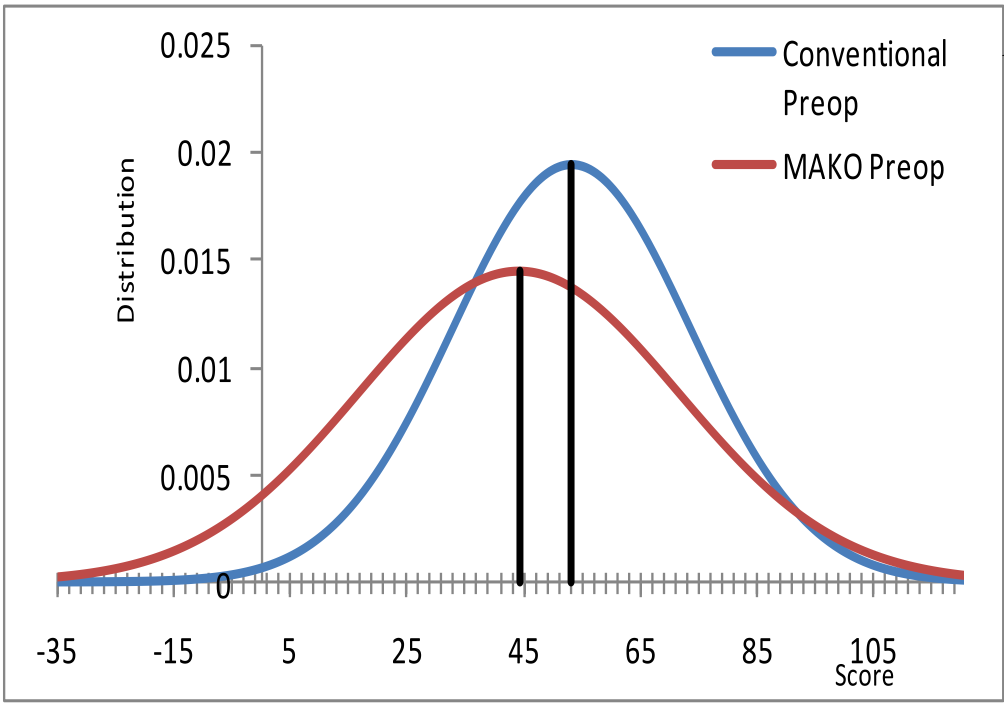
Table 18 shows the p-values derived comparing the preoperative scores to those post operatively.

Table 18: Scores VAS Paired t-test

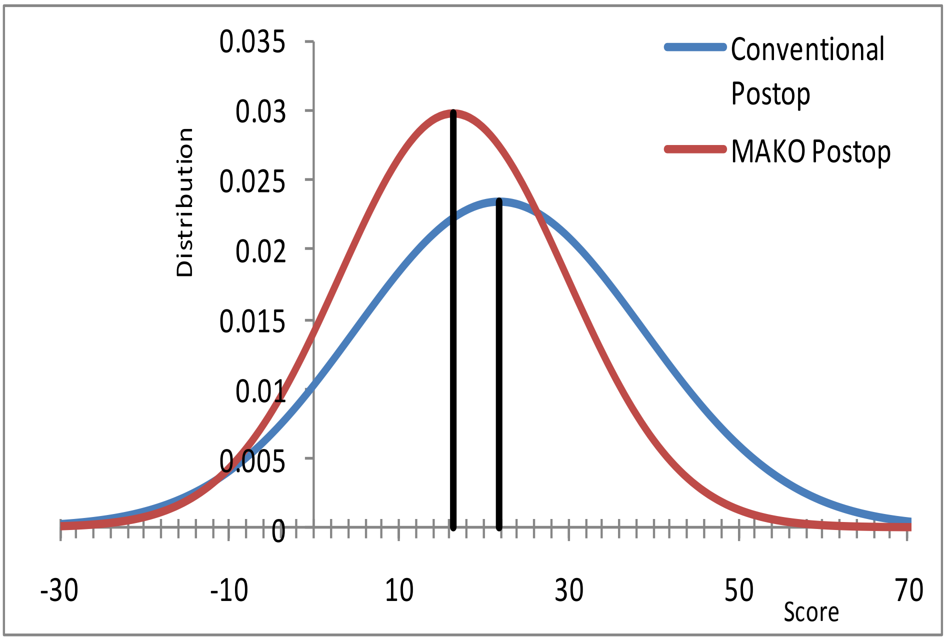
	MAKO	**Conventional**
Paired Ttest P-value	0.02	0.0004

There is a significant change (decrease) in pain scores for both groups from pre to post surgery, showing both surgeries to significantly reduce pain.

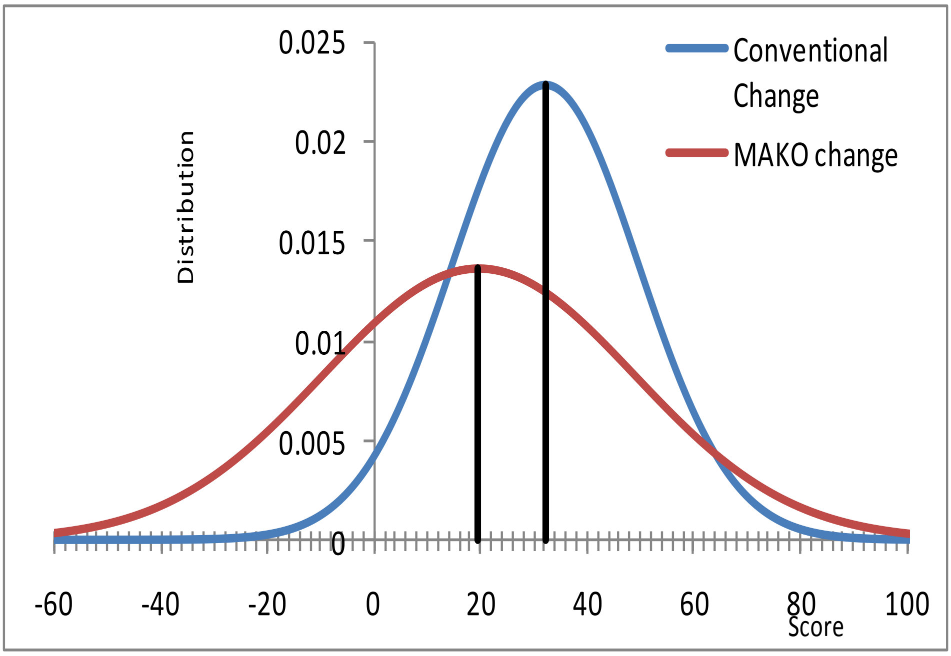
Figure 53 shows the frequency distribution of scores preoperatively (a), post-operatively (b) and change in score (c) for both groups. Negative scores indicate a higher level of pain perceived 3 months post operatively and a zero score indicates no change in pain percieved.



A



B



C

Figure 26: Frequency distribution VAS; Preop(a), postop(b) and change in scores(c)

The graph demonstrates a significant change in scores for group M, showing that the large distribution seen before surgery becomes much smaller after the operation. Graph (c) shows there is a greater range of changes in score for group M, whilst the changes in group C are more centrally distributed.

8.7 PCS

The final scores for the PCS 3-month post operative are compared, average and standard deviation for each is presented in Table 19. Again, negative scores show that the score postoperatively is worse than that preoperatively. The maximum possible score is 52 and the minimum 0. The higher score pertains to a more extreme tendency to catastrophizing pain.

Table 19: PCS scores P values are calculated using the student T-test (unpaired)

	Post-op		**Change**	
	MAKO	**Conv**	**MAKO**	**Conv**
Average	10.5	8.9	7	1.6
Stdev	10.52	9.01	13.43	11.11
Ttest p-value		0.79		0.34

The tables illustrates that there is little variation in the pre and post operative means and standard deviations, with the group C's average only varying by 1.3 points and group M by 4.

Table 20 shows the p-value, produced by comparing group M pre-operatively to post-operatively and group C pre-operatively to post-operatively.

Table 20: p-values comparing pre and post scores

	Mako	**Con**
Paired Ttest p-value	0.13	0.66

There is no significant change in score for either of the two groups.

To evaluate the general perception of pain, Figure 53 shows a box plot comparing the total preoperative PCS scores of group M to those postoperatively . Depicted is the mean value as well as the standard deviation in scores. Figure 54 repeats the process with group C

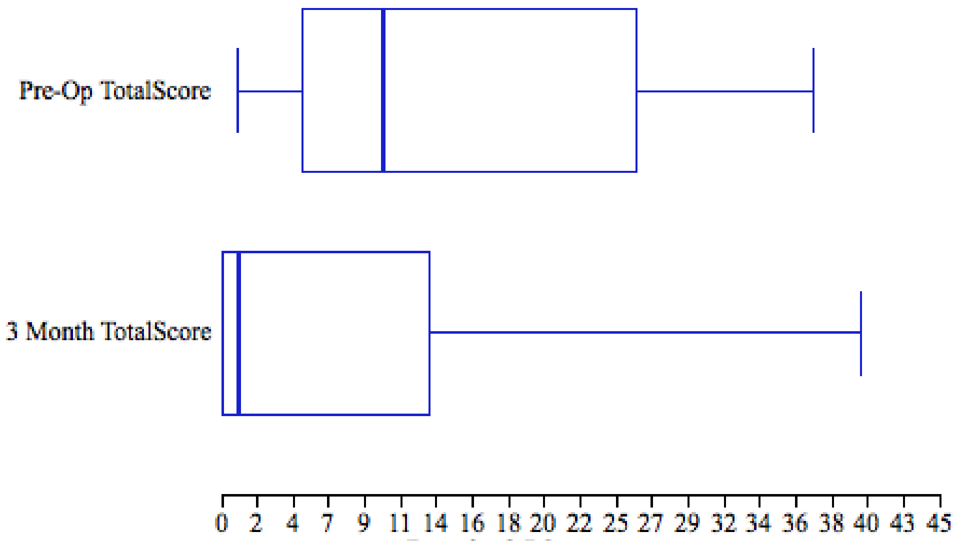


Figure 53: Boxplot of MAKO scores PCS

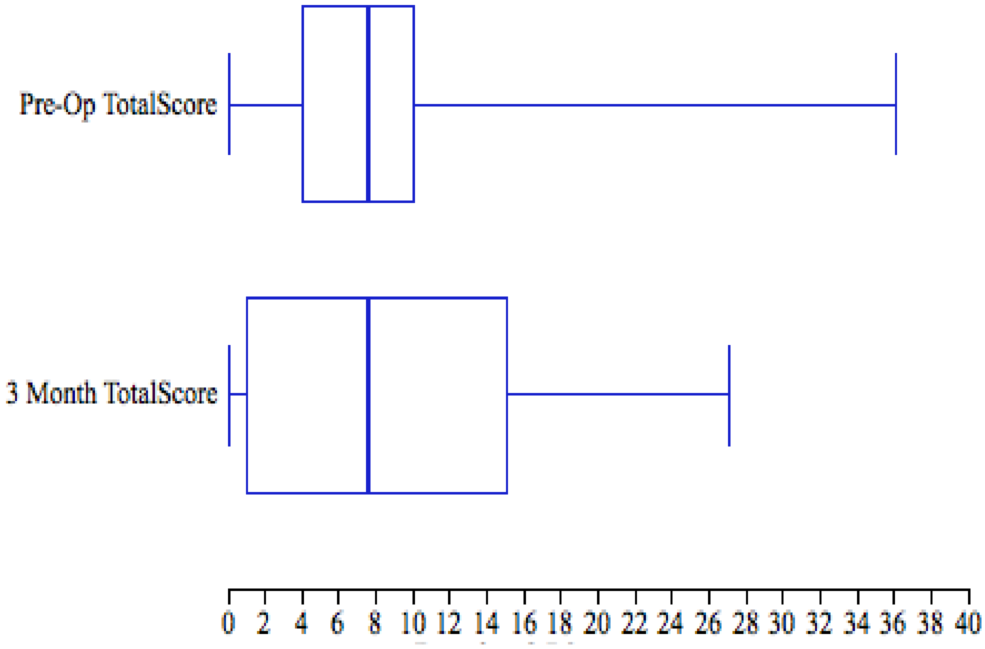


Figure 54: Boxplot of Conventional scores

The boxplots show, that although there is some change the distribution of scores remains very similar post surgery. Group C shows a mean that is almost identical pre and post operatively.

Although group M does demonstrate some change in mean score, the range of scores show no significant difference (p>0.05)

The significantly insignificant change in scores indicates that the possible emotional influence on the other scores recorded is minimal.

8.8 HAD

The final scores for the two sections (anxiety and depression) of the HAD are recorded 3-month post-operative and an averaged and standard deviation for each is presented in Table 21.

Again, negative scores show that the score postoperatively is worse than that preoperatively. The maximum possible score for each section is 21 and the minimum 0. P-values are derived from student Ttest.

The higher score pertains to elevated feeling of anxiety or depression.

Table 21: HAD scores

		Postop		**Change**	
		M	**C**	**M**	**C**
Anxiety	**Mean**	6.8	5.1	0.9	2
	StDev	7.38	3.9	6.69	2.75
	Ttest p-value		0.53		0.64
Depression	**Mean**	6	2.7	0.1	1.2
	StDev	6.82	3.27	5.67	1.69
	Ttest p-value		0.35		0.56

The average improvement in score was 2 points (anxiety) and 1.2 points (depression) for group C (compared to 0.9 points and 0.1 for group M.)

Although the average score for group C is consistently lower, the change in score is seen, in Table 21, to be higher (i.e. greater improvement in mood.) This is also due to the more consistent level of change. The preoperative scores range from -2 to +6 points for anxiety and -2 to 4 points for depression in group C. Whilst, group M has a consistently wide spread range of results.

This large range of different outcomes scores and small sample size effects the significance of the change on results.

The p-values comparing pre and postoperative scores are seen in Table 22.

Table 22: p-values derived from student T-test

		Pre :Post	
		MAKO	**Conv**
Anxiety	**Ttest p-value**	0.68	**0.05**
Depression	**Ttest p-value**	0.96	**0.05**

There is significant change (decrease) in both anxiety and depression scores for group C (when comparing pre to post operative scores.)

The change in anxiety and depression scores for group C shows a significant decrease in levels of these negative emotions.

Figure 53 shows the frequency distribution for group M and group C for anxiety scores ; Pre surgery (a) and post surgery (b) as well as the frequency distribution of changes in score (c)

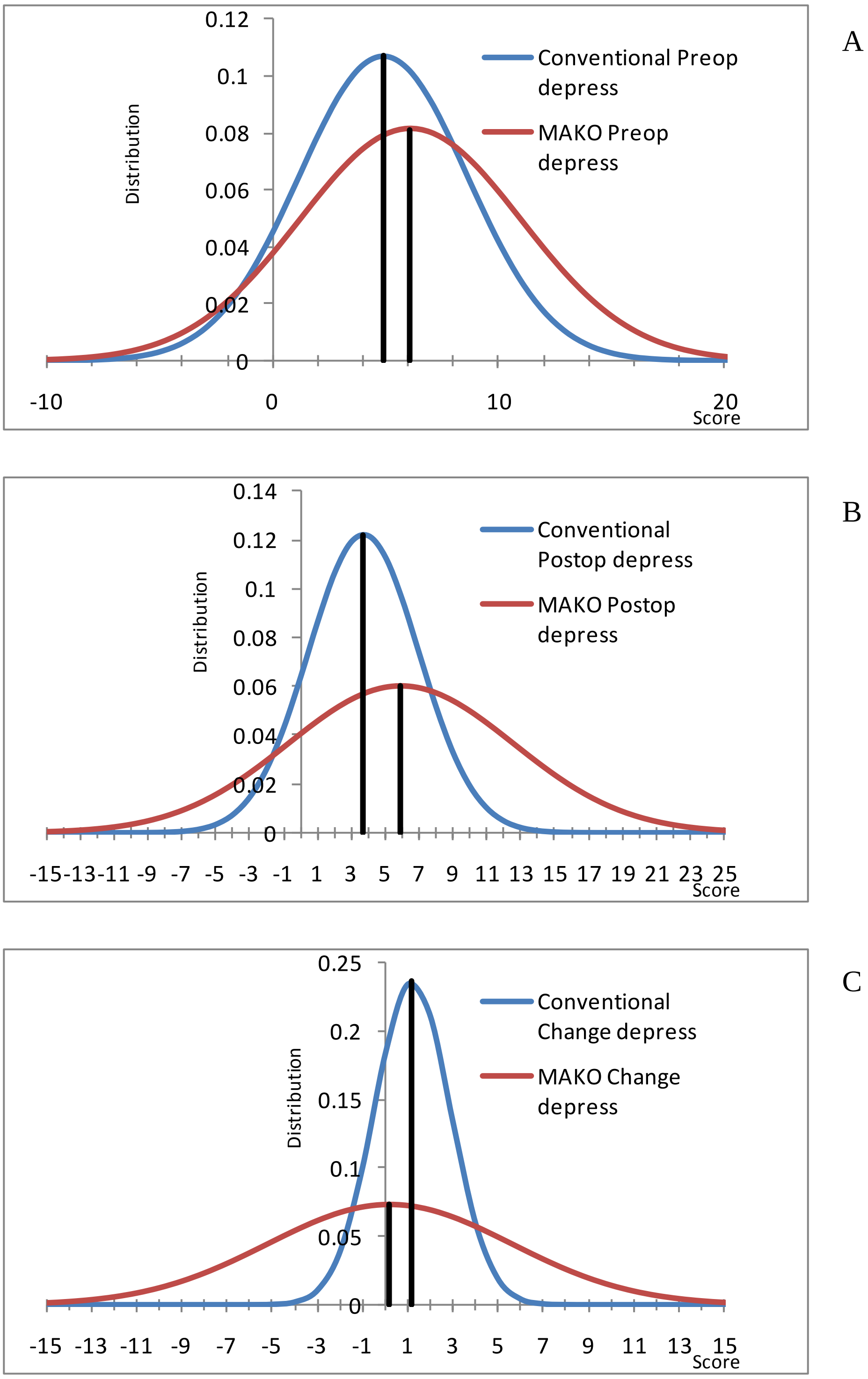
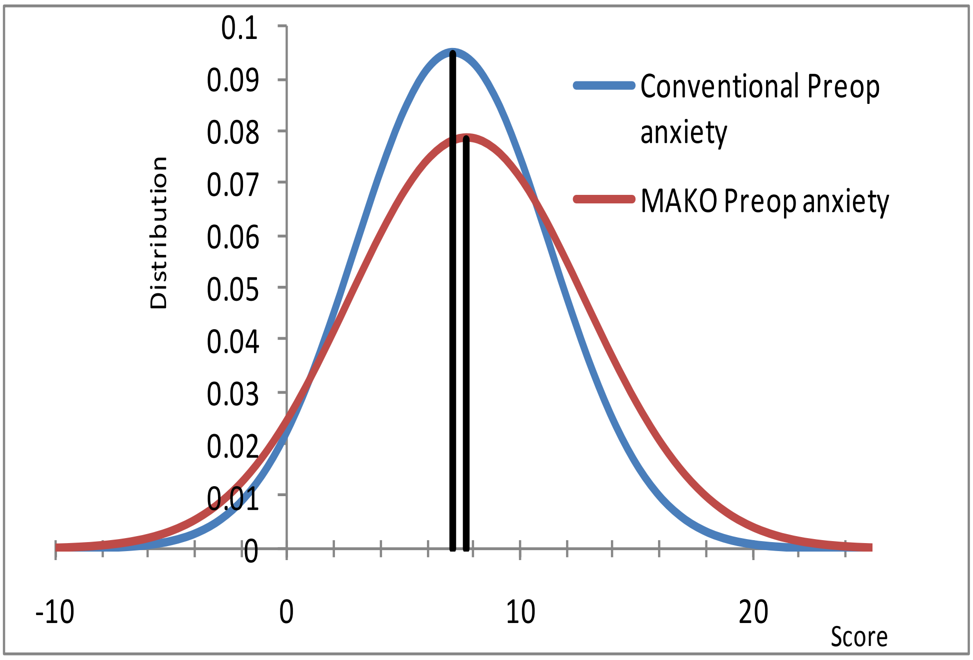


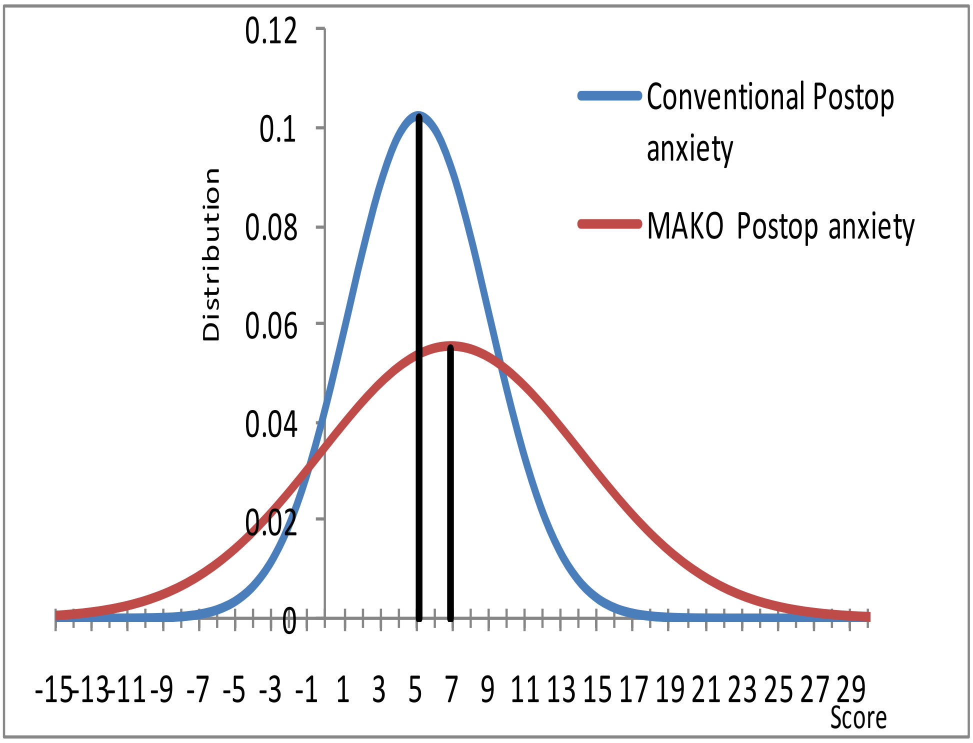
Figure 53: frequency distribution for Depression scores Pre (a), post (b) and the change in these scores (c)

These graphs show that , although the preoperative ranges are very similar, group M shows a much wider distribution post operatively in depression scores.

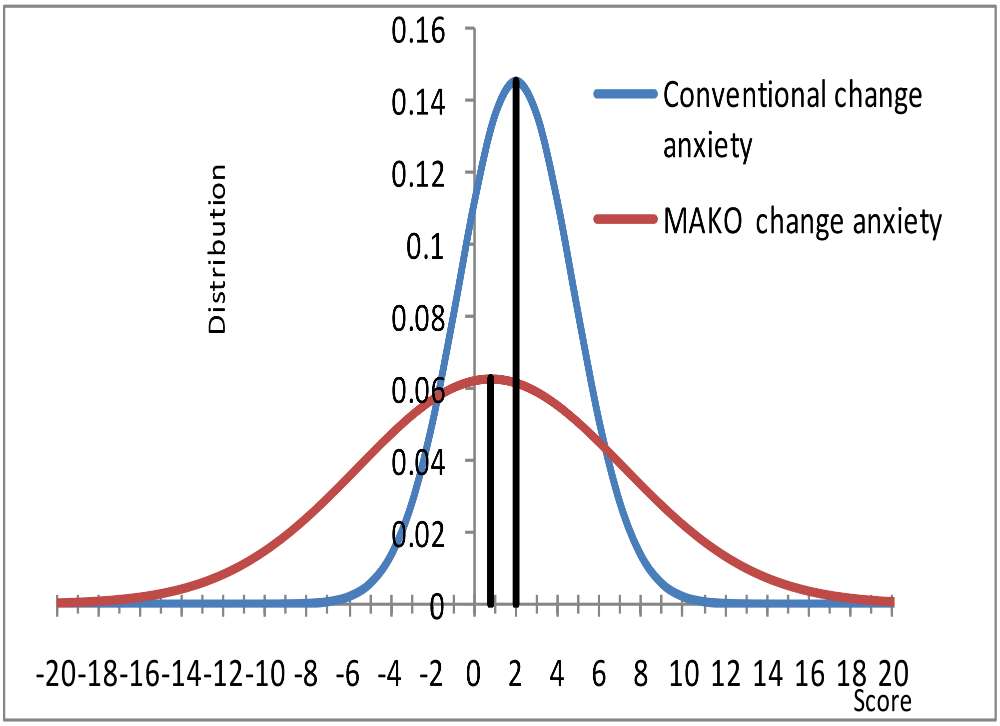
Figure 54 depicts the same frequency distribution for anxiety scores in the two groups.


0.1
0.09
0.08
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0
Distribution
-10
0
10
20
Score
Conventional Preop anxiety
MAKO Preop anxiety

A


0.12
0.1
0.08
0.06
0.04
0.02
0
Distribution
-15 -13 -11 -9 -7 -5 -3 -1 1 3 5 7 9 11 13 15 17 19 21 23 25 27 29
Score
Conventional Postop anxiety
MAKO Postop anxiety

B



C

Figure 54 frequency distribution for Anxiety scores Pre (a), post (b) and the change in these scores (c)

Again, these graphs show that group M has a much wider distribution post operatively in anxiety scores.

Most patients experienced an increase in anxiety and depression, with one patient in group M experienced a 10-point increase in anxiety and 9 points increase in depression. This group also shows the patient with the greatest decrease in anxiety and depression (15 and 13 points respectively)

8.9: Operation times

The average tourniquet time for each group is displayed in Table 23, values are in minutes, rounded to the nearest minute.

Table 23: Average tourniquet time

MAKO total	107
Conven total	66
Ttest Pvalue	1.4348E-07

The mean tourniquet time for group C is 66.3 mins (range from 57 -79 min.) For group M, the mean time is 106.7 mins (range 87-143 mins.) This outcome shows an extremely high significant different between the two groups. The MAKOplasty® takes a significantly longer time in surgery.

Figure 55 shows a Box plot of the range of the tourniquet times along with the mean of the two groups.

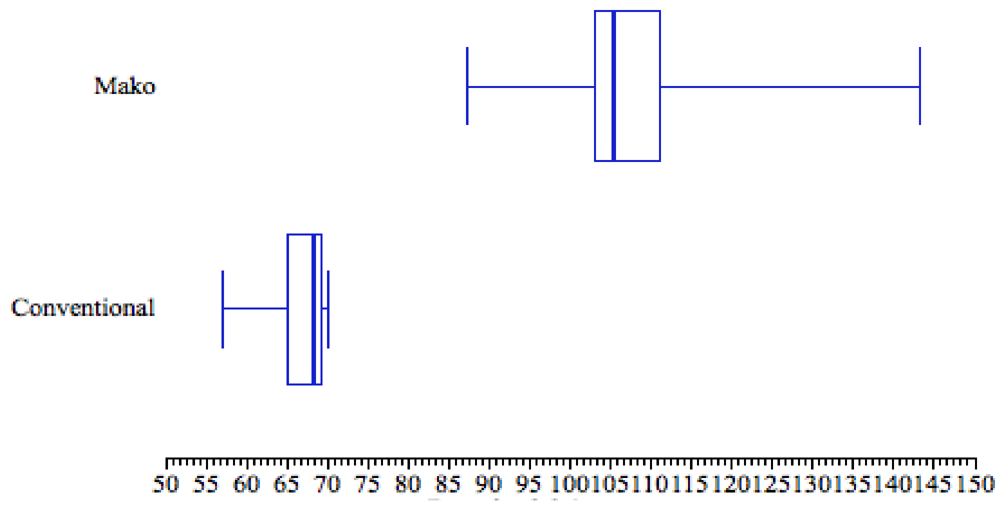


Figure 55: Box plot of tourniquet times.

The MAKOplasty® operation requires the patient to be under anaesthetic for a longer period, due to the initial time taken set up the planning. The question is raised as to whether this extended period of time has negative implications for the patient. There is a distictivly larger range of times for group M than for group C.

The average tourniquet time for each doctor and each group is displayed in Table 24, values are, again, rounded to the nearest minute.

Figure 56 shows a bar chart conveying the information from Table 24. To highlight any differences

Table 24: Tourniquet time specific to doctor

Average time:	Dr 1	Dr 2	Dr 3
MAKO	127	101	105
Conven	67	66	69

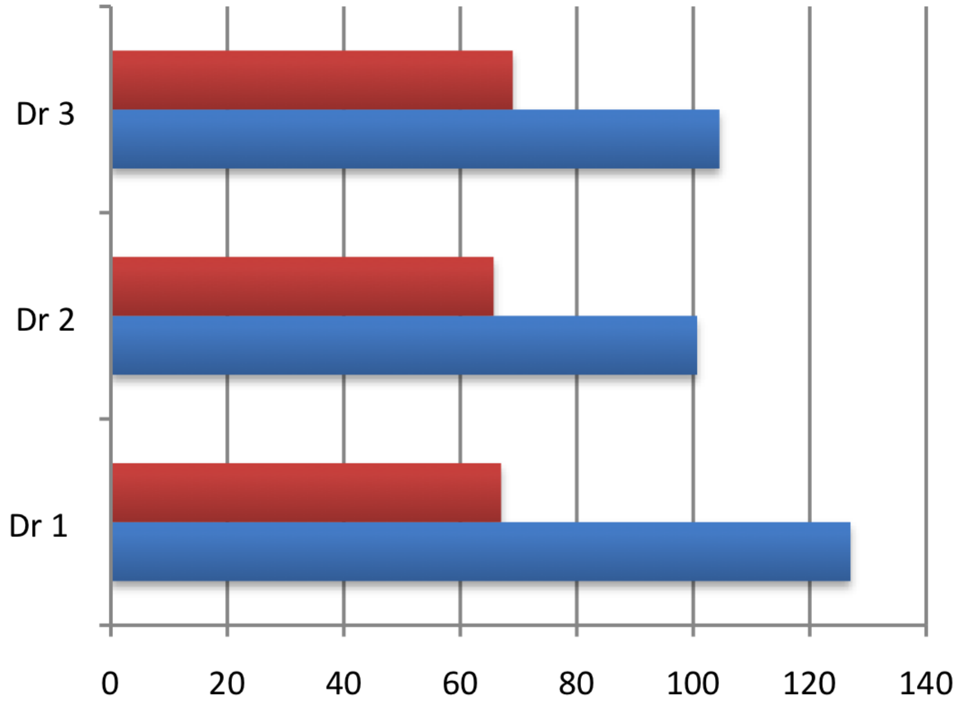


Figure 56: Bar Chart of average tourniquet times per surgeon

Of significant note is the average time taken to complete a conventional UKA was very consistent for all three surgeons, with an overall standard deviation of 4.27 minutes (compared to SD 12.78 minutes for MAKOplasty®.)

As seen from the operation times and the consistency of these times for the conventional surgeries, surgeons experience has a large impact on consistency of time in surgery.

8.10; Length of stay in hospital

Table 25 shows the average number of days spent in hospital for each group and the p-value.

Table 25: Days in hospital

	MAKO	Conventional
Average	2.5	4.1
Ttest Pvalue		0.25

The difference in days spent in hospital is considered statistically insignificant, although the average number of days spent in hospital by group C patients is approximately 1.5 times the length of the average from group M and this has financial implications.

The number of days the patients spent in hospital were either 2, 3, 4 or (in one case) 16 days. Once the anomaly of 16 days is removed from the statistics, the average number of days in the hospital for the conventional group becomes 2.7 days, demonstrating a much smaller difference between the groups.

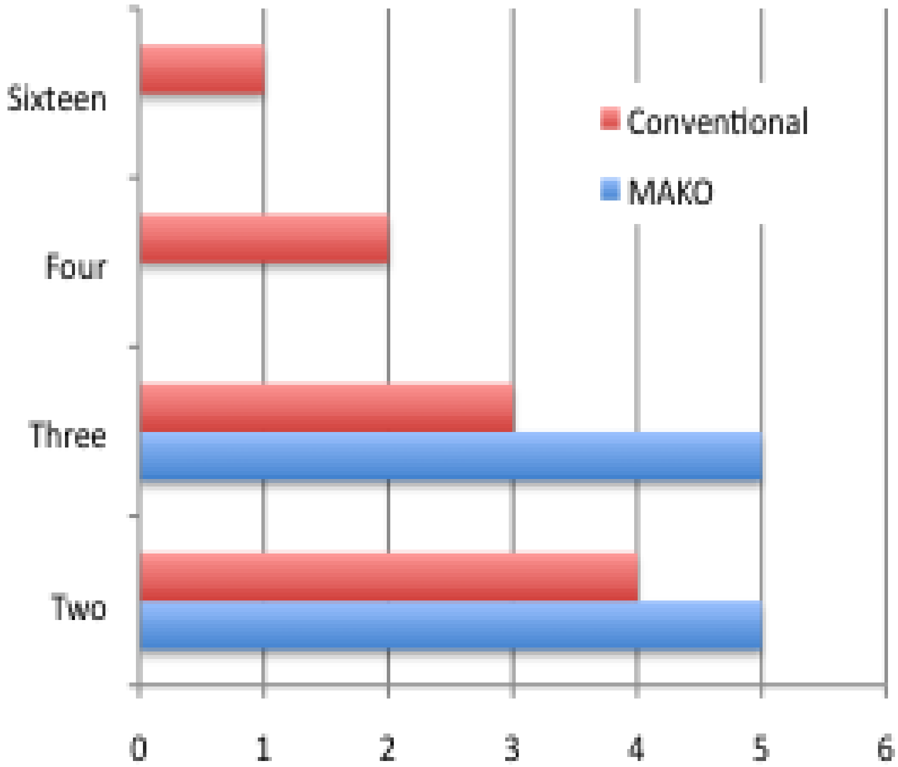


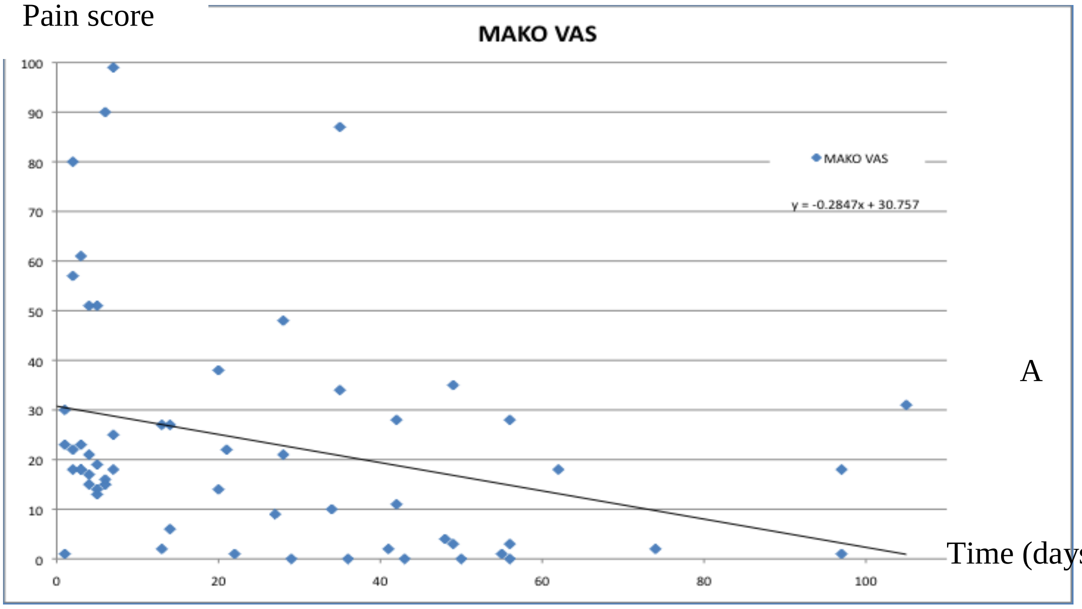
Figure 57: Bar chart, showing number of days spent in hospital

We observe from Figure 39 that all of group M had been able to leave hospital within 2 or 3 days.

8.11: Diary VPS

Figure 58 shows scatter graphs depicting the distribution of pain scores comparative to the number of days post operation of group M (a) and group C (b), as recorded by the patient. The score can range from 0 to100 and a higher score indicates a higher level of pain.

Pain score



Pain score

B

Time (days)

Figure 58: VAS from diary for group M(a) and group C(b)

In the graphs the score are seen to decreases (pain reduces) on average by 0.3 points every day for both groups. Also shown is the correlation of the results is greater the more days that have passed since surgery.

The results show a tendency for the MAKO group to record a greater improvement on a day-to-day basis. This is supported by the p-values for both the overall scores (p = 0.001.)

Change in score refers to the score on the relevant day compared to the baseline score recorded prior to surgery. A positive score shows an improvement, i.e. a reduction in pain and a negative score shows an increase in pain relative to the base score.

Figure 59 shows the results found from the first 7 days by examining the average change in score recorded in the first week postoperatively.

Change in pain score (y)

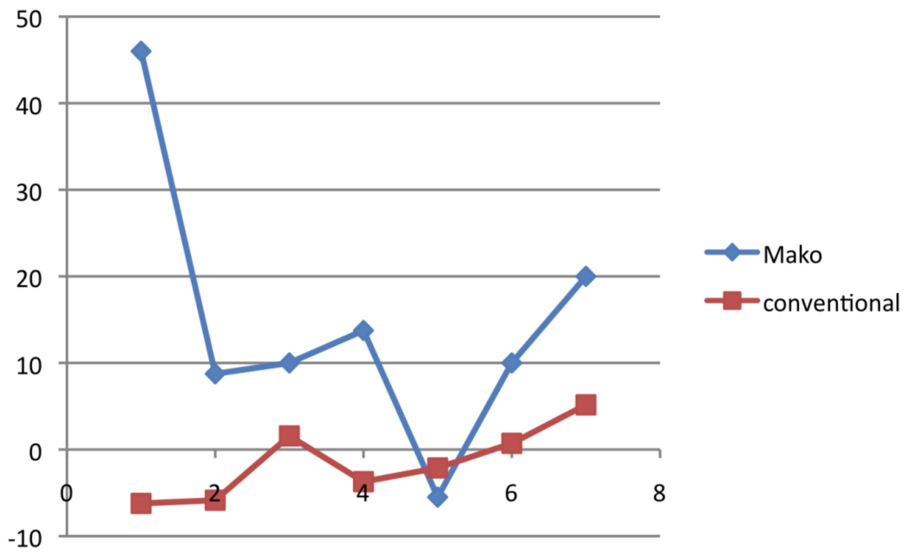


Figure 59: 1st week post operative VAS scores.

The distinction between the groups is clearer and statistical analysis, using the 2-tailed unpaired t-test, shows that the null hypothesis must be rejected ($p<0.05$). If the null hypothesis is changed to state that MAKO improvements would be greater than conventional, a 1 tailed t-test is preformed to prove this difference as highly significant ($p = 0.011$)

The implication is that there is greater improvement seen immediately postoperatively for group M. It was not possible to further analyse diary results at this stage, as many patients were not compliant to completion of the dairy scores.

Chapter 9: Discussion

9.1: Pre operative patient demographics.

Although it is clear that a similar preoperative population is present, this section highlights the effect of the sample size on results. 10 patients are included in each group and as there are 3 more men in the MAKO group than in the conventional group. In a larger sample this would be of less significance. Although it is important to establish a similar population, Ritter and Stringer (1997) established sex of patient has no general effect on outcomes such as ROM.

9.2: Alignment

There greater distribution of alignment deviation values in group M may be influenced by their preoperative distribution.

The importance of alignment has been discussed and the AKSS score awards more points for alignment closer to 0, and normal alignment is considered to be between 5° and 10° valgus. However, the aim of UKA is to correct deformity and place the knee in a natural alignment specific to the patient. If over compensated the wear on the opposite compartment would increase and could lead to further damage. Although a better alignment creates a tighter fit of the articulating surfaces, studies such as Thornhill et al (1986) and Scott et al (1980) discuss the preference for leaving some tibial opening in extension above over correction.

When looking at the other outcome scores of patients who had large deviations from neutral, no notable pattern of high or low outcomes was reported. This implies that in the early stages this has little impact on the outcomes measured. The literature review of previous studies in one study (Ridgeway 2002) states that there is little evidence that undercorrection improves outcome or overcorrection causes progression. However, further investigation into the long term effect of these alignment parameters is needed to assess the full impact on wear rate and patient improvement for the MAKO.

9.3: ROM

3-months postoperation both groups showed improvement in flexion and extension (although for group C these improvements were insignificant.) With group M having a significantly higher maximum flexion angle than group C after the surgery.

Most papers addressing this look at the average total ROM, prior to surgery this range was 110.5 degrees for group M and 108.5 degree for group C. 3 months post surgery the MAKO average total ROM is 127.3 degrees, compaired to 113.5 degrees for the conventional method. This range is often used as there is very limited range of possible extension degrees and therefore a small change can be seen as very significant.

This preoperative average is very similar to that stated in a 10-year minimum follow up (Cartier R. Sanouiller P. Grelsamer J 1996). In this paper the follow up measurement was taken up to 10 years post surgery and is 13 degrees higher than our result. The ROM must therefore be recorded at further interval to identify ROM after maximal recovery.

9.4: OKS

There is a very small difference in the mean OKS score of the two groups, this differences is statistically insignificant. Although both groups experience a significant improvement in score after the UKA.

The Oxford knee score deals with patients ability to perform activities of daily living (ADLs), these result indicate the MAKO group had a marginally lower level of ability to deal with these ADLs, this trend is seen both pre and post surgery. There are however, greater improvements in ADL ability for the MAKO group as an effect of surgery. Further investigation into the true significance of this difference must be preformed to view the early ADL recovery of patients, It would be of benefit to establish if this outcome is reproducable when baseline ranges of the two groups are more correlatory. A long term study would demonstrate whether the MAKO group maintained a higher level of improvement.

9.5: AKSS

As shown, the difference in average score for the two groups is 8 points prior to surgery compaired to 23 after the surgery. With group M recording higher scores consistantly.

The average AKSS score recorded for the conventional group postoperativly is clearly lower that seen in a paper by Luscombe an Lim (2006). However, this score (91.8 knee and 84 function) is given 2 years post operativly and, again highlights the need for a longterm study.

In the breakdown it is again seen the influence of the size of the sample on reliability of significance in results, as a small difference in answers can be statistically different in the calculations. Most responses found no significant difference in the answers. This is consistent with findings in the early study conducted by Lonner et al (2009) in the states, where there was not significant difference in the AKSS scores of MAKO to conventional neither in the total score, nor in the breakdown scores.

9.6: VAS

There is a possibility that the level of pain or lack of pain felt could be different in each group due to the amount and strength of pain killers used. It is also possible that those experiencing a higher level of pain have a lower pain threshold or are over exerting themselves in rehabilitation exercises or ADLs

The patients are asked to notate the exercises they are doing on a daily bases and the medication used. These factors could be cross referenced in later studies to identify any possible significance.

Pain is a subjective parameter, but a very important one for suffers of arthritis. Using the VAS we aim to give a numerical value to the level of pain felt. This has been seen to be an efficient method of measurement for pain. It has also been demonstrated to have a high correlation with quality of life (Boer, et al. 2004) In spite of this, the general public are not accustomed to rating their pain in this way, and it has been shown that at baseline (first use of scale) the association with pain felt (derived from other scales) was low (Boer, et al. 2004). Further to this, it is clear that pain can be affected by many factors on a daily basis. This is the reason the diary questions include a daily recording of the VAS, giving the patient a general reference point for increased/ decreased pain day to day and become accustomed to the concept.

9.7: PCS

There is little variation in the pre and post operative means and standard deviations, with the group C's average only varying by 1.3 points and group M by 4. Also observed is a similar distribution of scores for both groups pre-operatively, demonstrating a parallel population.

Riddle (2009) Shows substantial evidence that the higher the PCs score, the poorer the patient's prognosis. In this study the results reveal no significant change in score for either group ($P>0.05$) from prior to post surgery. This distinct lack in change of scores shows that the possible emotional influence on the other scores recorded is minimal.

9.8: HAD

Most patients experienced a decrease in anxiety and depression, with one patient in group M experienced a 10-point decrease in anxiety and 9-point increase in depression. This group also shows the patient with the greatest increase in anxiety and depression

Although the average score for group C is consistently lower, the change in score is seen to be higher (i.e. greater improvement in mood.) This is also due to the more consistent level of change. Whilst, group M has a consistently wide spread range of results. This large range of outcomes and small sample size effects the significance of the change on results.

These outcomes confirms that anxiety and depression level are generally reduced after the surgery.

9.9: Operation time

This outcome shows an extremely high significant difference between the two groups. The MAKOplasty® takes a significantly longer time in surgery.

The average time taken to complete a conventional UKA was very consistent for all three surgeons, with an overall standard deviation of 4.27 minutes (compared to SD 12.78 minutes for MAKOplasty®.) The average tourniquet time for the oxford surgery is significantly lower than the average (87.4 mins) see in the paper by Pearle et al (Pearle, O'Loughlin and Kendoff 2010).

Time under anaesthetic is believed to be linked to increased risks; the major mechanisms causing death or brain damage are respiratory and cardiovascular (Cheney, et al. 2006). Longer times under anasthetic increase the time period in which this can occur. This could be taken to indicate the importance of experience in use of a specific technique. Statically however, there is no significance in the different amounts of different time taken by each surgeon to perform the MAKOplasty®.

As seen from the operation times and the consistency of these times for the conventional surgeries, surgeons experience has a large impact on consistency of time in surgery. Again, as seen in the initial review by Lonner et al (2009,) these results represent the early learning curve of the surgeons' use of the Mako RIO™. Currently, however it would not be feasible for the MAKOplasty® to be performed by someone who was not previously trained in conventional arthroplasty, due to surgical risks involved. Possible specific training for the MAKOplasty® must be explored for future surgeon training.

9.10: Days in hospital

Group C had one patient who required a longer stay of 16 days. However, the majority of patients stayed only two days. This is consistent with the average of 2.2 days recorded in (Pearle, O'Loughlin and Kendoff 2010), where an early version of the MAKO Rio© was used to perform UKAs.

This is of importance as it establishes that the extra operation time for the MAKOplasty® does not impeded the patients initial recovery and they are able to return to daily life within an average of 2 days.

9.11: Diary

Pain perceived by all patients decreases on average by 0.3 points every day. The correlation of the results is greater the more days that have passed since surgery.

The results show a tendency for the MAKO group to record a greater improvement on a day-to-day basis. This difference is seen more pronouncedly in the first week immediately after surgery.

The patients fill in the diary at their own home and own convenience. This means that the results are dependant on the patients adhering to the schedule of completion and honest response. Patient compliance cannot be guaranteed, and with a small sample of patients any anomalies in results are not clearly defined.

It was not possible to further analyse diary results at this stage, as many patients were not compliant to completion of the dairy scores.

9.12: Correlation of results.

Again, due to the size of the sample it is impossible to draw any clear conclusions from any trends, a general trend for patients to gain ,either constantly high, low or average scores can be fathomed. This could be further investigated in the long term study.

9.13 : Further discussion

N>30 is generally considered a small sample and, with a total of 20 patients this can only be taken as an initial insight into the outcomes.

The small sample size effects the statistical outcome. Once the surgeons are more established in the technique and more patients can be assessed the benefits (or lack there of) of the MAKO system can be better reviewed.

A further point of discussion would be the bias cause by questions presented by the research assistant. As pointed out in the study by Grimes et Schulz (2002) researcher bias can affect the internal validity of the study whilst this must be balanced by the outlined effects of inexperience and continuity (Liow G 2010).

However, as we see from the overall diary results, the variance in results remains the same from preoperative to finally diary score.

A general trend towards 'better' scores for the MAKOplasty® cannot be statistically clarified at this stage. This is, in part, due to the use of a surgery that is new to the surgeons. This, as seen above, produces a wide variation of results, with the MAKO group showing greater standard deviations in most categories.

Chapter 10: Conclusion

The flexion angle for MAKO patients is significantly better postoperatively compared to conventional method.

We must take careful note that the other outcomes show that there is little or no difference in the three-month post operative outcomes for MAKOplasty® compared to conventional UKA. Within this early learning curve for the MAKOplasty® it proves to have equal short term outcomes as the conventional method of UKA surgery.

Currently the Oxford UKA is a significantly faster procedure, with less time for the patient under anaesthetic. This is a factor that may alter with more experienced use of the MAKO Rio©.

However, the results do show promise for the MAKO robot, as the trend in this study is towards a better mean score for the measured outcomes (when compared to Conventional UKA.)

It is necessary to assess more patients in the short-term outcomes and further investigation into the long-term outcomes to truly assess any benefit in the use of the MAKO Rio©. It will also be important to take note of when results (such as operation time) become more consistent, therefore implying a level of experience has been achieved in this surgery. This study forms part of a larger study, which will follow a large group of patients for a total of ten years of follow up.

The overall outcomes show that both methods of surgery gave improved ROM, and functional ability (scores in AKSS and OKS.) As well as reducing pain.

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Appendix

Appendix 1: Knee society score

<u>Pain</u>	<u>50 (Maximum)</u>
Walking	
None	35
Mild or occasional	30
Moderate	15
Severe	0

<u>R.O.M</u>	<u>25 (Maximum)</u>

5°= 1 point

Extension =

Flexion =

Excursion =

Stability	25 (Maximum)
Medial/Lateral	
0-5 mm	15
5-10 mm	10
> 10 mm	5
Anterior/Posterior	
0-5 mm	10
5-10 mm	8
> 10 mm	5
Deductions	
Extension lag	
None	0
< 4 degrees	-2
5-10 degrees	-5
>11 degrees	-10
Flexion contracture	
< 5 degrees	0
6-10 degrees	-3
11-20 degrees	-5
>20 degrees	-10
Malalignment	
5-10 degrees	0

(5°= -2 points)

Pain at rest

Mild	-5
Moderate	-10
Severe	-15
Symptomatic plus objective	0

(Now, total the scores to obtain the Knee Score for the patient.)

Knee Score 100 (Maximum)=

Appendix 2: HAD scale

Hospital Anxiety and Depression Scale (HADS)

1.I feel tense or 'wound up':

Most of the time

A lot of the time

From time to time, occasionally

Not at all

2. I still enjoy the things I used to enjoy:

Definitely as much

Not quite so much

Only a little

Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly

Yes, but not too badly

A little, but it doesn't worry me

Not at all

4. I can laugh and see the funny side of things:

As much as I always could

Not quite so much now

Definitely not so much now

Not at all

5.Worrying thoughts go through my mind:

A great deal of the time

A lot of the time

From time to time, but not too often

Only occasionally

6. I feel cheerful:

Not at all

Not often

Sometimes

Most of the time

7.I can sit at ease and feel relaxed:

Definitely

Usually

Not Often

Not at all

8. I feel as if I am slowed down:

Nearly all the time

Very often

Sometimes

Not at all

9.I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all

Occasionally

Quite Often

Very Often

10. I have lost interest in my appearance:

Definitely

I don't take as much care as I should

I may not take quite as much care

I take just as much care as ever

11. I feel restless as I have to be on the move:

Very much indeed

Quite a lot

Not very much

Not at all

12. I look forward with enjoyment to things:

As much as I ever did

Rather less than I used to

Definitely less than I used to

Hardly at all

13. I get sudden feelings of panic:

Very often indeed

Quite often

Not very often

Not at all

14. I can enjoy a good book or radio or TV program:

Often

Sometimes

Not often

Very seldom

Appendix 3: Oxford knee Questionnaire

How would you describe the pain you usually have from your knee?

None

Very mild

Mild

Moderate

Severe

Have you had any trouble with washing and drying yourself (all over) because of your knee?

No trouble at all

Very little trouble

Moderate trouble

Extreme difficulty

Impossible to do

Have you had any trouble getting in and out of a car or using public transport because of your knee? (with or without a stick)

No trouble at all

Very little trouble

Moderate trouble

Extreme difficulty

Impossible to do

For how long have you been able to walk before the pain from your knee becomes severe? (with or without a stick)

No pain/>30 min

5 to 15 min 49

16 to 30 min 30

Around the house only

Not at all - severe on walking

After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful

Slightly painful

Moderately painful

Very painful

Unbearable

Have you been limping when walking, because of your knee?

Rarely/never

Sometimes or just at first

Often, not just at first

Most of the time

All of the time

Could you kneel down and get up again afterwards?

Yes, easily

With little difficulty

With moderate difficulty

With extreme difficulty

No, impossible

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

No nights

Only 1 or 2 nights

Some nights

Most nights

Every night

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

Not at all

A little bit

Moderately

Greatly

Totally

Have you felt that your knee might suddenly “give way” or let you down? 2

Rarely/never

Sometimes or just at first

Often, not just at first

Most of the time

All of the time

Could you do the household shopping on your own?

Yes, easily

With little difficulty

With moderate difficulty

With extreme difficulty

No, impossible

Could you walk down a flight of stairs?

Yes, easily

With little difficulty

With moderate difficulty

With extreme difficulty

No, impossible

Appendix 4: Pain Catastrophizing Scale

Instructions

We are interested in the types of thoghhts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

Rating	0	1	2	3	4
Meaning	Not at all	To a slight degree	To a moderate degree	To a great degree	All the time

When I'm in pain ….

Number		Rating
1	I worry all the time about whether the pain will end	
2	I feel I can't go on	
3	It's terrible and I think it's never going to get any better	
4	It's awful and I feel that it overwhelms me	
5	I feel I can't stand it anymore	
6	I become afraid that the pain will get worse	
7	I keep thinking of other painful events	

8	I anxiously want the pain to go away	
9	I can’t seem to keep it out of my mind	
10	I keep thinking about how much it hurts	
11	I keep thinking about how badly I want the pain to stop	
12	There’s nothing I can do to reduce the intensity of the pain	
13	I wonder whether something serious may happen	

Appendix 5: Patient Diary

This is a sample of the first section of the diary, the questions are repeated daily for the first seven days and then once a week for the following 7 weeks.

STUDY INFORMATION & QUESTIONNAIRE BOOKLET

MAKOplasty Unicondylar Knee Arthroplasty using MAKOplasty® and the MAKO RIO® System *versus* OXFORD® Partial Knee Arthroplasty

Study ID: ______________

This booklet provides information about the study and will guide you through recording important questionnaire data following your unicompartmental knee replacement. A researcher will visit you on the orthopaedic ward and discuss the questions and how best to fill out this booklet. Further contact details can be found on the back page.

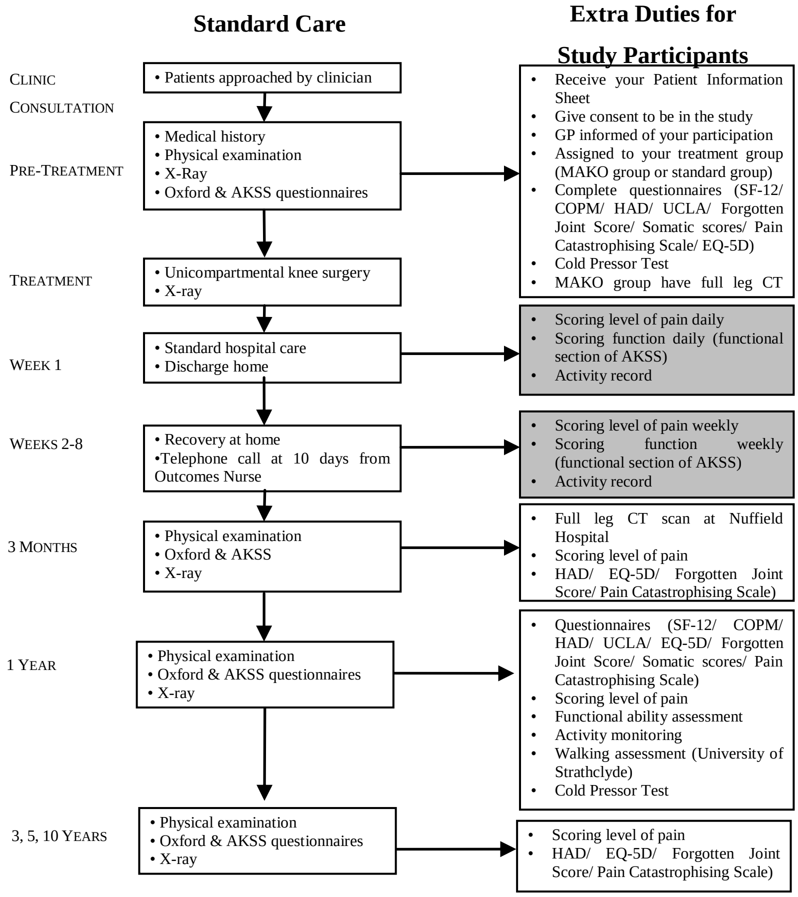
Please return the completed booklet at your 3 month follow-up appointment.

For further information see the trial website:

http://www.glasgoworthopaedicresearch.co.uk/mako.html

INTRODUCTION:

You will have received an information sheet before giving consent to be in this study. This information sheet detailed what is required of you in addition to the standard care you might have otherwise received if you were not in the trial. This is summarised below:



The shaded boxes show the information that is to be recorded in this booklet, using this booklet as a diary of pain, function and activity.

GUIDANCE NOTES:

The following information should be referred to before filling out your diary of pain, function and activity.

PAIN SCORE:

The pain score is a horizontal line which has two extremes labelled “Least possible pain” and “Worst possible pain”. To score your level of pain, you will mark the line at the level which best describes how sore you are. An example of a completed pain score is shown below:

Once you mark the line, the researcher can allocate a score and this will allow your progress to be monitored.

FUNCTION SCORE:

The questions for the function score have been taken directly from the functional section of the American Knee Society Score (AKSS), which you will have completed before your operation. The questions relate to your ability to walk, your ability to negotiate stairs, whether you require walking aids, and what type of walking aid you are using. From the information you give, the researcher will allocate a score and this will allow your functional progress to be monitored.

ACTIVITY RECORD:

For each time you fill out the pain and function scores, there is also space for you to report the types of activity you have been doing and how often. You are also welcomed to briefly note anything which you think might be relevant for the researchers to know.

Range of motion exercise

Static quadriceps hold

'Inner-range' quadriceps

Straight-leg raise

DAILY SCORING:

For the *first 7 days* after your operation, you will be required to record your level of pain and answer some questions on the function of you knee by scoring the functional section of the AKSS questionnaire. This should be done *every day*. The information should represent the best overall summary of how you felt on that day. It is recommended that you complete the diary in the evening, allowing you to reflect on your day as a whole. The pain score and the appropriate questions are laid out in this booklet for you to fill out on a day-by-day basis.

WEEKLY SCORING:

After the first week following your knee replacement, you will continue to record your level of pain and score your knee function, but this will only be required on a *weekly basis*. This should be done from week 2 to week 8 following your surgery. The information should represent the best overall summary of how you felt that week. It is recommended that you complete the diary at the end of that week, allowing you to reflect on your week as a whole. The pain score and the appropriate questions are laid out in this booklet for you to fill out on a week-by-week basis.

SCORING TECHNIQUE:

For each daily or weekly score, record the date in the space provided. Fill out the information as detailed on page 3. When selecting boxes on the questionnaires, please clearly mark a cross within the box. On the function score, make sure you only cross one box for each question. Please answer all questions.

REHABILITATION GUIDE:

Your rehabilitation will be lead by the physiotherapist on the orthopaedic ward.

BREATHING AND CIRCULATION EXERCISES:

Routine deep breathing exercises and circulation exercises are used to reduce complications following any surgical procedure. The circulation exercises include moving the toes and ankles, squeezing the back of the knee into the bed and squeezing the buttocks.

RANGE OF MOTION EXERCISES:

These consist of moving your knee through its full range of motion. This is important to increase and maintain the movement available at the joint after surgery. You will use a re-education board with a 'donut' under your heel and practise bending and straightening your knee.

QUADRICEPS EXERCISES:

These are used to strengthen your knee following your unicompartmental knee replacement. There are three exercises, including static quadriceps holds, 'inner-range' quadriceps exercises and straight-leg raise exercises.

MOBILITY:

Your 'mobility' is your ability to move around. From the first day following surgery it is routine to be out of bed and weight-bearing as tolerated through your new knee. The physiotherapists will lead this and they will progress your mobility with the aim of walking independently with elbow crutches before you go home. Before discharge from the ward, you will also have to ascend and descend stairs.

Day 1, Week 1

Please fill out the pain score and the activity and function questions for today. If you require more information please refer to the guidance notes on pages 3 and 4.

DATE:____________

PAIN SCORE:

Mark the line at the level which best describes your pain today:

LEAST POSSIBLE PAIN WORST POSSIBLE PAIN

Have you had to take any pain killers because of pain in your knee today?

ACTIVITIES:

Put a cross in the boxes to show what activities you have been doing today:

Deep breathing ◻

Circulation exercises ◻

Knee bending and straightening ◻

Quadriceps strengthening ◻

Sitting up in a chair ◻

Standing ◻

Stepping ◻

Walking ◻

Other (please note) ◻

____

FUNCTION SCORE:

For each question please tick one box that best describes your current condition.

(Please note this is an American questionnaire and the first question relating to how far you can walk refers to blocks as distances. 5 blocks is approximately 500m or 550 yards)

Walking

Unlimited ☐

Greater than 10 blocks ☐

5-10 blocks ☐

Less than 5 blocks ☐

Housebound ☐

Unable ☐

How do you go up and down stairs?

Normal up and down. ☐

Normal up, down with rail ☐

Up and down with rail. ☐

Up with rail; down unable ☐

Unable ☐

What type of support do you use when walking?

None used ☐

Use of cane / walking stick	☐
Two canes / sticks	☐
Crutches or frames	☐

PAIN SCORE:___________________

Walking		**Stairs**	
None	☐	None	☐
Mild or occasional	☐	Mild or occasional	☐
Moderate	☐	Moderate	☐
Severe	☐	Severe	☐

WHAT NEXT:

You have come to the end of your post-surgery diary. Thank you for providing us with this valuable information. Please return this booklet to the research staff or outcomes staff at your 3 month follow-up appointment.

We look forward to your ongoing participation in the trial. You can find details of the next stages of your trial participation on page 2 of this booklet.

CONTACT INFORMATION:

Mr Mark Blyth, Principal Investigator, MAKO Trial

Dr Iain Anthony, Research Manager

Department of Trauma and Orthopaedics

Glasgow Royal Infirmary

84 Castle Street

Glasgow

G4 0SF

United Kingdom

Tel: 0141 211 4107

FURTHER INFORMATION:

http://www.glasgoworthopaedicresearch.co.uk/mako.html