The Effect of Modular Stems and Cement Fixation Techniques on the Initial Stability of the Tibial Prosthesis and the Strain Distribution within the Proximal Tibia in Primary and Revision Total Knee Arthroplasty

Alastair J McLean
PhD Thesis
The University of Edinburgh
July 2007 AD

"Success consists of going from failure to failure without loss of enthusiasm."

Winston Churchill

Declaration

I hereby declare that this thesis is composed entirely of my own work, as a member of a research group. Contributions and help from other members of the research group are acknowledged. I have not submitted this thesis in candidature for any other degree, diploma or professional qualification.

Alastair J McLean BEng

Acknowledgements

I would like to express my gratitude to all my co-workers at the Edinburgh Orthopaedic Engineering Centre, for their support, advice and help during the course of my PhD research. In particular I would like to thank Deborah MacDonald, Brendan Hawes, Karl Geisinger, Mark Reeves, Andrew Philips and Andrew Muir.

I would like to thank Mr Colin Howie, Prof. Simpson and Prof. McGeough for all their help and encouragement as my supervisors.

I would like to thank Stryker, UK and Craig Malcolm in particular for their financial and technical support through out this project.

Special thanks and gratitude resides with my girlfriend Ania for her unending support and understanding during my research and writing up. She helped instil in me the determination to succeed and for that I will always be grateful.

Lastly I would like to thank my parents for teaching me that I could achieve anything I set out to, with a little hard work and self belief.

Abstract

AIMS

The primary aim of this thesis was to determine what effect modular intramedullary stems of differing lengths have on the initial stability experienced by the tibial tray and the strain magnitude experienced within the proximal tibia due to the differing modular stems in a primary and revision TKA. The effect of different modes of fixation was also examined. This was carried out with the aid of in-vitro experiments and FE. computer simulations.

NULL HYPOTHESIS

Increasing the length of the implant stem has no affect on the micromotion of the tibial tray relative to the bone surface. Adding a modular stem does not affect the strain distribution within the proximal tibia.

METHODS

Phase 1 – The axial mechanical stability of different tibial constructs were examined under loading measuring both axial migration and micromotion. Primary TKA and revision T2A specimens were studied. Hybrid and cementless fixation with 40mm and 80mm modular stems were specifically looked at.

Phase 2 – A measuring system was designed that allowed the complete implant motion, (both inducible displacements and subsidence), with respect to the tibia to be recorded throughout several thousand in vitro loading cycles in three-dimensions. Primary TKA and revision T1 and T2A specimens were studied. Hybrid and fully cemented fixation with an 80mm modular stem were specifically investigated.

Phase 3 – A 3D FE model of the proximal tibia was created, with special consideration given to the incorporation of a realistic boney geometry, material

properties, and loading patterns to provide an improved analysis of the stresses and strains found in primary and revision TKA. Primary TKA and revision T1 and T2A specimens were studied. Hybrid and fully cemented fixation with an 80mm modular stem were studied.

CONCLUSIONS

Phase 1 – A 40mm or 80mm press-fit modular stem does not enhance initial fixation with hybrid or cementless implantation in either primary or T2A revision TKA. The addition of a modular stem when implanting an uncemented tibial tray may well increase the instability of the construct. Cemented implants with no modular stem have better initial fixation compared to all uncemented implants tested.

Phase 2 –In a primary and revision T2A TKA scenario the addition of a press-fit or fully cemented 80mm modular stem offers no added translational or rotational stability. In the bone impaction grafting group a fully cemented tibial tray with an 80mm modular stem significantly increased the migrational and inducible displacement stability.

Phase 3 – The use of cemented modular stems in primary TKA and simple revision TKA reduces the strains experienced in the proximal tibia and causes excessive strains within the distal cancellous bone at the stem tip. Press-fit stems do not cause significant stress shielding but do cause localised areas of high strain at the stem tip, (which may be linked to patient pain and discomfort). A cemented long modular stem provided the best strain distribution within the proximal graft in the T1 models.

Table of Contents

Chapter 1

Background and Literature Review

1.1 INTRODUCTION

Biomechanics is a vast and constantly evolving field of science which
incorporates the study of internal and external forces and the effect that they
have on and within the human body at both macro and micro levels.
Biomechanics has a variety of applications, such as ergonomics, rehabilitation,
and orthopaedic surgery, however it can be basically defined as "the
interdisciplinary interaction between medicine and engineering". Engineers bring
problem solving and analytical skills as a result of their training, which can be
applied to develop methods and equipment to provide a solution for practical
clinical problems and applications posed to them by clinicians and medical
practitioners.

This project was born out of a clinical question that, Mr Colin Howie, (Consultant
Orthopaedic Surgeon, Royal Infirmary of Edinburgh,) presented to the Edinburgh
Orthopaedic Engineering Centre, "What effect does the length of a central
modular stem have on the initial stability experienced by the tibial tray in revision
total knee arthroplasty, (TKA)?" This project was then developed to examine
experimentally and computationally what effect varying modular stem lengths
and modes of fixation have on the initial micro movement and micro strain
experienced by tibial components in primary and revision TKA settings.

There continues to be an increase in the number of TKAs performed each year
across the globe and in Scotland alone the number of primary knee replacements
implanted increased by 11% from 1999 - 2003 (3104 to 3430)[1]. In general, TKA
is a successful operation with several authors reporting patient satisfaction rates
of 90 – 95%[2,3] and implant survival rates at 10 – 15 years of greater than 90%[4-6].
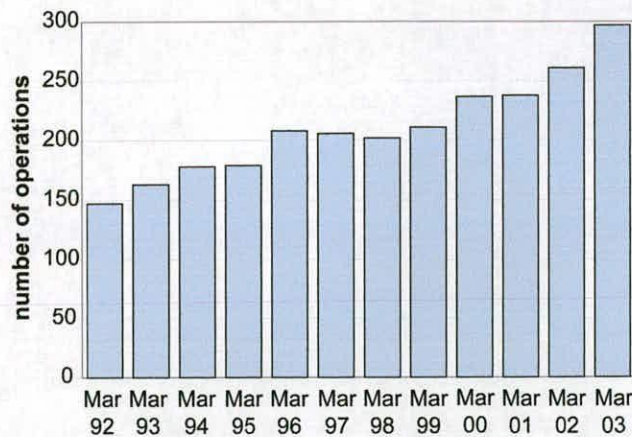
Fig.1.0. No. of Revision TKAs performed in Scotland from 1992-2003, (taken from the Scottish Arthroplasty Project Annual Report 2004).

Despite this, some patients do not fair as well and experience poor early results after surgery. Consequently, as the number of primary TKAs performed annually rises, the number of knee revisions performed annually will also increase. In Scotland the number of revision knee replacements has increased from 211 in 1999 to 297 in 2003, an increase of 41%[1], (Fig 1.0). This trend can also be seen on a global scale. In the United States 5 % of all TKAs now performed are revisions, accounting for over 30,000 operations in 2003. Heck et al[7], reviewed global data for TKAs and reported a global revision rate of less than 3% in first 2 years after primary surgery. Although this percentage is low when one considers the number of TKAs performed globally each year, the number of revisions performed is still a significant amount. Over 22,000 revision TKAs are performed each year in the USA alone[8].

Knee revision surgery carries with it an emotional distress for the patient and their family and the risk of morbidity is not inconsequential. The financial cost of a revision TKA is also not inconsequential, the Ingenix: data analyst group, (1999) put the cost of a revision TKA at $11,922. With over 22,000 surgeries performed in America each year this is a cost in excess of $262 million per annum. When this figure is extrapolated globally the cost is vast. Thus more

work is needed: 1) to understand the mechanisms of primary TKA failure, 2) to correct the causes of failure, and 3) to improve the treatments for failed arthroplasties so that the patient will not have to undergo further revision surgery. As Gofton et al[9] state, at the current rate of revision surgery a significant number of patients will require more than one revision in their lifetime.

In 1982 Cameron and Hunter[10] as well as Bryan and Rand[11] produced studies evaluating the modes of failure of TKAs. Cameron and Hunter[10] reported on a cohort of 94 revision knees, listing infection, polyethylene wear, instability and loosening as the most common causes of failure. Bryan and Rand[11] retrospectively reported on 142 failed knees, reporting loosening, instability and malalignment as the regular indications for revision surgery. In 1978 Lacy carried out a statistical review of a hundred consecutive UCI low friction knees, once again loosening was listed as a concern. These studies have been criticised in the literature for being outdated and perhaps not pertinent to modern implant failure mechanisms. However, in 2002 Sharkey et al[8] reported on a series or 212 revision arthroplasties, citing the three primary causes of failure as, polyethylene wear, (25%), aseptic loosening, (24.1%), and instability, (21.2%). This data shows that loosening is still a common mode of failure in modern TKA. Despite the introduction of newer implant designs, the fixation of joint implants to bone remains a clinical and scientific challenge.

As mentioned previously, the survival rates of cemented TKA have been reported to exceed 90% at 5-15 years[5,6,12]. However, some reports raised concerns over loosening[10,11,13] linked to the use of cement and this gave rise to the development of uncemented knee systems which rely on boney ingrowth for fixation. Cementing provides advantages such as the immediate interlock of the prosthesis which allows early weight bearing[14]. Cement may also compensate somewhat for poor bone quality and deficiency in the bone stock by filling voids

in the bone and increasing the mechanical properties of the bone through increased cement penetration. There are however disadvantages linked to the use of cement including, the development of thermal bone necrosis[15]. This can stimulate a cellular response, (osteoclast activity) which can result in a fibrous layer developing between the bone and the cement, rather than a boney one, thereby resulting in potential loosening.

Cementless fixation theoretically provides strong interface stability between the implant and the bone through osseointegration. This biological stabilisation would not be susceptible to long term fatigue cracking, which can cause issues with cement interfaces such as the production of cement debris which can result in third body polyethylene wear. To achieve good long term biological stabilization, initial secure mechanical stability is vital. Relative motion must be minimised in order to allow boney ingrowth to occur. If early fixation is not achieved micromotion between the bone and implant interface can lead to the formation of a soft tissue layer rather than the desired boney ingrowth[16]. The exact amount of relative motion between the implant and the bone that inhibits bone ingrowth is not known exactly, however it is thought to be around 150 µm. Pillar et al[17] reported that micromotion of 150 µm or greater can result in the attachment of connective tissue ingrowth rather than the desired boney ingrowth, in their dog model. McKellop et al[18] also state that a lack of initial stability can lead to resorption of bone at the implant-tissue interface and can consequently result in loosening and failure of the prosthesis.

As aseptic loosening of the tibial component is a significant cause of failure in both cemented and uncemented TKA[10,19-28], surgeons have introduced a hybrid technique for securing the tibial tray. This method involves using cement on the proximally resected tibial plateau only, and not cementing distally down the tibial component's stem or keel. Hybrid fixation is thought to combine the initial stability provided by fully cementing, while allowing potential for long term

biological stability through boney ingrowth at the stem / keel – bone interface. Some surgeons favour the hybrid cementing technique due to the potential risk of increased tibial bone loss during removal of a fully cemented tray should a revision procedure become necessary. Fully cementing the tray has also been linked to increased stress shielding of the proximal tibia[29].

The current evidence regarding which fixation method provides the optimal fixation is somewhat contradictory. Lombardi et al[30] compared surface cemented versus fully cemented tibial components. They reported that 2 knees required revision from the surface cemented group of 23, while none of the 45 fully cemented tibias required revising. Bourgeault et al[29] in a cadaver study showed that there was no significant difference in micromotion between tibial trays which were fully or surface cemented. However, as mentioned above the fully cemented stems did increase the level of stress shielding experienced in the proximal tibia. Fehring et al[31] reported on 279 TKA revisions that were carried out within 5 years of the index surgery between 1986 and 1990. 37 (13%) had revision surgery because of failure of ingrowth of a porous-coated implant where as only eight of the 279 patients with early failures (3%) had revision surgery because of aseptic loosening of a cemented implant. If all of the arthroplasties in the patients in this early failure group would have been cemented routinely and balanced carefully, the total number of early revisions would have decreased by approximately 40%, and the overall failures would have been reduced by 25%. They concluded cementless knee arthroplasty should be abandoned. In a Roentgen Stereophotogrammetric Analysis, (RSA), series Nilsson et al[14] reported that there was no statistically significant difference between the migration or micromotion experienced at two years between the cemented and cementless prosthesis. From these conflicting reports it is clear that further investigation is required into implant fixation examining the effect each method has on the stability given to the prosthesis and the strain transferred to the underlying bone particularly in the revision scenario.

Regardless of the method of fixation, all of the relevant literature concludes that initial mechanical stability is crucial to obtaining long term survivorship. Ryd et al[32,33] demonstrated using RSA that early instability and continuous migration of the tibial component is a predictor of subsequent clinical failure as a result of component loosening. His clinical observations suggest that prosthesis migration exceeding 2mm at two years post op correlates with implant loosening. Fukuoka et al[34] goes even further and suggests that future migration of the tibial component can be predicted as early as the time of implantation by observing the inducible displacements (defined as the displacement recovered when the implant is unloaded,) produced by applying 20kg on to the implant at the time of surgery. Their results in 28 patients (34knees) showed a significant correlation between the initial stability achieved and the amount of migration experienced by the tray over a two year period, emphasising the importance of initial stability for survivorship. The number of patients studied by Fukuoka et al[34] is small however when his results are taken in context with other larger studies looking at loosening a correlation can be seen. Sharkey et al[8] carried out a retrospective study of all patients who had revision surgery over a 3 year period at the Rothman Institute on 203 patients (212 knees). The results demonstrate the need for secure initial fixation with 16.9% of the revisions carried out in the first two years following index surgery, done for component loosening, with early loosening linked to uncemented components. From the 212 TKA revisions carried out in this study 55.6% were done less than 2 years after the index TKA which may indicate poor initial surgical technique.

When it comes to revision TKA achieving durable long-term fixation of the tibial implant is dependent on the component's initial stability within the host bone[27,35]. Good tibial fixation however is especially difficult in the revision scenario as there is often a lack of metaphyseal bone stock or the presence of boney defects in the proximal tibia. Thus component fixation poses a significant challenge. Poor bone

stock can be due to sinkage of the previous tibial component, excessive loss of bone stock during the extraction of the previous prosthesis or infection. The increased challenges faced during revision surgery are reflected in the clinical results and survivorship data for revision TKA which do not match the results for primary TKA[11,36-38]. These earlier studies were small and involved older styles of prosthesis, a more recent study by Hass et al[21], reported an 83% survivorship at three years. Although an improvement, these figures are still not comparable with primary TKA.

The goal in revision surgery is like that of primary TKA, to attain a pain free stable knee with a functional range of motion. Experience has shown that primary TKA components often prove inadequate in providing the support required in the revision situation[9,39], thus a variety of implants and fixation techniques have been developed to try and combat the problem of loosening. Companies have developed modular revision knee systems, which were introduced to allow the surgeon a range of options when attempting to restore lost bone, reconstruct the joint line and add stability to the knee joint. This is achieved through the use modular augmentations to deal with tibial and femoral bone loss.

Minor defects of the tibial plateau can be dealt with by cutting the tibia lower down to a site with better bone quality, but as cancellous bone strength reduces as you move distally from the subchondral plate[39], this method is not appropriate for defects involving a large loss of bone stock. Larger deficiencies in the bone stock can be treated with metallic augments, bulk allograft or morsalised bone impaction grafting. Smaller deficiencies can also be treated with cement to fill any voids. When repairing defects specifically with bulk allograft or morsalised bone graft, a period of stress-strain protection has been recommended to prevent excessive loading of the graft which could lead to resorption of the repaired site[38,40,41]. Surgeons will often add a modular intramedullary stem to the

tibia in an attempt to provide additional protection, (personal communication, C. Howie).

Manufacturers provide various stems to enhance fixation in revision situations. Variable stem lengths, designed to engage in the metaphysis or diaphysis of the bone in an attempt to secure the implant in better quality bone stock, are commonly offered options. Such stems can be implanted in a press-fit or cemented fashion. Although there is now agreement that use of components specifically designed for revision surgery is essential to improve clinical results and implant survivorship[42], there is no consensus on how best to use the various modular attachments to provide the best stable fixation when faced with varying revision scenarios.

Tibial components are often implanted with modular stems in the revision TKA setting in order to enhance the stability. However, the scenarios where a stem is implemented and the specific fixation techniques used to achieve rigid initial stability vary from surgeon to surgeon. As for in primary TKA the debate between cemented and cementless fixation continues in the revision setting, with some surgeons contending that modular stems should be fully cemented[27], while others advocate uncemented canal-filling stems[9,21]. Concerns over stress-shielding in fully cemented implants and the difficulty in component extraction should another revision be required has lead to hybrid fixation in revision TKA as it did in primary TKA. Although Hass et al[21] reported favourable early results for hybrid fixation, a paper by Vince and Long has suggested that there may be an increased risk of component loosening with highly constrained inserts with press-fit modular stems.

Many surgeons add a modular stem to the tibial tray primarily due to their potential to protect the remaining host bone from excessive stress-strains and component migration[19]. Modular intramedullary stems are thought to guide any migration of the tibial component so that it occurs along the vertical axis, thus

minimising the risk of recurrent malalignment and loosening due to tilting. Experimental studies and clinical data has been supplied to show the justification for the use of stems in aiding stability[43,44].

There are controversies associated with the use of modular stems. Adding a central intramedullary stem increases the components in the system and introduces another possible failure site at the stem tray junction. There is also an increased potential for corrosion, fretting and debris generation[45,46]. Some patients have also reported thigh or shin pain at the stem tip following revision TKA with modular stems[47]. It is thought that stress concentrates at the stem tip, leading to a large force being applied over a small surface area and this may manifest as pain for the patient.

Links with stress shielding of the proximal tibia and the use of modular stems have also raised questions about the effectiveness of their use. Although there is little evidence in clinical follow up data to conclude that stress-shielding is a predominate mode of failure in revision TKA, the effects of modular stems on stress shielding have been identified in finite element, (FE.), and cadaver studies[48,49]. Van Lenthe's[48] findings suggested that a stem which can increase stability initially may reduce stability in the long-term, due to an increase in stress-shielding and bone resorption around the stem tip.

A number of in-vitro studies have looked at the effects of stem length on implant stability. The primary role of a modular stem is to enhance component stability and hence implant survival. However, there are conflicting reports within the literature about the effect of stem length on implant stability. Yoshii et al[50] presented data showing a positive correlation between stem length and implant stability, but Stern et al[51] showed that longer stem implants were associated with increased micromotion.

Although support can be found in the literature for the use of modular stems, there is mixed advice and no specific guidelines exist concerning their use in revision TKA. Many of the in-vitro reports that have examined the effects of modular stems have done so in undamaged bone stock as would be found in primary TKA where in most clinical situations modular stems would not be implemented. There is no consensus on what length of central stem delivers the best load transfer or on the fixation of the stem. Although the use of modular stem extensions have become almost universal in revision TKA, many questions remain unanswered. Is a modular stem required for all tibial revisions? If so what length provides the optimal fixation? Should a stem be used if an augment is incorporated? How does a stem affect the strain within morsalised bone graft, should the stem be fully cemented or press-fit? These are some of the questions where surgeons must rely on surgical experience as there is little evidence in the literature to guide them.

The primary aim of this study was to determine what effect modular intramedullary stems of differing lengths have on the initial stability and the strain magnitude experienced by the tibial tray in a primary TKA and a revision TKA. The effect of different modes of fixation will also be examined. This will be carried out with the aid of in-vitro experiments and FE. computer simulations.

The hypothesis to be investigated is that as the stem increases in length the micromotion of the tibial tray, relative to the tibial bone surface, will decrease in both primary and revision TKA.

1.2NULL HYPOTHESIS

Increasing the length of the implant stem has no affect on the micromotion of the tibial tray relative to the bone surface. Adding a modular stem does not affect the strain distribution within the proximal tibia.

1.3 BACKGROUND

1.3.1 Knee joint Anatomy

A joint can be defined as where two bones meet; the joints hold the skeleton in place and provide the ability to move our limbs. Joints are often the weakest part of the skeletal frame. The knee is a particularly exposed joint in terms of its protection. Although the knee joint may look like a simple joint, it is one of the most complex in the entire body. (Embryologically it is derived from three separate joints). Moreover, the knee is more likely to sustain an injury than any other joint in the body.

The knee is essentially made up of three bones. The femur, which is the largest bone, is attached by ligaments and a capsule to the tibia. Just below and next to the tibia is the fibula, the fibula runs parallel to the tibia. The patella, (the knee cap), rides on the knee joint as the knee bends. When the knee moves, it does not just flex and extend, there is also a rotational component in knee motion. This component has been recognized only within the last 50 years. Indeed the normal motion of the knee involves deep flexion and the complex relationship between the joint surfaces and menisci has only recently been investigated with fluoroscopy.
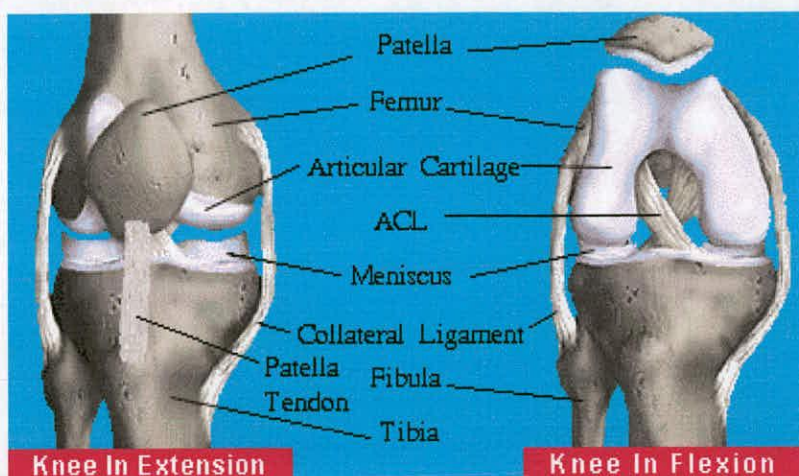
Fig1.1. The anatomy of the knee in flexion and extension

The knee has been classified as a hinge joint but is more accurately described as a four bar linkage. As well as being able to perform a flexion action, in the range of a 145 degrees, the femoral condyles also roll and slide over the tibial condyles. This only occurs when the knee is in flexion. Movement of the knee joint can be classified as having 6 degrees of freedom: 3 translations, including anterior/posterior, medial/lateral, and inferior/superior; and 3 rotations, including flexion/extension, internal/external, and abduction/adduction. Movements of the knee joint are determined by the shape of the articulating surfaces of the tibia and femur and the orientation of the 4 major ligaments of the knee joint, including the anterior and posterior cruciate ligaments and the medial and lateral collateral ligaments as a four bar linkage system.

Knee flexion/extension involves a combination of rolling and sliding referred to as femoral rollback, which allows an increased range of flexion in the joint. Because of asymmetry between the lateral and medial femoral condyles, the lateral condyle rolls a greater distance than the medial condyle during 20 degrees of knee flexion. This causes coupled external rotation of the tibia, which is known as the screw-home mechanism, and locks the knee into extension. These complex mechanisms may be unique to the individual, and the extent of these
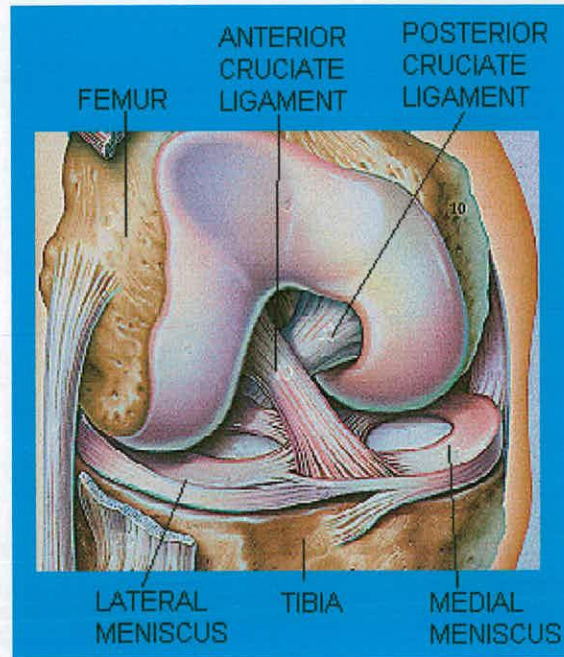
Fig1.2. the orientation of the Anterior Cruciate Ligament and the Posterior Cruciate Ligament within the knee joint.

The main function of the posterior cruciate ligament (PCL) is to allow femoral rollback in flexion and to resist posterior translation of the tibia relative to the femur. The PCL also controls external rotation of the tibia with increasing knee flexion. Retention of the PCL in total knee replacement has been shown biomechanically to provide normal kinematic rollback of the femur on the tibia. This also improves the lever arm of the quadriceps mechanism with flexion of the knee. The other two ligaments found on either side of the knee joint are the medial and lateral collateral ligaments. The primary function of the medial collateral ligament is to restrain valgus rotation of the knee joint, with its secondary function being control of external rotation. The lateral collateral ligament restrains varus rotation and resists internal rotation.

Another characteristic of diarthrodial joints is that they possess fibro-cartilage disc shaped structures called menisci. The menisci allow the femur and tibia, two different shaped bones to sit on top of each other. Without the meniscus, any weight placed through the femur would be concentrated onto a small area on the flat tibial plateaux. This concentration of force on to a small area on the tibial condyles would otherwise cause damage leading to degeneration of the joint. The menisci play a crucial role in joint stability, lubrication, and force transmission. Under a weight bearing load, the menisci maintain a balanced position for the femur on the tibia and distribute the compressive forces by increasing the surface contact area between the two bone condyles, thereby decreasing the average stress by a factor of two to three. The surface stress becomes smaller, the load bearing area wider, the compliance higher, and the stiffness of the joint lowers with the menisci in place. Additionally, the menisci interact with the joint fluid to produce a coefficient of friction that is five times lower than ice on ice. There are also bursae around the knee joint. A bursa is a fluid sac that helps the muscles and tendons slide freely as the knee moves.

POSTERIOR

PCL

LATERAL

MEDIAL

Lateral
meniscus

Medial
meniscus

ACL
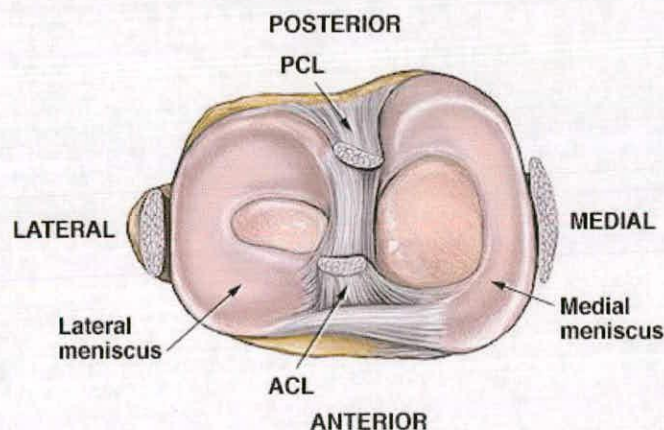
ANTERIOR

Fig.1.3. the position and attachments of the lateral and medial menisci within the knee joint

The bearing surfaces of the knee are covered with articular cartilage, this covers the ends of the femur and tibia, as well as the posterior aspect of the patella. Articular cartilage provides cushioning and ensures a good fit between the meeting surfaces of the femur and the tibia. For the knee to function perfectly,

gradually wears away. It most often affects middle-aged and older people and may be caused by changes in the articular cartilage or sub articular bone.

2. Rheumatoid arthritis (RA). This is an inflammatory type of arthritis that can destroy the joint cartilage. RA can occur at any age. RA generally affects both knees.

3. Post-traumatic arthritis. This can develop after an injury to the knee. This type of arthritis may be similar to osteoarthritis and may develop years after a fracture, ligament injury or meniscus tear.
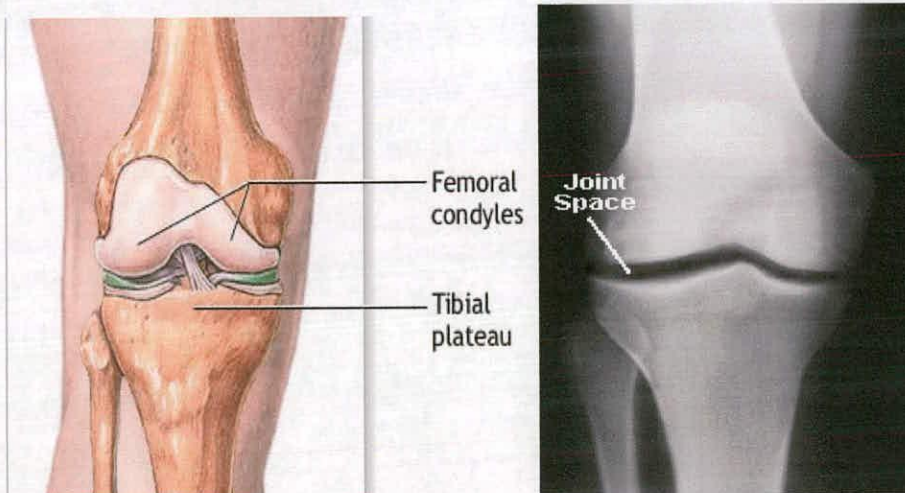
Fig.1.4. A healthy knee joint with intact articular cartilage, no bone spurs and good joint space on the x-ray.

Fig.1.5. A knee joint with severely damaged cartilage, the joint space is reduced on the x-ray and signs of osteoarthritis are clearly present.

In arthritic cartilage, degenerative changes affect the knee cartilage resulting in it becoming, worn, frayed at the edges, and split. This leads to a roughening of the weight bearing surfaces, which in turn can cause changes in the underlying bone. This damage to the cartilage is illustrated in the views shown in Fig 1.5 and Fig 1.6.

Fig 1.4 depicts the appearance of normal, healthy cartilage, and Fig. 1.5 depicts a knee joint with severely damaged cartilage. Bones will attempt to compensate for the damaged cartilage by forming bone spurs. However, the bone spurs can also suffer considerable degenerative changes. This can lead to a complete loss of cartilage, which in turn leads to bone on bone contact, and changes in alignment, which is extremely painful for the patient.

Initially these arthritic joint problems can be dealt with symptomatically, with oral medications, exercise programs, weight reduction and occasionally braces, sticks or ambulatory assistance devices. However when the pain and disability increases to the point where simply standing, walking, and climbing stairs results in severe patient discomfort, surgery is often recommended. The procedure to relieve the pain is known as a Total Knee Arthroplasty, (TKA), this involves replacing the damaged bearing surfaces in the knee with prosthetic bearing

surfaces to reduce the pain. A total knee replacement involves implanting artificial surfaces on all parts of the joint that come into contact with each other as the knee bends. First, the surgeon removes the damaged cartilage, along with a small amount of bone, using precise guides and instruments. The surgeon will then fit implants to both the femoral condyle and the tibial plateau. The implants, usually made of metal, with a plastic spacer in between, provide an artificial surface that causes no pain to the patient when the joint is moved during daily activities.
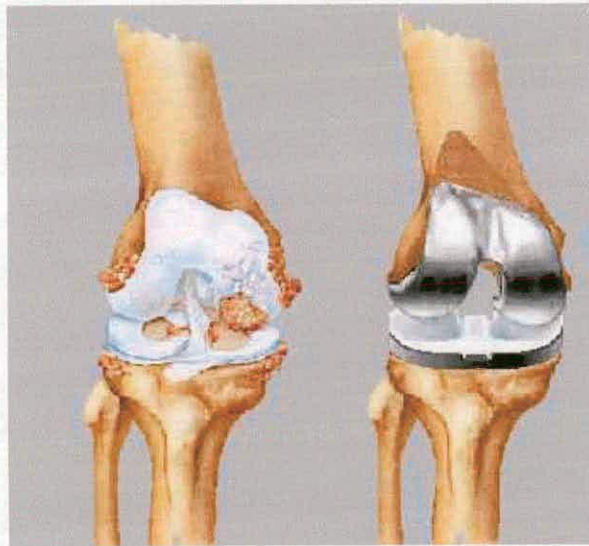
Fig.1.6 a degenerated knee joint, due to arthritis before it has undergone a TKA and the same knee after the implant has been fitted.

the meniscal cartilage, articular cartilage and ligaments must be smooth and strong. Problems occur when any of these parts of the knee joint are damaged or irritated.

1.3.2 Arthritis in the Knee

There are a number of conditions which can cause arthritis of the knee. The term arthritis means inflammation of a joint, but it is used to describe any condition in which there is damage to the cartilage. Inflammation, if present, is in the synovium. The section of cartilage damaged and the extent of the synovial inflammation varies with the type and stage of the arthritis. Usually the pain early on in the condition is due purely to inflammation. In the later stages, when the cartilage is worn away, it is thought that most of the pain comes from the mechanical friction of raw bones rubbing on each other; however the exact mechanism of this pain is not yet clear.

Arthritis of the knee joint can lead to the joint becoming stiff and painful, and can prevent a patient from performing even the simplest of activities. Arthritis afflicts many people and may arise as a result of injury, inflammatory joint disease, mal-alignment of the knee joint or from the accumulated effects of use over many years. Arthritis can affect people at any age, not just the elderly. However, it is more common for problematic arthritis to be present in the older age group. With arthritis, the articular cartilage covering the ends of the bone within the knee joint is badly worn and causes the patient to experience pain in the joint.

There are three broad types of arthritis that can affect the knee joint, they are:

1. Osteoarthritis (OA). This is the most common form of knee arthritis. OA is usually a slow progressive degenerative disease in which the joint cartilage

aforementioned interrelationships have only recently become evident through the use of vector fluoroscopy.

The knee is a diarthrodial joint and as such has no fixed point of contact between the rounded femur condyles and the relatively flat tibia condyles. The stability in the knee comes from the ligaments and muscles attached to the femur, the tibia and the menisci. The knee muscles, which go across the knee joint, are the quadriceps, the hamstrings and the gastronemius. The quadriceps muscles are on the anterior aspect of the knee, and the hamstrings are on the posterior aspect of the knee. The ligaments are equally important within the knee joint as they hold the joint together. There are two cruciate ligaments located in the centre of the knee joint, the anterior cruciate ligament, (ACL), and the posterior cruciate ligament, (PCL). These are the major stabilising ligaments of the knee. The primary function of the anterior cruciate ligament is to resist the anterior displacement of the tibia on the femur when the knee is flexed and to control the screw-home mechanism of the tibia in the extension of the knee. A tertiary function of the ACL is to resist varus or valgus rotation of the tibia, especially in the absence of the collateral ligaments. The ACL also resists internal rotation of the tibia.

1.3.3 History of Knee Joint Replacements

TKA has been performed in some form for over 60 years. However, the complexities of the knee joint were only beginning to be understood around 30 years ago. Due to this, TKA initially was not as successful as the artificial hip, which was first perfected by Sir John Charnley. Early implants were fraught with clinical difficulties, including instability, component loosening, and polyethylene failure along with a limited range-of-motion. The mid-1970s signalled the start of the modern era of TKA, and over the last 30 years dramatic advancements in knowledge of knee mechanics have led to design modifications that appear to be more durable. Designs are now available to reduce the problems that early implants experienced, making TKA an effective treatment for arthritis.

Although the Total Condylar and Kinematic prostheses were effective, long term analyses of the failures that did occur led to an evolution in designs many of which are still the basis for most new designs today. There have also been significant advances in material science, which has enabled designers to experiment with new types and qualities of metals and metal alloys, polyethylene and more recently ceramics, all of which are now used in the prosthesis manufacturing process leading to improved longevity of the TKA. As with most techniques in modern medicine, the envelope is constantly expanding as more and more patients are demanding greater longevity and function after surgery, thus implant technology must continue to evolve to keep pace with the demands placed on a modern TKA and the increasing size of the ageing population.

1.3.3.1 Early Knee Implants

The first artificial implants were tried in the 1940s. These were moulds fitted to the femoral condyles following similar designs in the hip. In the 1950s, tibial replacements were also attempted, but the designs led to problems with the

fixation of the implants, and the patients experienced loosening and persistent pain in the joint.

Combined femoral and tibial articular surface replacements were trialled in the 1950s as simple hinges. These implants failed to account for the complexities of knee motion, which at the time was not fully understood, and consequently had high failure rates from aseptic loosening. They were also associated with high rates of post-operative infection and therefore never really took off as a widespread technique for relieving arthritic joint pain.

The major breakthrough in knee implant design came in 1971, when Gunston[52] recognized that the knee does not rotate on a single axis like a hinge, but rather the femoral condyles roll and slide over the tibia with multiple instant centres of rotation. This lead to the development of the polycentric knee replacement. This design had early success with its improved kinematics over hinged implants, but failed due to the inadequate fixation of the prosthesis to the surrounding bone stock, as this design did not incorporate a stem.

The highly conforming and constrained Geomedic knee arthroplasty introduced in 1973 at the Mayo Clinic ignored Gunston's work, and a kinematic conflict arose leading to implant loosening. Other designs followed, either following Gunston's principle in attempting to reproduce normal knee kinematics or using a conforming articulation to govern knee motion.

The total condylar prosthesis was designed by Insall at the Hospital for Special Surgery in 1973. This prosthesis was designed purely around the principles of mechanics and did not try to reproduce normal knee motion. Ranawat et al[4] reported a survival rate of 94% at the 15-year follow-up in 1993, (the basic design of artificial knee joints has not changed significantly over the past 20 years,) which is the most impressive reported to date. The implant was subsequently altered to introduce normal kinematics to improve the patient's

range of motion. At the same time, prostheses with more natural kinematics were developed at the Hospital for Special Surgery, relying on the retained posterior cruciate ligament to provide knee motion. The debate as to whether knee ligaments should be preserved or sacrificed then started among the surgeons, and continues to this day. Other discussions have also arisen over the years such as whether implants should be cemented or press fitted, but essentially the articulating design for primary and revision TKA is agreed upon by the majority of clinicians although there are concerns about the bearing surfaces and specifically the use of mobile bearings. Thus recent research has concentrated on improving the current designs and the materials used in them rather than radically altering them. This has lead to headway being made in the quest to reproduce the natural gait accurately and to solve problems of polyethylene wear, along with implant loosening, as these are the major cause for revision surgery.

1.3.3.2 Knee Implant design and Construction

Three bone surfaces may be replaced during a TKA: the rounded femur condyles, the tibial plateau and the under surface of the patella. TKA implant components are designed in such a way that metal always articulates against plastic. This provides smooth movement and results in minimal wear to the artificial joint.
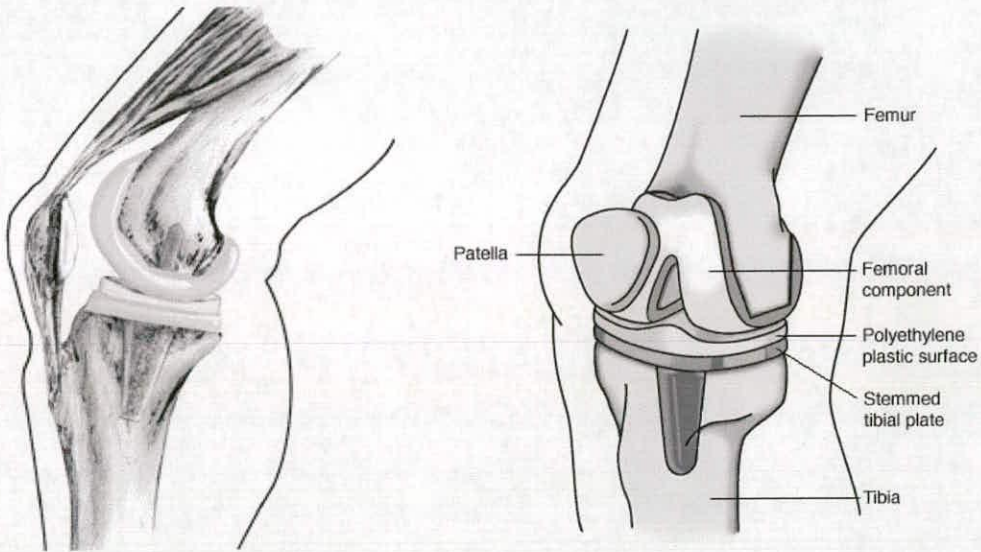
Fig.1.7. TKA components situated in the knee joint

The femoral component, (see Fig 1.7), is made from a single piece of metal which is usually die cast. The femoral component curves around the femur condyle ends and has an anterior groove so that the patella can translate up and down the implant as the knee flexes and extends. Some femoral component designs (posterior stabilized designs) have an internal post with a cam which works with a corresponding tibial component to help prevent the femur from sliding forward too far on the tibia when the knee flexes.

The tibial stemmed component is a flat metal platform, which incorporates a stemmed section for implant fixation, along with a polyethylene spacer. The spacer also acts as a cushion. The polyethylene component may be fixed to the platform or can be a separate component inserted onto the tibial tray. The polyethylene component has either a flat surface, (for when the posterior cruciate ligament is retained during surgery,) or a raised, curved surface (for when the posterior cruciate ligament is removed during surgery). The curved surface adds more stability to the implant.

The patellar component is a dome-shaped piece of polyethylene that duplicates the shape of the knee cap anchored to a flat metal plate. There are more than 150 knee replacement designs on the market today.

The metal components of the knee implant are manufactured from either titanium or a cobalt-chromium based alloy. The most important problem in the complex field of implant design is the issue of wear resulting from the metal parts moving on the plastic component continuously over time and the tiny particles produced by such wear. These particles may cause an adverse response in the surrounding tissue and bone resulting in the implant becoming loose. It has been found that the greatest rate of wear and thus the largest numbers of particles is produced by titanium metal components moving over the plastic (ultrahigh-density polyethylene) component. Thus the rounded femoral condyle section of the implant is manufactured from a cobalt-chromium alloy, as this produces less wear in the replaced joint.

Fig.1.8. A cobalt chrome primary tibial plate, the ultra high-density polyethylene component atop it, the highly polished cobalt-chromium alloy femur condoyle component and the patella section.

primary and revision TKA are so high that the attainment of the perfect design is not yet possible with the materials currently available. Normal kinematics of the knee causes problems in the fixation of implants due to the high loads and the constant movement of the points of application of these loads during the gait cycle. However, a relatively new feature now incorporated into virtually all revision implant tibial components to try and reduce the problems encountered in fixation, is a central tibial stem of varying diameter and length, in order to suit differing surgical requirements. There is now general agreement among clinicians that an intramedullary tibial stem should be used when there is substantial damage to the condylar surface and an augment or bone graft is required to rectify the defect.
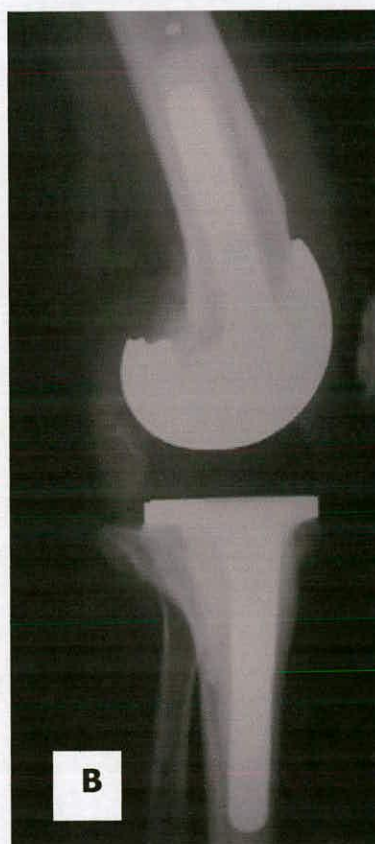
Fig.1.9. A) modular revision components with the ability to add modular stems and augment blocks. B) x-ray of revision components in situ in the knee joint.
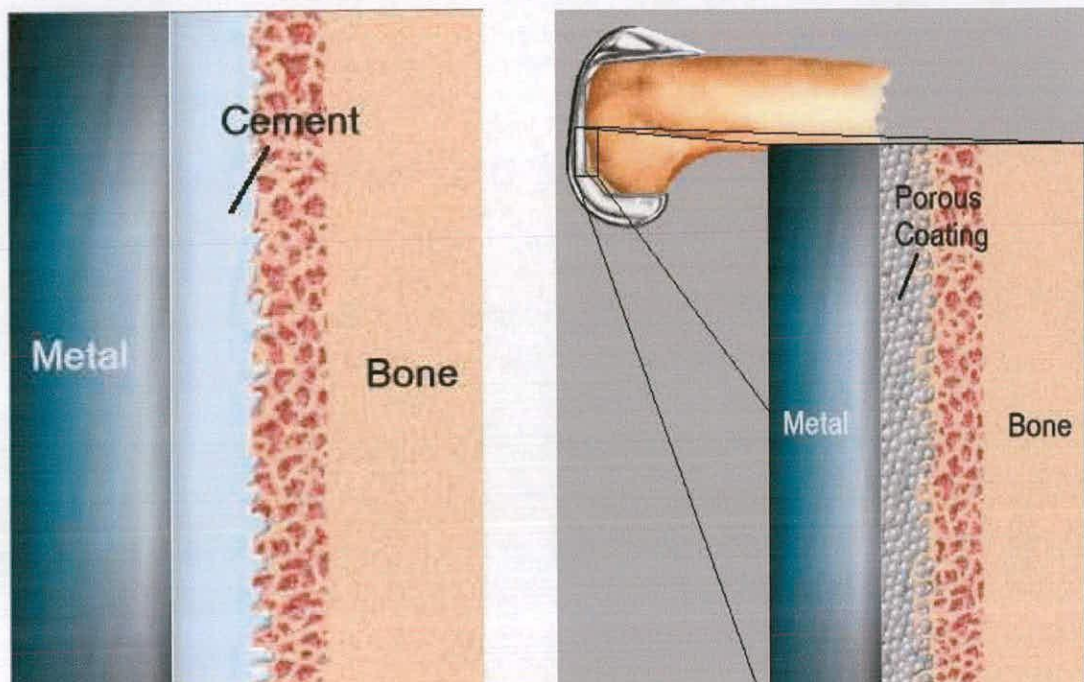
Fig.1.10, The two most widely used methods for interfacing the implant with the bone: 1) Polymethylmethacrylate (PMMA) cement to adhere the metal to the bone or 2) A porous metal surface to create a bone ingrowth interface, a press-fit stem.

To try and achieve the optimal initial stability associated with cemented stems and the secondary stability by osseointegration found in cementless stem fixation, the concept of hybrid fixation occurred. This procedure consists of restricting the application of cement to a 2-3mm mantle over the proximally resected surface only and using press fit modular stems that engage the diaphysis region of the tibia. This method has provided favourable early results[21] and is now in widespread use.

The construction materials used in any biological implant must meet several strict criteria:

1. The implant must be biocompatible with the environment in which it is placed; that is, it must be able to function in the body without causing either a local or a systemic rejection response.
2. The mechanical properties of the implant components must be able to duplicate the structures they are intended to replace; i.e., they must be strong enough to withstand all weight bearing loads, (including those placed through the joint during strenuous activity, i.e. up to 8 times body weight.).
3. The implant must be strong enough to bear stress without breaking, and the component must be able to operate with minimal effort when sliding over each other as required during the movement of the joint. They must be able to retain their strength and shape through out the lifespan of the implant.

To date all the problems of wear and fixation have not been solved in man-made joints. Every time bone rubs against bone or metal rubs against plastic, the friction creates microscopic particulate debris. Just as wear in the natural joint can contribute to the need for a replacement joint wear in the prostheses may lead to fixation and alignment complications that require revision surgery.

1.3.3.3 Mechanisms of Failure in TKA

TKA is becoming a more predictable and routine operation and the number performed each year continues to grow in line with the ageing population of the world. Results of TKA are generally good, with high rates of functional improvement and pain relief after surgery. There are published studies that cite a success rate at the 10-year follow-up stage of more than 90%[5,6,12].

Unfortunately, small subsets of patients do not fare as well and require revision surgery due to post surgery complications. Both patients and surgeons have come to expect superior results following a primary TKA. However, with the demands being placed on these implants is ever increasing in terms of longevity and function. The fact that more active and younger people are now receiving TKAs the long term survivorship of these implants continues to be a problem for some patients.

Traditionally the mechanisms in the artificial knee joint that lead to aseptic loosening, (the main mode of failure in TKA), are failures in fixation of the implant to the remaining bone, problems relating to the stability of the knee, which can lead to malalignment of the prosthesis and failure due to wear of the polyethylene component creating debris that erodes the joint.

Fixation of the tibial tray was the major cause of failure in early knee replacement designs. Most early designs consisted of constrained components, which created huge torsional stresses in the bone cement interface, and led these designs to fail as these forces caused the tibial tray to loosen. Other mechanisms that led to tibial fixation failure were found to be varus / valgus malalignment and poor cementing techniques. Improved surgical techniques, better instrumentation, and the knowledge that ligamentous balancing and equalization of flexion gaps along with retaining a good balance of the surrounding soft tissues are all vital to the overall success of the surgery, and have significantly reduced the incidences of malalignment of the knee components since the early designs.

Cementing techniques have also improved since the early 1970s; better cement penetration into the bony surfaces has enhanced the fixation of tibial and femoral components. In cemented TKA, however, the bond of the cement to the bone can become loose. This loosening results in the micromotion of the prosthesis components, which can result in pain. If the pain or bone loss from

implant micro-motion becomes too severe, a second surgery is sometimes necessary. Due to the problems with cemented components, a method of fixation without using cement was developed. These new prosthesis had a rough surface into which the bone could grow. It was thought that this biological bond between the implant and the bone would be more durable than cement fixation. The problem with this method arose with the initial fixation of the components, as the bone took time to grow into the implant, and if the implant experienced too much micromotion in the early stages after surgery the bone was unable to attach to the implant surface, thus causing failure. It was the introduction of a central stem into implant designs that enhanced the longevity of the cementless method as the central stem reduced micro-motion and improved fixation. However, little work was carried out on the length or shape of the central stem and what effect these variables may have on tibial tray stability.

Polyethylene wear was also a major factor in fixation failure in early implant designs as it was discovered that the contact stresses in the knee joint exceeded the yield strength of the polyethylene. Thus the durability of the polyethylene was the primary factor which limited the longevity of early TKA designs. Delamination and pitting resulted in the plastic components due to the high cyclic fatigue loads which act on the inserts during daily activity. The damaged caused to the plastic inserts contributed to degeneration of the joint due to the debris produced, rubbing against the bone, which in turn causes bone loss as the body produces an osteolytic response. Wear damage to the polyethylene inserts was influenced by both clinical and design factors, designs used today have manipulated these factors in order to minimize wear debris degeneration.

However, it is because these problems still hinder TKA patients today, all be it less frequently and in smaller numbers that surgeons and bioengineers continue to strive to develop new techniques and designs to improve the fixation and wear of total knee implants.

1.4 REVISION TOTAL KNEE ARTHROPLASTY

Total joint replacement is a standard surgical technique employed in the treatment process of various types of damaged and diseased joints (e.g., osteoarthritis, and rheumatoid arthritis.) However a major long-term problem with knee replacement is loosening of the implant components. The bond between the cement and the bone can become loose causing micromotion of the implant and in turn can result in pain. It can also cause a loss of bone and if the pain or bone loss from loosening becomes severe, a second revision surgery is necessary.

As the number of primary knee replacements performed each year continues to grow, so too does the number of patients undergoing revision knee surgery[21]. Revision TKA is becoming an increasingly common procedure. The most common causes for revision TKA are infection, mechanical loosening and instability[8]. Although most patients experience long term pain-free results, a subset of patients do not fare as well, 5-10% of all patients that undergo a primary TKA will require revision surgery within 10 years. With the increasing demands placed on primary and revision TKAs in terms of longevity and function, the problem of failure has manifested itself as a substantial reconstructive challenge for the surgeon. Revision patients present a requirement for a higher degree of technical expertise and suffer higher risks than primary knee replacement patients. It is more difficult to obtain consistent results in revision surgery as component alignment and fixation often present the surgeon with difficulties due to the lack of bone stock, loss of bony landmarks and because of the poor quality of the remaining bone.

In an attempt to improve the quality and consistency of revision TKA new implant designs are continually being developed. The demands placed on the

Thus two defect classifications, one requiring bone impaction grafting, (a T1 defect) and the other requiring an augment, (a T2A defect) were chosen for this study into how the central stem length affects the micromotion of the tibial tray in revision TKA.

Successful revision knee surgery depends on obtaining good restoration of the knee's mechanical alignment in 3 planes, maintenance of the joint line, balance of ligaments and soft tissue, reconstruction of substantial bone loss with metal augments or bone graft and, most importantly, achieving stable fixation at the bone-implant interface with the correct intramedullary stem. This is all designed to enable bone ingrowth to occur, thus providing long term stability for the implant.

There is still some debate however about whether these stems should be press fitted into the cancellous bone or whether cement should be used. Some researchers have shown less micromotion occurs when a stem is cemented, however Albrektsson et al[43] showed that a long cementless intramedullary stem provided the optimal stability for the implant.

1.4.1 Cemented and Cementless TKA

Both fixation techniques have advantages and disadvantages associated with them. Cemented designs rely upon bone cement such as polymethylmethacrylate to give the prostheses adequate fixation. Cementless designs rely on bone growing onto the surface of the implant (bone in-growth) for the required fixation.

1.4.1.1 Cemented Stems

In cemented stems the initial stability of the implant is ensured. Cement is a well-proven fixation method that has been in use for more than 40 years in both hip and knee replacements. The cement creates a supporting layer in the gap between the bone and implant interface. Another theoretical advantage of fully cemented stems is the potential to deliver antibiotics to the site if they are incorporated into the cement. Nevertheless, there are problems associated with its use. Cement is a brittle material with little resistance to the repeated loads experienced by joints. Furthermore, it has little adhesive properties. It simply acts as a grouting agent to fill the gaps between the prosthesis and the bone, thereby helping the bone to support the prosthesis. In the long term, fully cemented stems may be susceptible to fixation failures that are linked directly to the failure of the brittle cement mantle. Fully cemented implant failures are predominantly of mechanical origin, and the mechanical loading and motion of the joint experienced during activity and the extensive stress shielding causes fatigue in the cement mantle. Due to the damage in the cement mantle, cracks originate at the implant-cement interface causing separation of the cement from the prosthesis. This separation results in motion and rubbing between the implant and the cement, which in turn produces wear particles. The cracks created in the cement mantle act as pathways for the wear debris particles to move around in, causing abrasion within the joint. This can trigger a biologic response leading to the degeneration of the surrounding bone. The microscopic debris particles are absorbed by cells around the joint and initiate an inflammatory response from the body. This inflammatory response can also trigger cells to remove areas of bone from around the implant, a process known as osteolysis.

As the mechanical loosening and wear continues, so does the bone loss. The degeneration of the mechanical properties of the cement mantle and the adverse biological effects brought on by the cement mantle debris leads to increasing bone weakening and loosening of the implant increases. This bone loss can cause the patient pain and loss of function and may eventually require revision surgery. Significant bone loss due to this wear process greatly increases the difficulty of the revision TKA and reduces the chance of a successful result.

The major objections of most clinicians to fully cemented stems is the extreme difficulty faced in removing such components without damaging large amounts of bone stock in the event that revision surgery become necessary for any reason other than stem loosening.

1.4.1.2 Cementless Stems

In the 1980s, implant designs were introduced which were intended to attach directly to bone without the use of cement. These designs have a surface topography that is conducive to attracting new bone growth. The stems are textured or coated so that new bone actually grows onto the surface of the implant achieving a secondary stability by osseointegration. The problem occurs if the primary stability of the stem is not sufficient and micomovements prevent the osteointegration process from taking place. This ultimately leads to the aseptic loosening of the implant.

Some designs incorporate screws or pegs that stabilize the implant until bone ingrowth occurs, however these are not always successful. Also, due to the fact that cementless fixation depends on new bone growth for stability, cementless implants require a longer healing time than cemented replacements.

1.5 CLASSIFICATION AND MANAGEMENT OF TIBIAL BONE DEFECTS

Bone loss is commonly encountered during revision TKA. The most significant bone loss is caused by debris generated osteolysis or by aseptic-septic loosening of the components. These processes occur due to malalignment of the implant, infection or trauma, and can all lead to an inflammatory reaction within the joint resulting in resorption of the surrounding bone. Intraoperatively, even more bone stock may be lost if the primary TKA implant is fully cemented as, during the removal of the implant component, significant bone stock may also be removed. Thus the surgeon should always be prepared to find more extensive bone loss than may be apparent on preoperative radiographs. This bone loss can compromise the stability of any revised TKA component; often requiring bone grafts and or augments with stemmed components to restore durable revision implant fixation and knee stability.

Defects may be contained or non-contained. Non-contained defects may be described as circumferential or non-circumferential. A bone defect classification system is a useful tool for surgeons when a revision knee arthroplasty is being planned. The classification system allows the surgeon to effectively define the extent of bone damage from preoperative radiographs, enabling the surgeon to select an appropriate revision system to maximise the effectiveness of the knee reconstruction. In a number of cases the bone damage found can be successfully managed with the aid of modular augments; however custom devices, rotating hinges and allograft impaction grafting with long stemmed components may be necessary when the bone loss is more severe.

A bone defect classification system was developed by the Anderson Orthopaedic Research Institute, (AORI)[53] to provide a rational and easily remembered description of bone loss for use in revision TKA. It is this system which has been

chosen to provide the information for creating the bone defects within the biomechanical bone test pieces as it provides an excellent clear descriptive analysis of the defects. It also provides separate classifications of the femoral and tibial, side thus enabling the accurate creation of the tibial bone defects.

1.5.1 Tibial Bone Loss Classification

The AORI bone defect classification system defines three levels of bone loss. These are as follows:

AORI Type 1, (T1), defects generally range from intact to damaged cancellous bone stock however in extreme cases the cancellous bone stock maybe found to be deficient and in such cases bone impaction grafting would be required. However for a tibial defect to be classified as a Type 1 defect the defect must possess an undamaged metaphyseal segment, i.e. the cortical bone wall must still be intact. A reasonably normal joint line level must also be present. Primary style components may be used for revisions in cases with reasonably intact cancellous bone, however in cases where deficient bone stock is encountered component fixation would be precarious without bone impaction grafting and the addition of a stem to the tibial tray.

AORI Type 2, (T2), defects are most commonly seen when the primary component fails due to loosening. Small areas of osteolysis can often be detected, and again the level of cancellous bone stock may vary from case to case. However, in Type 2 defects the cortical wall is not intact, as subsidence of the tibial tray can result in bone defects on either one or both tibial condoyles. Due to this, Type 2 defects are split into either T2A or T2B defects. The "A" indicates that only one condyle is involved. In T2A defects, bone of the other condyle is relatively undamaged and at a normal joint line level. The "B" indicates that the defect is bicondylar or involves the total tibial plateau. Modular

augments are the most commonly used method of repair in type 2 defects with either wedge or step shaped augments being used in tibial repair. The augments fill the space between the deficient bone stock and the tibial tray, thus restoring a normal joint line. A stemmed tibial component is again recommended in order to control the implant's subsidence in the future.

AORI Type 3 defects commonly demonstrate a deficient metaphyseal segment, large osteolytic lesions along with large areas of bone loss, due to severe component migration or the removal of a fully cemented component from earlier surgery. T3 defects are identifiable by the loss of the trumpet shaped proximal expansion of the tibia. In T3 defects the metaphyseal segment can either be reconstructed using a morsellised or structural allograft and a long stemmed tibial component, impacted cancellous allografts provide a reasonably stable platform in most cases with the aid of a long press fit intramedullary stem or sacrificed and replaced with a rotating hinge or custom made component.
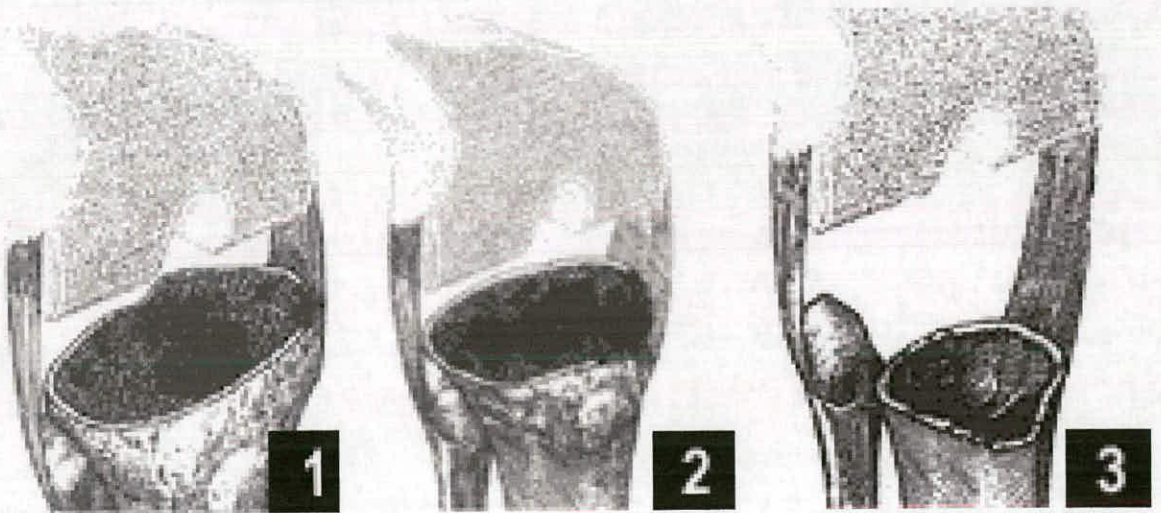
Fig.1.11. All three AORI tibial defect classifications. No.1 shows a T1 tibial defect with only slightly damaged cancellous bone, No.2 shows a T2A defect where the lateral side is undamaged but the medial side has deficient cortical and cancellous bone stock. No.3 shows a T3 defect where there is deficient bone stock on both condyles and thus the tibia is unable to provide any support to a revised implant.

1.5.2 Management of Bone Defects in Revision TKA

Significant bone loss in a revision total knee arthroplasty can pose a complicated and technical reconstructive challenge, as revision knee deformities are usually more advanced and thus insecure fixation occurring is a major concern. Pre-operative planning for revision TKA should include obtaining accurate radiographs that permit both the evaluation of bone loss in the metaphyseal region of the femur and tibia and visualization of the intramedullary (IM) canal to determine appropriate stem diameter and length. Surgeons currently have a number of options for facilitating the reconstruction and repair of these defects including augments, polymethylmethacrylate, (PMMA) cement and bone grafting. Often the final repair technique will depend on the type and amount of bone loss, the age, size and activity level of the patient and the surgeon's experience and comfort levels in using each repair method.

The use of PMMA cement on its own is generally restricted for use in small contained defects such as a simple T1 defect, however cement with screw reinforcements can be used to fill larger defects if the patient is less active and preferably of a small stature. Generally for patients with larger defects and more substantial bone loss the repair would involve the use of either metal augments or bone grafts. These methods are often used in T2A and T2B type defects and are the two repair methods the author will be investigating during the course of this study.

AORI Tibia Classification	Description	Modularity Considerations
T1	cancellous bone defects following removal of primary implant and cement.	Defects may be filled with autograft or cement. Implant will be stable with no modularity if bone loss is not severe. Altering tibial insert restores joint line.
T2A M-Medial condyle (common) L-Lateral condyle	Metaphyseal bone loss from either condyle. Tibial component loosening.	Joint line restored using wedges or blocks with or without structural bone graft. Prosthesis stabilised via a short or long intramedullary stem.
T2B Both condyles	Bone loss from both condyles, one of which extends to the level of the fibular head	Joint line restored using structural bone graft, wedges, blocks, or extra thick tibial inserts. Prosthesis stabilised with a long intramedullary stem.
T3	Extensive metaphyseal cancellous and cortical bone loss.	Joint line difficult to restore. Structural bone graft and long intramedullary stem required.

Table 1.0. Anderson Orthopaedic Research Institute (AORI), bone defect classification and reconstruction considerations in revision TKA.

1.6 HUMAN BONE

Bone is alive, it is a dynamic biological tissue composed of metabolically active cells. As such, the structure and mechanical properties of bone can vary, depending on the biological function and loading applied to the bone, within the human body. Changes to the bone structure are dependent upon the type of mechanical loading the bone is subjected to. Bone adapts to the forces placed upon it and it has been noted, that the bone mineral density, (BMD) increases in bones which are continually experiencing higher loads (i.e. the bone hypertrophies) and decreases with disuse, (i.e. the bone atrophies)[38,54,55]. This

process can cause problems when implants replace the natural joint, as often joint replacements change the loading patterns experienced by the surrounding bone[56]. The loading of the bone usually decreases as more force is directed through the implant, this is known as stress shielding. In some instances this can cause the bony support to atrophy, which in turn can lead to the loosening of the implant due to a lack of quality bone to support the prosthesis. At the other end of the scale overloading of the surrounding bone leads to necrosis, (cells die due to physical damage), and subsequent resorption of the surrounding bone stock[56]. Bone resorption is a process which is characterised by the formation of fibrous tissue between the bone and the implant. This fibrous tissue allows relative motion between the bone and the prosthesis to occur, hence the loosening of the implant. The structure and mechanical properties of bone can thus alter due to a biological process which is triggered by the body. The process is known as bone remodelling, and occurs continually within the human body, repairing damaged and replacing aging bone with new healthy bone.

1.6.1 The Bone Remodelling Cycle

The bone remodelling cycle has two basic stages, the first is bone resorption and the second is bone formation. During the bone resorption phase, cells called osteoclasts invade the bone surface and erode it, dissolving the older bone minerals and releasing them into the blood stream in order to satisfy other bodily needs. The space created by the eroding of old bone cells provides the room for newer mineral deposits to be made. During the bone formation phase, bone forming cells called osteoblasts begin to fill in the cavity created by the osteoclasts by depositing newly formed bone.
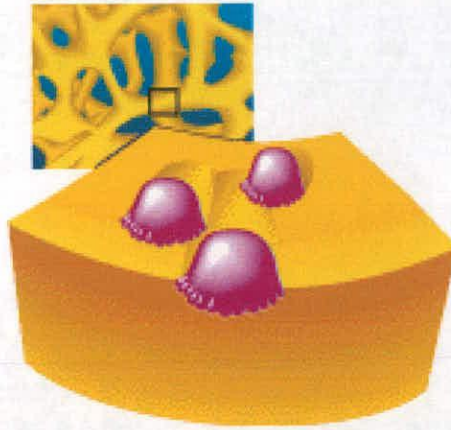
Fig.1.12. During bone resorption, osteoclasts invade the bone surface and attach to the mineralized bone matrix and excavate small pits on the bone surface, releasing broken down products and minerals in the circulation.
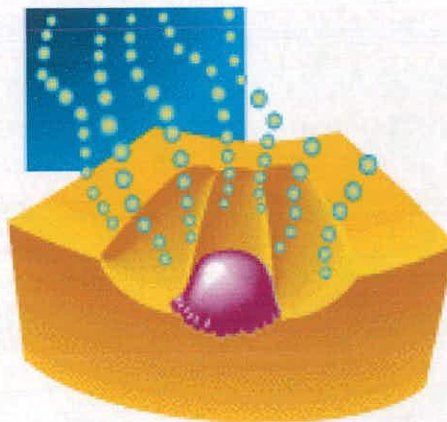
Fig.1.13. Cross-linked N-telopeptides (NTx) are released into the bloodstream during osteoclastic activity, small cavities are created in the bones surface and the resorption phase is complete.
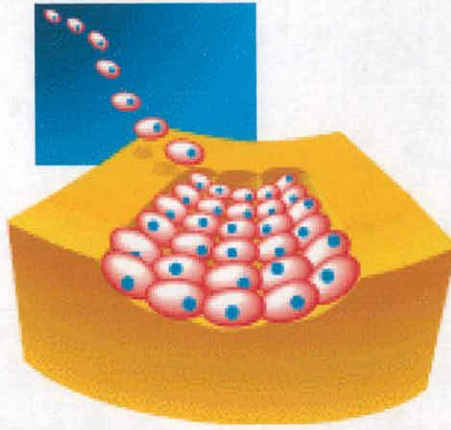
Fig.1.14. During bone formation, osteoblasts are recruited to the newly resorbed areas on the bone where they begin to fill in the cavity with new bone.
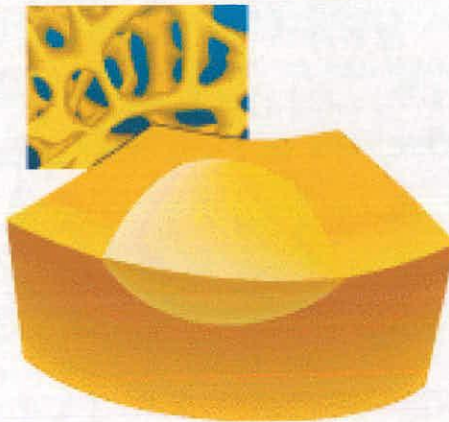
Fig.1.15. The bone surface is completely restored. When resorption and formation are in balance, there is no net change in bone mass. After a resting phase during which the bone is mineralized, the remodelling cycle begins again.

1.6.3.1 Cortical Bone

Cortical bone represents nearly 80% of the skeletal mass; it has a dense structure, and always constitutes the exterior of bone. Cortical bone forms a protective outer shell around every bone in the body. It has a slow turnover rate and has a high resistance to bending and torsional forces. Cortical bone is predominant in the Appendicular skeleton (the limbs), and is responsible for the skeleton's strength. It provides strength to the bones where bending and rotation would be undesirable, e.g. in the middle of long bones such as the femur. Cortical bone has three layers: the Periosteal layer (the bones outer surface), the Intracortical layer (the middle layer), and the Endosteal layer (the layer found next to the bone marrow cavity). Within cortical bone there are neurovascular channels known as "Haversian canals" or osteonic canals. These canals transport nutrients to the surrounding bone stock. Cortical bone mainly consists of Collagen (a protein) and Hydroxipatite (Calcium phosphate salts).
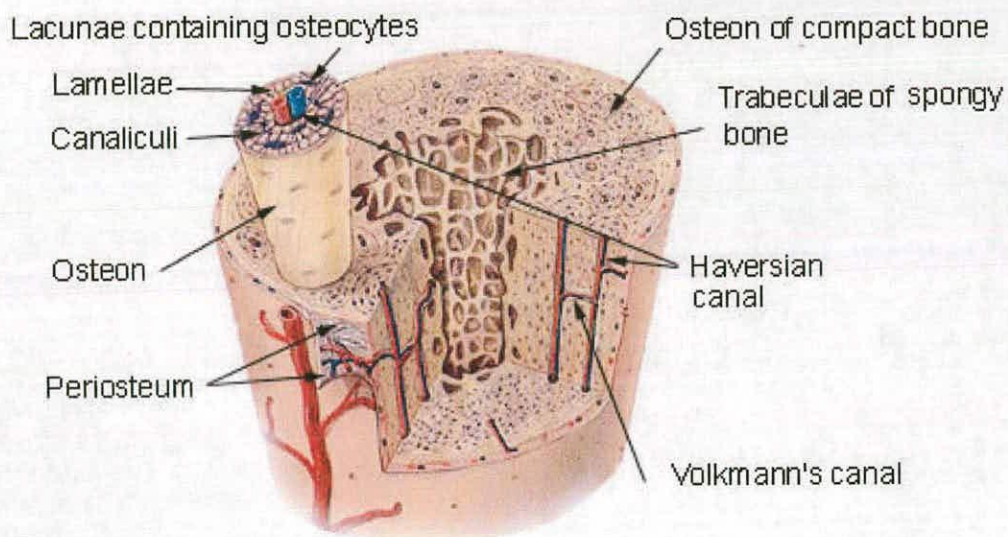
Fig.1.17. Depicts the basically solid structure of cortical bone with the spaces for blood vessels, ostecytes, and canaliculi.

Usually without the removal of old bone by the osteoclasts new bone formation by the osteoblasts does not occur, the processes work in a partnership. Hormones regulate the remodelling process. However as we age and our bones stop growing, the bone reformation equilibrium is thought to become impaired. The balance becomes disproportionate resulting in more bone being removed from our bodies than reformed, so gradually the bones become weaker and more prone to fracture, leading to increased human frailty with age. The imbalance is more pronounced in elderly women who have gone through menopause.

1.6.2 Human Bone Composition

Bone is composed of organic and inorganic elements. By weight, bone is approximately 20% water[57]. Bone is made up of inorganic calcium phosphate (65-70% of the weight) and an organic matrix of fibrous protein and collagen (30-35% of the weight)[58]. Osteoid is the unmineralized organic matrix secreted by osteoblasts. It is composed of 90% type I collagen and 10% ground substance, which consists of noncollagenous proteins, glycoproteins, proteoglycans, peptides, carbohydrates, and lipids. The mineralization of osteoid by inorganic mineral salts provides bone with its strength and rigidity. The inorganic content of bone consists primarily of calcium phosphate and calcium carbonate, with traces of magnesium, fluoride, and sodium. The mineral crystals form hydroxyapatite, which precipitates in an orderly arrangement around the collagen fibres of the osteoid. The initial calcification of osteoid typically occurs within a few days of secretion, but is finally completed over the course of several months.

1.6.3 The Structure of Human Bone

The skeleton comprises of two differing types of bone, these are cortical bone, (also known as compact bone), and trabecular bone, (also known as cancellous bone.) Cortical comes from the Latin term that means "bark" as in the bark of a tree and trabecular comes from the Latin word "trabs" meaning beams or timber. Cortical bone is basically a solid, and the little voids it does have are for blood vessels, ostecytes, canaliculi, and erosion cavities. However, cancellous bone has large voids present in its structure, and the difference between the two types of bone is clearly visible to the naked eye.

Trabecular bone
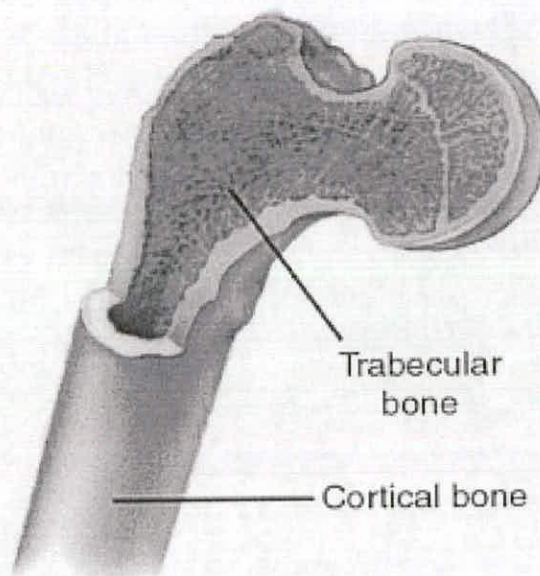
Cortical bone

Fig.1.16. A cut away view of a human femur, depicting clearly the regions of cortical and trabecular bone.

1.6.3.2 Trabecular Bone

Trabecular bone (also known as cancellous or spongy bone) only represents 20% of the skeletal mass, but represents 80% of the bone surface. Trabecular bone is less dense, lighter, more elastic and has a higher turnover rate than cortical bone. It is found in the epipheseal and metaphysal regions of long bones, and throughout the interior of short bones. The bones of the axial skeleton, which include the rib cage, the backbone and the skull, have a higher proportion of trabecular bone than the bones in the appendicular skeleton. Trabecular bone only plays a small role in providing skeletal strength compared to that of cortical bone, but does play a very important role in the body's metabolic duties.

Trabecular bone is rigid but appears spongy. Trabecular bone is made up of a network of tiny strands of bone called trabeculae. When viewed, trabeculae appear to be arranged in a haphazard manner, however they are positioned in such away as to provide the maximum strength with in the bone. It is the pressures that are placed on the trabeculae during development which determines the way they are laid down and positioned. The trabeculae of cancellous bone align in the direction of the stresses being applied to them and in this way can realign if the direction of stress changes. Trabecular bone forms the interior scaffolding of the bone, similar to braces that are used to support a building; this helps bones maintain their shape even when experiencing compressive and torsional forces.

Fig.1.18. A trabecular bone image from a human vertebral body

1.7 BONE GRAFT

Bone graft represents one of the earliest devised reconstructive approaches to the musculoskeletal system, and it still remains a commonly used orthopaedic procedure. Bone grafts are used annually in over 2 million procedures worldwide to repair bone defects caused by either trauma, tumour resection and or failed prostheses. Bone grafts are used for enhancing the osteogenic potential of bone as well as restoring structural integrity to the damaged bone.

Originally, autologous bone grafts were used in bulk form for large defects, as this was thought to provide the most stable construct for long term stability of the new implants[20]. However, bulk allograft has a limited ability to heal to the host and undergo incorporation to the patients healthy bone stock, so reports of bulk allograft failures at intermediate and long term follow ups led many surgeons to seek alternative methods of repair. The use of morselized allograft in revision hip surgery started to show good long term results and this along with

the ability of morselized grafts to incorporate and remodel more fully into the hosts bone stock[59], led to its use in revision TKAs. Its importance in revision TKA leads to its inclusion as one of the repair methods being investigated in this study.

Professor T. Sloff and his colleagues in Nijmegan first used the technique of morselized bone impaction grafting in the acetabulum in the 1970s. The technique was then introduced to the UK by Professor R Ling in 1987. Since then the technique has changed little in principle, but the introduction of more dedicated instruments have aided surgeons.

There are three different types of bone graft. The first is an auto graft, where individuals receive a bone graft from a donor site within their own skeleton, (frequently the iliac crest. The second is an allograft, which is a graft from a donor individual of the same species. The third is a xenograft; this donor bone is taken from a different species, such as an animal. It is widely accepted, however, that autogenous cancellous bone provides the best bone for reincorporation when used in impaction grafting, as it provides good osteoinductive and conductive behaviour, it is biomechanically stable, it does not carry the risk of transmitting disease and it is not antigenic. These are all the interdependent elements necessary to maximize the body's potential for bone graft incorporation.

1.7.1 Factors Affecting Bone Graft Incorporation

The major contributions provided from the graft in the processes of incorporation are osteoconduction, osteoinduction and osteogenesis. It is these physiological properties of the bone graft that directly affect the success or failure of graft incorporation.

Osteoconduction is characterised when the graft provides a scaffold onto which new bone is deposited. The actual graft acts in a passive manner. Osteoconduction allows for the ingrowth of neovasculature and the infiltration of osteogenic precursor cells in to the graft site.

Osteoinduction is the ability of graft material to induce stem cells to differentiate in to mature bone cells. This process is typically associated with the presence of bone growth factors within the graft material or as a supplement to the bone graft. The stimulation source emanates from the bone matrix in the form of bone morphogenetic proteins.

Osteogenesis is the ability of the graft to produce new bone, and this process is totally dependent on the presence of live bone cells being found within the graft. Osteogenic graft materials contain cells with the ability to form bone (osteoprogenitor cells) or the potential to differentiate into bone-forming cells (inducible osteogenic precursor cells). These cells, which participate in the early stages of the healing process to unite the graft with the host bone, must be protected during the grafting procedure to ensure viability, as they can die easily once disconnected from their vascular supply. Osteogenesis is a property found only in fresh autogenous bone and in bone marrow cells. However, the acquisition of autogenous bone increases operative time and often the donor site does not have a sufficient volume of bone suitable to meet the patient's requirements. Donor site complications and procurement morbidity can result in increased patient recovery time, disability and chronic pain at the bone graft donor site. These are the factors that usually sway the surgeon from harvesting autogenous bone for grafting at the same time as performing revision TKA surgery.

Allograft is an alternative to fresh autogenous bone and is the preferred substitute when autografting is not a realistic option. Femoral heads removed during primary hip replacement surgery are a steady supply of allograft and will

be the source of graft for this study. However, allograft tissue yields more variable clinical results than autograft, and has known risks of bacterial contamination, viral transmission, and immunogenicity. To lessen the potential risks to the recipient, allograft bone is intensively treated and subsequently deep frozen. Incompatibility between the donor and the recipient is negated by the act of freezing. These processes can contribute to increased costs and also diminish the mechanical and biologic properties of the donor bone.

1.7.2 Cortical bone Graft Versus Cancellous Bone Graft

Bone grafts can also be classified according to their structural anatomy, i.e. either cortical or cancellous bone can be used in the grafting procedure. In the early stages of incorporation cancellous and cortical grafts behave in an identical manner. However, cancellous bone grafts differ from cortical bone grafts in the rate and completeness of repair. Cancellous (or trabecular) bone is more porous in nature than cortical bone, and it is the porous nature of cancellous bone that allows for a more rapid revascularization. This earlier revascularization allows cancellous grafts to induce new bone formation earlier than cortical grafts, and this enables cancellous grafts to become progressively stronger over time. With cortical bone grafts in the initial remodeling stages it is the osteoclastic activity that dominates and this in turn leads to bone resorption. Consequently cortical grafts actually become progressively weaker with time before they become incorporated. Other drawbacks encountered during the incorporation of cortical bone grafts include the fact that they have fewer osteoblasts and osteocytes compared with cancellous grafts and that they present less surface area per unit weight than cancellous graft. The advantage of cortical bone, however, is its superior structural strength. It is the factors mentioned above that subsequently lead to cancellous grafts being able to incorporate more fully than their cortical graft counterparts.

1.7.3 Biology of Bone Graft Incorporation

The process of bone graft incorporation is similar to the bone healing process that occurs in fractured long bones. Unlike other tissues, bone heals by regeneration and replacement, such that additional bone and not scar tissue is the characteristic of a reparative response. The human body's bone maintenance, repair and re-incorporation response is achieved by the bone remodelling cycle as described in section 2.6. Fracture healing restores the bone tissue to its original physical and mechanical condition and is influenced by a variety of systemic and local factors. Fracture healing occurs in three distinct but overlapping stages: the hematoma, the inflammatory stage and the remodeling stage[60]. Graft incorporation occurs in a similar fashion.

During the initial events of the graft incorporation, a haematoma develops around the implanted bone. Inflammatory cells and fibroblasts infiltrate the bone under prostaglandin mediation as well as many other factors. This results in the formation of granulation tissue and ingrowth of vascular tissue. During this stage necrosis of the graft occurs; this triggers a local inflammatory response and it is this response that stimulates the fibroblasts to lay down a fibro vascular stroma. The stroma helps to support the vascular ingrowth within the graft. As the vascular ingrowth progresses, there is also some resorption along the edge of the graft. The graft must not have substantial loads placed upon it with out the aid of additional fixation during the reforming phase of incorporation. Fracture healing is completed during the remodeling stage in which the healing bone is restored to its original shape, structure, and mechanical strength however this is where the bone graft incorporation process differs from the fracture healing process. Bone grafts are incorporated by an integrated process in which old necrotic bone is slowly eaten away and simultaneously replaced with new viable bone. This incorporation process is termed creeping substitution[61]. Primitive mesenchymal cells differentiate into osteoblasts. The osteoblast cells then deposit osteoid around the cores of the necrotic bone. This process of bone deposition and remodeling eventually results in the necrotic bone within the graft

being replaced with new healthy bone. When this has taken place the graft is deemed to be fully incorporated, and the deficient bone stock will have been significantly increased.

Bone graft incorporation is strongly influenced by local mechanical forces[62,63]; therefore it is extremely important to have sound mechanical links between the implant and the graft, especially in the early stages of the incorporation process. If excessive implant movement takes place, large forces will be experienced by the graft causing the biological incorporation procedure to fail and inevitably the bone graft will also fail. This will lead to excessive implant motion, malalignment and failure of the revision TKA. Thus it is extremely important for the long term success of revision total knee arthroplasties to establish which stem provides the securest initial fixation method when using impaction grafting. In this study experiments will be carried out using biomechanical composite bones and therefore no biological incorporation will take place. Thus it is only the initial fixation strength of the graft and varying stems that will be studied and not the final incorporated graft stem fixation strength.

1.8 TIBIAL AUGMENTS

A lack of quality proximal tibial bone stock is not uncommon in revision TKA and modular tibial augmentations have been designed to solve the problems associated with these deficiencies. When surgeons are faced with a revision TKA situation, they must identify how much quality bone stock is left to work with, as peripheral deficiencies of tibial bone must be addressed at the time of surgery in order to help ensure the long term stability of the tibial tray component. The surgeon must also consider which reconstructive material the bone defect will require, the choice of repair techniques include autografts, modular tibial augments (such as wedges and blocks, Fig.1.19), cement, screws and allograft. During tibial reconstruction, the initial emphasis is on restoration of the joint line to ensure sound mechanical alignment. This reduces the chance of malalignment occurring within the knee and the resultant need for further revision surgery. The next step is to obtain adequate bony support for the tibial tray component. If there is a proximal defect which is contained (i.e. the cortical wall of the tibia is undamaged), then the defect can be managed through the use of a bone graft, (as described in section 1.7), cement, or cement with screws. However, if the defect is uncontained, (i.e. the cortical wall has become damaged, and is unable to provide adequate support), then the reconstruction will require the use of a prosthetic augment such as a wedge or block. The amount of proximal tibia that can be reconstructed with prosthetic components varies but generally it is in the range of 10 - 15 mm.

The use of prosthetic augments be it wedges or blocks, often requires the use of a longer stem to provide added stability for the prosthetic construct. In a study evaluating the stability of TKA repairs using wedge augments it was found that repairs involving wedges resulted in the tibial trays experiencing a significant increase in micromotion compared to trays without augmentation, (Farless et al). Metallic wedge augmentation has been reported by Brooks et al[19] to be biomechanically superior to cement alone or cement with screws. However, the

use of augmentation blocks provides a more stable system when axial loading is applied to the implant as compared to the use of half or one-third wedges. Shear forces are vastly reduced between the augment and cement interface when using blocks compared with wedges, where the shear forces can be high leading to cement fractures resulting in the increased chance of loosening. It is for these reasons that this study will investigate what effect varying the stem length has upon the micromotion of the tibial tray when the T2A defect is repaired using a modular block augment.
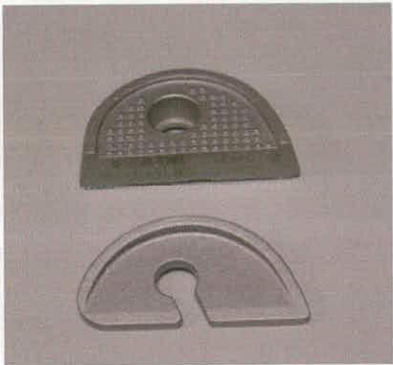
Fig.1.19. Depicts a modular tibial wedge, (bottom), and a modular tibial block, (top).

Chapter 2

Initial Fixation of the Tibial Tray in Revision and Primary Total Knee Arthroplasty

2.1 INTRODUCTION

The fixation of joint implants to bone remains a clinical and scientific challenge, with components continuing to loosen causing patient discomfort. Tibial component aseptic loosening is still a major cause of revision total knee arthroplasty, (TKA). Despite research to improve prosthetic fixation, the mechanisms of tibial component loosening are not fully understood and cases of loosening continue to be reported.

Loosening of total joint replacements has vexed clinicians, scientists and engineers ever since John Charnley's pioneering efforts in the 1960s. In spite of large amounts of clinical and experimental data, we still have no clear understanding of this complex pathophysiology, referred to as aseptic loosening or osteolysis. It is likely that multiple mechanisms are at play simultaneously, and specific processes may take precedence, depending upon the individual patient's specific genetic makeup. However, after in vivo and in vitro experiments it is widely believed that the key to achieving long term implant survivorship is stabilisation through osseointegration. In order to achieve this biological stability, adequate initial mechanical stability is crucial, especially in uncemented TKA. If early fixation is not achieved, micromotion between the bone and implant interface can lead to the formation of a soft tissue layer rather than the desired boney ingrowth. Furthermore, excessive micromotion can lead to the resorption of bone around the implant bone interface, which can result in loosening, failure of the implant, and revision surgery[18]. Component loosening on the tibia is one of the major causes of failure, both in cemented and uncemented TKAs[8,64].

Revision TKA is becoming an increasingly common reconstructive procedure. As the number of primary TKAs continues to increase year on year, the need for revision surgery will likewise increase[9]. Therefore, it is important to determine the best surgical techniques to manage revision problems as they are encountered.

The absolute value of micromotion that will prevent bone apposition at the implant bone interface is not known exactly. However, Pillar et al[17], reported that motion in excess of 150 microns hindered boney ingrowth in their canine model. It was also shown by Ryd et al[32,33] that early instability and continuous migration of the tibial component is a predictor of later clinical failure through component loosening. Ryd's clinical observations suggest that prosthesis migration exceeding 2mm at two years post-op correlates with implant loosening. Fukuoka et al[34], goes even further and suggests that future migration of the tibial component can be predicted as early as the time of implantation, by observing the inducible displacements (defined as the displacement recovered when the implant is unloaded), produced by applying 20kg on to the implant at the time of surgery. These results showed a significant correlation between the initial stability achieved and the amount of migration experienced by the tray, thus emphasising the importance of initial stability for survivorship.

In revision TKA, however, obtaining secure fixation often proves more complex due to the lack of quality bone stock which is frequently encountered. Due to this, clinical results and survivorship of revision TKA are poorer than those for primary TKA[36,37]. The goal in revision surgery is like that of primary surgery, to attain a pain free stable knee with a functional range of motion. Primary components often prove inadequate in providing the support required in the revision situation, thus a variety of implants and fixation techniques have been developed to try and combat the problem of loosening. These modular knee systems were introduced to allow the surgeon a range of options when attempting to restore lost bone, reconstruct the joint line and add stability to the knee joint. This is achieved through the use modular augmentations to deal with tibial and femoral bone loss. In addition to augments, manufacturers provide various stems to enhance fixation in revision situations. Variable modular stems are designed to engage in the metaphysis or diaphysis of the bone in an attempt to secure the implant in better quality bone stock. Such stems can be implanted

in a press-fit or cemented fashion. Stem usage in revision surgery is now widespread, however there are problems associated with stem usage[46]. Stems have been shown to increase stress shielding in finite element and cadaver studies[19,37,65]. While adding a stem introduces another possible failure site[45], some patients have also reported pain at the stem tip[47].

There is no consensus on what length of central stem delivers the best load transfer and fixation for common tibial revision defects requiring augmentation. A number of in vitro studies have looked at the effects of stem length[50,51,66] but most have done so in undamaged bone stock as would be found in primary TKA, where in most clinical situations modular stems would not be implemented.

Unfortunately, little comparative information is available in the literature to guide the surgeon in determining what type of stem fixation, and what length of central stem, delivers the best fixation while carrying out revision TKA on common tibial revision defects. Therefore the purpose of this study was to determine the role metaphyseal engaging stems of differing lengths have on the initial micromotion experienced by the tibial tray in primary TKA and common revision TKA settings.

2.2 HYPOTHESIS

The use of a longer modular stem will reduce the subsidence and micromotion of the tibial tray in both the primary and revision case. The addition of a modular stem to an uncemented tray can provide similar stability to surface cement.

2.3 MATERIALS AND METHOD

2.3.1 Experimental Design Overview

The in vitro testing protocol used in this study was developed to investigate the biomechanical factors which govern the initial stability given to the tibial tray in primary and revision TKA by cement, and differing lengths of central modular stems. The protocol followed was derived from previous studies found in literature and from the experience of Mr Colin Howie, Consultant Orthopaedic Surgeon, at Edinburgh Royal Infirmary.

Twelve tibias were divided into two equal groups of six. Group one consisted of the primary TKA scenario specimens, looking at surface hybrid cement fixation versus cementless fixation with no modular stem, a 40mm modular stem and an 80mm modular stem. Group two consisted of the revision T2A scenario specimens, investigating surface hybrid cement fixation versus cementless fixation with no modular stem, a 40mm modular stem and an 80mm modular stem. Testing was conducted such that the prosthesis was first implanted without cement and subjected to the test loading cycle. After this the implant was cemented in place in the same tibia previously tested using a hybrid cementing technique, and again tested under the same loading cycle. Therefore each tibia underwent two test runs. No modular stems were cemented during the course of this study.

2.3.2 Specimen Bones

For this study biomechanical composite bones were used rather than cadaveric human tibias. Cadaveric bone segments have often been used to test in vitro prosthetic components in past studies within the literature. In most cases comparative tests are performed to compare the effect of primary stability of the implant or the stress shielding caused. The variability of cadaveric specimens

however does often pose an issue requiring enormous sample sizes to obtain a satisfactory significance and power of statistical comparisons. The inter-specimen variability for cadaveric specimens has been reported to reach 100% of the mean[67][68]. Thus, if a difference of 10% of the mean must be detected with a confidence of 95%, a sample of several hundred specimens would be required[68]. This alone causes an issue due to the availability of human cadaver specimens.

Composite tibias provide a more reliable test bed than cadaver specimens: they reduce the sources of variability found in human bone, apart from those associated with the behaviour of the stem, and those linked to the procedures followed in the implantation of the tibial components. This allows for a smaller sample size to be investigated. Cristofolini et al[68] found that the external geometry and bending properties of composite tibias were a good match to those of cadaveric specimens. They concluded that composite tibia models were a suitable replacement for cadaver tibia in tests where bending and compression predominated the loading, but not for when torsional loads predominate. The material properties of the Pacific Research Labs composite bones used in this study can be found in the literature. Szivek et al[69], tested a synthetic foam similar to that used in the commercial models, obtaining stress-strain curves similar to those obtained for human cancellous bone, with a Young modulus of between 63 and 104 MPa. This matched well with the value reported by Pacific Research Labs of 69Mpa. The values obtained lie within the range for human trabecular bone reported by Martens et al[70]. The Young's modulus values indicated for the synthetic cortical bone, 14.2 GPa in bending and 18.6GPa in tension also match well with values for human cortical bone reported in the literature[71,72].

Human bone used in past in vitro studies is often deep frozen. Freezing bone radically alters the material properties of fresh bone, there by adding another uncontrollable variable. Composite bones, on the other hand, provide a uniform test bed with the same physical properties as real bone. However, as the bones

are made from non-biological materials and provide no vascular blood flow, no biological incorporation of the implant or graft can take place during this study, as would still be the case if frozen human cadaver bone had been used. Biomechanical bones are specifically designed to be used in the testing, comparing and designing of implants and implant components. Biomechanical composite bones also eliminate the need for any special handling or preservation requirements linked to cadaver samples.

The bones chosen for this study were third-generation biomechanical composite tibial bones, (Pacific Research Laboratories, Vashon Island, WA). These bones model natural cortical bone using a mixture of short e-glass fibres and epoxy resin pressure injected around a cancellous core material which is manufactured from solid rigid polyurethane foam, (Fig. 2.1). There is an intramedullary canal running down the centre of the bone.
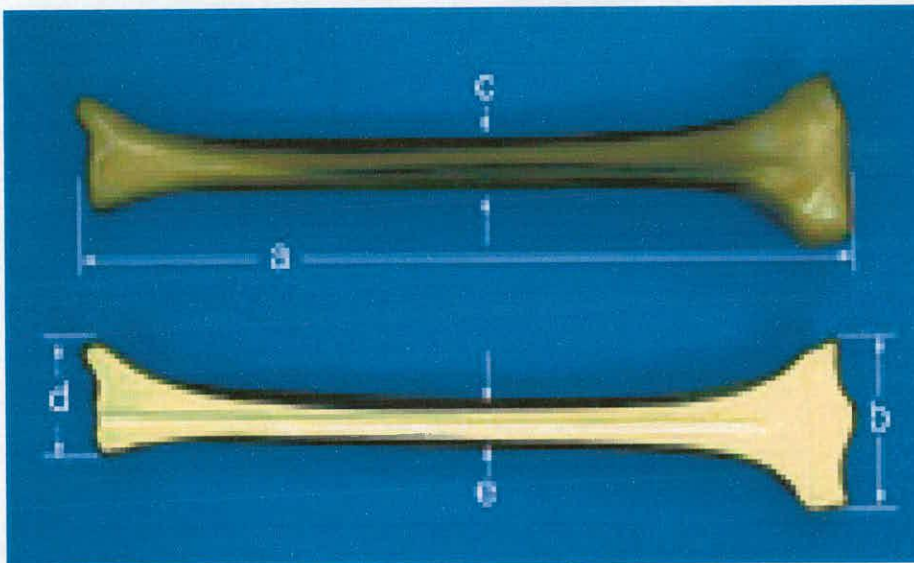
Fig. 2.1.The composite bones chosen for this investigation along with their dimensions. a) 405 mm b) 84 mm c) 28 mm d) 58 mm e) 10 mm canal.

stems. For standardisation purposes all experiments were carried out using a large tibial tray and large femoral component, with a 10mm poly insert.

2.3.4 Specimen Bone Preparation

Each tibia was treated identically in the first instance; the tibia underwent preparation techniques for placement of the primary tibial tray done according to the manufacturer's standard surgical technique, (Stryker, Kinemax Plus primary operative technique manual, written by Mr Colin Howie, and Mr Richard Burnett, Consultant Orthopaedic Surgeons, Royal Infirmary of Edinburgh).The proximal tibial cut was made using extramedullary instrumentation designed to make a perpendicular cut to the long axis of the tibia.

Fig.2.2. The position of the bones in the soft tissue knee holder

The composite bones were placed into a soft tissue knee holder which is normally used for teaching and demonstration purposes. The knee holder is designed as a permanent holder for Sawbones full length large knee models and allows the bones to experience the full range of flexion. The knee holder was positioned in a manner that allowed the knee to be flexed as shown in Fig. 2.2.

With the knee in flexion, the extramedullary, (EM), tibial alignment guide clamp was placed around the distal tibia just above the malleoli, (Fig 2.3). The head of the instrument was then placed over the tibial eminence, making sure that a finger's breadth clearance between the proximal shaft of the guide and the anterior cortex was present to ensure proper positioning of the head. The proximal fixation pins were then centred over the eminence and the most posterior pin tapped down into the bone. This fixed the anterior/posterior position of the head. Rotation and axial alignment was then checked to ensure the vertical shaft of the EM tibial alignment guide was parallel with the long axis of the tibia in both the anterior/posterior and medial/lateral views, before setting it by anchoring the second pin, (as shown in Fig 2.4). Axial alignment was then re-checked to ensure that the jig lay over the centre of the ankle and the tibial tubercle, (the alignment rod should lie over the medial third of the tubercle), before tightening the thumbscrews on the guide.

Fig 2.3. Depicts the guide attached to the soft tissue knee holder and Sawbone.
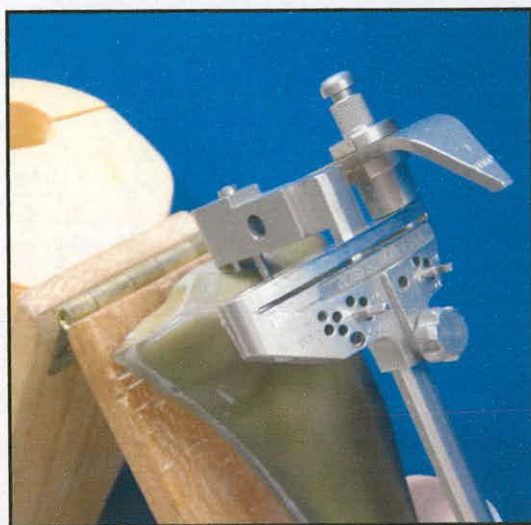
Fig.2.5. The orientation of the tibial resection guide and tibial stylus when attached to the EM proximal shaft prior to resection of the tibial plateau.

The tibial stylus has two resection levels, one set at 2mm and the other at 12mm. The depth of resection for all tibias used in this study was 12mm. The resection depth was referenced from the lowest point of the lateral condyle on the tibial plateau: this allowed 12mm of bone to be removed from the same point on all tibia tested. After the resection level had been established, the screw on the resection block was tightened and the stylus removed. The tibial resection guide was then secured to the tibial bone stock by the use of two drill pins. The pins were inserted through the neutral "zero" holes for this study. Once the pins were in place the screws on both the resection guide and the EM alignment guide were loosened, and using the surgical slap-hammer the fixation pins in the head of the EM alignment guide were extracted. It was then possible to remove the EM alignment guide. The tibial resection guide was then slid posteriorly until it came into contact with the tibial bone surface. At this point an alignment handle was attached to the cutting block to verify the rotational varus / valgus alignment of the cutting block. Once the rotation had been deemed to be correct another drill pin was added through the "X" pin hole.

Fig.2.6. A proximal tibial resection as carried out on the composite test bones in the lab

The purpose of this was to add further stability to the cutting block and prevent the resection cutting block sliding away from the tibias anterior surface during cutting due to the vibrations produced from the saw. The tibial plateau was cut using a Stryker System five surgical saw with a 1.25mm blade attached, (Fig 2.6). Once the cut had been completed the tibial resection guide was removed.

A large tibial template component with an alignment handle attached was then placed over the resected tibial plateaux, (Fig 2.7). The alignment handle allows one to again verify rotational, varus / valgus alignment before proceeding. The varus/valgus alignment is verified with the aid of a long alignment pin which should fall to the centre of the ankle if the correct alignment has been achieved. All tibia tested in this study were found to have an accurate alignment with this check.

Fig.2.7. A resected tibia with tibial template and alignment handle attached to verify alignment of your cut.

Fig.2.8. The punch guide in place on top of the tibial template ready to be impacted down to make the central stem hole for the fixed short stem.

Fig.2.9. The holes for the tibial tray pegs being reamed out. The pegs aid with rotational stability of the tray.
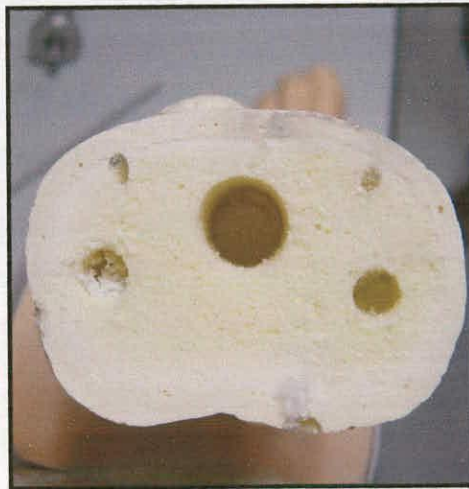
Fig.2.10. The resected and prepared tibial plateaux ready to receive a primary tibial tray insert.

The temporary tibial template was attached after the alignment check had been carried out using two drill pins. The punch guide was then placed on top of the tibial template and used to cut the central hole for the fixed stem on the tibial tray. A punch was then used to impact the bone down, thereby leaving space for the tibial tray's fixed central stem, (Fig 2.8). This is done with the aid of a surgical hammer. The peg reamer was then attached to the surgical drill and used to ream the medial and lateral peg holes, (Fig 2.9). These holes are reamed

2.3.4.2 Cementing technique and preparation

All tibia and implant combinations were first tested without any cement either down the modular stem or on the proximal surface of the resected tibial plateau. This represented the uncemented testing. All tibia / implant combinations were then cemented using a hybrid cement technique. Hybrid cementing involves applying bone cement to the resected proximal surface of the tibia to secure the tray to the bone, but not cementing down the canal made for either the tray's fixed stem or the attached intramedullary modular stem.

Fig.2.13. Vacuum cement mixing bowl used for cement preparation

Surgical Simplex P bone cement, (Stryker, Newbury, UK) was used in all the bone model scenarios tested. The cement was prepared following the manufacturer's instructions, using a vacuum cement mixing bowl, (Fig. 2.13), (Mixevac III, Stryker, Newbury, UK) and a vacuum pump. The cement was spread on to the resected surface of the tibia and on to the underside of the tray being implanted. In the T2A revision models the cement was placed on the resected surface including the 10mm augment resection more distally. The cement was then applied to the underside of the tray and the 10mm medial augment. Each tibial implant construct was inserted into the prepared tibia and

Four DVRTs were positioned around the tibial tray to measure the micromotion parallel to the long axis of the bone. The four DVRTs were held in place by the use of a custom designed tibial bone ring which was anchored to the proximal tibia via four sharpened bolts, (Fig 2.15). Miura et al[76] demonstrated that when a mount is placed within 20mm of the resected tibial surface there is no relative deflection between the cut tibial plateau and the point at which the mount is anchored. Thus the tibial bone ring was mounted 15mm distally from the resected surface in all cases studied. The tibias tested had four holes pre-drilled into them to ensure that the bone ring was mounted consistently and accurately. The bone ring was mounted in such a way that the DVRTs held in it were positioned perpendicular to the resected tibial surface. The bone ring was machined from plastic.
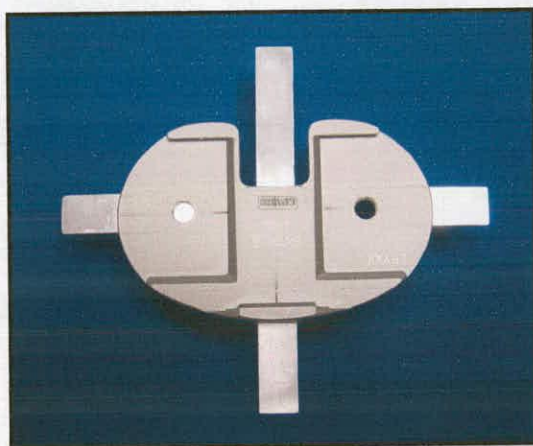
Fig.2.16. The orientation of the sensor target platforms on the tibial tray.

BONE TYPE	Density (g/cc)	Strength (MPa)	Modulus (MPa)
Simulated Cortical Bone	1.7	120	7600
Simulated Cancellous Bone	0.32	5.4	137

Table. 2.1. Compressive material properties of Composite Biomechanical Bone.

2.3.3 Prosthetic Implants

All implants tested in this study come from the Stryker, (Newbury, UK), Kinemax Plus Total Knee System range of implants. The Kinemax Plus Total Knee System is the result of a design evolution that descends back to the Total Condylar and Kinematic Knees, (designed by Prof. Peter Walker in the 1970's), which obtained a survival rate of 94% at 15 years[4]. The Kinemax Plus implants combine the philosophies and biomechanical principles of the earlier systems, with detailed anthropometric analysis using the latest computer aided design technology to optimise the implant's articular geometry.

The Kinemax Plus system consists of an integrated series of implants and modular accessories. This allows the surgeon to address the complete needs of TKA, from a simple primary knee to the most complex revision case, involving bone loss and ligament instability. The Kinemax Plus implants are designed to be implanted with the use of bone cement. However, cemented and uncemented tibial components were tested in this study in order to assess the effect of cement and any additional stability that may be provided by varying modular

Medial Lateral View

Anterior/Posterior View

Fixation Pins

Tibial Eminence

Extra Medullary
Tibial Alignment
Guide Rod

Proximal Shaft

Vertical Srew

Medial/Lateral
Adjustment Screw

Spring Loaded
Clamp

Anterior/Posterior
Adjustment Screw
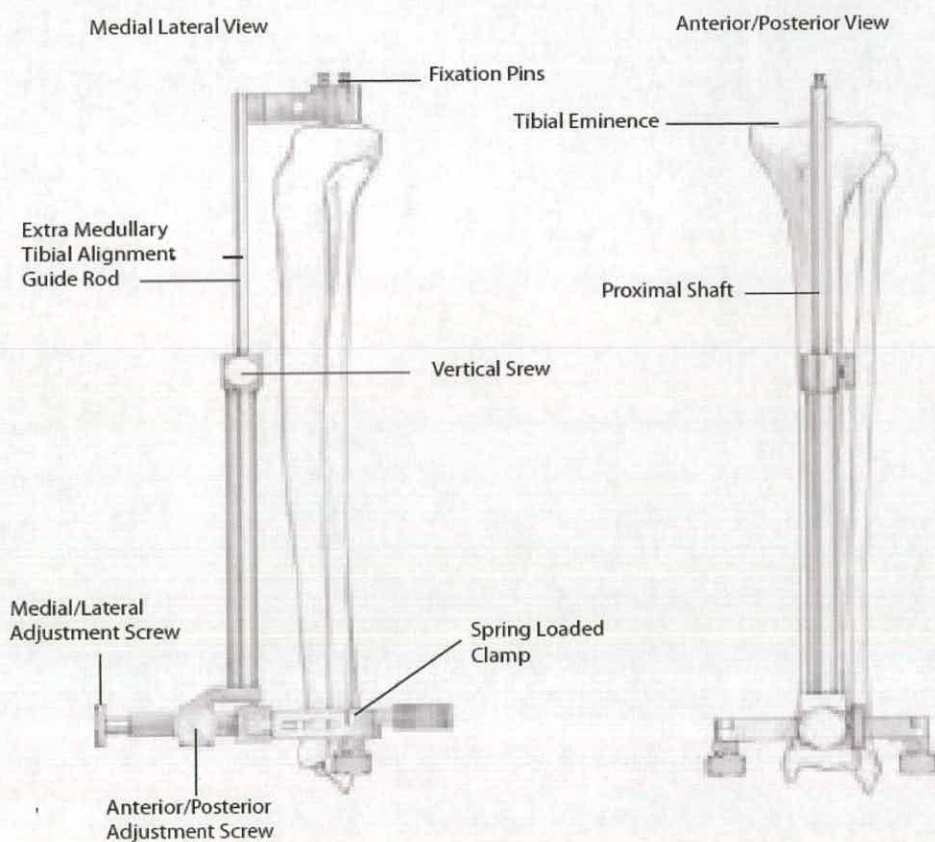
Fig. 2.4. The arrangement of the EM tibial alignment guide on the tibial shaft.

The next step was the tibial resection. The tibial resection guide used in these experiments has a 3 degree posterior slope built in to it, as this is the recommended angled cut for use with the Kinemax Plus Total Knee System. A slotted tibial resection guide was then slid onto the proximal shaft of the EM tibial alignment guide, and a tibial stylus was used to determine the amount of tibial plateau to be resected. The stylus was placed in to the lateral hole on the tibial resection block, (Fig 2.5).

level with the first line on the peg reamer. The punch guide and tray were then removed; the tibia plateau was ready to receive a primary tibial knee component, (Fig 2.10).

Two bones were left in this state ready to receive a primary tibial tray with no modular stem. The metaphysis on the remaining four bones in the primary group were prepared to receive either a 40mm stem or an 80mm stem, using the appropriate intramedullary reamer. The primary bone group was then ready for testing. The primary bone group would provide a reference point to which the data collected on the tibias with repaired T2A defects could be compared. The six bones in the revision T2A group after this initial preparation stage were then ready to have a further 10mm resected from the medial side, in order to enable the tibia to receive an implant with an additional 10mm medial augment prior to testing.

2.3.4.1 Tibial Block Augmentation Preparation

All tibias in the T2A revision group required tibial block augmentation preparation to be carried out. Based on the nature and location of the T2A deformity found at the time of surgery, the surgeon has the option to add a 5mm or 10mm tibial augment block to either the lateral or medial side of the tibia. It was decided for this study that a 10mm medial block would be investigated.

The tibial augment cutting guide was attached to the tibial template by securely tightening the locking knob. The template and augment cutting block was placed on to the resected proximal surface of the tibia. Pins were then drilled through the holes located on the block cutting guide. This attached the block directly to the bone surface, thereby enabling the tibial template to be removed in order to make the appropriate cuts to the bone while keeping the cutting guide in the

correct orientation. The cut was then made for a 10mm tibial block augment on the medial side using the appropriate slot on the block. The cut was made using an oscillating surgical Stryker saw, (Fig 2.11).
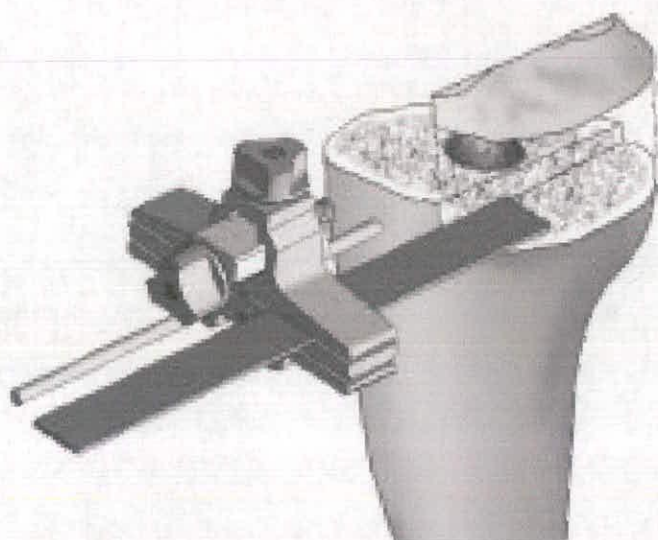
Fig.2.11. A 10mm resection of bone being removed from the medial side using the augment cutting block.

At this point the tibia was then ready to receive a tibial implant with a 10mm medial augment attached to the underside of the tray, (Fig 2.12). All the tibial block augments were secured to the tibial tray by attaching a screw through the stabilizing peg hole and tightening it with the use of a torque wrench.
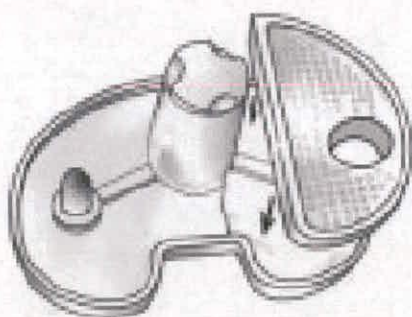
Fig.2.12. A 10mm augment being attached to the underside of the tibial tray.

impacted into place using a mallet and tibial impactor. The goal was to achieve a cement mantle of 2-3mm for all models. This helps to level the resected bony surface, fill any gaps between bone and implant and provide initial stability and fixation. All excess bone cement was removed from the construct with a curette. The cement was then left to cure at room temperature (20-22 °C) for an hour. A 5kg weight was applied to the top of the tibial tray to provide a constant force to the tibial tray while the cement was curing.

2.3.5 Measuring the Micromotion of the Tibial Tray

The stability of the tibial tray at the time of surgery and thereafter, is a major factor in determining the long-term success of the operation. Even relatively small motions have been found to significantly reduce the chances of bone ingrowth occurring, (Haddad et al), thus preventing the biological fixation of the implant. Due to the nature of micromotion, (roughly $1/20^{th}$ of a millimetre), measuring the stability of the tibial trays on the repaired tibias precisely does not present a simple task, especially as bones themselves deform under loading, hence providing the scenario of measuring a moving target.

The primary stability of a prosthetic implant can be defined as the three-dimensional motion at the interface between pairs of points consisting of the layer of bone forming cells closest to the implant and their corresponding point on the implants surface[73]. There are two different types of motion that may occur during the loading of implant components. The first is a dynamic movement of the stem or tray in response to a single loading cycle. This is termed stem micromotion or inducible displacement, (when micromotion or inducible displacement is referred to within this thesis they are one and the same). During dynamic motion the stem moves and then returns to its original start position. The second type of motion occurs when loading causes the stem

to displace irreversibly within the intramedullary canal over time. This phenomenon is termed stem migration or subsidence. These motions are also referred to as dynamic motion and total motion. The measuring system designed for this study will be capable of measuring both total and dynamic implant motion.

2.3.5.1 Tibial Tray Micromotion Measuring Apparatus

Several ideas originated for how best to measure the micromotion and subsidence of the tibial tray but the final design was based on a construct described by Shimagaki et al[74] and a similar system used by Peters et al[75]. The system allowed any micromotion, subsidence or lift off of the tray from the resected tibial surface that may occur during the loading cycles to be detected.

The motion of interest was detected and measured with the use of four contact S4-gauging differential variable reluctance transducers,(DVRTs), (MicroStrain Inc., Vermont, USA), (Fig 2.14). (Full Specification for the DVRT sensors can be found in Table 2.2). The DVRTs provide sub-micron resolution, linear analogue output, and flat dynamic response up to kHz frequencies. The transducer cores are free sliding, extremely lightweight and utilize flexible, biocompatible alloys to provide resistance to kinking and permanent deformation. The DVRT has Teflon insulated leads and connectors that are multistranded and reinforced with stainless steel. All the G-DVRT-S4 sensors were factory calibrated by MicroStrain Inc., Vermont, USA at 20 °C. The calibration frequency was static and done in 50 μm increments. Full calibration data was provided with each sensor.

Fig.2.14. A Microstrain G-DVRT-S4 sensor used for determining the motion of the tibial tray during cyclic loading tests.

Total Measuring Range	4mm (+/- 2mm)
Repeatability	0.1µm
Operating Temperature Limits	-10 to +65 ºC

Table.2.2. Technical data for the G-DVRT-S4 sensors.
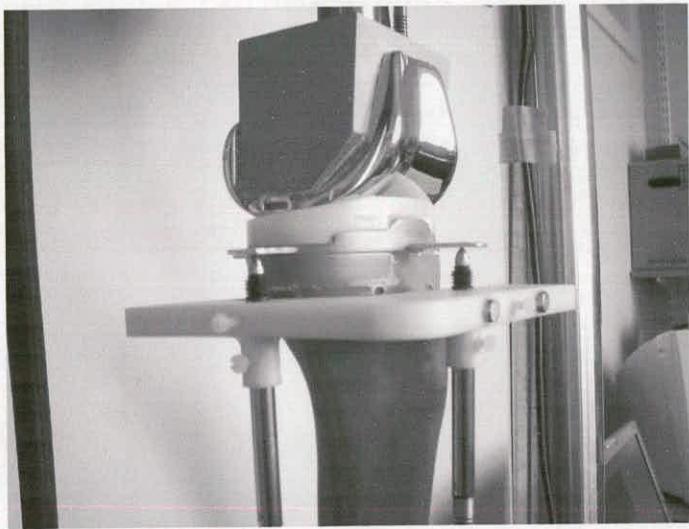
Fig. 2.15. The bone ring positioned and anchored via bolts to the tibia such that the four DVRT micromotion sensors are centred directly beneath each tibial reference target.

Before the tibial trays were implanted, each tibial tray had four rectangular holes 2mm deep and 10mm wide created medially, laterally, anteriorly and posteriorly, (Fig 2.16). The rectangular slots were created within the tray via electro discharge machining, EDM. Four Aluminium target pieces were inserted and glued into the slots on the tibial tray. The target platforms measured 2mm thick by 10mm wide and were between 15mm and 25mm in length depending on their position around the tray. The targets were positioned such that the centre line of the targets ran through the centre point of the tibial tray. The glue placed around the connecting surfaces of the targets and the tibial tray reduced any residual movement between the components which could have introduced errors into the measurements recorded. The target platforms acted as a reference plane for the micromotion transducers. The bone ring was positioned and anchored to the tibia such that the four DVRT micromotion sensors were centred directly beneath each reference target, (Fig 2.15). Due to the fact that the DVRTs were mounted in the bone ring which was attached directly to the tibia, it was possible to measure the component tray micromotion relative to the tibia in which it was implanted while a cyclic load was applied to the tibial tray via a materials testing machine.

2.3.6 Specimen Loading Procedure

The specimen loading procedure for this set of experiments was decided upon after analysis of the literature to find the average gait and the forces that occur in the knee joint during everyday and sporting activities. The ability to walk pain free, climb or descend stairs and carry out other daily activities with relative ease is important to one's quality of life. If these activities are accompanied by pain and instability causing the patient's functional ability to deteriorate then the operation cannot be termed a success. It is vital that implants inserted during TKAs can withstand the loading encountered during daily activities. Thus the

loading sequence derived for this study mimics the tibiofemoral compressive loads experienced within the knee during such daily activities.

In a study by Schmalzried et al[77], 111 volunteers who had undergone at least one total hip or knee replacement were monitored using digital pedometers in order to determine their average gait per day. The average daily activity ranged from 395 to 17,718 steps per day, with the patients averaging 4988 steps per day. This extrapolated to 9,000,000 cycles per year for each joint. However, age was found to significantly affect the activity levels of the patients, with patients over sixty averaging between 3000 - 4000 steps per day. As the average age of a patient undergoing revision TKA surgery at The Royal Infirmary of Edinburgh is over sixty-nine, (Howie personal communication) it was decided that for this study the cycles experienced by the repaired tibia should be 4000. Thus the total number of loading cycles the bone endured in this study was 4000. The 4000 loading cycles were broken down into segments of increasing body weight reflecting the forces experienced by the knee and thus knee implants during a variety of daily activities, (Table 2.3). Each specimen was initially loaded with 100% body weight for 50 cycles at 1 Hz.

The 4000 loading cycles were then broken down as follows:

- 100% BW for 500 cycles
- 200% BW for 750 cycles
- 300% BW for 1000 cycles
- 400% BW for 1000 cycles
- 500% BW for 500 cycles
- 600% BW for 500 cycles

The loading rate for all tests was set at 1 Hz as this represented the best compromise with in vivo loading conditions, in addition to providing a reasonable experimental execution time. The average weight of a large framed 60 year old

5'10" male is 72kg (Ref: information corner.com), therefore 1 Body Weight, (BW), was taken as 706N for this study.

While simply standing, the tibial implant experiences the force of one times Body Weight exerted upon it, and a study by Ericson stated that the estimated bone-on-bone reaction force incurred during the activity of cycling was 1.2 x BW. These findings have been reflected in the first and second loading cycles of the experimental procedure of 100% BW for 500 cycles, and 200% BW for the next 750 cycles.

Several Biomechanical evaluations have measured the tibiofemoral compressive loads experienced by the knee during different activities[78-82], (Table 2.3), and they demonstrate that the load experienced by the knee is dependent on both the physical activity and the BW of the patient. A number of studies, (Table 2.3), report that total knee replacement patients can produce tibiofemoral compressive loads of 3-4 times BW during level walking[78-82]. Due to the fact that most daily activities involve level walking, this fact has been reflected in the loading procedure for this study by applying the largest number of cycles at 3 and 4 times BW. Ellis et al also found that the bone-on-bone compressive force experienced by the knee while rising from a chair was 3.2 x BW; thus this cycle also includes the force experienced by the implant during this daily activity.

The Dahlkvist et al[83] study investigated the dynamic joint forces experienced by the knee during deep knee flexion. It was calculated that the tibiofemoral forces in the vertical direction were between 4.7 and 5.6 times BW while lowering into a squat and rising from a squat. Deep knee flexion beyond 90 degrees is not required by all TKA patients, however squatting and kneeling is common practice in many cultures, especially in the Far and Middle East, and thus deep knee flexion is a necessity for their every day activities. For example, in the Muslim world squatting and rising from a squat is a daily activity during prayers. It is

therefore essential that the forces occurring in the knee during this activity are experienced by the repaired tibia, in order to evaluate the effect this action has on the tibial tray motion. Andriacchi et al[84] showed that the axial compressive force experienced in the knee during stair descent was 6 times BW. Ascending and descending stairs is a common activity of everyday living and as such was included in the loading pattern. Walking uphill has been shown to produce tibiofemoral compressive forces of 4-5 BW[80]. Thus the phase at 500% BW for 500 cycles followed by 600% BW for 500 cycles incorporates the maximum tibiofemoral compressive forces reached during these daily pursuits.

Tibiofemoral bone on bone compressive loads as high as 8-9 times BW can be experienced by the knee whilst jogging. Although it is not expected that many patients who undergo TKA or revision TKA surgery will be jogging regularly, (due to the age of most patients who under go revision surgery), a loading phase of 8 x BW for 250 cycles was originally planned in the experimental loading procedure. This was due to the fact that Kuster et al[82] reported tibiofemoral compressive forces reaching an average load of 8 times BW for downhill walking, which is an action carried out on a daily basis by TKA patients. With the increasing long-term successes being achieved with total knee replacements it means that younger, and consequently more active, patients are being treated. This will place an increased mechanical demand on the prosthesis and thus it is imperative that we understand what effect higher end loading, experienced during daily activities has on the implant micromotion to enable the surgeons to more accurately determine the best method for secure fixation. However the 800% BW loading phase was not implemented due to limitations of the materials testing machine load cell and frame capacity, thus the maximum load investigated was 600% BW during the course of this investigation.

Author	Daily Activity	Tibiofemoral Axial Compressive Joint Loads (xBW)
Morrison		3
Harrington		3.5
Reilly et al	Level Walking	3.4
Collier et al		3.2
Kuster et al		3.9
Andriacchi et al	Stair Decent	6
Ellis et al	Rising from a chair	3.2
Kuster et al	Down Hill Walking	8
Morrison	Up Hill Walking	4 - 5
Ericson	Cycling	1.2

Table 2.3: Reported tibiofemoral joint loads for a varied range of daily activities.

2.3.6.1 Cyclic Loading

The application of sinusoidal compressive cyclic loading, typical of in vivo knee joint forces taken from literature, (Table 2.3), was achieved by fixing the repaired tibias and custom-made femoral condyle section into a Zwick hydraulic dynamic materials testing machine, (ZwickHC5, Herefordshire, UK), with the use of specially designed attachments.
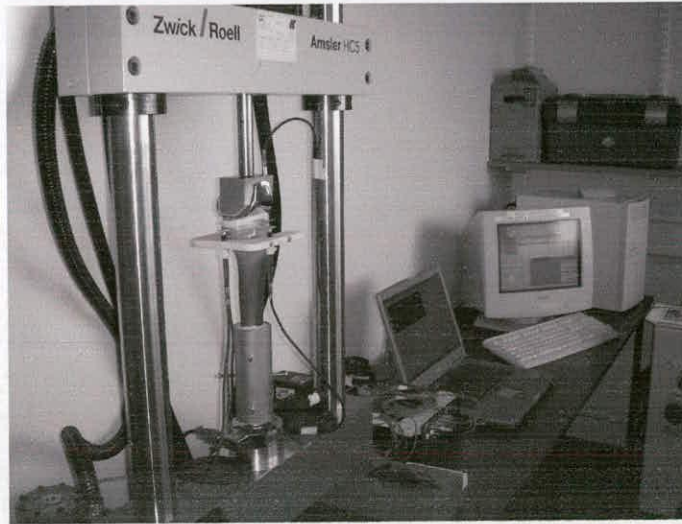
Fig.2.17. A specimen mounted in the Zwick hydraulic dynamic materials testing machine.

Specimens were mounted vertically in the Zwick materials testing machine in order that the tibial cut surface was perpendicular to the applied load, (Fig 2.17). The load was applied to the tibial tray through the femoral component, as would be done in vivo. The central loading position was determined by adjusting the custom-made femoral component attachment until the femoral component fully seated into the polyethylene insert in the tibial tray. This enabled the force to be applied over the same surface area for all the bones tested, and also ensured that an even load distribution was maintained between the medial and lateral compartments of the tibial tray.

No attempt was made to simulate specific muscle forces experienced by the knee during the experiments in this study. Only the implant movement associated with the axial loading of the knee in extension was investigated. However, the knee can also experience high contact forces when it is loaded at higher flexion angles. When the knee is loaded and in flexion, higher contact stresses can result in the implant due to the lower conformity of the implant contact surfaces at these angles. This can lead to increased polyethylene wear which in turn increases the chance of implant failure.

With an aging population causing a rise in the incidence of osteoarthritis, the data collected during this study is invaluable when it comes to trying to reduce the number of revision TKAs a surgeon is required to perform each year while increasing the quality of life for patients after TKA surgery. This experimental loading procedure is designed to mimic the gait and force that may be experienced by revised implants within the tibia during the course of a normal day's activity. However, certain limitations were encountered. Firstly, only static loads were applied to the repaired tibia, but the loading procedure did apply the peak values for a varied range of daily activities. Thus, it is likely that the addition of a dynamic loading into this investigation would not alter the conclusions, as the loads would be smaller than those applied to the tibia. Secondly, an even load distribution was assumed across the tibial tray, however it is known that often varus or valgus moments do occur within the joint during loading. Thirdly, no torque loading was applied to the tested tibia; although torque is know to occur during many of these daily activities it was not replicated in this experimental investigation.

2.3.6.2 Data Collection

Micromotion and subsidence data generated by the four DVRTs were acquired through the use of an analogue to digital acquisition card for each DVRT located in the MicroStrain Data Acquisition box, (MicroStrain Inc., Vermont, USA). The results were recorded and displayed via the MicroStrain Data Acquisition Display software, (MicroStrain Inc., Vermont, USA), which had been loaded onto a personal computer. The output from the DVRTs was logged at 10 Hz and recorded continuously throughout the entire test period. The data was then analysed using a spreadsheet template, which converted the voltage data for each sensor into micrometer data using the equation derived from the calibration data provided with each DVRT. This data provided information on the micromotion and subsidence / lift -off of the tibial tray relative to the tibial bone

in the anterior, posterior, medial and lateral target positions. Data were analysed for each percentage BW cycle.

2.4 EXPERIMEMTAL RESULTS

During the cyclic testing all specimens were observed and no gross failure occurred. All tibia tolerated the loading without visible fracture or subsidence. All components tested without the addition of a modular stem appeared to be fully seated without space between the tray and the underlying bone. Some components tested with the addition of a modular stem were translated anteriorly after implantation. This caused a visible space between the tray and the underlying bone, which was reflected in the micromotion values recorded. This was particularly evident in the cementless experiments.

All components were correctly sized, with no overhang of the tibia's cortical rim. Each scenario tested was repeated twice, and the displacement readings were averaged. Displacement readings obtained by the DVRTs were repeatable. Translational and rotational displacements were not measured, consequently the displacements reported here represent only primary vertical displacement. The displacements for all tibia tested were measured at an offset from the edge of the tibial component. The offset was dictated by the design of the tibial tray tested and the anatomy of the proximal tibia used. The offset was the same for all scenarios tested in order to ensure that displacements are directly comparable.

The stability of the prosthetic implant being tested was analysed by measuring two types of motion. The micromotion or inducible displacement was defined as the recoverable displacement of the tray between the peak load and the minimum load for each cycle. The subsidence or migration was defined as the tray's permanent displacement relative to the bone surface over time.

2.4.1 Results for Group One: Primary tibias

The inducible displacements recorded for group one varied from specimen to specimen in both the cemented and uncemented specimens. The results shown here represent the average micromotion recorded for each scenario tested. The maximum micromotion generally occurred in the anterior or posterior region within group one. The maximum average motion detected by any of the four DVRTs for both the hybrid cemented and uncemented specimens during each phase of the loading cycle varied from 9.6 μm to 766 μm. The maximum micromotion recorded for all tibias in the uncemented group varied from 46 μm to 766 μm, while the maximum micromotion induced for all the tibias within the hybrid cemented group varied from 5.5 μm to 120 μm for the same loading regime. The average micromotion determined by all four DVRTs at each load increment for all primary bone models can be seen in Fig 2.18. Fig. 2.19 shows the average tray subsidence for the primary tibial trays tested with and without modular stems and with and without cement.

It can be seen from Fig.2.18 that the addition of a modular stem to an uncemented tray reduces the micromotion experienced by the tray when the load exerted on the tray is minimal in the range of one to two times BW. In this range the addition of an 80mm modular stem provides the optimum resistance to micromotion. Furthermore it clearly shows that the addition of a modular stem to an uncemented tray does not reduce micromotion values to the same level as those experienced by the hybrid cemented trays. At the higher load cycles of five to six times BW especially, the addition of a 40mm or an 80mm modular stem increased the micromotion experienced by the uncemented tibial tray rather than reducing it.

Fig.2.18. Average micromotion determined by all four DVRTs at each load increment for all Primary bone models.

Fig.2.19. Average tray subsidence for the primary tibial trays tested with and without modular stems and with and without cement.

Fig.2.20. Visible separation between the tray with a modular stem and the test bone in posterior region.

This could be due to the fact that the addition of a central modular stem translated the tray anteriorly. Such a result occurs due to the fact that the tibial resection cut is made at three degrees whereas in contrast the canal which is reamed to receive the modular stem is parallel to the long axis of the bone. This causes improper seating of the implant on the resected tibial surface, which in turn leads to visible separation between the tray and the bone, particularly in the posterior region, (Fig.2.20). The posterior lift-off phenomenon can be seen in surgery when using press-fit stems.

When the higher loads were applied to the tray the addition of a modular stem alone could not prevent the gap from closing, resulting in increased micromotion values for the uncemented trays. In the cemented trays this was not an issue as the surface cement mantle filled the void between the tray and the bone. If a gap is noticed during implantation in the surgical scenario the surgeon can downsize the stem from the size reamed to and use a cemented stem rather than a press-fit one to gain adequate seating. Alternatively, the tibia could be re-cut to reduce the posterior slope and consequently the level of separation. What was noted from the results is that even gaps of 0.3 – 0.5 mm between the uncemented tray and the resected surface translate directly to tray micromotion,

ANTERIOR

MEDIAL

LATERAL

POSTERIOR

- ☐ No Cement - Pressfit
- ■ Hybrid surface cemented

Fig.2.21. Average micromotion at 1-6 x BW for Primary hybrid cemented trays with no modular stem versus cementless press fit trays with no modular stem.

It can be noted from Fig.2.21 that the highest micromotion occurred in the anterior and posterior region of the tray, in both the uncemented and hybrid cemented trays tested. The posterior region experienced the highest levels of micromotion in both cases, 525 μm in the uncemented tests and 114 μm in the hybrid cemented tests. This region also experienced the highest levels of micromotion in the 40mm and 80mm modular stemmed groups for both the cemented and uncemented specimens, (Fig. 2.22 & Fig. 2.23). The medial and

lateral aspects of the tray experienced very similar micromotions, showing the tray was being displaced about the medial-lateral axis of the tray.

2.4.1.2 Micromotion results of hybrid cemented trays with a 40mm modular stem compared to cementless press fit trays with a 40mm modular stem.

Fig.2.22. Average micromotion at 1-6 x BW for Primary hybrid cemented trays with a 40mm modular stem versus cementless press fit trays with a 40mm modular stem.

and open during the cyclic loading. This did not occur for the cemented trays tested due to the fact that the cement fills the voids between the bone and tray.

ANTERIOR

MEDIAL

LATERAL

POSTERIOR
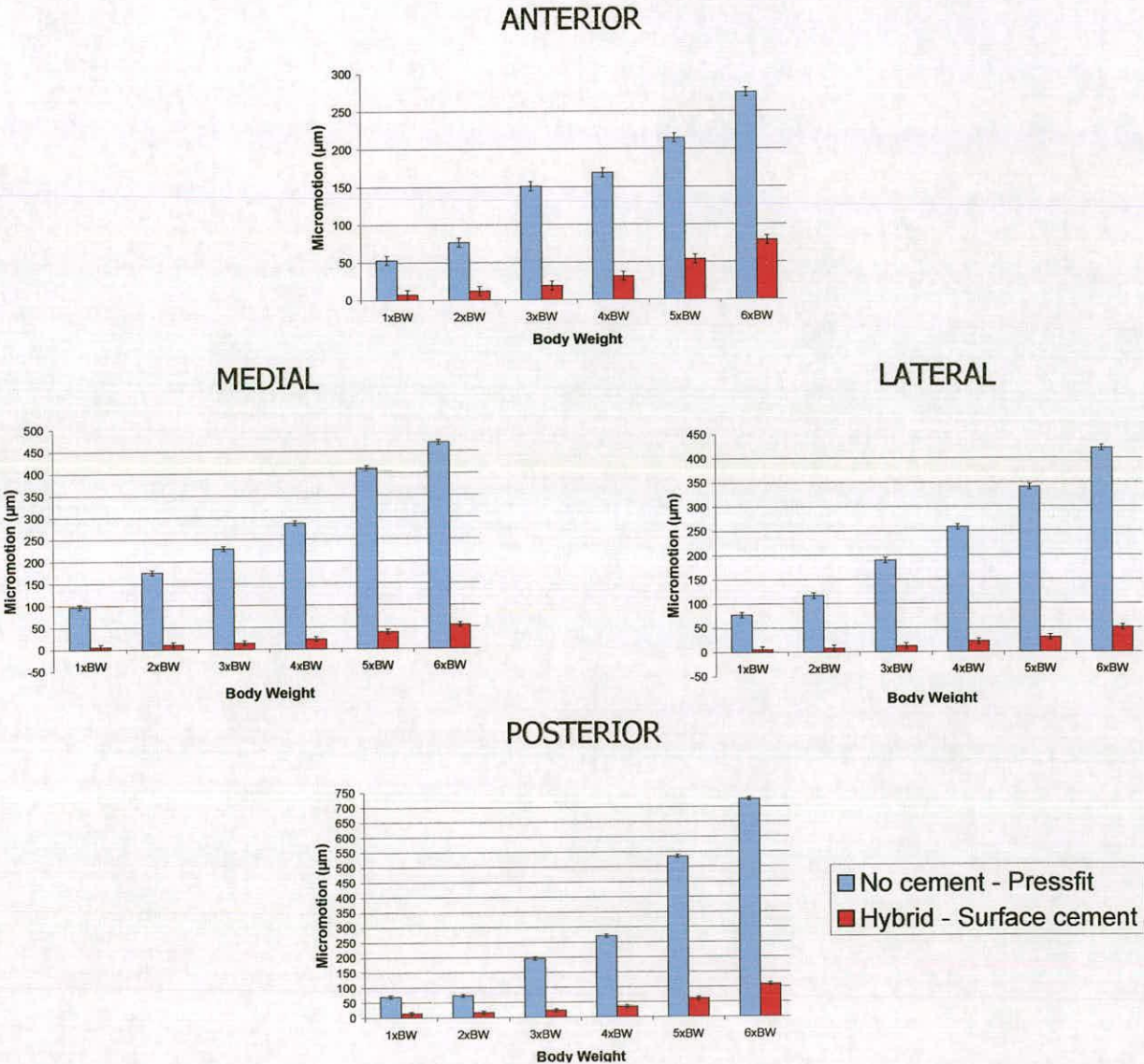
Fig.2.23. Average micromotion at 1-6 x BW for Primary hybrid cemented trays with a 80mm modular stem versus cementless press fit trays with a 80mm modular stem.

From Fig. 2.21 – Fig. 2.23 it can be seen that the micromotion experienced by the uncemented trays increases by a greater proportion with every load increment when contrasted to the hybrid cemented trays. With the cemented trays the increase in micromotion often does not increase substantially until
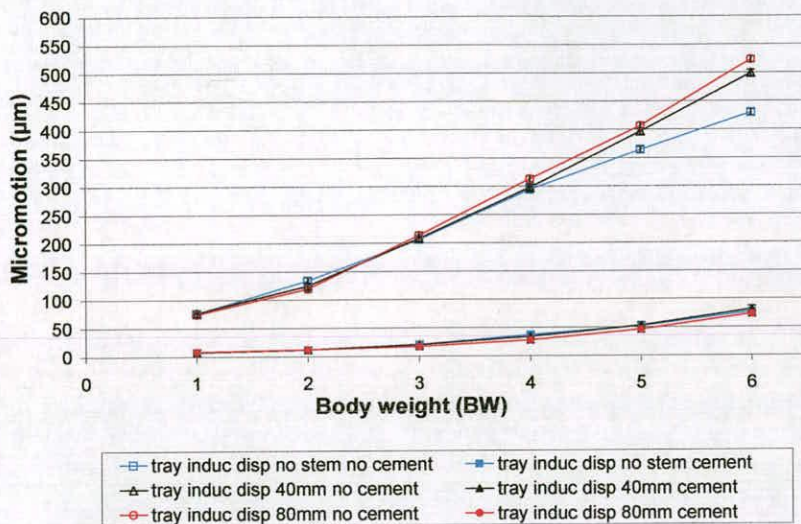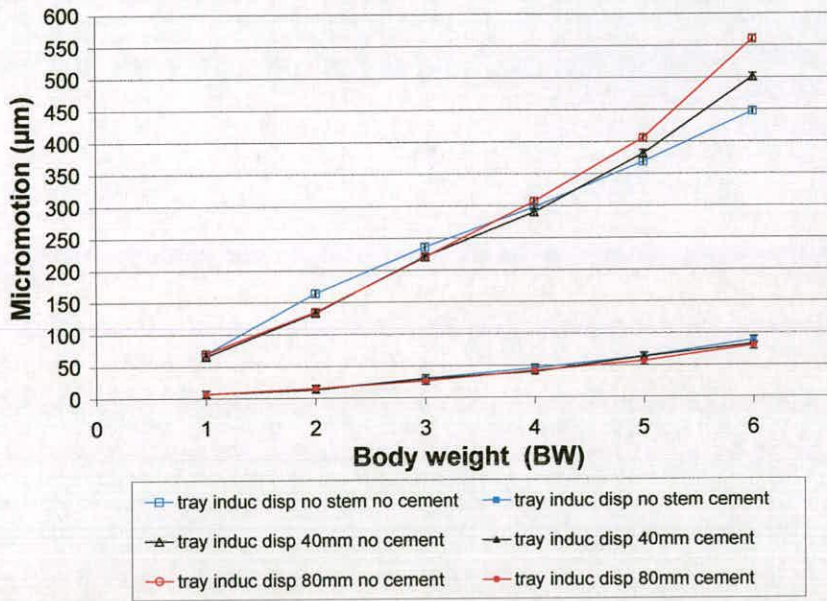
Fig.2.24. Average micromotion determined by all four DVRTs at each load increment for all Revision T2A bone models.
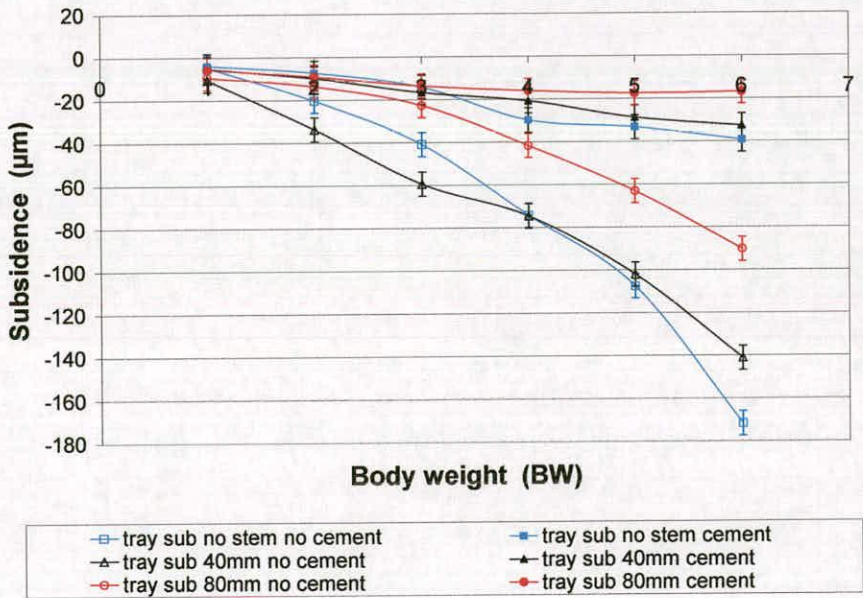
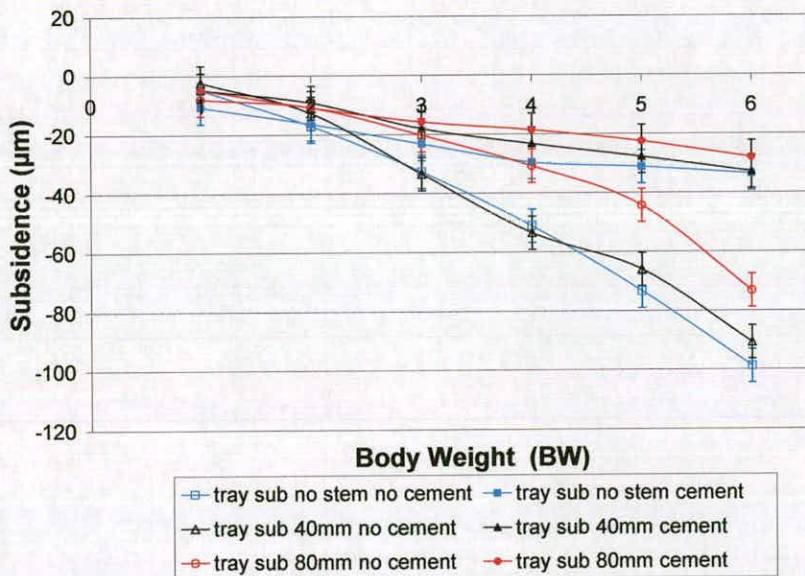
Fig. 2.25. Average tray subsidence for the revision T2A tibial trays tested with and without modular stems and with and without cement.
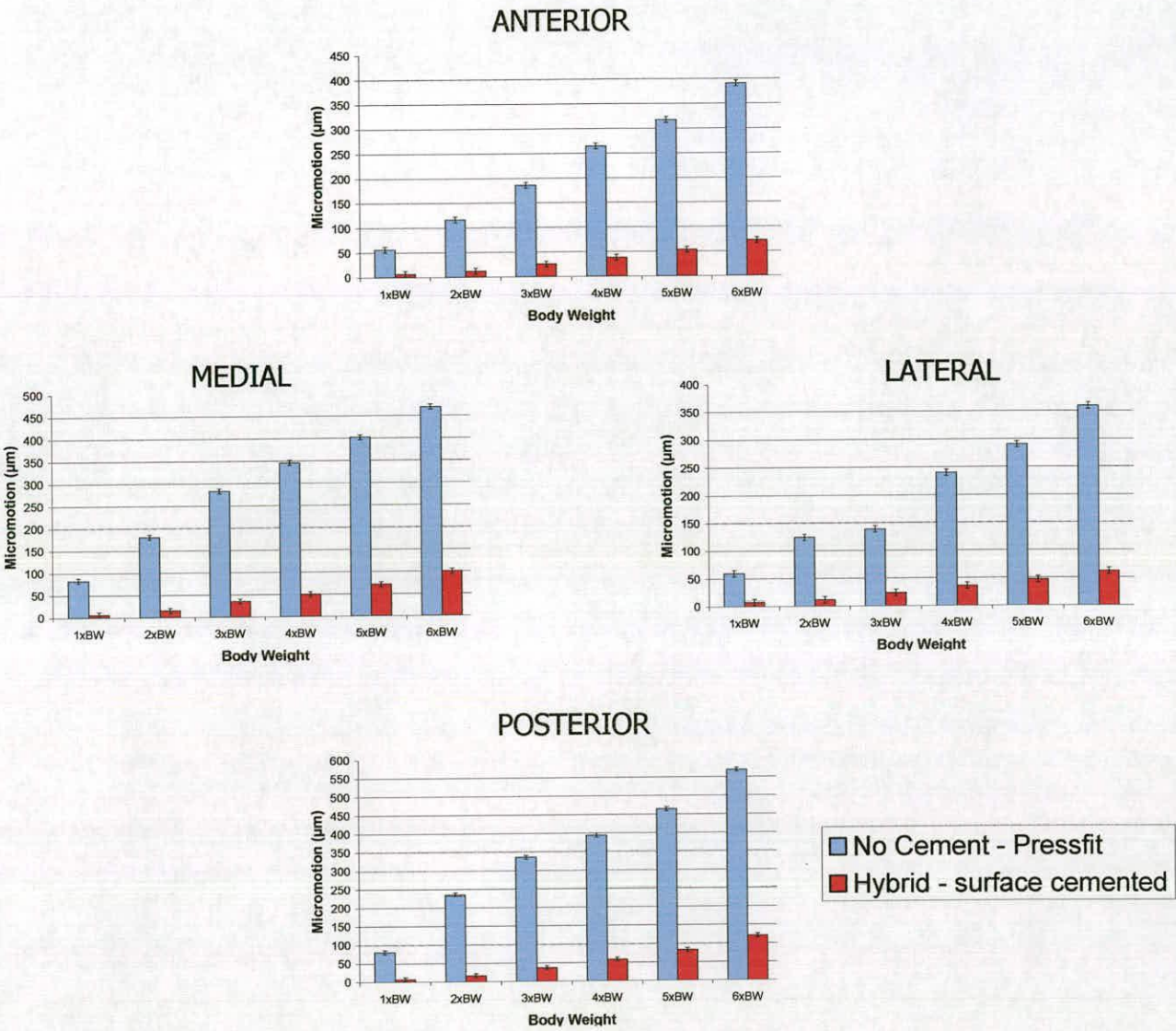
Fig.2.26. Average micromotion at 1-6 x BW for T2A hybrid cemented trays with no modular stem versus cementless press fit trays with no modular stem.

ANTERIOR

MEDIAL

LATERAL

POSTERIOR

■ No Cement - Pressfit
■ Hybrid - surface cemented
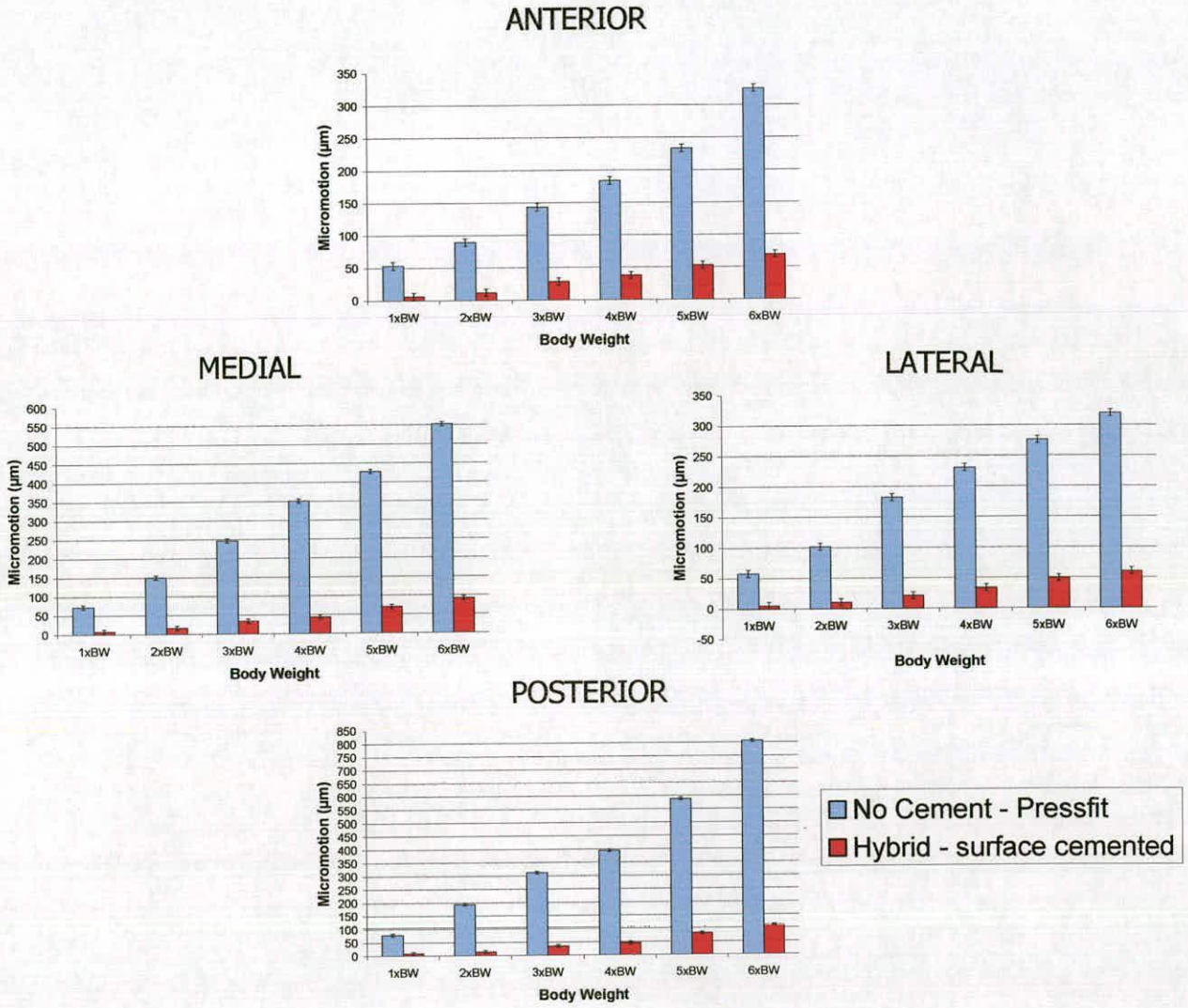
Fig.2.27. Average micromotion at 1-6 x BW for T2A hybrid cemented trays with a 40mm modular stem versus cementless press fit trays with a 40mm modular stem.

ANTERIOR

MEDIAL
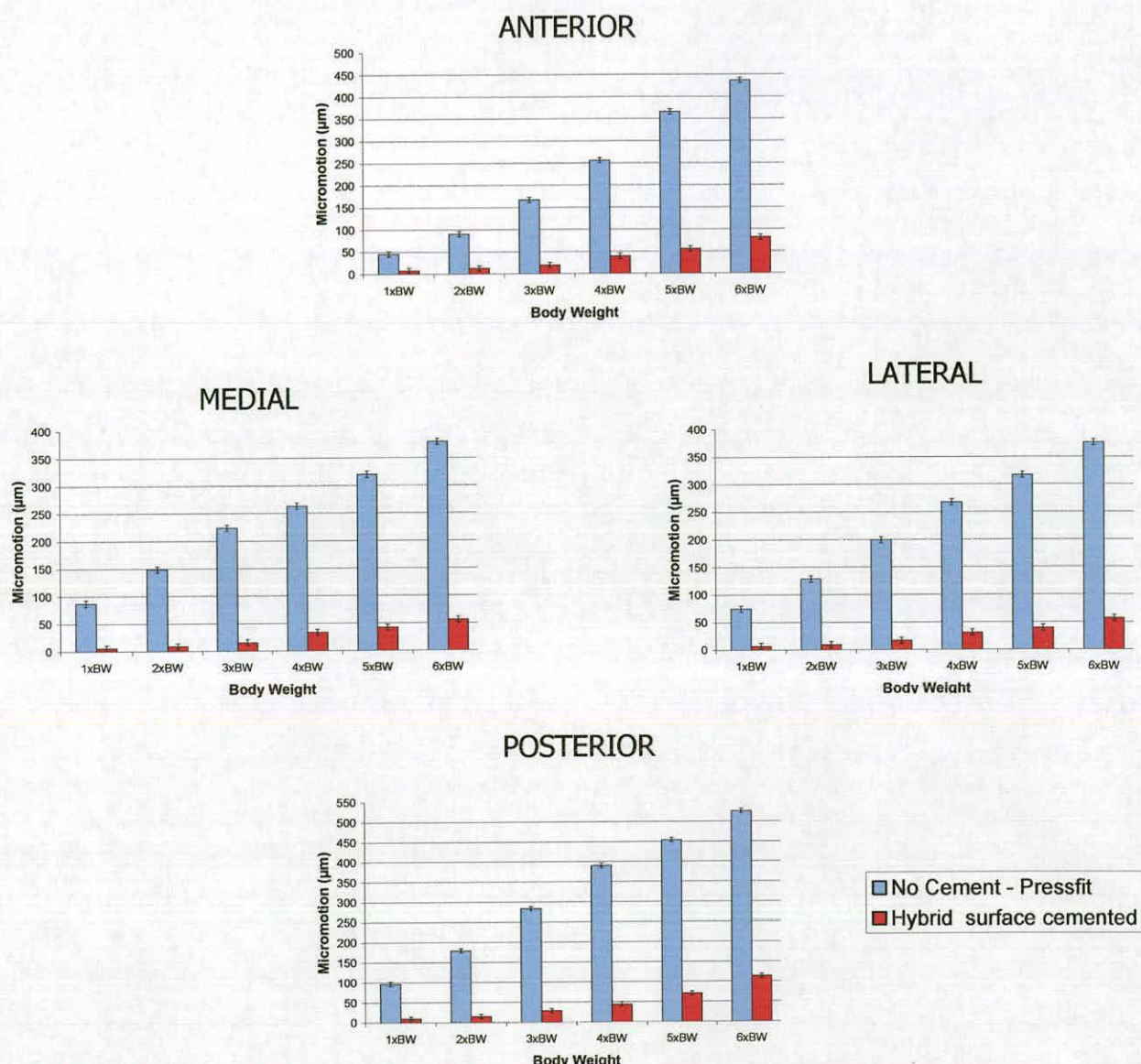

LATERAL

POSTERIOR

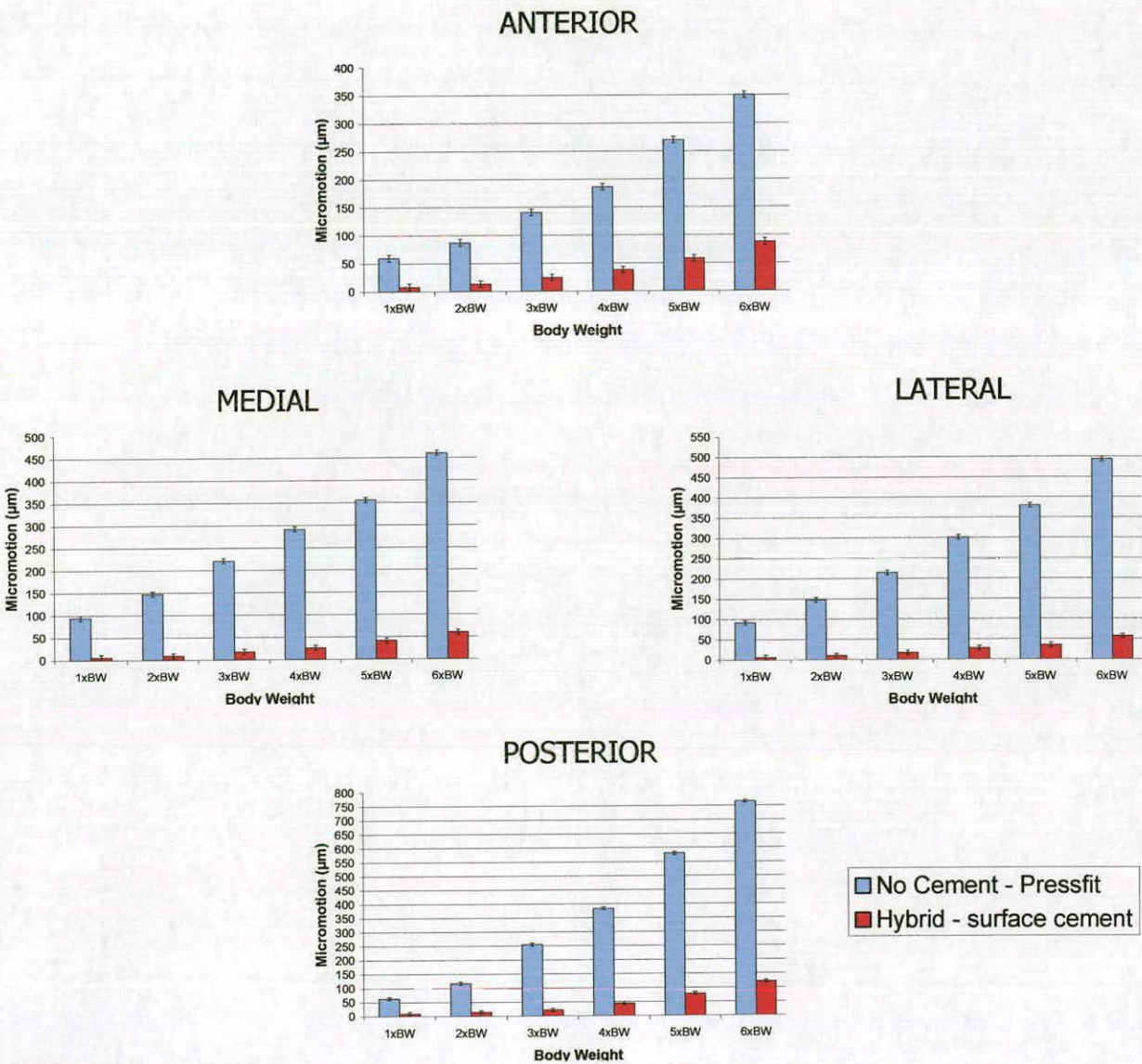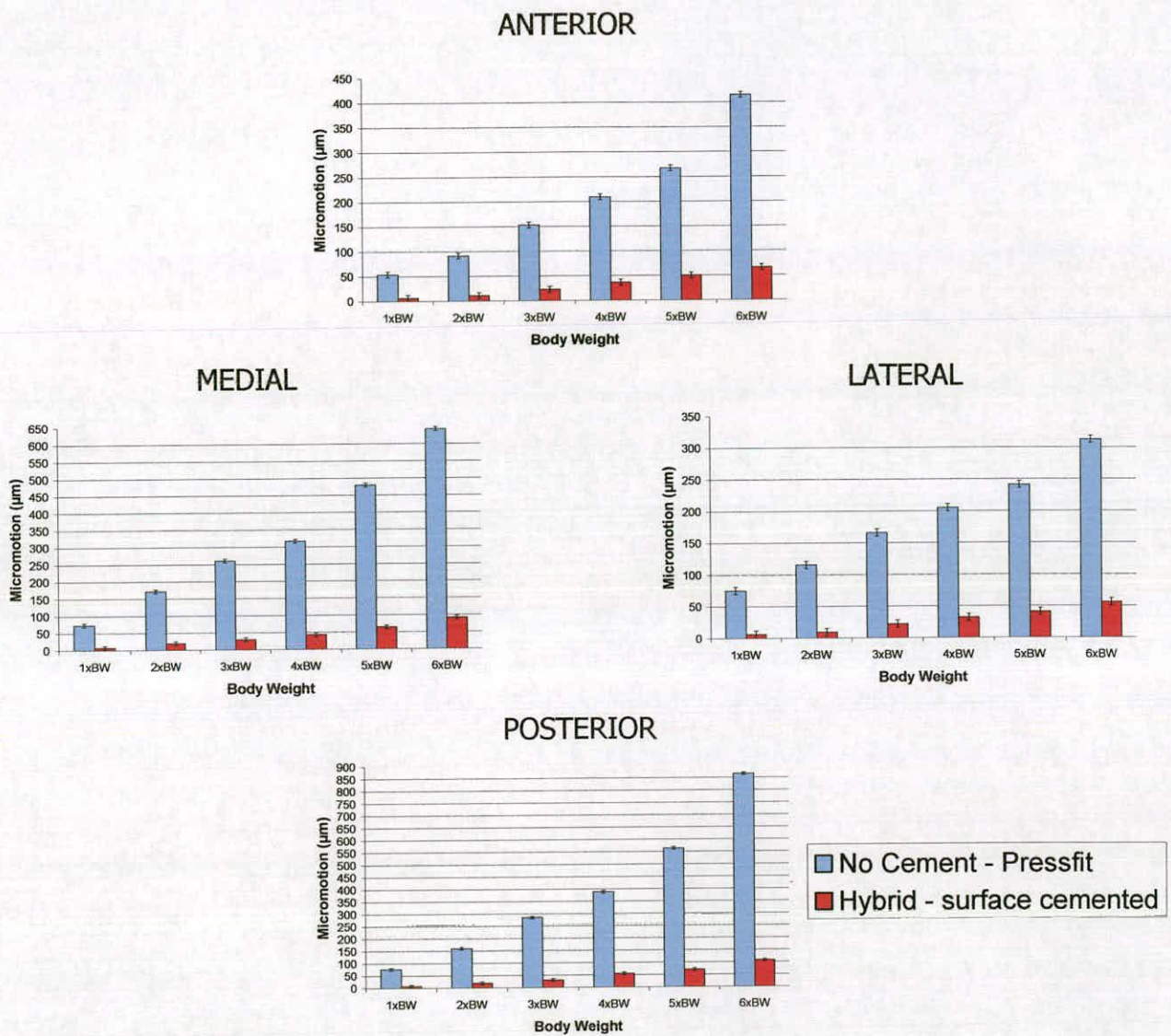
Fig.2.28. Average micromotion at 1-6 x BW for T2A hybrid cemented trays with a 80mm modular stem versus cementless press fit trays with a 80mm modular stem.

especially when the knee experiences the higher loading cycles. Such small gaps may be hard to notice in the surgical environment.

In the cemented group, the micromotion recorded was significantly reduced when compared to the cementless group across the entire loading regime. The maximum average micromotion detected in the uncemented group was 517 μm. In the cemented group it was just 82 μm a difference of 435 μm for the same loading pattern. The addition of a modular stem did not lower the micromotion experienced by the uncemented trays to that experienced by the cemented trays at any point throughout the loading cycle. The addition of a modular stem to the hybrid cemented trays did not provide a dramatic reduction in the micromotion experienced. The average difference in micromotion measured by all four DVRTs between the hybrid cemented tray with no modular stem and the hybrid cemented tray with an 80mm modular stem was just 5.1 μm. This lies within the error band of the sensors. The maximum difference in micromotion detected between the two trays was 9.8 μm. It can therefore be concluded from these results that adding a modular stem to a hybrid cemented tibial tray in the primary scenario makes no difference to the level of micromotion experienced.

The addition of a modular stem did reduce the average overall subsidence experienced by the tray in both the cemented and uncemented groups, with the 80mm modular stem again providing the optimum resistance against subsidence in both groups. The subsidence experienced by the uncemented tray with an 80mm modular stem was 40 μm more than that experienced by the cemented tray experienced with no modular stem, and 45 μm more than the cemented tray with an 80mm modular stem. Therefore it can be concluded that the addition of a modular stem does not provide the equivalent resistance to subsidence that surface cementing does.

In the cemented group the addition of an 80mm modular stem did reduce the subsidence experienced by the tray. The subsidence was reduced from 33.5 μm for the hybrid cemented tray with no modular stem to 28 μm for the tray with an

80mm modular stem, a difference of just 5.5 µm. This difference lies within the error of the sensors (+/- 5.7 µm) so there is no advantage in adding a modular stem to a surface cemented tray in the primary situation in order to reduce the subsidence of the tray.

A sound cement mantle provides the optimal resistance against excess motion. It should be noted that a sound cement mantle and no modular stem reduces both micromotion and subsidence by a greater margin than the longest 80mm modular stem without a cement mantle present. As a result the addition of a modular stem does not provide the same initial fixation as a cement mantle. Adding a modular stem to the hybrid cemented specimens provides no extra benefit in reducing the micromotion or subsidence experienced by the tray, but may add to complications linked to the use of modular stem, such as stem fracture and pain at stem tip.

2.4.1.1 Micromotion results of hybrid cemented trays with no modular stem compared to cementless press fit trays with no modular stem.

Figs. 2.21 – 2.23 depicts the average micromotion at one to six times BW for all primary hybrid cemented and uncemented trays tested. The average micromotion that occurred in the anterior, posterior, medial and lateral aspects of the tray can be seen. This provides information on where the tray was being displaced and the magnitude of the displacement throughout the loading cycle, thereby giving a better picture of the tray motion.

It can be seen from Fig. 2.22 that the average micromotion experienced in the anterior, posterior, medial, and lateral aspects of the trays tested increases for the higher loads when compared to the uncemented test results in Fig 2.21. The highest micromotion recorded for the cementless press fit trays with a 40mm modular stem was in the posterior region, reaching 766 μm.

Higher micromotion was also seen in the posterior region for the hybrid cemented trays with a 40mm modular stem, when compared with the hybrid cemented tray with no modular stem a difference of 120μm compared to 114μm. The micromotion results in the medial and lateral aspects remained similar but were also higher when compared to the results in Fig.2.21.

2.4.1.3 Hybrid cemented trays with an 80mm modular stem compared to cementless press fit trays with an 80mm modular stem.

Fig.2.23 shows that the highest micromotion with the hybrid cemented trays with an 80mm modular stem and the cementless press fit trays with an 80mm modular stem occurred in the posterior region. For the uncemented tray, displacements of up to 469 μm were also seen for the six times BW loading phase in the medial region.

As mentioned previously, the elevated micromotion values recorded for the higher loads illustrated in Fig 2.22 and Fig 2.23 when compared to Fig 2.21 are due to the modular stems negating the posterior angle of the resected tibial surface by translating the tray anteriorly, (Fig 2.20). This caused separation between the bone and the tray, and at the higher loads in particular the modular stem alone could not overcome the deforming forces, causing the gap to close

five – six times BW with relatively constant micromotion experienced by the tray in all regions for the lower load phases.

2.4.2 Results for Group Two: Revision T2A Tibias

The results from the stability tests performed with the augmented tibial trays are shown in Fig. 2.24. The data falls into groups which are determined by the type of fixation which was applied. The inducible displacements, (micromotions), which were recorded, varied from specimen to specimen in both the cemented and uncemented T2A specimens. The results presented here once again represent the average micromotion recorded for each scenario tested at the different load increments. The maximum micromotion for the revision T2A tibias generally occurred in the posterior and medial region, beneath the augment. This differed from the primary tibias tested, where the greater displacements occurred in the anterior and posterior regions. The least stability and greatest micromotion was provided by the uncemented specimens, as was the case in the primary models tested.

The maximum average motion detected by any of the four DVRTs for both the hybrid cemented and uncemented specimens during each phase of the loading cycle varied from 8.7 μm at one times BW to 866 μm at six times BW. The maximum micromotion recorded for all tibias in the uncemented group varied from 80 μm to 866 μm, while the maximum micromotion induced for all the tibias within the hybrid cemented group varied from 8.7 μm to 123 μm for the same loading regime. The average micromotion determined by all four DVRTs at each load increment for all revision T2A bone models can be seen in Fig 2.24. The average tray subsidence for the revision T2A tibial trays tested with and without modular stems and with and without cement is illustrated in Fig 2.25.

The addition of a modular stem to an uncemented tray in the revision T2A group once again reduced the micromotion experienced by the tray for the lower load phases. The addition of an 80mm modular stem provided the optimum resistance to micromotion in this range, as it did for the primary group, (Fig. 2.24). As in the primary group, adding a modular stem to an uncemented tray in the revision T2A group does not reduce the micromotion values to the same level as those experienced by the hybrid cemented trays. For the higher loads of four, five and six times BW the non modular stem trays provided the best stability. The addition of a 40mm or 80mm modular stem increased the micromotion experienced by the uncemented tibial tray, especially during the five and six times BW loading phase, (Fig. 2.24). Possible reasons for this have already been discussed. In addition to the previous factors considered, the T2A tibias require a 10 mm resection to accommodate the tibial augment. Achieving a perfect parallel 10mm cut is not always possible. Any errors in depth or angle translated directly to increased space between the augment and underlying bone. These errors were then translated into the higher micromotion values recorded, in particular on the medial and posterior side.

As in the primary group, the cemented T2A group recorded significantly reduced micromotion levels when compared to the cementless T2A group, across the entire loading regime. The maximum average micromotion detected in the uncemented group was 843 μm. By contrast in the cemented group it was 121 μm, a difference of 722 μm for the same loading phase of six times BW. Once again the addition of a modular stem to the hybrid cemented T2A trays did not provide a dramatic reduction in the micromotion experienced. The addition of a sound cement mantle alone was enough to provide stability to the tray, even with the addition of a 10mm modular augment to the tray's underside.

The average difference in micromotion measured by all four DVRTs between the hybrid cemented T2A tray with no modular stem and the hybrid cemented T2A tray with an 80mm modular stem was just 5.6 μm. This lies within the +/-5.7 μm

error band of the sensors. The maximum difference in micromotion detected between the 80mm modular stemmed tray and the non stemmed tray was 13.5 µm. Thus from these results it can be concluded that adding a modular stem to a hybrid cemented tibial tray with an augment in the simple T2A revision scenario makes no difference to the level of micromotion measured.

The addition of a modular stem did reduce the average overall subsidence experienced by the tray in both the T2A cemented and T2A uncemented groups, as it did in the primary group. The 80mm modular stem provided the optimum resistance against subsidence in both groups. The subsidence experienced by the uncemented tray with no modular stem was 172 µm. With the addition of an 80mm modular stem the subsidence experienced was reduced to 90 µm, (Fig. 2.25). This, however, was still more than the cemented tray experienced with no modular stem. The average overall level of subsidence that occurred with the cemented tray and no modular stem was 39 µm. Once again with the addition of an 80mm modular stem the average overall subsidence dropped to 18 µm, (Fig.2.25).

As in the primary scenario, it can be deduced from these results that the addition of a modular stem to an uncemented tray does not provide the equivalent resistance to subsidence that surface cementing does in a revision T2A setting. However, unlike in the primary cemented group the addition of an 80mm modular stem to the T2A tray did reduce the subsidence experienced by the tray by a greater margin, with the subsidence reducing by 11 µm, (+/- 5.7 µm), compared to just 5.5 µm in the primary cemented experiments. Thus there is an advantage in adding a modular stem to a surface cemented tray in the T2A situation in order to reduce the subsidence of the tray.

Overall, as in the primary group one results a sound cement mantle provides the optimal resistance against excess motion, both subsidence and inducible micromotion. It should be noted that a sound cement mantle and no modular

stem reduces both micromotion and subsidence by a greater margin than the longest 80mm modular stem without a cement mantle present in the revision T2A setting. The addition of a modular stem to an uncemented construct does not provide the same initial fixation as a cement mantle to the same construct. Adding a modular stem to the hybrid cemented specimens provides no extra benefit as regards reducing the micromotion, but it does reduce the subsidence experienced by the tray to a greater margin in the T2A group when compared to the primary group.

2.4.2.1 Hybrid cemented trays with no modular stem compared to cementless press fit trays with no modular stem.

Fig. 2.26 – 2.29 illustrates the average micromotion at one – six times BW for all revision T2A hybrid cemented and uncemented trays tested. The average micromotion that occurred in the anterior, posterior, medial and lateral aspects of the tray is depicted.

From Fig.2.26 it can be seen that the highest micromotion occurred in the posterior - medial region of the tray. This trend was seen in both the uncemented and hybrid cemented trays tested. (This differs from the primary group where the highest motion originated in the anterior and posterior regions). The posterior region experienced the highest average levels of micromotion in both the uncemented and hybrid cemented tests, an average of 570 μm and 121 μm respectively at six times BW. The motion on the medial side, (the same side as the 10mm augment), averaged 470 μm in the uncemented tests and 100 μm in the hybrid cemented tests, (Fig.2.26) at six times body weight.

2.4.2.2 Hybrid cemented trays with a 40mm modular stem compared to cementless press fit trays with a 40mm modular stem.

As in the primary group, higher levels of micromotion were recorded at five and six times BW in the uncemented T2A 40mm modular stemmed group when contrasted with the uncemented T2A no modular stem group. This was due to greater separation between the bone and tray in the medial and posterior regions, for reasons already discussed.

Micromotion in the posterior – medial region was dominant in the 40mm modular stem group, as it was in the no modular stem group for both the uncemented and cemented tests. The posterior region of the tray experienced average micromotion at six times BW of 807 μm in the uncemented experiments. This dropped to 110 μm when the tray was secured with a surface cement mantle. On the medial side, the average micromotion levels reached 553 μm for the uncemented tray and 92 μm for the cemented tray, (Fig. 2.27). The anterior and lateral displacements were of the same magnitude, suggesting that the T2A tray was being displaced around a anterior – medial / posterior - lateral axis, unlike the primary tray that experienced the greatest motion about the medial-lateral axis.

2.4.2.3 Hybrid cemented trays with an 80mm modular stem compared to cementless press fit trays with an 80mm modular stem.

Fig.2.28 demonstrates that the highest micromotion was again recorded in the medial and posterior aspects of the tray. For the uncemented trays, an average displacement of 643 μm was seen for the six times BW loading phase in the medial region. This dropped to 92 μm when the tray was secured with cement.

From Fig. 2.26 – Fig. 2.29 it can again be seen that the micromotion experienced by the T2A uncemented trays increases by a greater proportion with every load increment when compared to the T2A hybrid cemented trays, as it did in the primary group. The data demonstrates that in the revision T2A scenario a sound metaphysis cement fixation provides the optimum stability to the tray for all loads. An 80mm modular stem does not provide the same initial stability to the tray even at low BW loads.

2.5 DISCUSSION

The long-term results of cemented TKA have generally achieved excellent follow up data, with survival rates as high as ninety to ninety five percent at ten to fifteen years follow up[4,26]. However, loosening of the tibial component remains the major mode of failure in cemented and cementless TKA[8,21,23,25]. One of the most important factors in achieving long term survivorship for TKA is the initial fixation of the tibial tray[34]. It is believed that the addition of a modular stem may enhance initial fixation especially in the revision tibia scenarios. Current studies provide varying evidence on the use of stems, and few have examined the role of modular stems in the revision tibia.

In this in vitro experimental series, hybrid cemented and non-cemented implants were investigated using a cyclic loading phase representative of physiological loads for different daily activities. The comparisons between the differing configurations of stemmed and non-stemmed trays was made using a measuring system that allowed the axial displacements of four targets, (an anterior, posterior, medial and lateral target), to be recorded throughout the loading cycle. This method allowed the stability of the prosthetic implant undergoing testing to be analysed by measuring two types of motion. Micromotion defined as the recoverable displacement of the tray between the peak load and the minimum load for each cycle and subsidence, defined as the tray's permanent displacement relative to the bone surface over time.

From the micromotion data presented in this study,(Fig. 2.18 and Fig.2.24), it was found that within both the primary and T2A uncemented groups tested the addition of a 40mm or an 80mm modular stem did not decrease the motion experienced by the tray. In fact, the micromotion results show a clear increase with the addition of a modular stem, especially during the higher loading phases which the tray was subjected to. The most prominent increase in micromotion was seen in the T2A tray with an 80mm modular stem cases at six times BW.

114

This data suggests that instead of increasing the stability of the implant construct, the addition of a central intramedullary modular stem to an uncemented tibial tray actually increases the micromotion experienced by the tray, thus lowering the stability of the tibial tray in both the primary and revision T2A setting. This phenomenon has also been reported by Stern et al[51], in a cadaver study looking at the stability associated with central stems in the primary TKA setting. They also observed an increase in micromotion as the length of the central stem progressed from no stem, to short stem, to long stem, with the highest increase being for the addition of a 75mm modular stem.

It is the considered opinion of this author that increased micromotion associated with the longer modular stems is due to the fact that the addition of an increased central stem prevents full seating of the tibial tray against the resected tibial surface, (Fig. 2.20). These were also the thoughts of Stern et al[51]. Jasty et al[85], demonstrated in a dog study that the presence of gap of between 0.5 – 1mm reduced boney ingrowth by 50%. It can therefore be inferred that improper seating can prevent initial and long term fixation in the uncemented tray scenario.

It became clear during this study that in order to achieve a sound proximal fit between the bone and tibial tray, the accuracy of the tibial proximal cut is critical, especially so in the cementless samples. In the cementless samples it is the accuracy of the cut alone that is relied upon to provide a flush fit and stability between the resected tibial plateau and the implant. Cutting errors directly translated into displacements during the loading cycle in the cementless groups tested. The surface morphology of the resected tibial plateau is not perfectly flat. There can be large variations in the morphology of the resected surface, which are dependent on the patient's pathology, the instruments used, the surgeon and the surgical technique employed.

Toksvig-Larsen and Ryd[86], reported the flatness of the resected tibial surface, defined as the standard deviation of the measuring points, was 0.26 mm (range, 0.16–0.38 mm). This lack of smoothness created gaps between the bone and prosthesis, which were large enough to prevent direct bone contact when using uncemented fixation. The variations in separation between the tibial tray and resected bone for the uncemented prosthesis correspond directly to the micromotion values recorded for both the primary and T2A uncemented specimens under loading. These gaps open and close as the specimens are loaded resulting in micromotion. These errors were magnified with the addition of a central intramedullary stem. Pillar et al[17] demonstrated that excessive micromotion of 150μm or more can result in attachment of fibrous tissue rather than bone, hindering the stability of the implant. Consequently it should be noted that cutting errors can have a direct impact on initial and long term stability in uncemented implants.

The basic principle of press-fit intramedullary stems is that they enter the tibial medullary canal with the aim of aligning the prosthesis with the long axis of the tibia. Thus any posterior cut that has been built into or occurred during the tibial resection can be negated, creating a larger void between the tibial tray and the bone surface, (Fig. 2.20). In conjunction with this, the press-fit stems are designed to engage the cortical bone and thus the medullary canal is reamed until cortical contact is achieved. As the stem is placed down the intramedullary canal it contacts with the inner cortical surface. This helps to transfer the load down the shaft of the tibia away from the proximal resected plateau. However if the stem tip only contacts the cortical inner surface over a small area, poor fixation and seating of the implant may occur. Consequently as the loads experienced by the tray increases the stability provided by the stem fails. This could lead to pain at the stem tip of the uncemented stem as high forces are being transferred over a small surface area.

More importantly, the small contact point could act as a pivot point about which the implant construct could sway during loading, leading to a "teeter - totter" effect about the stem tip or point of stem contact as the implant is loaded. The observation that as the stem length increases the micromotion increases during this study provides further weight to the argument that this "teeter – totter" effect is what is occurring. As one would expect increasingly larger micromotions to be detected as the length of the modular stem increased, because the distance from the targets, (the point where the micromotion is being measured), to the stem tip pivot point is increasing.

Larger average micromotion displacements were recorded for the T2A uncemented group, in particular during the higher loading cycles when contrasted with the primary uncemented group. One explanation for this could be the combined cutting errors, (as two resections had to be made in order to implant the augmented tray), leading to an increased level of separation between the underlying bone and implant, which in turn can close during loading especially in the posterior – medial region. Due to the increased displacement in the posterior medial region of the tray, it was noted that the bone often deformed more than in the primary tests. This could have lead to slight eccentric loading of the base plate. The slight eccentric loading could have caused the increased micromotion witnessed in the T2A specimens, as the line of the force is applied through a different axis from that of the stem.

As already stated, the modular stems used in this study were press-fit cortical contacting stems. The 80mm modular stem had a diameter of 18mm and the 40mm modular stem had a diameter of 20mm. If thinner non-cortical contacting stems had been used then perhaps this "teeter-totter" effect may not have been recorded. It has been noted by this author that surgeons will often ream for a long press-fit stem to use during surgery, in order to help with cutting block alignment. The surgeon will then down size the stem diameter and cement a stem in place to achieve better seating of the implant and eradicate the "teeter-

totter effect witnessed in this study. Also, if a greater percentage of diaphyseal cortical canal engagement was achieved intraoperatively this may also decrease the level of "teeter – totter" experienced by the tibial tray.

The addition of a modular stem did reduce the average overall subsidence experienced by the tray in both the primary and T2A uncemented groups, (Fig.2.19 and Fig.2.25). The 80mm modular stem provided the optimum resistance against subsidence in both uncemented groups. However it did not lower the subsidence levels experienced by the tibial tray to those recorded for a surface cemented tray with no modular stem, in either the primary or T2A specimens.

No real differences were detected in the averaged tibial component micromotions between the different stemmed components investigated in the primary and the T2A groups when the hybrid surface cemented technique was applied. The addition of a modular stem made little difference to the magnitude of micromotion or subsidence experienced by the tibial tray for both the primary and revision T2A specimens. No increase in micromotion was witnessed with the addition of a modular and a surface cement mantle, as the cement mantle fills any voids between the tray and resected tibial plateau, thereby providing a more secure fit between bone and implant. There is a clear trend of reduced micromotion and subsidence with the addition of a surface cement mantle. The addition of a surface cement mantle and no modular stem provides more favourable stability measurements than an uncemented tray with the addition of a modular stem. If differences in initial stability did exist between the non-stemmed, 40mm stem and 80mm stem prosthesis studied, they may not have been discernible with the testing protocol implemented, which only examined central axial loading over a range of physiological loads.

In current literature there are only a few studies dealing with tibial tray stability, and these are inhomogeneous. Therefore a comparison is only possible to a limited extent.

Fehring and Griffin[87] reported in their series of revisions done for aseptic loosening that cementless implants loosened earlier than cemented implants and led to the need for revision much sooner. They concluded that cementless knee arthroplasty should be abandoned. From the series of data presented here it can be clearly seen that a reason for this could be the high levels of micromotion experienced by uncemented trays in both the primary and the revision T2A scenarios. The results put forward confirm that tibial implants should be cemented to achieve the best mechanical stability.

Branson et al[88], carried out a study of cemented versus non cemented tibial components using human tibia. A cyclic load of 10-2000N was applied to the implant. The uncemented trays exhibited greater motion than the cemented specimens, (a maximum motion of 290 µm and 100 µm respectively, were recorded). Branson et al[88] suggest that the magnitudes of implant – bone interface separation are sufficiently large to hinder bony ingrowth even at the low physiologic load range. This concurs with the conclusions of this study. The results they present are also consistent with what is reported within this report regarding the use of cement. Both studies report less micromotion occurs with the use of cemented implants. The maximum motion of 100 µm recorded at 2000N for the cemented implants is higher than reported here, however this could be down to cement technique or implant design.

Bert and McShane[89], found that significant micromotion occurred with a cementless stem and a 1mm cement mantle under the tibial tray. However, if the cement mantle was increased to 3mm, excellent stability of the implant was seen. In this study all specimens were tested with a cement mantle of 2-3mm, and no micromotion greater than 121 µm was recorded for any specimen tested

with a surface cement mantle, and this motion occurred at six times BW. The 121 µm recorded is still below the value of 150 µm, values greater than which are thought to inhibit bony ingrowth as reported by Pillar et al[17]. Thus the findings of this study match the findings that a surface cement mantle of 2-3mm provides adequate stability to the tibial tray.

Volz et al[90] examined the mechanical stability of porous coated cementless implants. For the AMK and the Whiteside tibial tray, (two stems with a fixed central stem similar to that used in the no modular stem groups in this study), they reported maximum micromotion of 100 µm and 200 µm respectively. The maximum average micromotion recorded in our study was closer to 550 µm, but this was at six times BW. Volz et al[90], loaded the specimens to 115kg roughly equivalent to two times BW loading. Micromotions of between 50-200 µm were recorded in this study providing comparable values.

In a comparative manner with the present findings, Lee et al[23] reported implant stability was greatly enhanced in "poor" quality foam when the implant was cemented. They also reported that the addition of a central stem added stability to the implant in "poor" foam only; perhaps suggesting that if the bone density had been lower in the current study the central stem may have played a greater role in providing stability. It is also worth noting that Lee et al[23], found that adding a stem to a cemented implant did not significantly lower the medial subsidence experienced.

The effect of a central stem and its length on cementless tibial tray micromotion was investigated using cadaver specimens by Yoshii et al[50]. Axial loads of 50-1000N were applied to a stemless group, a 75mm stemmed group and 150mm stemmed group. For axial tests, the 150mm stem significantly reduced subsidence and lift-off. The 75mm stem minimized subsidence and lift-off but not significantly. For shear loading both the 75mm and 150mm central stem

significantly reduced subsidence and micromotion. Yoshii et al[50] conclude that a tibial tray with a 150mm stem can achieve better initial fixation of the implant.

The differences between the findings of Yoshii et al[50] and the current study may be related to the design and length of stem. Yoshii et al[50] showed that a 150mm stem made a significant difference to stability however, a 75mm stem did not. In the study presented here only a 40mm and an 80mm stem were investigated, thus our results may differ for a longer stem. The design of the stem used by Yoshii et al may have been different to the one used in this study. If it was thinner this may have allowed better seating of the implant. They may have also achieved an increased stem - canal engagement zone with the aid of a longer stem, which may account for the improved stability. The loading used in this study is also considerably greater than that used by Yoshii et al.

There are limitations linked to this study which should be borne in mind when evaluating the data presented. This study used four motion transducers to measure axial displacements of the tibial tray. By measuring motions only in the axial directions, the true three-dimensional movement of the stem is not achieved. The loading protocol, although incorporating loads that were representative of daily activities, was applied centrally and in line with the long axis of the tibia. If the loading protocol had included the application of torsional or shear loading, a central modular stem may have provided superior resistance against such forces and the findings of the study may have differed.
Other caveats of this study are linked to the limitations associated with biomechanical bones, and their ability to fully mimic human bone properties. However, if frozen cadaver bone had been used limitations in bone quality and consistency in mechanical properties would have still been present. This model did not incorporate surrounding soft-tissue and muscle interactions. Due to the aforementioned limitations, the absolute magnitudes of the micromotion and subsidence measured in this current study can not be extrapolated directly to the in vivo implant scenario. The purpose of this study however was more concerned

with comparing differences in motion between implanted tibial components placed in primary and T2A tibias with different combinations of central stem and fixation methods, (hybrid cemented and uncemented). The aim was to evaluate how these variables affected the initial stability of the construct rather than with recording absolute values of motion that could relate directly to the in vivo surroundings.

2.6 CONCLUSION

The results presented within this chapter suggest that in a primary and revision T2A TKA scenario it is preferable to use a tibial tray with no modular stem fixed to the bone via a hybrid cement mantle, ensuring sound contact between the tray and the cortical rim.

The findings set out herein indicate that a 40mm or 80mm cortical contact press-fit modular stem does not enhance initial fixation with hybrid cemented or cementless implantation in either primary or revision TKA.

The addition of a modular stem when implanting an uncemented tibial tray may well increase the instability of the construct. The addition of a modular stem can hinder the full seating of the component on the resected tibial surface, leading to potentially higher motion. Cutting errors can translate directly into micromotion when the tray is loaded in uncemented tibial trays, potentially leading to poor boney ingrowth.

Cemented implants with no modular stem have better initial fixation compared to all uncemented implants, (even those with an 80mm modular stem), thus the addition of a modular stem does not offer the stabilizing benefits of cement. Secure fixation of the tibial tray can be better achieved by a cement mantle of 2-3mm.

The routine use of intramedullary modular stems in primary and revision T2A knee arthroplasties is not recommended based on the current study. Avoiding excessive modular stem extensions may reduce a possible mode of implant failure. Longer stem extensions may be more advantageous when highly constrained implants are used and when sound metaphyseal fixation is unattainable, although further scrutiny of this area is required to confirm this.

Chapter 3

Analysis of Tibial Tray Micromotion in Primary and Revision TKA in Six Degrees of Freedom

3.1 INTRODUCTION

The experiments reported within the previous chapter used four motion transducers to measure axial displacements of the tibial tray. By measuring motions only in the axial directions, the true three-dimensional movement of the tibial tray is not achieved. Previously reported micromotion studies have also measured only one-dimensional displacements of a few selected points on the edge of the implant, using linear motion transducers or liquid metal strain gauges[23,50,74,88-91]. Often these studies could only measure axial displacements, termed lift-off, if the point on the tray moved proximally and subsidence if the point on the tray moved distally into the tibia. As a result the true motion of the tray could not be reported.

The findings set out in Chapter two indicated that a 40mm or an 80mm cortical contact press-fit modular stem, did not enhance initial fixation with either hybrid cemented or cementless implantation in both the primary or revision TKA models, however, this is only true for the axial direction. Due to the complex motion that occurs in the knee joint and the variation of forces and angles at which these forces act during ambulation, in order to conclude that modular stems do not enhance initial stability the full three-dimensional movement of the tray must be examined. By measuring the tray motion in all dimensions it may be found that modular stems reduce rotational and translational motion in certain planes but not in the axial direction. The full picture of tray motion is essential and may prove beneficial in understanding initial loosening and long term failure of cement mantles.

A number of studies have examined the three-dimensional movement of hip prosthesis[73,75,92-94], but only one has examined three-dimensional movement of knee components[51]. Stern et al[51] evaluated the three-dimensional motion of a tibial tray based on the motions of two specific points attached to the implant using computer based data collection and analysis. The study determined the

effect of various tibial stem lengths on the motion of a tibial tray, and although their findings were complimentary to those reported in Chapter two in that longer stem implants were associated with increased micromotion, the experiments were carried out in primary bone stock models and not in revision scenarios. The experimental series reported here sets out to measure tibial tray motion in primary and revision bone models in six degrees of freedom to evaluate the true effect that modular stems have on the stability of the tibial tray. The revision situations investigated within this chapter are the T2A scenario, (as investigated in Chapter two) and the T1 revision scenario requiring bone impaction grafting.

The use of morsalised bone graft to restore bone stock in the revision situation is a technique widely used in revision hip surgery. Bone impaction grafting in the hip has been shown to be a viable reconstructive method through mechanical and long term clinical and radiological studies[59,95,96]. Bone impaction grafting in revision TKA was first reported in 1996 by Ullmark and Hovelius[97] and has less clinical data than impaction grafting in the hip.

Due to the differences in the forces generated within the knee when compared to the hip, the same clinical results have not been achieved. Some clinical studies have reported good short term follow up following bone impaction grafting of the proximal tibia[98-100]. However, in 2000 van Loon et al[44] reported on a four year histological follow-up that showed that insufficient initial stability of the tibial tray was achieved following bone grafting of the proximal tibia. The report followed the case of one patient in which the defect repaired was a large uncontained defect requiring mesh and bone impaction grafting. It was reported that this technique may lead to a relatively unstable construct with subsequent poor graft incorporation. In the hip, migration of the stem after impaction grafting has been reported, but it does not seem to pose a clinical issue[59]. In the knee however, it appears that mechanical stability is crucial if the graft is to incorporate and restore the deficient bone stock. In the knee a lack of stability has significant

clinical consequences, as large cyclical movements between the tray and impacted bone graft may cause resorption[101]. Following histological data, modular intramedullary stems are often used in conjunction with proximal impaction grafting of the tibia in an attempt to aid stability of the components and to provide a stable construct and allow the graft to incorporate.

Benjamin et al[100] reported on a clinical study evaluating the use of morsellised grafting and revision prostheses with press-fit modular stems and showed good clinical outcomes at 10 to 72 months follow-up. They concluded that the use of morsellised allograft in revision TKA offers a reasonable option for the reconstruction of bone defects. Their histological retrievals showed that morsellised bone graft has the ability to incorporate and remodel rapidly and can be used successfully even in uncontained defects. They state that successful reconstruction requires the surgeon to obtain a stable construct at the time of surgery using rigid intramedullary fixation and rim seating of the components. Although modular stems may provide greater initial stability concerns have been raised about the use of modular stems. Modular stems by-pass the morsellised graft region and can cause stress shielding[65], which has been linked to poor graft incorporation.

The role of the stem in revision TKA is still unclear. Some authors have reported on a positive correlation between increased stem length and increased stability while others conclude that modular stems do not enhance initial fixation in the primary and quality bone stock scenario as was reported in the previous chapter. Lee et al[23], carried out tests on a foam model which concluded that stems did not improve the stability when bones with quality bone stock were simulated. Although, in the foam models simulating poor bone stock, stems did improve the stability of the tray. Toms et al examined the effect of initial stability with impaction grafting and concluded that the addition of a long stem achieved adequate initial stability. These studies suggest that modular stems may only be required in deficient or low quality bone; however these studies only measured

axial motion and not three-dimensional motion of the tibial tray. They therefore only report an incomplete understanding of the effects of impaction grafting and stems. Implant failure is often a function of both axial and rotational components, the measuring system used within this study maps independently the three dimensional movement of the tray relative to the tibia enabling more information on the true motion of the implant under loading to be gathered.

Given the results recorded in Chapter two it was decided not to investigate uncemented components within this experimental series. However, as debate continues regarding whether the modular tibial stems should be cemented or press-fit both fully cemented and press-fit stems were investigated. Proponents of full cementation of the tibial components argue that this technique provides better short and long term fixation[89]. Proponents of the hybrid technique, where the stem is uncemented argue sufficient implant stability is achieved without the potential for stress shielding which is thought to be associated with fully cemented modular stems[29,81].

Due to the uncertainties related to the use of modular stems within revision TKA and the role that they play in aiding initial stability in a variety of settings, this in-vitro study was designed to investigate the effect of modular stems on the three-dimensional motion experienced by the tibial tray. To achieve this, a custom made measuring system was designed to compare the bone-prosthesis micromotion and migration in three-dimensions for various implant combinations and fixation techniques in both the primary and revision setting. The main questions addressed by this study were: 1) does the addition of an 80mm modular stem reduce the three-dimensional motion experienced by the tibial tray? 2) Is a modular stem required only when poor quality bone is present? 3) Does fully cementing the tibial tray reduce the three-dimensional motion experienced by the tibial tray?

3.2 MATERIALS AND METHODS

Several studies have measured the relative prosthesis-bone motion[50,74,88,102].
These studies used various methods, however, all of the techniques used were
effectively measuring the gap between the implant and the bone in the axial
direction only and they did not provide a complete analysis of the prosthesis
motion with respect to the tibia in three-dimensions. The design and
methodology presented here provides a system that allows the complete implant
motion, (both inducible displacements and subsidence), with respect to the tibia
to be recorded throughout several thousand in vitro loading cycles in three-
dimensions.

Twelve tibias were divided into three groups of four. Group one consisted of the
primary TKA specimens, looking at surface hybrid cement fixation versus fully
cemented fixation with no modular stem and an 80mm modular stem. Group two
consisted of the revision T2A specimens, investigating surface hybrid cement
fixation versus fully cemented fixation with no modular stem and an 80mm
modular stem. Group three contained the T1 specimens repaired using bone
impaction grafting, examining hybrid cement fixation versus fully cemented
fixation with no modular stem and an 80mm modular stem.

The design of the migration and micromotion measuring system was based on
concepts employed by Berzins et al[103], Buhler et al[73], Maher et al[92] and Spiers et
al[94], who have measured the motion of cemented and cementless hips with
respect to the femur in three-dimensions.

3.2.1 Design of the Three-Dimensional Measurement System

The design of the 3D measuring frame has evolved over a number of iterations.
The initial idea for the three-dimensional measuring system was to attach
referencing targets to both the stem and the surface of the tibia itself. Laser

transducers and Linear Variable Displacement Transducer's, (LVDTs) would then use these targets to measure the micromotion of the implant. Three LVDTs would be aligned with the faces in the x, y and z planes on the cube target on the tibial target attached to the bones surface. These LVDT's could then measure the instantaneous three-dimensional motion of the tibia during loading. The laser transducers would be focused on the cube target attached to the tip of the implant stem, again in the x, y, and z planes, and would measure the instantaneous 3D motion of the stem and the tibia under loading for each test. The true implant motion relative to the tibia could then be deduced by subtracting the tibial motion, (measured by the LVDTs), from the tibia and stem motion, (measured by the laser transducers). The system design can be seen in Fig.3.1.

This system although providing a solution to the problem, did not present the neatest or the most economic solution. The number of LVDTs and Laser transducer required would have made the initial set up of the experiments both cumbersome and time consuming with many areas for errors to arise. This system also did not allow for the rotation of the tray and stem to be measured about the x, y and z axis. It was felt that if sensors could be attached directly to the bone then this would enable the system to measure the true stem movement relative to the tibia directly without the need for subtracting from initial reference measurements.

Laser Positions around Target
Measuring Tibia and stem Motion

1. Laser 1 Anterior/Posterior Plane
2. Laser 2 Axial Plane
3. Laser 3 medial/Lateral Plane

LVDT Positions around Target
Measuring Tibial Motion

4. LVDT 1 Anterior/Posterior Plane
5. LVDT2 Axial Plane
6. LVDT3 Medial/Lateral Plane
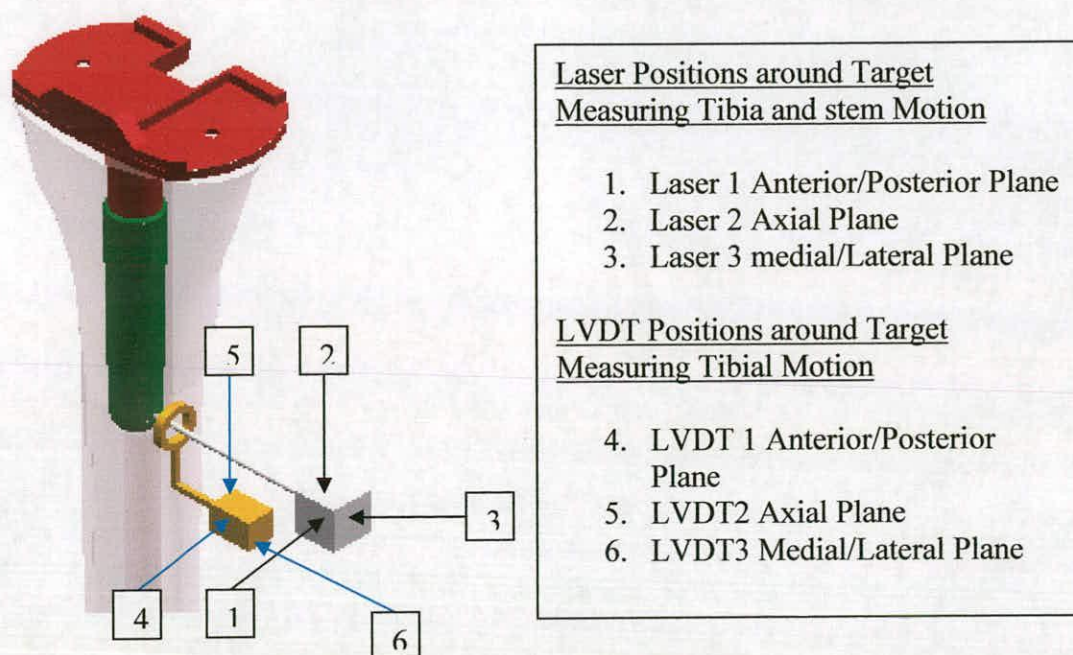
Fig 3.1 Shows the Initial system design involving Laser Transducers and LVDT's for measuring the Instantaneous 3D Motion of the Stem Relative to the Tibia.

The final three-dimensional measurement system developed for this study consisted of six differential variable reluctance transducers, (DVRTs), (see section 2.2.5.1 for full details of the DVRTs), and five custom-made components (Fig 3.2):

1) *The prosthesis target ring*, this consisted of three spheres positioned anteriorly, medially and laterally around the edge of the implanted prosthesis.

2) *The DVRT housing bracket*, capable of holding the six DVRTs in the correct alignment with the spherical targets.

3) *The tibial bone ring*, this was attached to the bone via pointed bolts to which the DVRT housing bracket was secured, assuring that all measurements recorded were with respect to the tibia.

4) *Flexible coupling bolts*, these bolts allow the DVRT housing bracket to be fixed to the tibial bone ring in the correct orientation.

5) *Alignment Pins*, these ensured that the six DVRTs in the DVRT housing bracket were aligned correctly with the axis of the prosthesis target ring.

Prosthesis Target Ring

DVRT

DVRT Housing Bracket

Alignment Pins

Flexible Coupling Bolts

Tibial Bone Ring

Composite Tibia
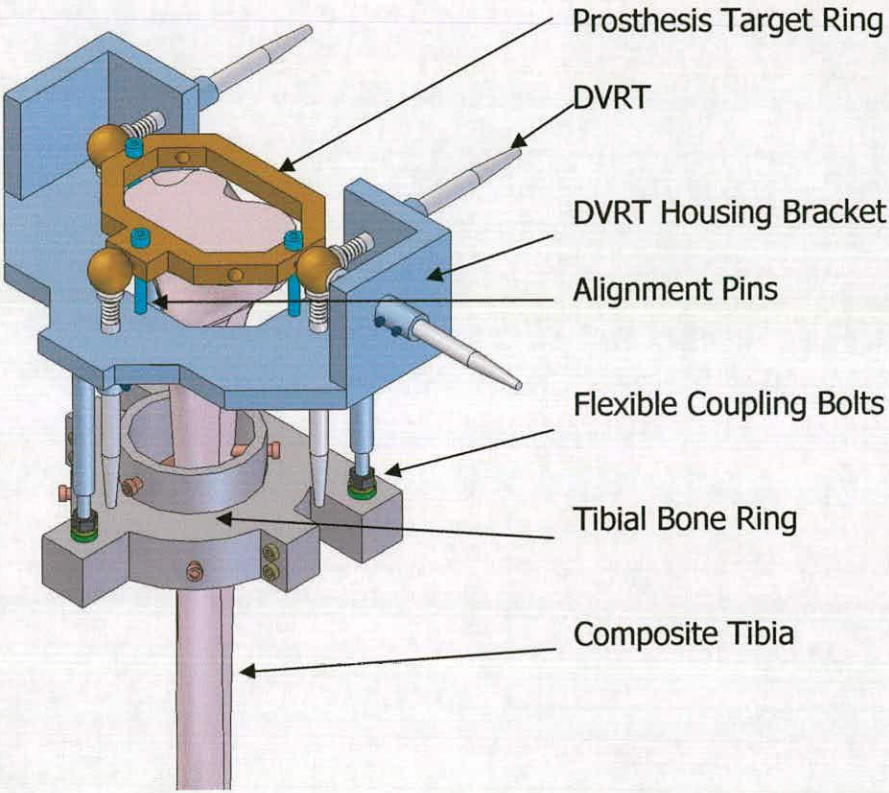
Fig. 3.2 The complete three-dimensional measuring system fully assembled

3.2.1.3 The DVRT Housing Bracket

The DVRT housing bracket, (Fig.3.6) aligns each DVRT around the corresponding target on the prosthesis target ring. Great precision was required in the design to ensure that each DVRT was aligned along the correct axis. It was vital that the contacting surface of each DVRT was perpendicular to the surface of the sphere and positioned along the axis passing through the centre of the sphere. Each DVRT was held in place via two polyethylene grub screws, (Fig.3.7).

Referring to Fig.3.7, the design of the bracket allowed three DVRTS to be positioned around sphere A on the lateral side, one along the x-axis, one along the y-axis and one along the z-axis. Two DVRTs were positioned around sphere C on the medial side, one along the y-axis and one along the z-axis. Sphere B positioned anteriorly had one DVRT positioned along the z-axis. The DVRT housing bracket was attached to the test tibia via the tibial bone ring and the Flexible coupling bolts.
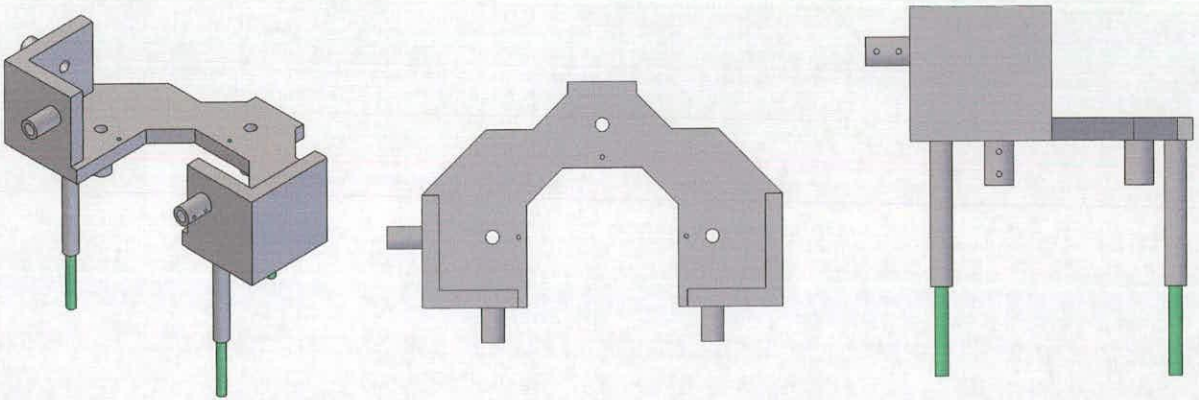
Fig.3.6. Three different views of the DVRT housing bracket.
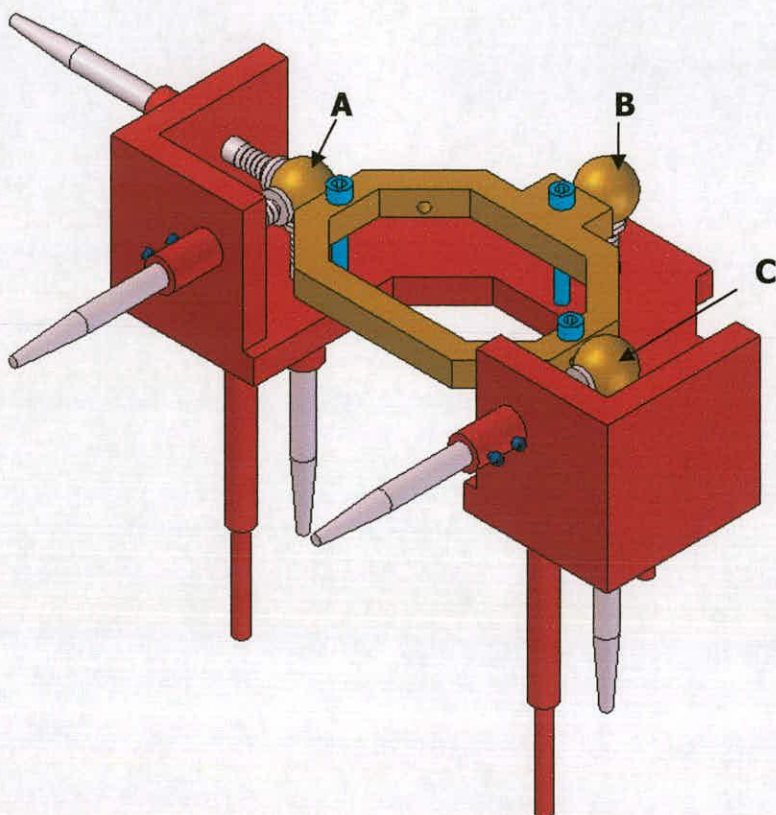
Fig.3.7. Six DVRTs positioned around the target spheres via the DVRT housing bracket.
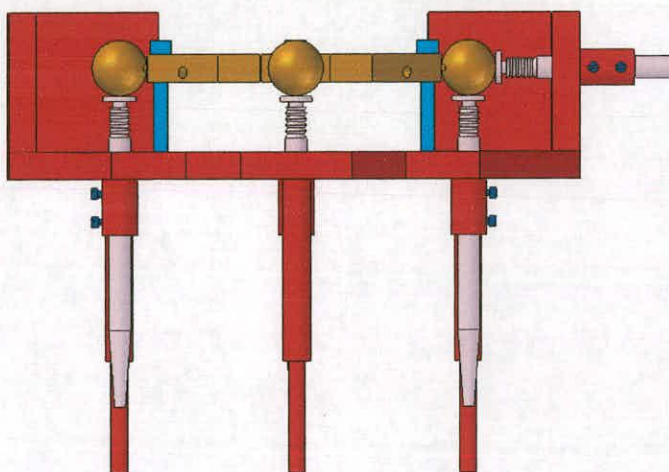
Fig.3.8. Shows how the alignment pins connect the DVRT housing bracket and the prosthesis target ring to each other to ensure proper alignment of the DVRTs and the target spheres. On the right is an alignment pin.

3.2.1.1 DVRT Customisation

The original DVRTs came with a cone shaped head with a spherical ball bearing at the tip. However, to enable pure translation without rotation to be accurately measured by the three-dimensional measuring system a flat headed end piece which was perpendicular to the shaft of the DVRT was needed for each DVRT, (Fig. 3.3). The custom-made flat heads were made of stainless steel to stop any excessive wear on the contact surface between the target and the DVRT head, which may have introduced errors into the system. Each flat head had a highly polished finish to reduce the friction between the sphere and the DVRT. All the DVRTs were positioned around the spherical target such that that the flat head of the DVRT was at a ninety degree tangent to the spheres edge.
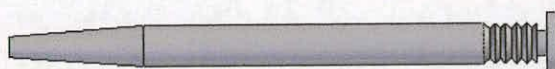
Fig. 3.3. Customised DVRT head sections

3.2.1.2 The Prosthesis Target Ring

The prosthesis target ring consists of three spheres one anteriorly, one medially and one laterally in a cruciform pattern. It was imperative that the centres of all the target spheres lay in the same plane and that the centre of each target ran through the centre of the tibial tray, to enable the mathematics to be simplified.

The original idea was to weld threaded brackets onto the edge of the prosthesis into which the spherical targets could be screwed. However, it was felt that these

brackets could not be accurately attached to the tray and thus there was a danger that the targets would not align accurately.

The method deemed to provide the best solution was a ring that would sit around the tibial tray onto which the three spherical targets could be attached and aligned, (Fig. 3.5). The prosthesis target ring was precision machined so that the centres of spheres A and C lay on the same axis, (the x-axis) and passed through the centre of the tibial tray. The centre of Sphere B ran through the centre of the tibial tray perpendicular to the line joining the centres of spheres A and C, (the y-axis). The prosthesis target ring was attached to the tray at four points via four locking screws which located into 4 dimples which were machined into each tibial tray tested via EDM. The under surface of the prosthesis target ring sat flush with the under surface of the tibial tray. Three holes orientated along the z-axis were created to allow the alignment pins to connect to the DVRT housing bracket.
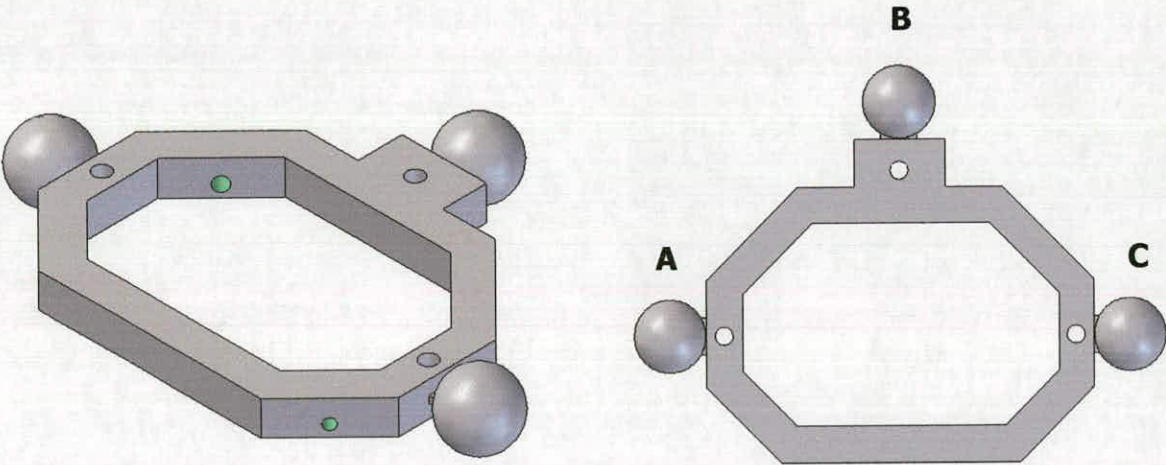
Fig.3.5. The prosthesis target ring, showing target sphere A, B and C along with the alignment pin holes and tray fixation holes.
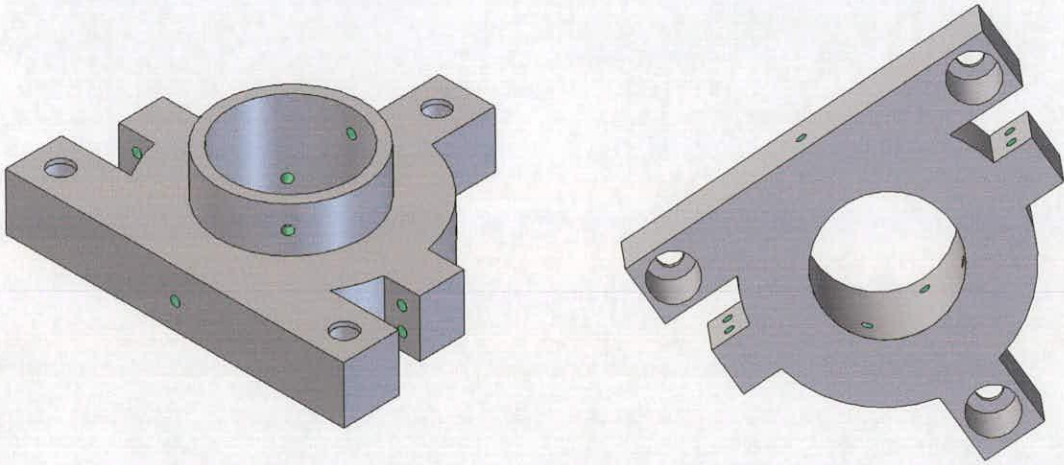
Fig.3.9. The tibial bone ring attached to the test tibia via six pointed bolts.

3.2.1.6 The Flexible Coupling Bolts

To compensate for any relative movement between the tibial bone ring and the DVRT Housing bracket during the tightening of the bolts attaching the bone ring to the tibia, flexible couplings, (Fig.3.10), placed between the tibial bone ring and the DVRT housing bracket were designed. The flexible coupling bolts consist of two locking nuts and two sets of spherical washers, (Fig.3.10), placed either side of the locating holes on the three legs of the tibial bone ring. As the holes in the tibial bone ring are larger than the diameter of the threaded sections on the legs of the DVRT housing bracket, translational adjustment in the x and y axis could be achieved. Translational movement in the z axis was available by moving the top and bottom locking nuts. Rotational adjustment is achieved via the concave and convex washers. Thus the flexible couplings allowed both translational and rotational freedom of movement between the two components. This allowed for the bolts securing the tibial bone ring to be tightened, then the

flexible couplings to be locked into place, rigidly connect the DVRT housing bracket to the tibial bone ring while maintaining the correct alignment of the system, (Fig 3.11).

Top Locking Nut

Spherical Washers. (one concave and one convex)

Bone Ring Locating Hole.

Bottom Locking Nut
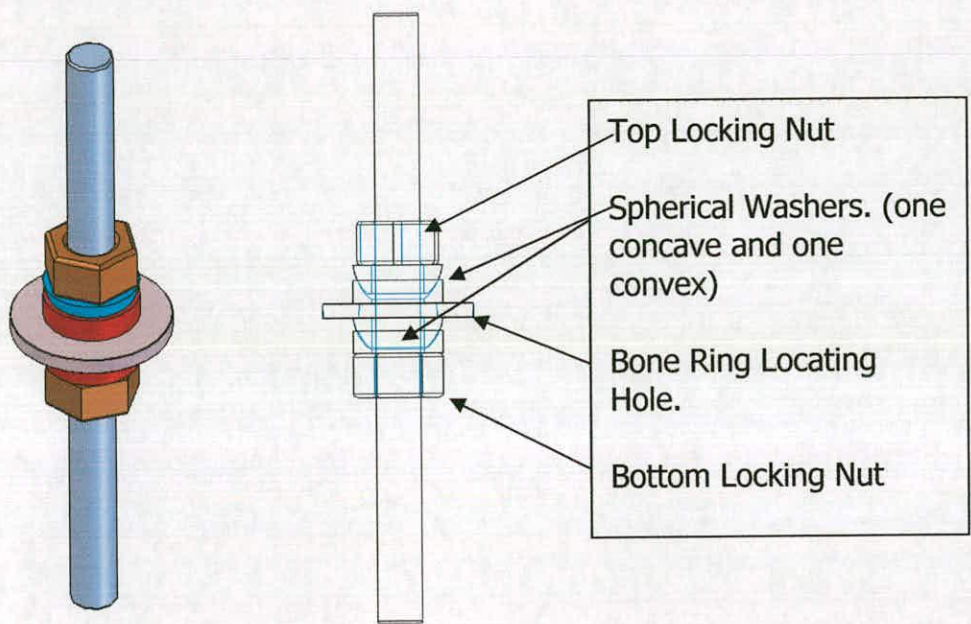
Fig.3.10 The flexible coupling bolts system.

Fig.3.11. The tibial bone ring is at an angle following tightening, but due to the flexible coupling bolts the DVRT housing bracket remains aligned ensuring the DVRTs are orthogonal to the targets.
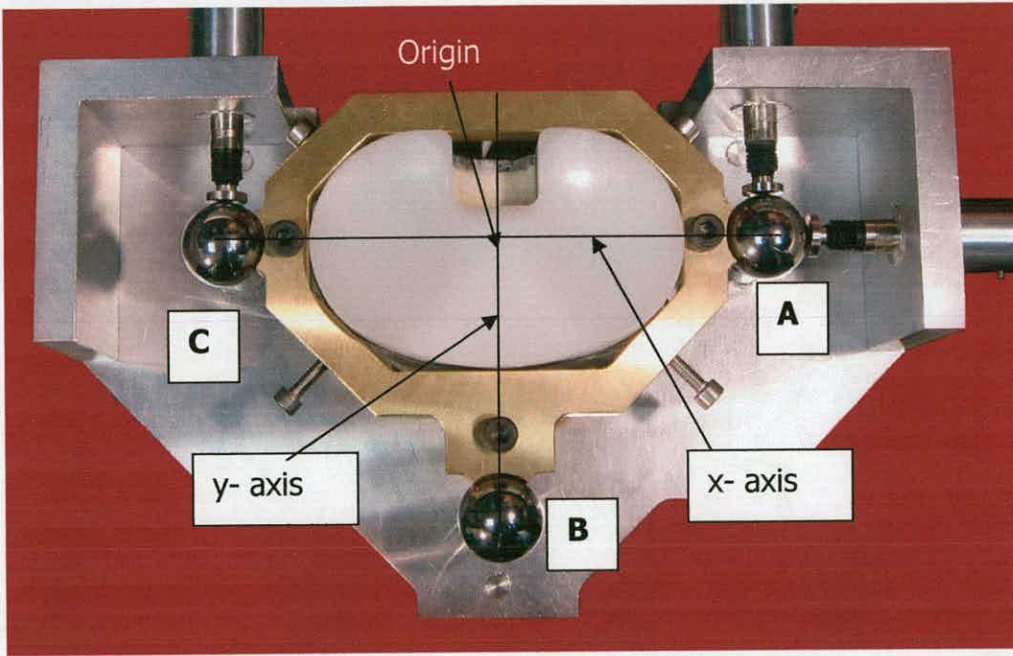
Fig.3.12. Shows the x and y axis and the origin with respect to the spheres and the tibial tray.

Referring to Fig.3.13 if one considers a single rotation of point P through an angle θ about the positive z- axis, the coordinates for a vector $\bar{r}_0 = (x_0, y_0, z_0)$ fixed in the body, are after rotation of the body fixed coordinate system through an angle θ:

$x_\theta = x_0.\cos\theta - y_0.\sin\theta$

$y_\theta = x_0.\sin\theta + y_0.\cos\theta$

$z_\theta = z_0$ (as the rotation occurred about the z- axis)

(Where X_θ, Y_θ and Z_θ are the coordinates of the vector in the space fixed system).
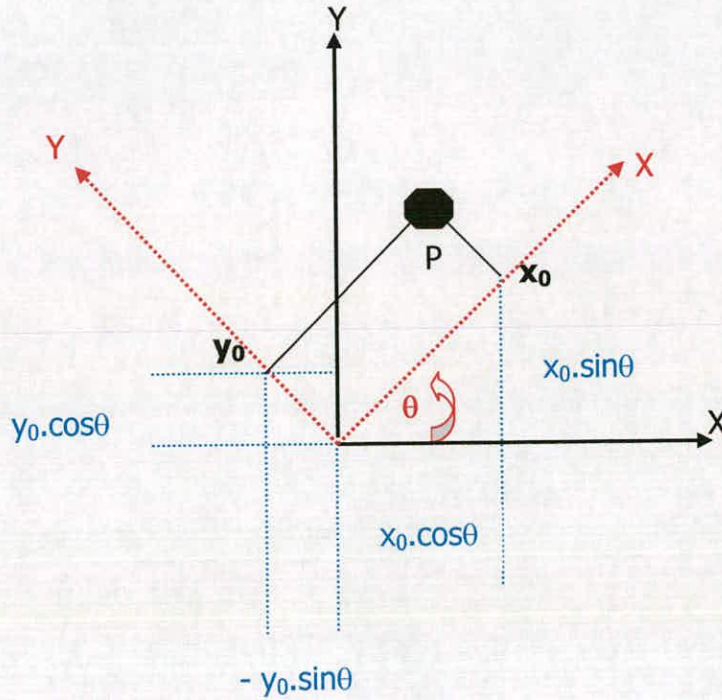
Fig.3.13. A single rotation of point P through an angle θ about the positive z- axis.

Using matrix notation, the rotation through an angle θ about the z- axis is written:

$$
\left\{ \begin{array}{c} x_\theta \\ y_\theta \\ z_\theta \end{array} \right\} = \left\{ \begin{array}{ccc} \cos\theta & -\sin\theta & 0 \\ \sin\theta & \cos\theta & 0 \\ 0 & 0 & 1 \end{array} \right\} \times \left\{ \begin{array}{c} x_0 \\ y_0 \\ z_0 \end{array} \right\} \qquad \text{(Equation 2)}
$$

It can be shown for multiple rotations, that if a rotation occurs with a fixed origin, O, first about the z- axis (θ_z), then about the y- axis (θ_y), and lastly about the x- axis (θ_x), a point (x_0, y_0, z_0) will translate to a point (x_θ, y_θ, z_θ), as the directions x, y and z in space are unchanged[92]. Using matrix notation the rotations about multiple axes can be expressed as:

3.2.1.4 The Alignment Pins

Fig.3.7 and Fig.3.8 depict how the alignment pins give the precision required to the positioning of the DVRT housing bracket with respect to the target spheres. The alignment pins ensure that the contacting surfaces of the six DVRTs are orthogonal and aligned with the axis of the prosthesis target ring. The alignment pins were precision machined to ensure that they were all the same length, thus ensuring the correct placement of the DVRT housing bracket every time. Each alignment pin had a threaded section protruding from its distal face, this was used to rigidly connect the DVRT housing bracket to the prosthesis target ring, in this way the DVRT housing bracket could be located orthogonal to the spherical targets. The alignment pins remained in place until it came time for the cyclic loading to begin.

3.2.1.5 The Tibial Bone Ring

The tibial bone ring, (Fig.3.9) is used to attach the DVRT housing bracket to the tibia being tested via the flexible couplings. This ensures that all measurements recorded by the DVRTs are with respect to the tibia. The tibial ring is fixed to the bone via six equi-spaced pointed bolts. The screws are inserted in a plane perpendicular to the long axis of the tibia. This method of fixation has been used successfully by McKellop et al, Gilbert et al and Maher et al with no issues of loosening reported. To compensate for any movement of the tibial bone ring during bone tightening, three larger holes were created in the legs of the ring; these accommodate the legs of the DVRT housing bracket and the flexible coupling bolts.

3.2.2 Calculating the Three-Dimensional Motion of the Tibial Tray

A Cartesian coordinate system (x, y, z) is fixed in space (initial frame of reference). A rigid body having its own Cartesian coordinate system, (x, y, z) is allowed to move relative to the initial frame of reference. If the axes of the rigid body coincide with the axes of the frame of reference then the motion of the rigid body and its coordinate system can be described in mathematical terms relative to the initial frame of reference. A description of this motion is achieved by determining a matrix, M and a vector, d. The rotational matrix, M and linear vector, d transform a point $\bar{r}_0$ in the body from its reference position $\bar{r}_0$ to its position $\bar{r}$ after a displacement. This can be written as:

$$\bar{r} = M. \bar{r}_0 + d \qquad \text{(Equation 1)}$$

The six DVRTs used in this study allow motion of the tibial target ring along the x, y and z space fixed axes to be measured. Referring to Fig.3.12 the body fixed co-ordinate x- axis is defined as the line that joins the centre of sphere A to the centre of sphere C. The body fixed co-ordinate y- axis is defined as the line running from the centre of sphere B through the centre of the tibial tray in the posterior direction. The body fixed co-ordinate z- axis is mutually perpendicular to the x and y axis. Initially the body fixed co-ordinate axis and the space fixed co-ordinate axis are the same. The x- axis has been defined as positive in the medial direction, the y- axis is positive in the anterior direction and the z-axis is deemed positive in the distal direction.

$$\left\{ \begin{array}{c} X_\theta \\ Y_\theta \\ Z_\theta \end{array} \right\} = \left\{ \begin{array}{ccc} \cos\theta_y.\cos\theta_z & -\cos\theta_y.\sin\theta_z & \sin\theta_y \\ \sin\theta_x.\sin\theta_y.\cos\theta_z+\cos\theta_x.\sin\theta_z & -\sin\theta_x.\sin\theta_y.\sin\theta_z+\cos\theta_x.\cos\theta_z & -\sin\theta_x.\cos\theta_y \\ -\cos\theta_x.\sin\theta_y.\cos\theta_z+\sin\theta_x.\sin\theta_z & \cos\theta_x.\sin\theta_y.\sin\theta_z+\sin\theta_x.\cos\theta_z & \cos\theta_x.\cos\theta_y \end{array} \right\} \times \left\{ \begin{array}{c} X_0 \\ Y_0 \\ Z_0 \end{array} \right\}$$

(Equation 3)

From theory on kinematics of rigid body motion for small angles of rotation the matrix in equation 3 can be reduced. The mathematical meaning of a small angle is that the sine and cosine of the angle are approximated by the first term in their series expansion and that the products of angles, being the second order of magnitude can be disregarded. Thus for the small angles that will be measured in this study equation 3 can be written:

$$\left\{ \begin{array}{c} X_\theta \\ Y_\theta \\ Z_\theta \end{array} \right\} = \left\{ \begin{array}{ccc} 1 & -\theta_z & \theta_y \\ \theta_z & 1 & -\theta_x \\ -\theta_Y & \theta_x & 1 \end{array} \right\} \times \left\{ \begin{array}{c} X_0 \\ Y_0 \\ Z_0 \end{array} \right\}$$ (Equation 4)

By direct matrix multiplication, it can be shown that the product matrix in equation 4 is independent of the order of the rotations. Thus the product of small rotations is commutative, i.e. the order of the rotations need not be specified. If {x, y, z} is taken as the change in position of a point then equation 4 becomes:

144

$$
\left\{ \begin{array}{c} x \\ y \\ z \end{array} \right\} = \left\{ \begin{array}{ccc} 1 & -\theta_z & \theta_y \\ \theta_z & 1 & -\theta_x \\ -\theta_Y & \theta_x & 1 \end{array} \right\} \times \left\{ \begin{array}{c} x_0 \\ y_0 \\ z_0 \end{array} \right\} + \left\{ \begin{array}{c} \mu \\ v \\ \omega \end{array} \right\} - \left\{ \begin{array}{c} x_0 \\ y_0 \\ z_0 \end{array} \right\}
$$

(Equation 5)

Where $\{\mu, v, \omega\}$ is the displacement of the centre of the tibial tray, the origin.

The co-ordinates for the centre of each sphere can be written as follows: sphere A has co-ordinates (Ax, 0, 0), sphere B has co-ordinates (0, By, 0) and sphere C has co-ordinates (Cx, 0, 0), as all spheres lie in the same plane none have a z-axis coordinate. The location matrix of the target sphere centres is as follows:

$$
\left\{ \begin{array}{ccc} A_x & 0 & C_x \\ 0 & B_Y & 0 \\ 0 & 0 & 0 \end{array} \right\}
$$

(Equation 6)

θ_x, θ_y and θ_z are defined as rotations about the x, y and z- axis respectively. The symbols μ, v and ω with subscripts of A, B or C describe the translation of the spheres A, B or C in the x, y and z directions respectively, (i.e. μ_A describes the translation of sphere A in the x direction, v_A describes it in the y direction and ω_A in the z direction). The symbols μ, v and ω without the subscripts of A, B or C describe the translation of the centre of the tibial tray in the x, y and z directions respectively. Substituting equation 6 into equation five gives:

$$
\begin{Bmatrix} \mu_A & \mu_B & \mu_C \\ v_A & v_B & v_C \\ \omega_A & \omega_B & \omega_C \end{Bmatrix} = \begin{Bmatrix} 1 & -\theta_z & \theta_y \\ \theta_z & 1 & -\theta_x \\ -\theta_Y & \theta_x & 1 \end{Bmatrix} \times \begin{Bmatrix} A_x & 0 & C_x \\ 0 & B_Y & 0 \\ 0 & 0 & 0 \end{Bmatrix}
$$

$$
+ \begin{Bmatrix} \mu & \mu & \mu \\ v & v & v \\ \omega & \omega & \omega \end{Bmatrix} - \begin{Bmatrix} A_x & 0 & C_x \\ 0 & B_Y & 0 \\ 0 & 0 & 0 \end{Bmatrix}
$$

(Equation 7)

Where Ax, By and Cx are the distances from the centre of the tray (the origin), to the centre of the target spheres. These distances were measured using precision callipers. The three rotations $\{\theta_x, \theta_y, \theta_z\}$ and the three translations $\{\mu, v, \omega\}$ are the six unknowns. Solving for these unknowns will give information on the movement of the tray centre.

Following multiplication and subtraction steps equation 7 becomes:

$$
\begin{Bmatrix} \mu_A & \mu_B & \mu_C \\ v_A & v_B & v_C \\ \omega_A & \omega_B & \omega_C \end{Bmatrix} = \begin{Bmatrix} 0 & -B_Y\theta_z & 0 \\ A_x\theta_z & 0 & C_x\theta_x \\ -A_x\theta_Y & B_Y\theta_x & -C_x\theta_Y \end{Bmatrix} + \begin{Bmatrix} \mu & \mu & \mu \\ v & v & v \\ \omega & \omega & \omega \end{Bmatrix}
$$

(Equation 8)
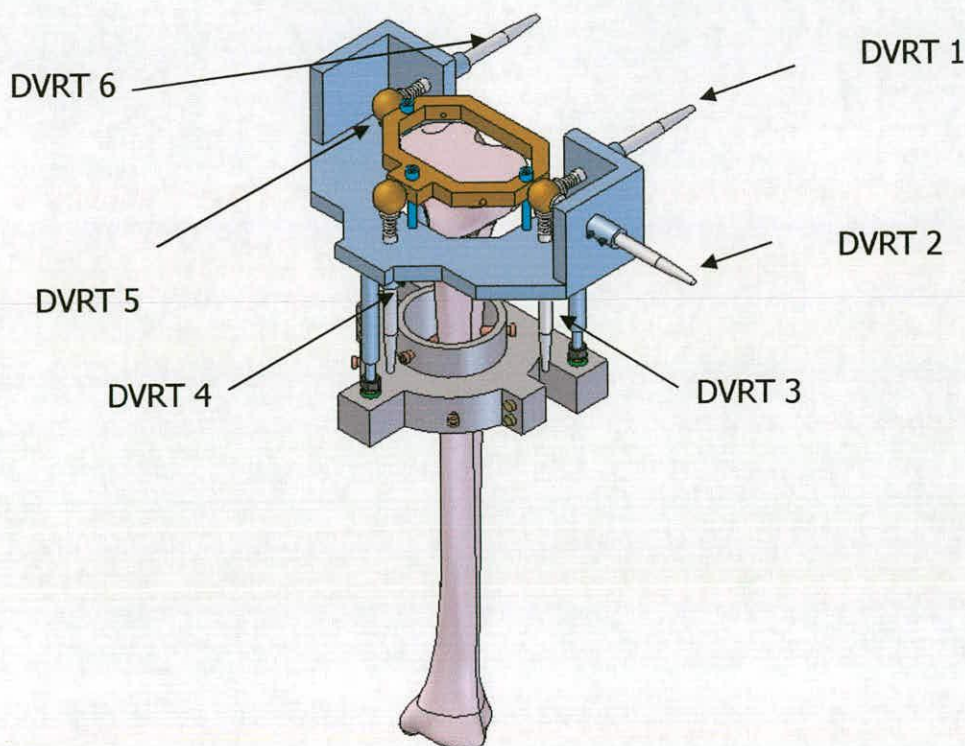
Fig.3.14. Shows how the DVRTs were labelled around the tibial target device

Referring to Fig.3.14 the displacement μ_A was measured by DVRT 2, v_A was measured by DVRT 1 and ω_A was measured by DVRT 3. DVRT 4 measured displacement ω_B and DVRT 5 and 6 measured displacements ω_C and v_C respectively. Extracting equations from equation 8 using the displacements measured by the DVRTs and solving for the rotations $\{\theta_X, \theta_y, \theta_z\}$ and the translations $\{\mu, v, \omega\}$ gives the following six equations by which the movement of the centre of the tibial tray can be measured:

1) $\mu = \mu_A$

2) $v = v_A - A_x\theta_z$

3) $\omega = \omega_A + A_x\theta_Y$
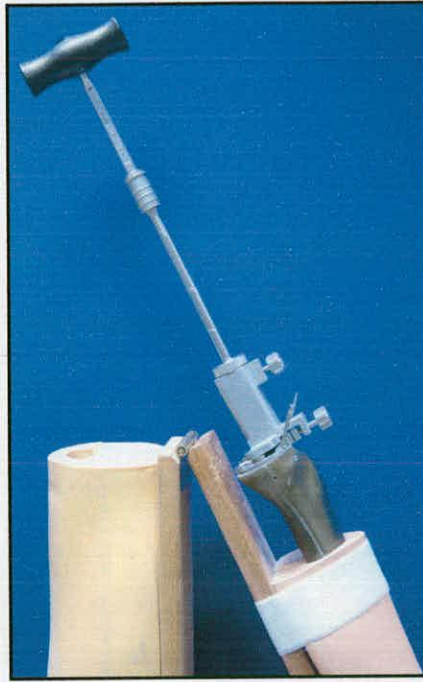
Fig.3.13 the composite tibias being prepared to receive a tibial tray with an 80mm modular stem.

In group one, the four bones were now ready to be prepared for the cyclic testing phase. In group two all four bones underwent preparation to receive a 10mm tibial block augment on the medial side, following the primary implant preparation. For a full description of how the bones in group two were prepared to accept a 10mm tibial augment please refer to section 2.2.4.1, in Chapter two. In group three following the primary preparation steps all four tibia specimens had cancellous bone stock removed from the proximal region to simulate an extensive T1 defect that would require bone impaction grafting.

3.2.3.1 Preparation of T1 Bone Defects

The T1 defects were created in the composite bones using the AORI bone defect classification system as a reference. The AORI defect classification system is discussed in full in section 1.5.1, Chapter one. The AORI bone defect classification was developed to provide a rational and easily remembered description of bone loss commonly found in revision TKA, it is because the AORI classification system provides such a clear image of the defects that it was chosen as the reference point for this experimental investigation.

Substantial T1 defects were created in all the composite bones in group three. The original T1 defect was created with the aid of a hand tool and an attached milling drill bit. All of the foam representing the cancellous bone was removed to a depth of 35mm distally from the resected tibial plateau, (Fig.3.14). In order to assess whether it was important to by-pass the defect in order to gain better initial stability the defect was created to be deeper than the length of the fixed stem. A depth of 35mm was chosen as the fixed tibial tray stem was 30mm in length.

Fig.3.14. A sample of the T1 defects created in the tibias within group three. All proximal cancellous bone was removed to a depth of 35mm.

The synthetic cortical bone was left undamaged all the way around the rim of the proximal tibia. A plaster mould of the first T1 defect created, Fig.3.15), was made and used as a reference for the other T1 defects created; this ensured that all T1 defects were of the same size and dimension. The original T1 defect created was approved by Mr Colin Howie, Consultant Orthopaedic Surgeon, Royal Infirmary of Edinburgh, prior to the mould being made, to ensure that it was representative of T1 defects encountered in practical surgery.

Fig.3.15. The plaster mould of the first T1 defect being created.

All T1 defects created for this study were repaired using a standard bone impaction grafting technique. Milled and washed cancellous equine frozen femoral head allograft was placed into the T1 tibial defect and was packed down distally with a blunt nosed impactor until the void in the proximal tibia had been filled.

3.2.3.2 Bone Graft Preparation

The bone used for all experiments in this study came from a large stock of frozen equine femoral heads, obtained via the pathology department at the Large Animal Hospital, Bush Estate, University of Edinburgh. All the femoral heads used were prepared and milled in the same manner. Each femoral head was thawed in warm water; any excess soft tissue was then removed. Once the bones had thawed they were cut into cancellous chunks, (Fig.3.16), all visible cortical bone remnants were removed at this point prior to milling.

Fig.3.16. Chunks of Cancellous bone thawed and awaiting milling.

The cancellous bone segments were then placed into the bone mill, (New Splint Ltd, Hants, UK), and morsellised by hand using the 9mm grating drum. All the milled bone was then inspected and any visible cortical bone pieces were removed. The graft was then washed thoroughly to remove any excess fat and marrow. Washing of the graft has been shown by Dunlop[104], to increase the mechanical strength of the morsellised bone graft. Removing the fat and marrow is important as these can act as a lubricant between the compacted bone particulates which can then cause subsidence of the graft. All bone graft was

prepared with adherence to all Health & Safety Guidelines using Universal Precautions where necessary.

3.2.3.3 Bone Graft Washing Method

The technique employed during the course of these experiments was taken from Dunlop[104]. A two sieve tower was created consisting of an upper sieve with a 2mm grating and a lower sieve with a grating of 0.3 mm, (Fig.3.17). The sieve tower was placed over a drainage vessel to catch any particulates smaller than 0.3mm and any fat and marrow which was washed off the morsellised bone. The milled bone was placed onto the top sieve and washed thoroughly. The top sieve helped to hold large particles stationary during washing and prevent blocking the lower 0.3mm sieve, (Fig.3.17). All bone particles greater than 0.3 mm were caught within the two sieve tower. Washing of the graft was performed using a pulse lavage (surgilav, Stryker, Newbury,UK), and warm water. In theatre this would be done with warm saline solution. The graft was pulsed with water until the milled bone was free of all obvious fat and marrow tissue.

Fig.3.17. The two sieve tower assembly with the milled cancellous bone being washed free of all obvious fat and marrow.
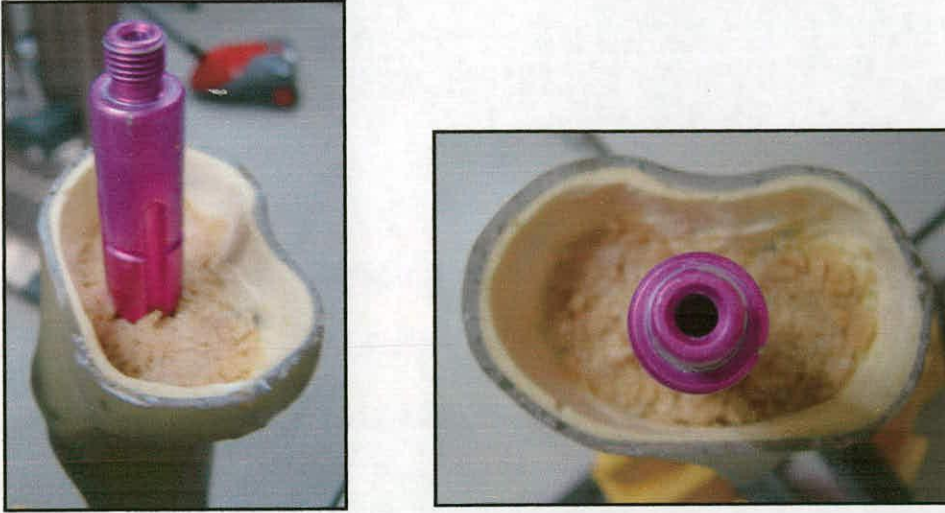
Fig.3.18. Shows the trial stem inserted into the prepared canal and the first layer of the morsellised graft after impaction.

A trial stem (matching the dimensions of the actual stem to me implanted), was partially inserted into the reamed intramedullary canal. The morsellised allograft was inserted into the contained defect and packed down distally with the aid of a blunt nose impactor, (Fig.3.18). The morsellised graft was added in layers continually being impacted distally. Kuiper et al[105] suggest that the level of migration of the prosthesis following bone impaction grafting correlates strongly with the degree of impaction, with insufficient impaction of the graft leading to a lack of stability. In order to obtain a well impacted graft and a consistent level of impaction through out for each specimen, each level of graft was impacted with the same impactors and received thirty blows with the mallet, fifteen blows on the medial side and fifteen on the lateral side. Once the defect had been filled to the level of the resected proximal cortical surface the trial stem was removed. The appropriate tibial tray could then be inserted into the hole left by the trial stem, (Fig.3.19). The tibial tray being examined was fixed in place using either hybrid cement fixation with a 1.5 -2.5 mm cement mantle or fully cemented fixation. The repaired T1 tibia was then ready to receive the measurement system attachments prior to cyclic testing.
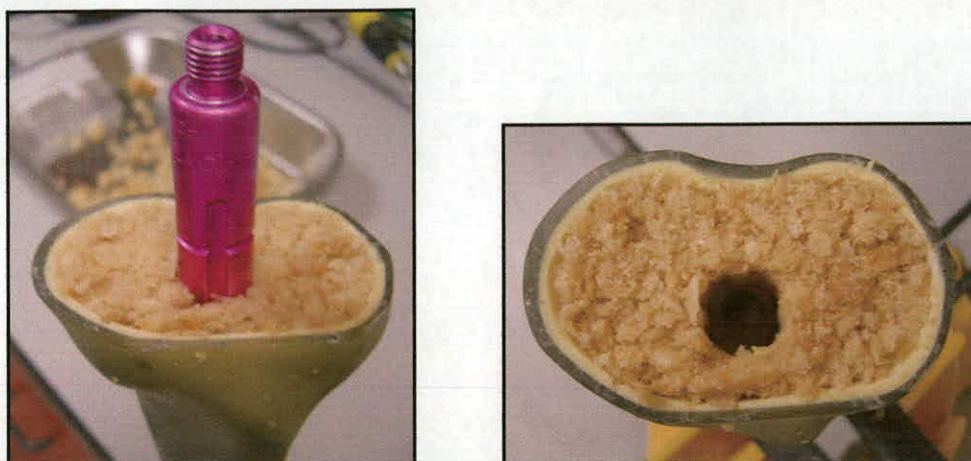
Fig.3.19. The T1 defect fully filled with morsellised bone graft around the trial stem. The stem removed leaving space for the definitive prosthesis to be implanted.

3.2.3.5 Protocol for the Assembly of the Three-Dimensional Migration Measuring System to the Test Prosthesis and Tibia.

A protocol for the assembly of the six degree of freedom, micromotion and migration measuring system, was required to ensure the exact alignment between the DVRTs and the tibial tray for all the tests carried out.

The first step in the protocol was the preparation of the composite tibias. The preparation steps for the tibias in each test group have been described previously. The prepared tibias were then implanted with the appropriate components depending upon the group and test being investigated. Each tibia was fixed in place using a hybrid or a fully cemented technique. For details of the cement preparation please see section 2.2.4.2 in Chapter two. A cement mantle of between 1.5-2.5mm was used in all tests, (Fig3.20). The cement was left to cure over night for a minimum of twelve hours prior to testing.

Fig.3.20. The cement mantle for all tests was between 1.5 - 2.5mm.

Each test specimen was then inserted into the tibial cylinder. The tibial cylinder held the tibia in place within the materials testing machine and allowed the tibia to be attached firmly to the load cell, in order to monitor the loads being applied to the tibial tray during testing. Each tibia was held in place in the tibial cylinder via six pointed bolts. The cylinder was attached to the load cell within the materials testing machine, the tibia was then aligned with the custom made femoral component attached to the loading actuator and clamped in place using the pointed bolts. A plaster mixture was then poured into the cylinder to further secure the tibia in place, (Fig.3.21). The plaster mixture was left to set over night for a minimum of twelve hours prior to testing.

The next step in the assembly protocol was to attach the prosthesis target ring to the tibial tray. The prosthesis target ring was placed over the tibial tray aligning the indents on the tibial trays edge with the locking bolts of the prosthesis target ring. The bolts were then tightened securing the prosthesis target ring to the tibial tray, (Fig.3.22)

Custom Made Femoral
Component Attachment

Composite Tibia

Plaster Mixture

Tibial Cylinder

Pointed fixation Bolts
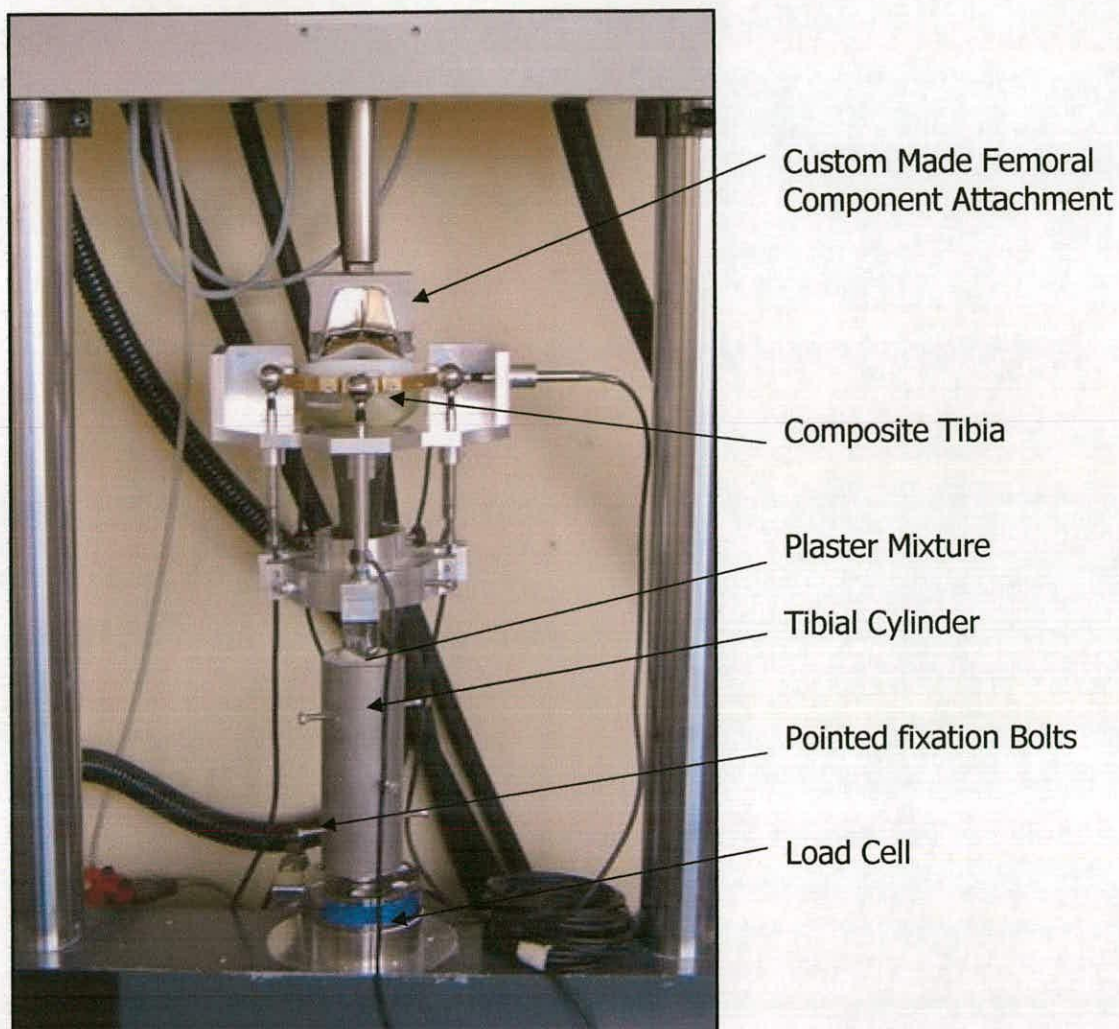
Load Cell

Fig.3.21. Assembly showing the tibial cylinder attached to the load cell and securing the composite tibia in position.

Fig.3.22. The prosthesis target ring secured to the tibial tray with the four locking bolts.

Alignment pins flush with the DVRT housing bracket and the upper surface of the prosthesis target ring ensuring correct alignment.

Fig.3.23. The Alignment Pins rigidly attaching the DVRT housing bracket to the prosthesis target ring ensuring the correct DVRT and target sphere alignment.

The three alignment pins were then inserted through the three alignment pin holes with the prosthesis target ring, (Fig.3.5). The three alignment pins were then screwed into the DVRT housing bracket, rigidly securing the prosthesis target ring to the DVRT housing bracket. This ensured that the correct alignment was achieved between the six DVRTs and the spheres on the target ring. It is imperative that the contacting surfaces of the DVRTs are orthogonal to the surface of the spheres and aligned in the correct plane. Thus it was critical to check that the alignment pins were fully inserted to the DVRT housing bracket and lay flush with the upper surface of the prosthesis target ring to achieve the required alignment, (Fig.3.8 and Fig.3.23).

The tibial bone ring was aligned with the legs of the DVRT housing bracket and then secured to the tibia by six equi-spaced pointed bolts. The six pointed bolts were made up of two layers of three bolts. Layer one contains three bolts spaced at 120 degrees apart. Layer two, found 15mm proximally from layer one, has another set of three pointed bolts again spaced at 120 degrees apart but off set by 60 degrees from those in layer one, (Fig.3.9 and Fig.3.24).

Six equi-spaced pointed
bolts on two levels of
three.

Fig.3.24. The tibial bone ring secured to the composite tibia via six equi-spaced pointed bolts.

To compensate for any relative movement between the tibial bone ring and the DVRT housing bracket during bolt tightening the flexible couplings were left loose. After the six bolts were fully tightened into the tibial wall and the tibial ring locked in place, the flexible couplings were tightened. The flexible couplings were tightened with the aid of two spanners. This rigidly secured the DVRT housing bracket to the tibial bone ring in the correct alignment. The alignment pins were then removed and the six DVRTs held within the DVRT housing bracket could be zeroed against the three spherical targets. The six-degree of freedom measurement system was then fully assembled and the tibia was ready to undergo the cyclic testing, (Fig.3.25).
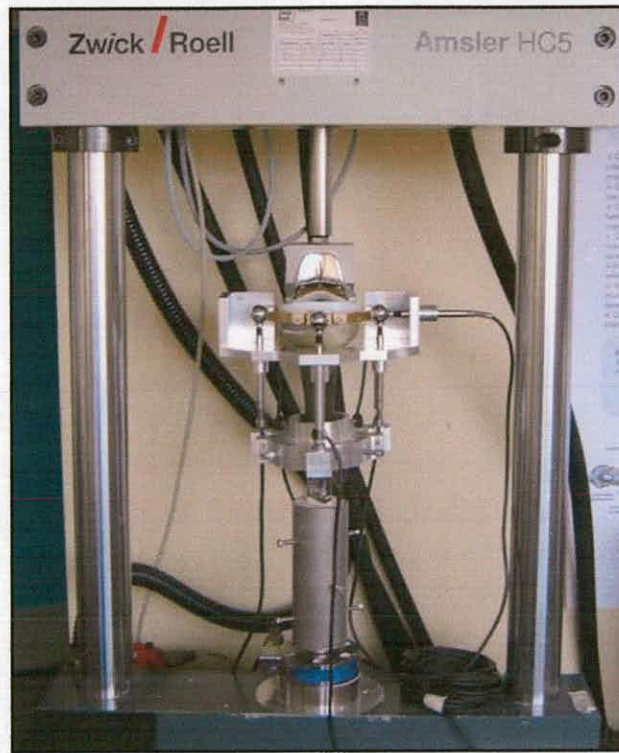
Fig.3.25. The fully assembled three-dimensional micromotion and migration measuring system ready to undergo cyclic testing in the materials testing machine.

3.2.3.6 Cyclic Loading Protocol

The loading sequence derived for this study attempts to represent the tibiofemoral compressive loads experienced within the knee during level walking. While simply standing, the tibial implant experiences the force of 1 x BW[106] exerted upon it and several biomechanical evaluations have measured the tibiofemoral compressive loads experienced in the knee during level walking and found them to be in the range of 3 - 3.9 x BW[79-82]. For the course of these tests compressive loads of ½ x BW to 4 x BW were applied to the implanted tibial prosthesis. As in the previous chapter, 1 x BW was taken to be 706N, therefore the prosthesis experienced cyclic loading of between 353N and 2824N. The compressive cyclic loads were applied to all samples tested at a frequency of 5Hz for 216,000 cycles, this represented a twelve hour testing period.

4) $\theta_X = \dfrac{\omega_B - \omega_A - A_x\theta_Y}{B_Y}$

5) $\theta_y = \dfrac{\omega_A + \omega_C}{C_x - A_x}$

6) $\theta_z = \dfrac{v_A - v_C}{A_x - C_x}$

Where $\{\mu, v, \omega\}$ give the translations of the origin in the x, y and z directions and $\{\theta_x, \theta_y, \theta_z\}$ give the rotations of the origin about the x, y and z axes respectively.

3.2.3 Bone Sample Preparation

During this study the motion of tibial implants inserted into twelve biomechanical composite bones was investigated. For justification of why composite bones were used rather than cadaveric human tibias and for the full specifications of the biomechanical bones used please see section 2.2.2, in Chapter two.

All the tibias underwent preparation to receive tibial prosthesis from the Kinemax Plus Total Knee System range of implants, (Stryker, Newbury, UK). For details of this system please see section 2.2.3, in Chapter two.

All the tibias in each group were treated identically in the first instance. Each tibia underwent preparation techniques for placement of the primary tibial tray according to the manufacturer's standard surgical technique. The proximal tibial cut was made using extramedullary instrumentation designed to make a perpendicular cut to the long axis of the tibia. For full details of this process please refer to section 2.2.4, in Chapter two.

Two bones in each group were left as prepared to receive a primary tibial implant. The further two bones in each group were prepared to receive a tibial tray with a modular stem, 80mm in length and 18mm in diameter. This was achieved by using a reaming guide tower and a set of intramedullary reamers, (Fig.3.13). The intramedullary canal of the composite tibia was reamed sequentially in 1mm increments starting at 10mm and finishing at 18mm. A stem diameter of 18mm was chosen as this was the diameter at which a good cortical fit could be achieved.

The contents of the two sieves were then mixed together to provide a well graded bone graft. The sieving is important as it provides a good particle size distribution and from the laws of soil mechanics it is known that the mechanical properties of any collection of particles is dependant primarily on the particle size grading and distribution, as well as the individual properties of each particle. Thus sieving and then mixing the contents of the two sieves produces a well graded morsellised graft which theoretically should provide the most stable graft structure when the graft experiences loading forces. Along with well graded particle size distribution, soil mechanics theory also states that to produce an aggregate most resistant to shear stress, it should be in a low state of hydration. Thus, all the milled bone graft mix used in this study was left to dry before being impacted. Theory also states that the impacted bone mix should be built up in layers and impacted with a high energy per volume, and should be rigidly contained. The cortical walls of the tibia provide the rigid containment and the impacted bone graft was built up in layers and was impacted using standard surgical impactors.

3.2.3.4 Bone Impaction Grafting Technique for Repair of T1 Defects

The technique of bone impaction grafting is often used in revision hip arthroplasty and more recently in revision TKA when there is severe bone loss. The morsellised graft restores deficient bone stock and provides stability to the newly implanted prosthesis. The crushed allograft provides a neo-endostium or scaffold onto which the patients own bone can grow to provide better implant stability.

In this study morsalised equine cancellous bone was used to repair all the tibias within group three. As the T1 defects examined in this study were contained there was no need for reinforcement of the cortical wall with wire mesh.

The application of sinusoidal compressive cyclic loading was achieved by fixing the repaired tibias and custom-made femoral condyle section into a Zwick hydraulic dynamic materials testing machine, (ZwickHC5, Herefordshire, UK), with the use of specially designed attachments. Specimens were mounted vertically in the Zwick materials testing machine in order that the tibial cut surface was perpendicular to the applied load, (Fig 3.25). The load was applied to the tibial tray through the femoral component, as would happen in vivo. No attempt was made to simulate specific muscle forces experienced by the knee during the experiments in this study. As previously, only the implant movement associated with the axial loading of the knee in extension was investigated.

3.2.3.7 Data Acquisition

The voltage output from each of the six DVRTs was acquired through the use of an analogue to digital acquisition card for each DVRT. The DVRTs and the acquisition cards were supplied by MicroStrain Inc., Vermont, USA. All six DVRTs were calibrated with their unique data acquisition cards by Microstrain at 20 deg C, the calibration frequency was static (0Hz) and carried out in fifty micron increments. All DVRTs were supplied with a calibration data sheet giving full details of the process.

The voltage range of the six DVRTs used in this study varied giving different theoretical voltage resolutions. All DVRTs had a range of +/- 2mm. DVRTs one to four had a voltage range of +/- 5V and DVRTs five and six had a voltage range of +/- 2V. In the analogue to digital converter, one bit of the twelve bits available was used to determine the sign of the signal leaving eleven bits to resolve the signal. Thus the theoretical voltage resolution for DVRTs one to four was +/- 2.44×10^{-3} V and the theoretical voltage resolution for DVRTs five and six was +/- 9.766×10^{-4} V. When this voltage was entered into the calibration

equation derived for each sensor the theoretical displacement resolution for each DVRT was obtained, this is displayed in Table 3.0 below.

DVRT No.	Theoretical Displacement Resolution
1	+/- 5.9 µm
2	+/- 5.6 µm
3	+/- 5.4 µm
4	+/- 5.7 µm
5	+/- 1.1 µm
6	+/- 1.0 µm

Table.3.0. Theoretical displacement resolutions for each of the DVRTs used in this study.

The digital output from the data acquisition cards was fed into a twelve bit data acquisition system, (National Instruments, Texas, USA). The output from the six transducers was logged at a frequency of 100Hz for a period of five seconds every hour throughout the entire testing period, through a programme written in Labview©. For each set of one hundred data points recorded over one second, (representing five cycles), the voltage from each DVRT corresponding to the minimum load of ½ x BW was computed. Over each recording phase of five seconds, twenty five cycles, this resulted in five values for each DVRT. The average of the five values for each DVRT was calculated; this represented the average minimum voltage corresponding to the minimum load. The average minimum voltage could be converted into displacement and used to track the change in position of the tray over time; this was deemed to be the migration of the tray. The average voltages corresponding to the peak loads of 4 x BW were also computed, the difference between the minimum and maximum voltages

were deemed to be the micromotion experienced by the tibial tray. Each tibial implant tested was assumed to move as a rigid body, enabling the motion of the centre of the tibial tray to be evaluated geometrically.

3.3 EXPERIMENTAL RESULTS

A general pattern of small cyclical movements, (micromotion), superimposed on a permanent movement, (subsidence) was witnessed for all cases. In the T1 specimens this was particularly evident. Therefore the following features of prosthesis-bone motion were quantified from this set of in-vitro testing:

1) The migration patterns for all specimens: translation and rotation of the centre of the tibial tray.
2) The absolute migration of the centre of the tibial tray at 216,000 cycles.
3) The micromotion of the implant, (the displacement recovered when the implant is unloaded), is six degrees-of-freedom.

There was considerable variation in the migration patterns and micromotions measured for the centre of the tibial tray configurations that were tested. The migrations measured were nonlinear, with rapid migration early in testing followed by steady state migration at a decreasing rate there on. This was true for both translational and rotational migrations, (Fig3.26-3.31). This pattern of rapid initial migration was most noticeable in the T1 tests especially when no modular stem was present and the tray was only proximally cemented, (Fig3.26-3.28).

The steady-state migration for the centre of all the tibial trays was calculated at the end of the 216,000 load cycles, (Table 3.1) It was found that the average steady-state migration rate for the primary specimens tested did not alter greatly when a modular stem was added to the construct and when the implant was

fully cemented the average steady-state migration was the same for the tibial tray with and without an 80mm modular stem at 2.7 x 10-4 μm / cycle. In the hybrid cemented prosthesis the tray with no modular stem experienced an average steady-state migration of 3 x 10-4 μm / cycle while the stemmed hybrid tray experienced a rate of 3 .1 x 10-4 μm / cycle. From the translational and rotational migration patterns seen in Fig 3.26 - 3.31 and the average steady-state migration rates in Table 3.1 it can be seen that for the primary specimens no great advantage is gained by either adding a modular stem or fully cementing the prosthesis in terms of initial tray subsidence. The overall trend for the trays tested in the primary group was for the tray centre to subside distally, and posterior / laterally, with a tendency for the tray to move in a slight varus direction.

Within the T2A group once again the addition of a modular stem did not increase the trays resistance to subsidence considerably. The average steady-state migration rates for the non-stemmed tibial trays in the T2A group were slightly higher than those in the primary group by 1 x 10-4 μm / cycle for the hybrid trays and 0.5 x 10-4 μm / cycle for the fully cemented trays, however these figures lay within the error band for the measurement system. When an 80mm modular stem was added the average steady-state migration rate was 2.8 x 10-4 μm / cycle for both the hybrid tray and the fully cemented tray, demonstrating that as in the primary scenario fully cementing the stem did not enhance the trays resistance to subsidence. From examining the migration patterns and overall subsidence in Fig3.26 - 3.31 it can be seen that all prosthesis and fixation methods delivered comparable results. With in the T2A group the centre of the tray tended to subside medially underneath the augmented side, with three out of four specimens migrating in that direction, (Fig3.26). In the primary group for all four specimens tested the centre of the tray moved laterally. The addition of a cemented modular stem in the T2A group did not prevent the tray centre subsiding medially but it did reduce the amount of subsidence experienced. Although the magnitudes of the migration experienced in the Primary and T2A

group were similar the pattern of movement differed. The overall trend for the trays tested in the T2A group was for the tray centre to subside distally and posterior / medially, with a tendency for the tray to move in a slight valgus direction, the opposite of what was recorded in the primary group.
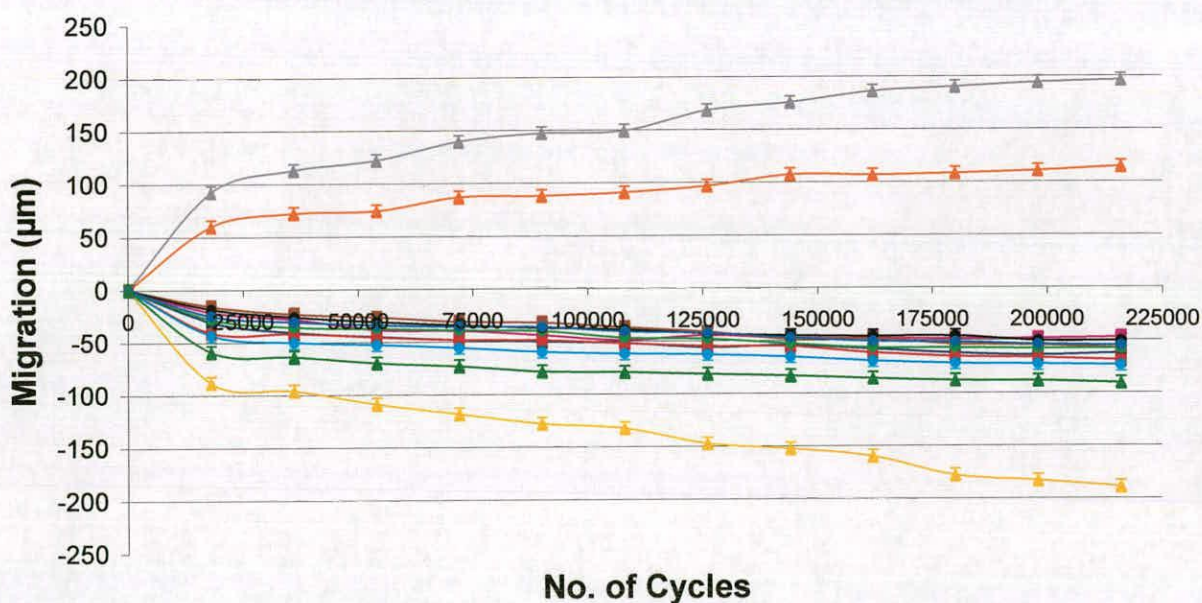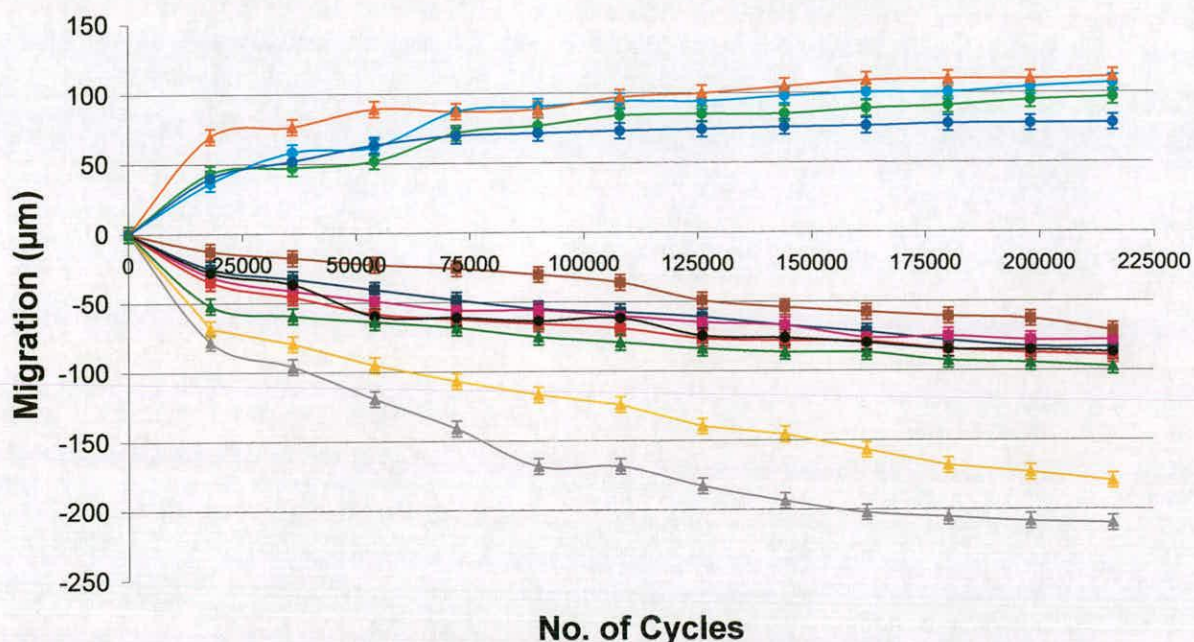
The hybrid and fully cemented tibial trays without an 80mm modular stem in the T1 group experienced the highest permanent translational and rotational migrations in all three planes. The migrations were on average 3.7 times higher for the T1 hybrid tray with no stem when compared to the Primary hybrid tray with no stem, and 3.5 times higher for the equivalent fully cemented tibial trays with no stem in each group. (Fig3.26 - 3.28). The addition of a fully cemented modular stem to the tibial tray in the T1 group reduced the average final translational and rotational subsidence in all three planes by almost 60% when compared with the T1 hybrid tibial tray with no modular stem. The steady-state migration rate was reduced from $9.8 \times 10\text{-}4$ µm / cycle, (rate for T1 hybrid tibial tray with no modular stem) to $4.1 \times 10\text{-}4$ µm / cycle for the T1 fully cemented tray with modular stem, a reduction of 58%. When a hybrid tray with a press-fit modular stem was tested the reduction in steady-state migration rate reduced by 45% when compared with the T1 hybrid tray with no stem. Therefore the addition of a fully cemented stem rather than a press-fit stem reduced the migration by a further 13%. There was no consistent pattern to the migration of the tray centres in the T1 group with hybrid no modular stem tray migrating distally and anterior / laterally, the hybrid stemmed tray centre migrated distally and anterior / medially while the two cemented components migrated distally and posterior / laterally.

TIBIAL TRAY SCENARIO TESTED	Steady state migration rate x-axis $(x10^{-4}/cycle)$	Steady state migration rate y-axis $(x10^{-4}/cycle)$	Steady state migration rate z-axis $(x10^{-4}/cycle)$	Average Steady state migration rate $(x10^{-4}/cycle)$
PRIM NO STEM HYB	-3.9 µm	-2.9 µm	-2.4 µm	3.0 µm
PRIM NO STEM CEM	-3.6 µm	-2.2 µm	-2.4 µm	2.7 µm
PRIM STEM HYB	-4.1 µm	-3.2 µm	-2.1 µm	3.1 µm
PRIM STEM CEM	-3.6 µm	-2.2 µm	-2.4 µm	2.7 µm
T2A NO STEM HYB	4.9 µm	-3.4 µm	-3.5 µm	4.0 µm
T2A NO STEM CEM	4.5 µm	-2.7 µm	-2.7 µm	3.3 µm
T2A STEM HYB	-4.0 µm	-2.4 µm	-2.0 µm	2.8 µm
T2A STEM CEM	3.6 µm	-2.6 µm	-2.1 µm	2.8 µm
T1 NO STEM HYB	-9.7 µm	-9.1 µm	-10.7 µm	9.8 µm
T1 NO STEM CEM	-8.3 µm	-8.7 µm	-10.0 µm	9.0 µm
T1 STEM HYB	-5.1 µm	5.3 µm	-5.3 µm	5.3 µm
T1 STEM CEM	-4.5 µm	-4.2 µm	-3.7 µm	4.1 µm

Table3.1 Steady-state migration of the prosthesis tested evaluated at 216,000 cycles.

Fig.3.26. Medial /Lateral migration of tibial tray centre. (positive = medial translation, negative = lateral translation)

Fig.3.27. Anterior / Posterior migration of tibial tray centre. (positive = anterior translation, negative = posterior translation)

PRIM NO STEM HYB	PRIM NO STEM CEM	PRIM STEM HYB	PRIM STEM CEM
T2A NO STEM HYB	T2A NO STEM CEM	T2A STEM HYB	T2A STEM CEM
T1 NO STEM HYB	T1 NO STEM CEM	T1 STEM HYB	T1 STEM CEM

Fig.3.28. Axial migration of tibial tray centre, (negative = distal translation).

■ PRIM NO STEM HYB	■ PRIM NO STEM CEM	■ PRIM STEM HYB	■ PRIM STEM CEM
● T2A NO STEM HYB	● T2A NO STEM CEM	● T2A STEM HYB	● T2A STEM CEM
▲ T1 NO STEM HYB	▲ T1 NO STEM CEM	▲ T1 STEM HYB	▲ T1 STEM CEM
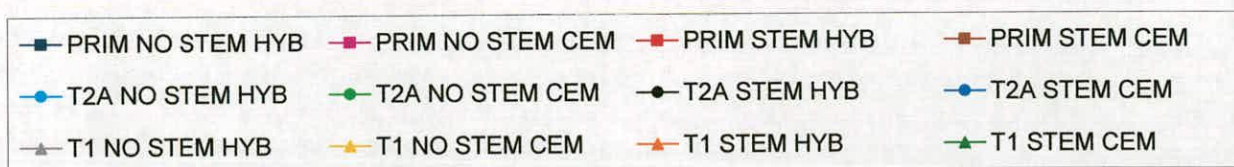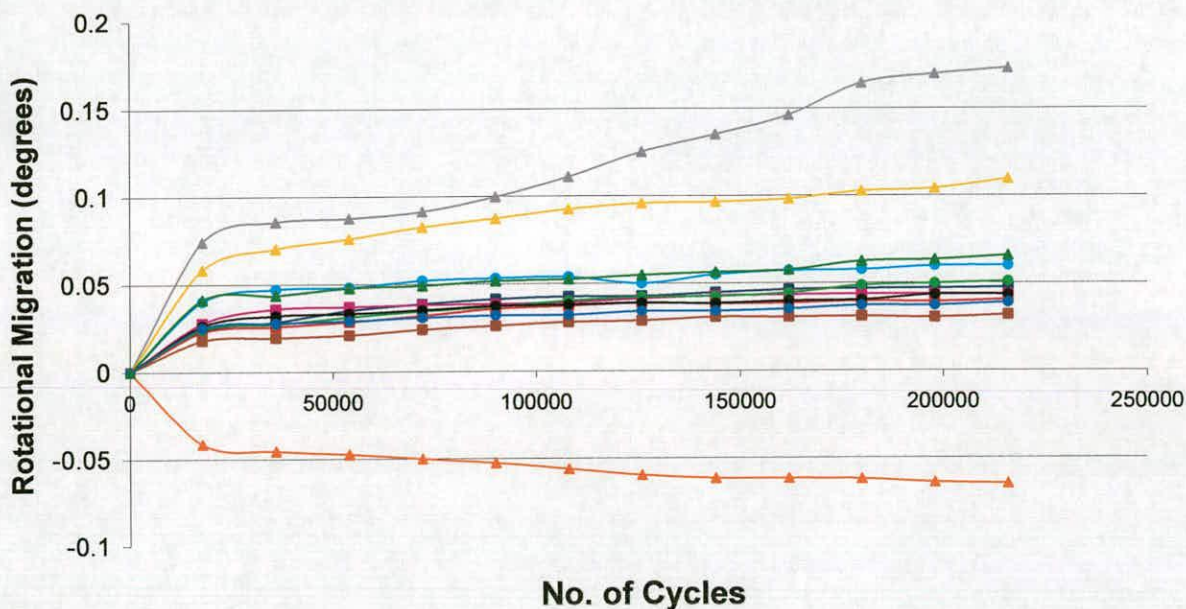
Fig.3.29. Rotational migration of the tibial tray centre in the sagittal plane, (positive = posterior rotation, negative = anterior rotation).

No. of Cycles
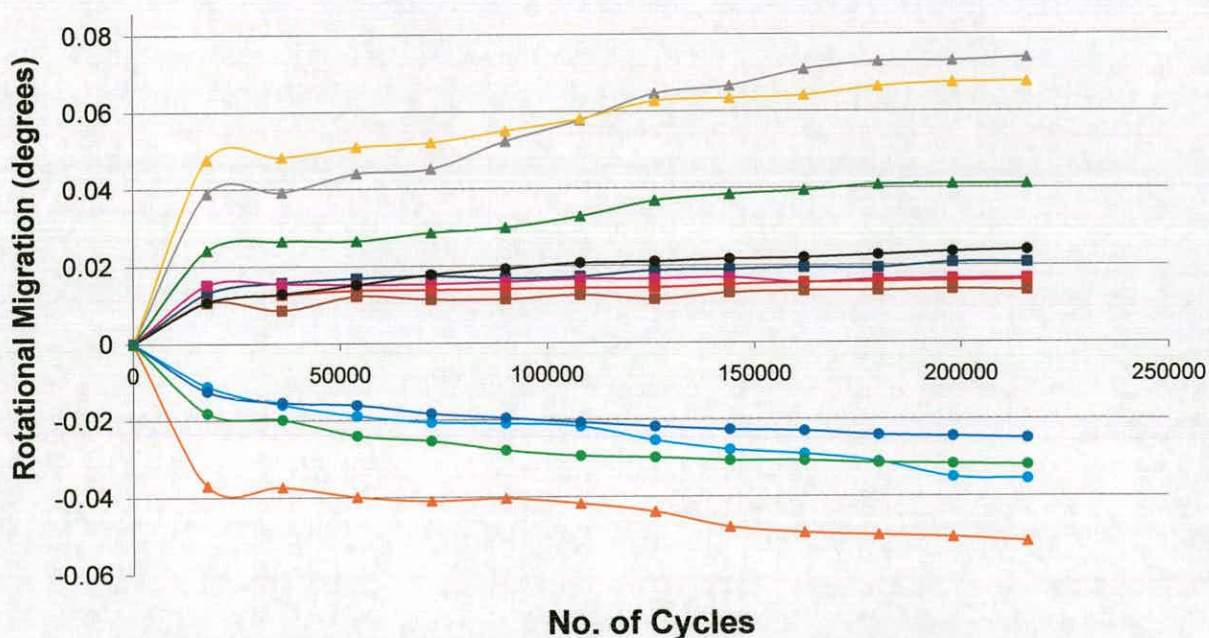
Fig.3.30. Rotational migration of the tibial tray centre in the coronal plane, (positive = rotation in varus, negative = rotation into valgus).

■ PRIM NO STEM HYB	■ PRIM NO STEM CEM	■ PRIM STEM HYB	■ PRIM STEM CEM
● T2A NO STEM HYB	● T2A NO STEM CEM	● T2A STEM HYB	● T2A STEM CEM
▲ T1 NO STEM HYB	▲ T1 NO STEM CEM	▲ T1 STEM HYB	▲ T1 STEM CEM
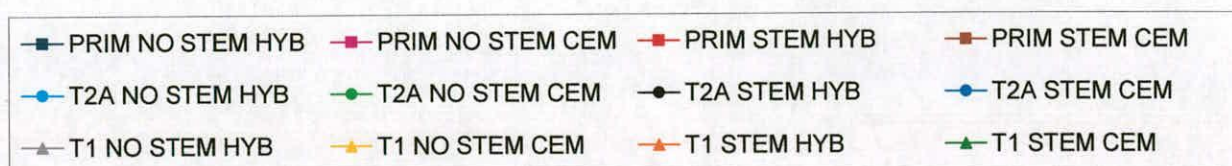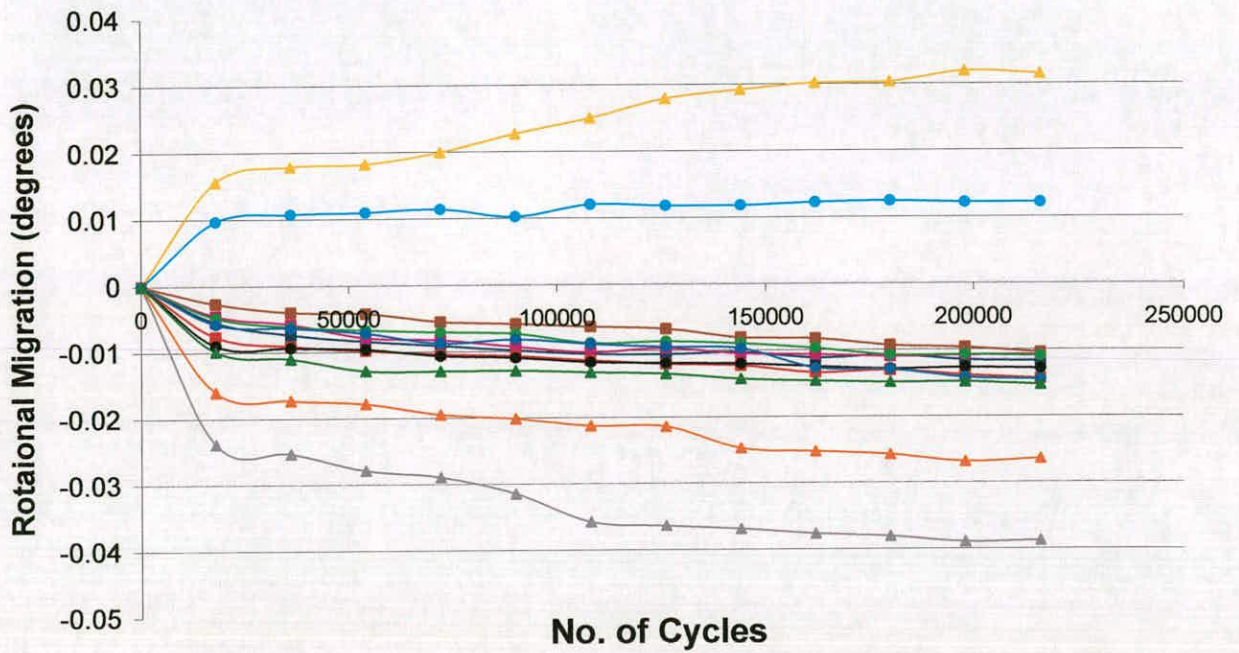
Fig.3.31. Rotational migration of the tibial tray centre about the longitudinal axis, (positive = rotation towards lateral, negative = rotation towards medial).
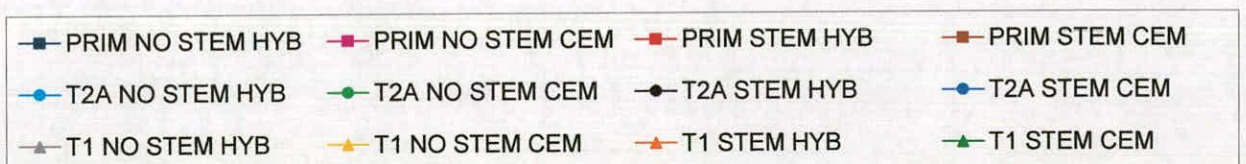
The micromotion (or inducible displacement) is the displacement recovered when the load on the tibial tray is removed. The translational micromotion recorded along all three axes was noticeably higher in the T1 group when compared with the equivalent primary and T2A specimens.

As with the migration patterns there was a rapid raise in the levels of micromotion experienced by the centre of the tibial tray early on. In the primary and T2A tests the rapid rise in micromotion levels was usually gave way to a
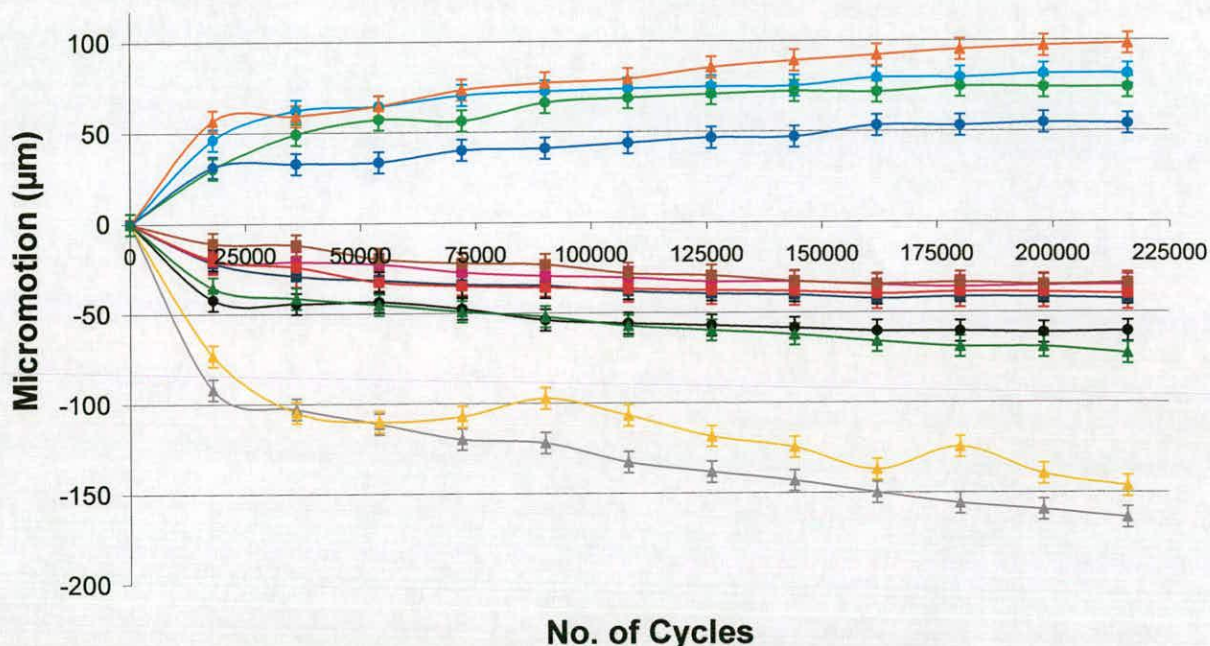
Fig.3.32. Medial / Lateral micromotion experienced by the tibial tray centre, (positive = medial direction, negative = lateral direction)
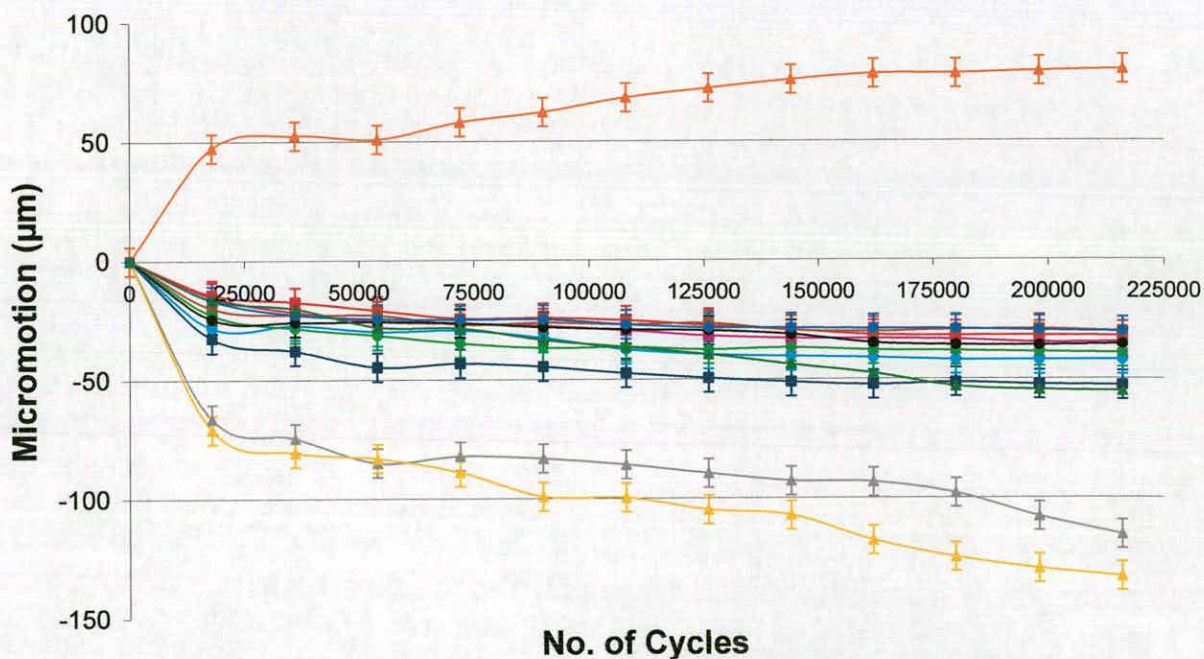
Fig.3.33. Anterior / Posterior micromotion experienced by the tibial tray centre, (positive = anterior direction, negative = posterior direction)

← PRIM NO STEM HYB	← PRIM NO STEM CEM	← PRIM STEM HYB	← PRIM STEM CEM
← T2A NO STEM HYB	← T2A NO STEM CEM	← T2A STEM HYB	← T2A STEM CEM
← T1 NO STEM HYB	← T1 NO STEM CEM	← T1 STEM HYB	← T1 STEM CEM
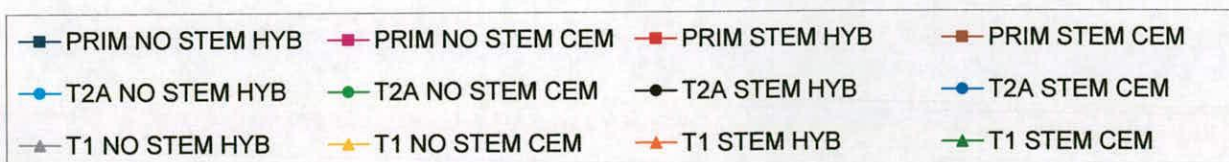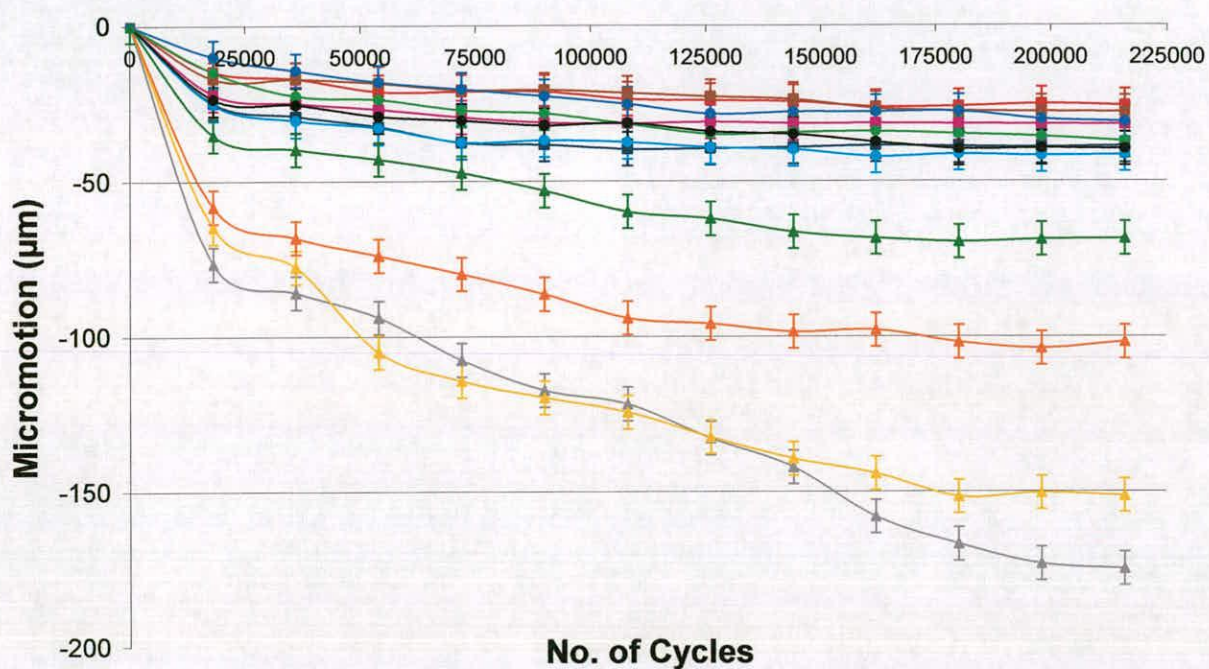
Fig.3.34. Axial micromotion experienced by the tibial tray centre, (negative = distal direction)

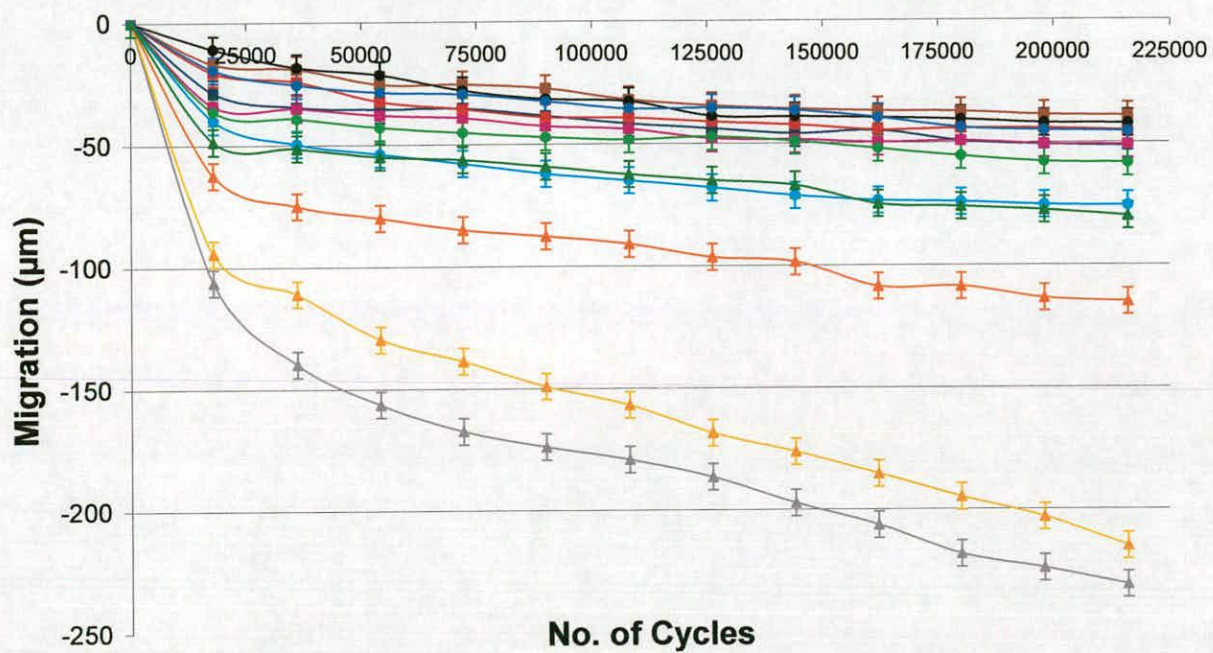|			
■ PRIM NO STEM HYB	■ PRIM NO STEM CEM	■ PRIM STEM HYB	■ PRIM STEM CEM
● T2A NO STEM HYB	● T2A NO STEM CEM	● T2A STEM HYB	● T2A STEM CEM
▲ T1 NO STEM HYB	▲ T1 NO STEM CEM	▲ T1 STEM HYB	▲ T1 STEM CEM

The addition of a modular stem did enhance the stability of the tibial tray in the T1 specimens tested, with a fully cemented modular stem providing the optimal stability. The results suggest that when the proximal bone is of a sound quality and a good cement mantle is achieved the addition of a modular stem is not needed to achieve sound initial stability, when the proximal bone is of poor quality the addition of a modular stem is necessary to achieve adequate initial tibial tray fixation.

phase of slowing levels of motion or the micromotion values reached a plateau and continued at a consistent level, (Fig3.32 -3.34).

In the T1 group however the level of micromotion in all three planes continued to rise through out the entire testing cycle especially when no modular stem was present. The addition of a fully cemented 80mm modular stem did greatly reduce the micromotion of the tibial tray centre but the levels of micromotion witnessed were still higher than those seen in the primary and T2A groups, especially in the axial plane, (Fig 3.34).

It was also noticed from the data that the tibial trays with high levels of micromotion along a particular axis also tended towards larger migration levels along that axis. This was particularly noticeable in translatory migration distally and posteriorly.

From Table 3.3 for each combination of prosthesis and fixation method tested within the primary group, it can be seen that the average micromotion values in the x, y and z directions are not significantly different. With the average overall micromotion recorded varying by less than the errors related to the system. All specimens in the primary group experienced micromotion of less than 150 μm, (the threshold for boney ingrowth to be achieved as reported by pillar et al[17].) in any plane.

The hybrid tray with no modular stem underwent micromotion 1.5 times that of the fully cemented tray with modular stem in the T2A group. The average micromotion for the hybrid tray was 44.7 μm with the average for the fully cemented tray with modular stem being 29 μm. This still only equates to a difference of 15.7 μm +/- 5.6 μm. Although the average micromotion values recorded for the T2A group are higher than for those in the primary group no specimen experienced micromotion greater than 150 μm in any plane. The hybrid and fully cemented trays with no modular stems delivered comparable

micromotion values in all three planes with the average micromotion recorded for the fully cemented tray with no stem being 39.6 μm.

The highest levels of micromotion were recorded in the T1 group. The micromotion that T1 hybrid tray with no modular stem underwent was more than three times greater than the micromotion experienced by the primary hybrid tray with no modular stem. The addition of a modular stem and fully cementing the prosthesis into position reduced the micromotion of the tray centre by almost 60% when compared with the T1 hybrid tray with no modular stem. This average micromotion witnessed for the T1 fully cemented tray with modular stem was still higher than the primary hybrid tray with no modular stem, (Table 3.3).

The micromotion for both the hybrid and fully cemented trays with no modular stem exceeded 150 μm in the coronal plane and the axial plane, (Fig3.32 and 3.34). The maximum micromotion of 175 μm occurred in the axial plane with the hybrid tray with no modular stem, the fully cemented tray with no stem experienced 154 μm. In the primary group the highest micromotion was 53 μm.

Overall the results obtained from this study of three-dimensional movement of the tibial tray indicate that the addition of a cemented or press-fit modular stem does not enhance the initial fixation of the tray greatly in the simpler revision scenario involving augmentation and in primary knee arthroplasty.

TIBIAL TRAY SCENARIO TESTED	Average Med / Lat Micromotion (+/- 5.6 μm)	Average Ant / Post Micromotion (+/- 5.9 μm)	Average Distal Micromotion (+/- 5.4 μm)	Overall Average Micromotion (+/- 5.6 μm)
PRIM NO STEM HYB	33.7 μm	39.1 μm	33.5 μm	35.4 μm
PRIM NO STEM CEM	27.6 μm	26.6 μm	27.3 μm	27.2 μm
PRIM STEM HYB	32.1 μm	23.9 μm	20.8 μm	25.6 μm
PRIM STEM CEM	25.3 μm	24.7 μm	20.9 μm	23.6 μm
T2A NO STEM HYB	66.4 μm	33.3 μm	34.3 μm	44.7 μm
T2A NO STEM CEM	59.0 μm	32.2 μm	27.6 μm	39.6 μm
T2A STEM HYB	49.6 μm	27.9 μm	30.6 μm	36.0 μm
T2A STEM CEM	41.0 μm	24.3 μm	21.8 μm	29.0 μm
T1 NO STEM HYB	122.4 μm	82.6 μm	119.3 μm	108.2 μm
T1 NO STEM CEM	106.9 μm	95.4 μm	113.5 μm	105.3 μm
T1 STEM HYB	74.5 μm	61.7 μm	81.6 μm	72.6 μm
T1 STEM CEM	52.3 μm	35.1 μm	52.5 μm	46.6 μm

Table.3.2. Average micromotion values experienced for each tibial tray tested

3.4 DISCUSSION

Previous tibial tray stability studies used various methods to measure micromotion and migration however; all of the techniques used were effectively measuring the gap between the implant and the bone in the axial direction only and did not provide a complete analysis of the prosthesis motion with respect to the tibia in three-dimensions. Essentially only the anticipated axial displacements were measured, with no way of recording non-intuitive movements in other planes. As a result of these limited measurements the true three-dimensional micromotion and subsidence of the tibial implant in a revision scenario has not been reported on in previous studies. The system designed and used in this study allowed for the complete implant motion, (both inducible displacement and subsidence), with respect to the tibia to be recorded throughout several thousand in vitro loading cycles in three-dimensions.

In this in vitro series fully cemented and hybrid cemented trays with and without modular stems were studied in three differing TKA settings, the primary setting , the revision T2A setting with medial augment and the revision T1 setting requiring proximal bone impaction grafting.

In the primary setting the translational and rotational migration patterns along with the levels of micromotion recorded in three dimensions show that no noteworthy advantage is gained by adding an 80mm modular stem or fully cementing the prosthesis in place (F3.26-3.34). The results of this series advocate that sufficient initial stability of the tibial tray is obtained without a modular stem and hybrid fixation of the tray. Hybrid fixation also reduces the risk of increased bone loss should a revision be required and the potential stress shielding of the proximal tibia that has been associated with fully cemented tibial trays[35,81].

The current data presented supports the findings of Peters et al, 2003, who reported that under an eccentric load, simulating three times body weight for

6000 cycles, there seemed to be no difference in the micromotion of the tibial components implanted with surface or full cementation techniques. However the current data contradicts the findings of Bert and Mcshane[89], who found that implant stability was enhanced by fully cementing the tray unless the proximal cement mantle was 3mm or greater. The average cement mantle thickness in this series was 2.1mm and sufficient initial stability was achieved. The three dimensional findings presented here also agree with the three dimensional findings of Stern et al[51]. Stern et al[51] used an array of sensors positioned around the tray. The data was then downloaded to a computer and manipulated to provide three dimensional data on the tibial trays motion in the primary setting. Their results indicated that modular stems did not enhance initial fixation of the tibial tray in cemented routine TKA.

As mentioned previously several studies have documented the effects of stem length and different modes of fixation, though the vast majority of these studies have been carried out using tibial constructs simulating bone quality that would be present at the time of a primary TKA. In this in vitro series the effects of a modular stem and differing modes of fixation, were evaluated in tibial constructs simulating common revision bone quality. Tibial constructs with T2A defects requiring augmentation and T1 defects requiring proximal bone impaction grafting, were investigated. This was done to evaluate the appropriate benefits of stems and fixation techniques when faced with proximal bone deficiencies commonly found at the time of revision TKA.

Gofton et al[9], presented data on eighty-nine revision knee arthroplasties, 32% of these revisions exhibited boney defects on the tibial side and half of them were classified as a T2A defect as described by Engh et al[53]. Despite the occurrence of T2A defects being routine in revision TKA a definitive protocol for dealing with such defects does not exist. The results of this study suggest that the use of an augment alone does not mean that a modular stem must be employed to gain sufficient initial mechanical stability. The difference in the average steady state

migration rates in three planes between the T2A hybrid tray with no stem and the hybrid tray with modular stem was only 1.2 μm x10^{-4}/cycle, with the difference in the average micromotion being 8.7 μm +/- 5.6 μm. When the modular stem was fully cemented there was no change in the steady state migration rate but the level of micromotion was reduced, with the difference increasing to 15.7 μm +/- 5.6 μm; however the micromotion values recorded for the hybrid tray with no stem were well below 150 μm in all planes. The torsional migration patterns between the stemmed and unstemmed components also did not vary greatly, (Fig3.29-3.31). Rotational stability is particularly important in the revision setting as often a more constrained prosthesis is used which can lead to an increased torsional load being transmitted to the tibial component, when compared to the primary setting.

The findings of this study contradict those reported by Conditt et al[107] who examined the stability of a revision tibial prosthesis with augmentation and concluded that the mechanical stability of the tibial tray was increased by the addition of a canal filling stem. The study by Conditt et al[107] only examined cementless components and did not look at the effect that cement and no stem would have on the stability of the components. The load they applied to the tray was relatively small at 1500N had the load been higher a stem alone may not have been able to provide enough stability. Conditt et al[107] also acknowledged that the fixation achieved by canal engaging stems alone is dependent on the amount and type of distal fix achieved, not every patient's anatomy will allow the surgeon to achieve 30mm of parallel engagement which is what they recommend to provide sufficient stability for the entire construct. They also mention that if minimal engagement or only stem tip contact is obtained this can cause the stem to pivot potentially leading to more motion, this phenomenon was demonstrated in Chapter Two where the addition of a stem decreased the initial stability recorded.

The stability of revision components in vivo can be widely variable due to the bone quality and soft tissue integrity encountered at the time of surgery. The results obtained within this series for the revision T2A group used biomechanical bones and although a section was removed proximally to accept an augment the remaining bone simulated a bone quality that would more likely be present at the time of a primary TKA rather than a revision TKA. This may have contributed to the similar results for the stemmed and unstemmed components and had the proximal bone quality been of a poorer nature the addition of a modular stem may have had a greater role in providing stability to the construct. These results do show however that if a small or isolated defect is present that requires augmentation but sound metaphyseal fixation can be achieved in good proximal bone a modular stem is not required to gain sufficient stability in the revision setting.

The T1 group of tests using proximal bone impaction were designed to investigate the role of the stem when poor proximal bone was present in the revision scenario. In this group the addition of a modular stem greatly reduced the translational and rotational migration as well as the micromotion endured by the tibial prosthesis in all three planes. The data showed that a hybrid cemented modular stemmed tray reduced the average steady state migration rate by 55% and the average micromotion by 33% when compared to the hybrid tray with no modular stem. When the tray and modular stem were fully cemented the initial stability was improved further with average steady state migration rate falling by 60% and the average micromotion falling by 45%. Relative movement at the implant bone interface exceeded 150 μm in at least two planes for both the no stemmed trays, which can lead to preventing boney ingrowth into porous surfaces and hindering long term biological fixation. Relative motion of 150 μm at the interfaces was not reached in either of the stemmed tests.

It is the author's belief that the addition of a modular stem provides extra resistance to "teeter-totter" and lift-off of the tray in T1 group more than in the

primary and T2A group due to the poorer mechanical properties of bone graft when compared to cancellous bone. Morsalised bone graft has little or no strength in tension, which means the tibial prosthesis has little resistance to rotational and axial motion in the proximal direction. When no modular stem was used the tray relied solely on the cement mantle attached to the cortical bone to provide stability. The modular stem though by-passes the defect and secures the tray in bone with better mechanical properties enabling the tray construct to better resist lift off and rocking motions more advantageously. These results suggest that when poor proximal bone is present a stem long enough to by-pass any defect and secure the tibial tray in good quality bone should be employed. The fact that the fully cemented stem provided improved stability could again be due to the increased mechanical properties of the graft directly surrounding the tray and stem when bone cement was introduced to the surrounding graft.

The beneficial effects of modular stems when used in tibias requiring bone impaction grafting were also reported by Toms et al[101]. The findings of this study collaborate those of Toms et al[101] who showed that longer stems reduced permanent displacement of the tray by 77% and cyclical displacement by a mean of 40%. The magnitudes of the motion recorded by Toms et al were higher than in the present study but the trends seen were similar. The higher magnitudes could be due to the fact that Toms et al[101] used a cortical shell filled completely with morsalised bone graft where as tibial construct used within this study used a cortical shell filled with a polyurethane foam to represent cancellous bone distally and morsalised bone graft in the proximal tibia only representing the in vivo revision construct more closely. Therefore the differences may be a consequence of the mechanical properties of the graft versus the polyurethane foam and graft. The level of impaction and the density of the graft used in each study could also account for the differences between the two studies.

In a comparative manner with the present findings, Lee et al[23] reported implant stability was greatly enhanced in their "poor" quality foam models when the

implant was cemented. They also reported that the addition of a central stem added stability to the implant in "poor" foam only and not in the foam models representing good quality bone stock.

Van Loon et al[44] presented a case report on a 61 year old lady who underwent a revision TKA for polyethylene wear of the tibial insert. The tibial bone loss was repaired by applying a mesh to the proximal tibia to contain the defect and filling it with morsalised bone graft. A retrieval at four years showed that most of the tibial graft had not incorporated and the central tibial graft was necrotic. Van loon et al[44] concluded that this had been caused by a phase of relative instability and they discouraged the use of bone graft on the tibial side for large defects. However, Van Loon implanted a fully cemented short stemmed tibial tray into the repaired tibia, the results of this study and the results of Toms et al[101] and Lee et al[23] suggest that a tibial tray with a long modular stem would have increased the initial stability of the construct giving the graft the best opportunity to incorporate, leading to a stable long term fixation. The prospective multi-centre study evaluating morsalised bone graft for tibial defects by Benjamin et al[100], also supports this theory.

Benjamin et al[100], reported on 31 patients out of 409 who underwent morsalised bone impaction grafting for tibial defects. The defect volumes averaged 36 cc^3 and all tibial components were secured using either hybrid fixation with a long modular stem or full cementation with a long modular stem. The use of press-fit or cemented stems was down to surgeon preference. Radio graphic evaluation at two years showed remodelling of the graft consistent with viable incorporation of the graft. The incidence of radiolucent lines, at two years follow up, was not different between the patients who received grafting and those patients who did not. There were no clinical failures or revisions at two years in the patients who received morsalised bone grafting in the proximal tibia. Unlike Van Loon et al[44], Benjamin et al[100] concluded that the use of morsalised bone impaction grafting offered a suitable option for the reconstruction of tibial defects in revision TKA.

The results obtained in this study also support the findings of Nazarian et al[108], who did not show a significantly higher loosening in revision implants without stems when compared with revision implants with stems. They concluded that the use of a revision component does not alone constitute a requirement for the use of an intramedullary stem and that the bone quality alone at the time of revision was the most important criteria for determining whether a stem should be used or not.

There are limitations linked to this study which should be borne in mind when evaluating the data presented. If the loading protocol had included the application of torsional or shear loading, a central modular stem may have provided superior resistance against such forces and the findings of the study may have differed. Other caveats of this study are linked to the limitations associated with biomechanical bones, and their ability to fully mimic human bone properties. However, if frozen cadaver bone had been used limitations in bone quality and consistency in mechanical properties would have still been present. This model did not incorporate surrounding soft-tissue and muscle interactions. Due to the aforementioned limitations, the absolute magnitudes of the micromotion and subsidence measured in this current study can not be extrapolated directly to the in vivo implant scenario. The purpose of this study however was more concerned with comparing differences in motion between different implant combinations and we think the qualitative influence which is reported here is realistic.

Thus given the in vivo clinical findings of Benjamin et al[100] and Nazarian et al[108], along with the results of this in vitro experimental series it appears that successful tibial reconstruction relies on the ability to achieve a stable construct at the time of surgery. In the presence of poor bone quality and in the presence of proximal bone impaction grafting this requires a long modular stem to by-pass the defect and provide intramedullary fixation to the construct. In a primary TKA

or a revision scenario with minimal defects and sound bone quality stable fixation can be obtained through achieving cortical contact and a sound cement mantle proximally with a short stemmed tibial tray without the need for a modular stem.

3.5 CONCLUSION

The results presented within this chapter suggest that in a primary and revision T2A TKA scenario the addition of a press-fit or fully cemented 80mm modular stem offers no added translational or rotational stability to the tibial tray in all three planes. Suitable stability is achieved via a tibial tray with no modular stem using hybrid cement fixation.

The addition of a press-fit or fully cemented modular stem did not reduce the micromotion experienced by the tray in the x, y or z direction in the primary and T2A revision groups. When compared to the tibial tray with no stem and hybrid cement fixation.

Reducing the routine usage of modular stems in primary and revision TKA cases with sound bone quality could reduce some possible complications linked to TKA such as pain at stem tip, stress shielding of the proximal tibia and fretting at the stem tray junction.

In the T1 group a fully cemented tibial tray with an 80mm modular stem significantly increased the migrational and inducible displacement stability of the construct in all three planes when compared to the tibial tray with no stem and hybrid cement fixation.

The finding presented herein suggest in the presence of poor bone quality and in the presence of proximal bone impaction grafting a long modular stem which by-passes the defect and provides intramedullary fixation in the higher quality distal cancellous bone should be used to provide the most stable construct.

Chapter 4

Strain Distribution and Magnitudes within the Proximal Tibia Following Primary and Revision TKA with and without Modular Stems.

4.1 INTRODUCTION

As discussed in previous chapters aseptic clinical loosening of the tibial implant is a major cause of failure and thus revision in TKA[37,43,109], Initial stability of the prosthesis is a prerequisite for long term fixation and survivorship of the implant. Numerous clinical and experimental studies have investigated the effect of early tibial component migration and micromotion[37,43110-113] and early prosthesis migration has been shown to predict the incidence of aseptic loosening[33,114]. Fukuoka et al[34] showed that aseptic loosening and thus potential failure can be predicted as early as the time of surgery itself by observing the inducible displacements, (micromotion) of the tray during implantation. This study shows that migration and hence loosening, begins at the implantation phase and is both a mechanical and biological process rather than just a biological one.

Although the migration and micromotion process has been widely researched it is not known exactly what mechanism causes it to occur[115], and it is more than likely a combination of contributing factors including; component design, component fixation, and quality of bone stock into which the component is implanted, and the loading pattern of the implant. What is known is that all prostheses should be inserted in such a way as to achieve the best initial mechanical stability, Perillo-Marcone et al[115] showed that the degree of implant migration is dependent on the initial mechanical environment; in the revision situation it can prove difficult to obtain a sound mechanical environment due to bone loss and associated soft tissue laxity. Bone damage can compromise the fixation interface particularly when it involves the loss of large quantities of cancellous bone which is necessary for cement integration. For this reason many knee systems used today have the ability to attach modular parts such as medullary stems or augments to help balance the knee and aid initial stability. In

some revision TKA's bone defects are minor and may be dealt with using primary components and cement to fill small voids[53]. When larger boney defects are present requiring bulk allograft, bone impaction grafting or metal augments to repair the defects it is often recommended that a long modular stem is added. This helps to stabilize the prosthesis and transfer loads to the better quality diaphyseal bone[53].

Long stems although advocated in many revision scenarios, unfortunately can lead to an increase in the incidence of stress shielding, of the proximal tibia[49]. This is another mechanism that has been widely reported to cause implant loosening and migration. After implantation joint loads are transferred predominantly through the implant and cement rather than the bone, this alters the natural physiological stress patterns experienced by the tibial bone. This leads to a process in which the prosthesis carries part of or the entire load that was formerly carried by the bone alone, leading to the unloading of the proximal bone. This process is referred to as stress shielding. The areas of bone that experience this decrease in loading are principally within the proximity of the implant. This change in loading can cause a decrease in bone mass and strength surrounding the implant, resulting in weakened implant fixation, leading to increased micromotion and migration and thus potential failure[116].

As the long term goal of both primary and revision arthroplasty is the creation of a stable functional interface between the implant or cement and the supporting bone, stress shielding can present a problem. Although stems provide excellent resistance to lift off and shear, it comes at a price[49]. The ideal scenario to eradicate the effects of stress shielding and other biomechanical issues linked to implant design would be to develop an implant with the same Young's modulus as bone. This would provide the best stress transfer from implant to bone and would prevent stress shielding of the proximal cancellous bone and could lead to better long term fixation. However this is not possible with the current materials used for manufacturing implant components. Therefore industry must look to

develop implant designs that try not to violate vital biomechanical imperatives for natural bone design[56]. Frost [56], reports that many artificial joint designs fail to account for key features that allow human bone to survive for life. Such as microdamage thresholds of bone, load focusing and defocusing, and mechanical usage strain thresholds for controlling biological mechanisms such as bone remodeling. One of the key vital biomechanical imperatives that Frost[38,56,63] outlines is the effect of strain on bone. If peak strains are too high or too low this can have a detrimental effect on the bone stock surrounding the implant bone interface. Frost states that when looking at structural bone adaptations due to mechanical usage, based on Wolff's law to copy nature, typical peak strains should not reach or exceed the minimum effective strain that begins turning mechanically controlled, lamellar bone adaptive modeling drifts on, anywhere in the bone directly supporting the implant. This effective strain value is thought to centre on about 1500 µε. At values above 1500 µε there is an increased risk of microdamage occurring in the surrounding supporting bone. If this strain values exceeds 3000 µε this could define a pathologic overload window, where lamellar drifts are suppressed, woven bone drifts occur and excessive amounts of microdamage can occur. When typical peak bone strains stay below a certain strain value thought to be around 50 µε,[56] the bone can sense disuse and the remodeling process can start to resorb the surrounding bone causing the support for the prosthesis to weaken in that area. The exact strain values need to be further investigated as these thresholds may vary with age, bone mass and within different bones. Published models can predict many mechanical effects and longitudinal strain effects on bone modeling, remodeling, mass, stiffness and architecture[117-120].

Despite the importance of these vital biomechanical values being reported, very few studies have examined how differing tray designs, and differing fixation techniques affect the transfer of stress and strain from the implant to the underlying supporting cancellous bone. If it can be shown that certain tray and stem designs or fixation techniques improve the strain in the supporting

cancellous bone this could have effects on the long term survivorship of these implants. As little consensus has emerged from clinical follow up studies on which fixation technique in revision TKA provides the lowest rate of loosening[47] and with limited clinical data available on the efficacy of varying implant designs and fixation techniques in TKA[121] few objective methods have been used to compare differing designs. One way of assessing prosthesis performance that can asses stress - strain distribution in the bone is finite element analysis and a number of finite element studies have attempted to examine the stress distribution within the implanted proximal tibia for differing designs, however few have examined the effects of strain.

Early finite element studies investigated the intact and implanted tibia and mostly investigated the cemented base plate scenario using axisymmetric[35] and two-dimensional[122-126] finite element models. These early FE studies provided valuable information regarding implant design. Murase et al[35] reported that all polyethylene components generated high cement and cancellous bone stresses but with the addition of a metal backing to the polyethylene stress levels were reduced in the proximal cancellous bone and cement mantle significantly. In addition to a metal backing, Murase et al[35] reported that a cemented central stem in contact with the cortex, further reduced the cement and cancellous bone stresses. Vasu et al[125] and Beaupre et al[122] reported that the risk of cancellous bone failure was low in the intact tibia and when implanted with a metal backed osseointegrated prosthesis they also noted that the addition of a long intramedullary stem stress shielded the proximal tibia. Garg and Walker[123] and Rakotomanana et al[124] examined press-fit prostheses and both reported that they generated similar cancellous bone stresses to cemented devices. All these studies aided in the development of tibial tray designs and different fixation methods but the clinical impact of these early FE studies was limited due to the fact that the models used in many of the studies had a limited ability to mimic the real structure of the bone and the implant in terms of geometry, loading, and mechanical properties. Numerous FE studies have reported findings using

simplified loading conditions employing one-point, two-point, or axisymmetric loading but experimentally determined data prove that the contact patterns of the knee joint demonstarte non-uniform distributed loading patterns[80,127]. Consequently, the simplified conditions employed by some studies limited the clinical applicability of the results.

With the progression of finite element software more accurate 3D finite element models of the knee have been created. The 3D knee structure allows better capture of stress distributions in the bone and implant, which are not fully represented in two dimensional and asymmetric models[121]. The use of finite element analysis in orthopaedics has been predominately used as a tool to report relative changes in bone stresses due to different design features or methods of fixation, it is viewed purely as a comparative rather than a predictive test. This is due to the weaknesses of some FE studies previously mentioned, but recently Au et al developed a model with the ability to mimic a more realistic structure in terms of geometry, loading and bone properties. They achieved this by incorporating the heterogeneity and anisotropic nature of bone. This is significant due to the fact that heterogeneity alone can accurately characterize bone if the loading is mainly axial, (Huiskes et al, 1981) but the anisotropic nature of bone can alter stress results significantly[124]. Au et al[121] investigated stem shape and found that all implant models caused a reduction of cancellous bone stress, plus high compression beneath the central stem. This result is similar to the findings of past FE studies that used simpler models, perhaps suggesting that FE could be used to predict the clinical outcome of implant designs. Taylor et al tried to do just that and attempted to correlate their findings with actual clinical performance.

Taylor et al set out to establish a link between cancellous bone stresses predicted from a FE model and actual clinical performance by comparing their findings with known clinical migration and survivorship data for the implant designs tested. They reported on an all polyethylene tray, a press-fit stemmed

metal tray, and a cemented, stemmed metal back tray. The same rank order for the predicted cancellous bone stresses as found in the clinical data was reported. The cemented implant generated the lowest stresses and was found in the clinical data to migrate the least and had the lowest revision rate at 10 years. The all polyethylene implant generated the highest stresses, and was found in clinical studies to migrate the most and have the highest revision rate. Taylor et al believe that this supports their hypothesis that the mechanism of implant migration is due to the progressive failure of underlying cancellous bone. Although their findings are not conclusive it does demonstrate the potential of FE analysis as a predictive tool and not just a purely comparative tool. The work carried out by Perillo-Marcone et al[115] also supports the argument that inducible displacements, migration and implant loosening are closely related to the initial mechanical environment of the implanted tibial tray and that FE can be used to predict implant outcomes. They set out to predict the likelihood of implant migration using patient specific FE models and comparing there predictions with the patients clinical outcomes from a radiostereometric analysis (RSA) study. The results from the FE analysis were compared directly to the RSA data measured one year post-operatively for each patient. Two patients with press-fit implants were predicted by the FE study to have the highest risk of failure and were found to migrate the most by the RSA study up to 4.9mm. The two patients with bonded implants were predicted to have the lowest risk of failure and these implants migrated the least in the RSA study, 0.6mm.

In past FE studies investigating the initial mechanical environment provided by new tibial tray designs with and without the use of stems to aid initial stability have predominately been carried out using an FE model mimicking the primary TKA scenario and relatively few have examined the strain distribution within the proximal tibia when implanted with revision components such as augments and modular stems. This is despite the fact the use of modular stems is widely advocated in the revision scenario and not in the primary. As achieving a sound stable fixation with bone loss and tissue laxity is more challenging. Thus if

clinicians knew the stresses associated with differing modular augments and bone graft repair methods they may be able to predict what repair method will provide the best functional outcome for the patient, as demonstrated with the FE work of Perillo-Marcone et al[115]. If revision components can be placed on strong structurally intact bone is an additional modular stem required when using modular augments? Will adding a long modular stem while using bone graft hinder the incorporation of the graft due to stress-shielding and thus will the increased bone resorption lead to early failure? These are some of the question that have not been answered in previous FE studies.

In light of the limited number of finite element studies of the revision implanted proximal tibia, the objectives of this study are:

1. To compare the cancellous bone strains generated in the proximal tibia in the primary TKA and two differing revision TKA configurations.
2. To investigate how the addition of a modular stem and / or augment affects proximal bone strain.
3. To study the effect different fixation techniques have on the distribution of strain through out the proximal tibia.

In order to investigate the above objectives a 3D FE model of the proximal tibia was created, with special consideration given to the incorporation of a realistic boney geometry, material properties, and loading patterns to provide an improved analysis of the stresses and strains found in primary and revision TKA.

4.2 MATERIALS AND METHODS

4.2.1 Tibial Component Geometry

The tibial and modular components used in this study were created using computer software, Solidedge, (UGS, Plano, USA) and were modelled upon a

commercially available knee prosthesis system called Kinemax, (Stryker, Newbury, UK). The Kinemax has a short tapered central stem 35mm in length. The Kinemax tray used in this study measured 52 mm anterior/posterior and 82mm medial/lateral. The Kinemax tray has a minimum thickness of 2mm. The Kinemax tibial tray uses two stabilising pegs, one in the medial compartment and the other in the lateral, to aid with tray stability. The pegs measure 5mm in diameter x 10mm in length. The Kinemax implant is capable of receiving both modular augments and modular stems. This study investigated the use of both 10mm medial augments and an 80mm tapered modular stem. The diameter of the stem measured 18mm at the proximal end and 17mm at the distal end. A 2mm thick bone cement mantle was modelled at the implant / bone interfaces on the proximal surface of the resected tibia, mimicking the hybrid fixation method often used in TKA. No cement mantle model was used down the stem canal or around the pegs, however it was assumed that 100% bony ingrowth had occurred around the pegs in all models studied, this was represented as perfect bonding in the model. The effect of cemented stems versus uncemented stems was modelled using either perfect bonding at the metal – bone interface simulating a cemented stem or friction bonding at the metal – bone interface mimicking an uncemented stem.

4.2.2 Tibial Model Geometry

A three-dimensional, (3D) finite element model of a proximal tibia was reconstructed from a Large Left Third-Generation biomechanical composite tibia, (Sawbones, Pacific Research Laboratories, Inc) The geometry of the composite tibia is anatomically realistic[128]. The FE representation of the tibia was developed from a set of serial transverse computer tomography, (CT) scans taken of a composite tibia along the mechanical axis of the tibia from the proximal to the

distal end, using a scan separation distance of 2 mm for the first 80mm of the proximal tibia and then 5mm slices for the remainder of the bone, a total of 54 slices. A CAD package, (Autodesk Inventor) was used to extract the geometric contours of the tibia for each of the CT cross-sections. This data was used to define the boundaries of the outer cortical surface and the inner cancellous bone surface. Cortical bone thickness was taken to be constant at 2mm in this model thus the cancellous bone surface mimicked the cortical surface geometry but with an off set of 2mm. Patient CT scans have demonstrated cortical bone thickness lies in the range of 0.5 – 5mm, however previous studies have adopted a uniform cortical thickness of between 1-2 mm[121,125,126]. A uniform cortical thickness of 2mm was used in this study for all models so that results could be compared with models already reported in the literature. Each surface layer for the cortical bone and cancellous bone were lofted together to create a solid 3D CAD model of the two separate material sections of the model the cortical and cancellous bone. The two sections of bone were then imported to another CAD package, (Solidegde, UGS, Plano, USA) where the cancellous and cortical sections were aligned to form the full tibial bone. To reduce computational effort without reducing the accuracy of the simulations carried out, only the proximal tibia was modelled fully. A Sensitivity analysis on the whole tibial bone model carried out by Au et al to determine the optimal truncation length for the proximal tibia demonstrated that stress distribution results showed little sensitivity to the diaphyseal length therefore a proximal tibial length of 150mm was deemed adequate in this study. This allowed for 35mm of clearance with the end of the modular 80mm stem tip.

4.2.2.1 Tibial Model Revision Geometry

The complete 3D solid model of the proximal tibia was prepared in Solidegde, (UGS, Plano, USA), to receive the tibial components being investigated in each different scenario. The proximal tibia of the virtual model was prepared for implantation using a series of steps within the CAD package mimicking the

standard surgical techniques set out in the operation technique for all components implanted. The tibial model (cancellous and cortical structures) had 12mm of proximal bone resected referencing off the lateral condyle as this was the higher side. This was the case for all bone models being investigated: the primary model, the T2A revision model and the T1 revision model.

4.2.2.2 The Primary Bone Model

For the Kinemax primary bone models after the initial proximal resection described above, only the cancellous structure was adapted. To enable the Kinemax component to be implanted with and without a modular 80mm stem two cancellous bone models were created for each tray. For the first Kinemax tray model two peg holes, (5mm diameter x 10mm deep), were created laterally and medially and a central lofted cutout was created 35mm in depth to mimic the short central stem of the Kinemax implant in real bone this would be done with the aid of a bone punch. The 2nd Kinemax cancellous bone model had medial and lateral peg holes created and a central lofted cutout created 115mm in depth and 18mm in diameter, (this mimicked the reaming of the canal that would be carried out in live surgery), to enable the tray plus the modular stem to be implanted.

4.2.2.3 The T2A Bone Model

The initial proximal tibial resection was implemented and the two Kinemax cancellous models were prepared as described for the primary models. Once the cancellous models had been prepared to receive the implants a further 10mm of cortical and cancellous bone was resected from the medial compartment to resemble a tibial T2A defect repair scenario this was achieved using a simple planar cut out in the CAD package. The Kinemax trays were then attached with a 10mm medial metal block augment as would be done in surgery using screws also created in Solidedge, (UGS, Plano, USA).

4.2.2.4 The T1 Bone Model

As before initial proximal tibial resection was implemented and the two Kinemax, (one with a modular stem and one without) cancellous models were prepared as described for the primary models. In all T1 models a section of proximal cancellous bone was removed using a swept protrusion cut out within the CAD package, this represented a large cancellous bone defect as would be found in a T1 revision tibia. The section of bone removed formed the morsalised cancellous bone graft 3D model.

4.2.3 Assignment of Material Properties

Strictly considered cortical and cancellous bone exhibits anisotropic and viscoelastic properties, however the assumption that bone can be modeled as an isotropic and linear elastic material is adequate for the purpose of this study and has been used in many previous studies[129-132]. Thus for this model the material properties of the cortical and trabecular bone were assumed to be isotropic, homogenous and linear elastic. Bone graft undergoes significant plastic deformation under normal physiological loads and due to this should strictly be defined as an isotropic elastoplastic material similar to soil[133], however in this study it was defined as an isotropic, linear elastic material. The material properties for all the tibial components, the tray and modular sections were taken to be isotropic, homogenous and linear elastic, as was the cement mantle. The isotropy assumption for all materials used in this study is justified as the isotropy assumption has little effect on models in which loading along the long axis of the bone is dominant[134], as is the case for all models investigated during the course of this study. Furthermore the assumption of linear elasticity appears valid for physiological loading rates[135]. Young's modulus and strength of bone vary between each individual due to differences in the degree of porosity, mineralization and architecture of bone, depending on that person's diet, activity level, age and level of disease if any[136-139]. It has been shown that bone disease

can have a dramatic effect on the Young's modulus and ultimate strength values for cancellous bone[136,137] while the effect on cortical bone seems to be less perhaps due to the higher levels of bone turnover in cancellous bone[136]. It has been reported by Ding et al[137], that early stage osteoarthritis in the proximal tibia can reduce the Young's modulus value of cancellous bone by up to 42%, compared with healthy bone, while Li and Aspden[138], showed that in late stage osteoarthritis the Young's modulus of cancellous bone can actually increase by 15% when compared with healthy bone. Due to the vast range of values given for the Young's modulus of cancellous bone it was felt that a value from previously published studies should be used. The various values of Young's Modulus, E and Poisson's Ratio, v used for the differing materials in this model can be found in Table 4.1.

MATERIAL	Young's Modulus (N/mm2)	Poisson's Ratio	Reference
Bone Cement (polymethyl methacrylate)	2.0 x10^3	0.3	Taylor et al,1998 Perillo-Marcone et al, 2000
Cortical Bone	1.7 x 10^4	0.29	Taylor et al,1998 Perillo-Marcone et al, 2000
Cancellous Bone	0.4x10^3	0.29	Taylor et al,1998 Perillo-Marcone et al, 2000
Metal (Titanium)	1.1x10^5	0.33	Taylor et al,1998 Perillo-Marcone et al, 2000
Bone Graft	0.3x10^2	0.2	Voor et al, 2004

Table 4.1: Material properties of the materials in the implanted primary and revision tibia.

4.2.4 Mesh Generation

Following the generation of the tibial component models and the generation and preparation of the tibial bone solid 3D models, all CAD files were imported into ABAQUS/CAE V6.7 where the necessary tibial components were assembled, (an example of an assembled model can be seen in Fig. 4.1) to the tibia and then meshed. Viceconti et al[140] reported that tetrahedral meshing yielded the best results for a solid model of bone, thus three-dimensional four noded tetrahedral elements were used to generate an unstructured mesh for all implanted tibia models, (a meshed primary model and T2A model can be seen in Fig. 4.2). The element edge length found to be most suitable for this study was 2mm. The total number of elements and nodes used in each model investigated are listed in Table 4.2.

MODEL TYPE	Total number of elements in each model for all parts
Primary models with no modular stem	177,229
Primary models with an 80mm modular stem	187,414
T1 models with no modular stem	184,108
T1 models with an 80mm modular stem	194,311
T2A models with no modular stem	175,409
T2A models with an 80mm modular stem	184,161

Table 4.2: The total number of elements used in each type of model investigated.

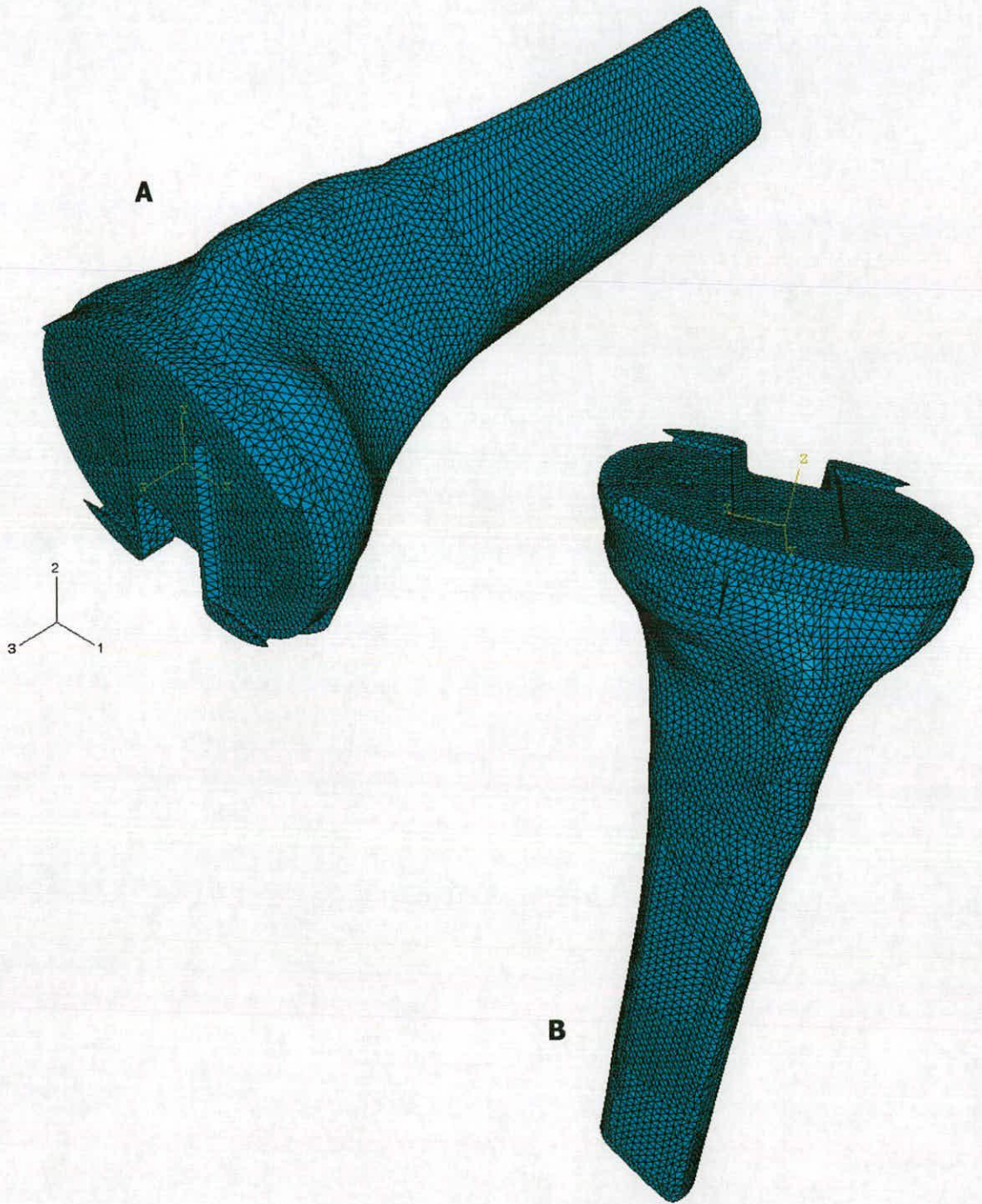

Fig. 4.1: A fully assembled T2A model in ABAQUS/CAE V6.7

Fig. 4.2: An example of an unstructured mesh for a primary model (A) and a T2A model (B) using three-dimensional four nodded tetrahedral elements.

4.2.5 Loading and Boundary Conditions

A bi-condylar load case was simulated for all models. A joint reaction force of 2.2kN was chosen for this study as 2.2kN represents 3 x body weight, the maximum force transmitted by the knee joint during a normal gait cycle for a 75kg person[80], The 2.2kN joint reaction force was shared by the medial and lateral tibial condyles, the joint reaction force being distributed 60% to the medial condyle and 40% to the lateral condyle as previously reported in the literature[80]. To simplify the analysis, the polyethylene insert was not considered in any of the models and the joint reaction force was applied directly to the tibial tray condyles. The loading was applied in the same direction as the long axis of the tibia in all cases, as can be seen in Fig. 4.3 below.

Fig 4.3: Load distribution, the pink arrows demonstrate the direction of the load applied along the long axis of the bone and the orange stars show where the bone was rigidly constrained.

4.3.1 The Primary Bone Models

4.3.1.1 Fully cemented tibial tray with no modular stem compared to proximally cemented tibial tray with no modular stem: Primary Models.

Examining the strain patterns and values for these two models demonstrates that fully cementing the tibial tray increases the strain concentration in the cancellous bone at the distal end of the tibial trays fixed stem in the Primary TKA scenario. (Fig 4.4) Cementing the tibial tray fully rather than just proximally on the resected tibial plateau also increases the maximum principal compressive strain experienced within the cancellous bone from 2754 µε in the proximally cemented tray (Fig 4.5) to 7753 µε in the fully cemented primary tibial tray, (Fig 4.4).
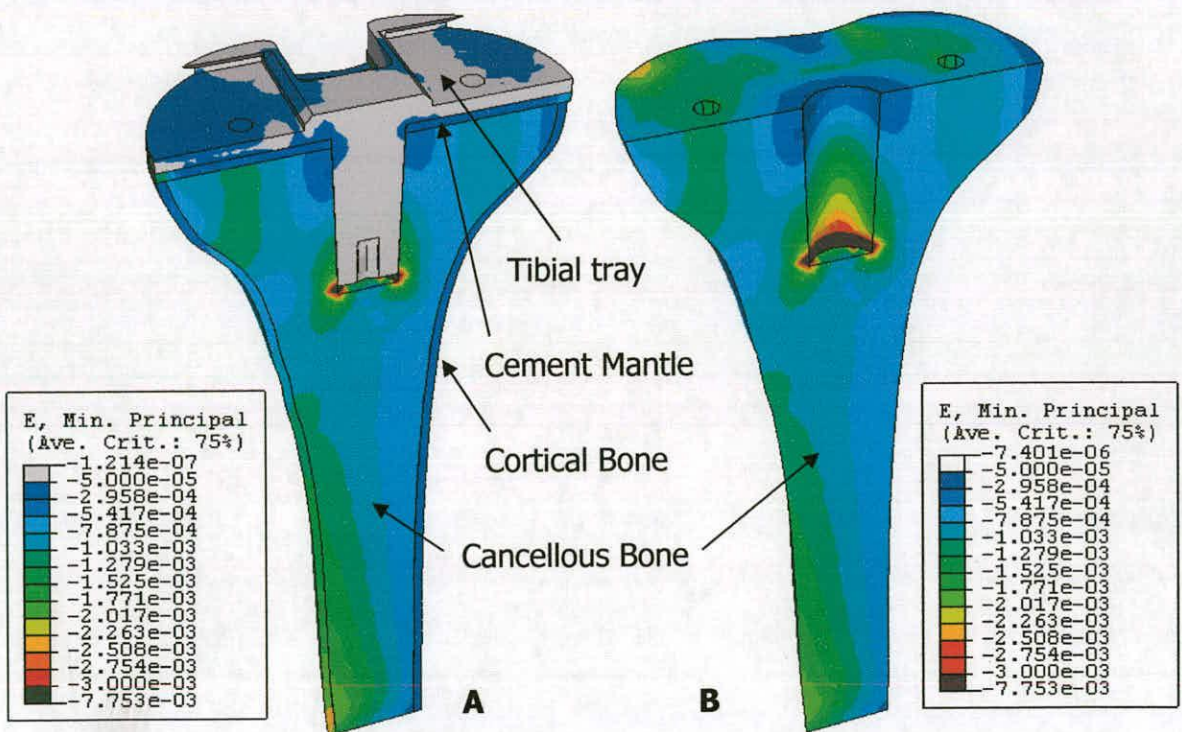

Fig. 4.4 Primary fully cemented tray with no modular stem. (A) Strain in the full system mid coronal plane view. (B) Strain in the cancellous bone compartment, mid coronal plane view. Black = > 3000 µε, White = < 50 µε.

In the fully cemented model 0.13% of the trabecular bone is loaded beyond 3000 µE, the value reported in the literature (frost) as the microdamage threshold for normal lamellar bone. This threshold could define a pathologic overload window within the cancellous bone. In the proximally cemented model none of the cancellous bone is loaded beyond 3000 µɛ. In the proximally cemented primary tibial tray only 0.1% of the cancellous bone tissue lies out with the 50 – 3000 µɛ window in which adult mammals should function for healthy bone remodeling compared to 0.32% of cancellous bone tissue in the fully cemented model. The proximally cemented model provides even strain patterns in both the proximal and distal sections of the bone and with no strain concentration zones through out the compartment, (Fig 4.5), unlike the fully cemented model where strain concentration zones can be seen at the fixed stem tip, (Fig. 4.4). Thus from these results it would seem that in the primary scenario the best method of fixation is the proximally cemented technique.
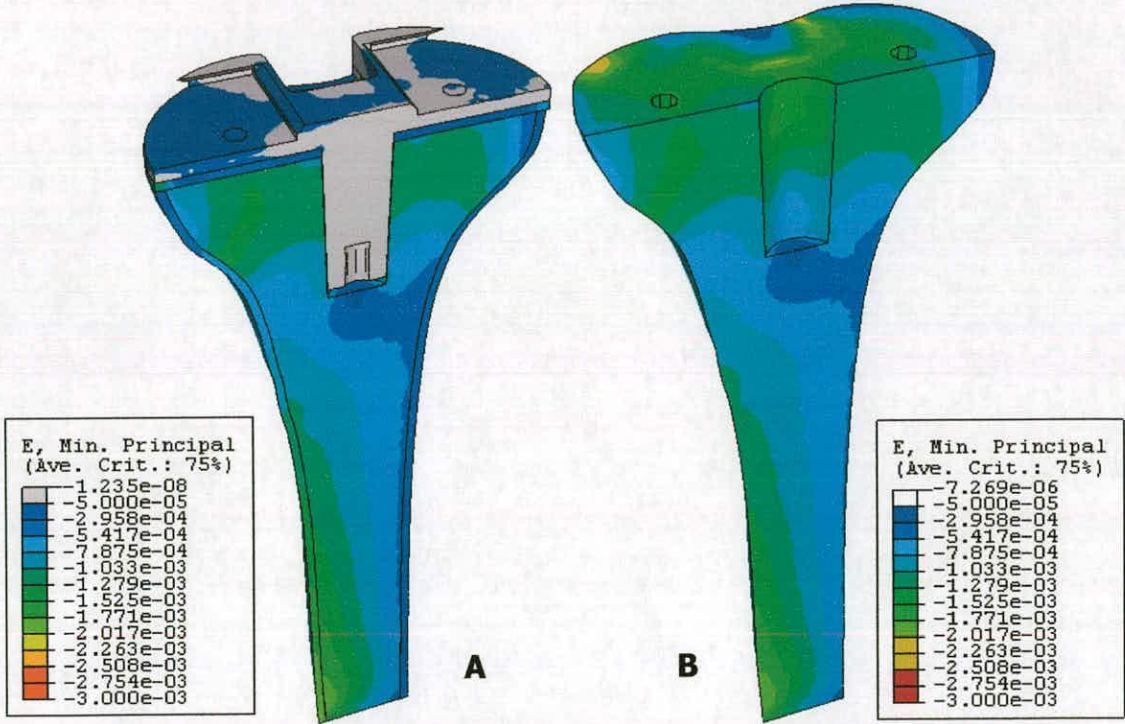

Fig. 4.5 Primary proximally cemented tray with no modular stem. (A) Strain in the full system mid coronal plane view. (B) Strain in the cancellous bone compartment mid coronal plane view. Black = > 3000 µɛ, White = < 50 µɛ

4.3.1.2 Fully cemented tibial tray with an 80mm modular stem compared to proximally cemented tibial tray with an 80mm modular stem: Primary Models

By examining Fig 4.6 and Fig 4.7 it can be seen that when the 80mm modular stem is added to the tray and fully cemented (Fig. 4.6) the strain concentrates at the distal tip of the stem and shields the proximal area of the cancellous bone from experiencing a natural strain pattern. However when the modular stem is not cemented and only the proximal surface of the tibia is fixed with cement the strain distribution within the cancellous bone becomes evenly distributed in both the proximal and distal regions of the bone, (Fig 4.7) In the fully cemented model the peak compressive strain experienced was 9822 µε this is well above the 3000 µε threshold and is also well above 7000 µε; the yield strain value of normal cancellous bone.
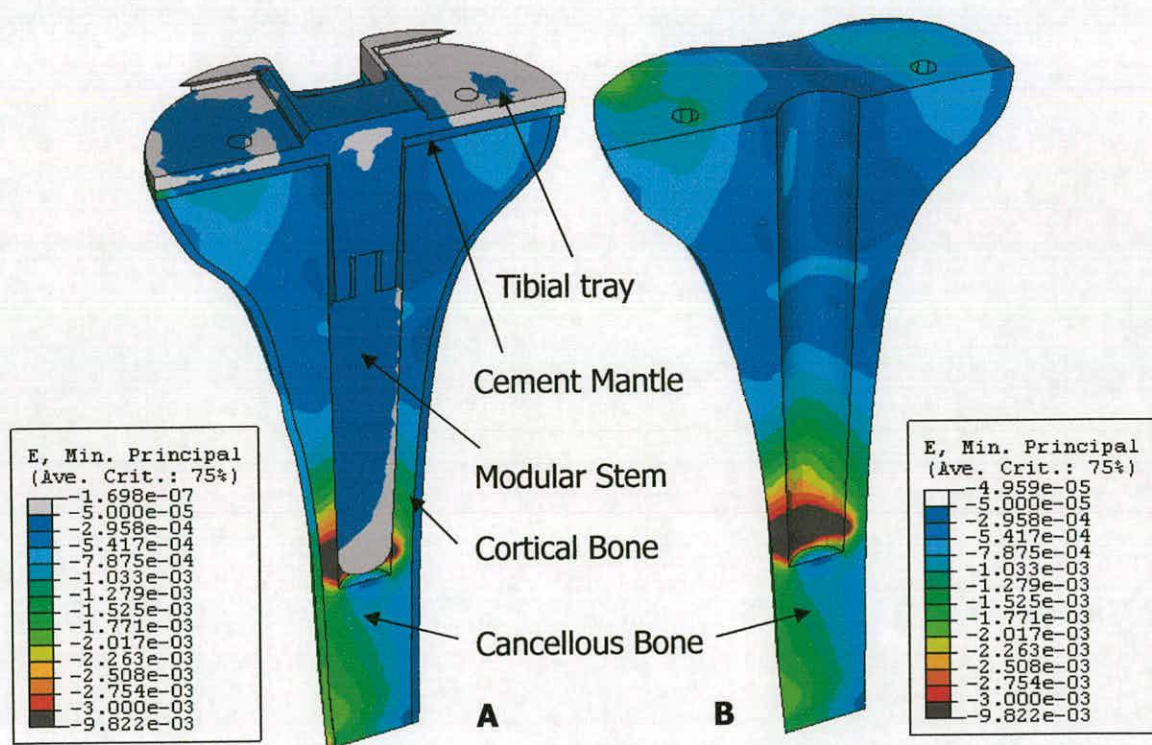

Fig. 4.6 Primary fully cemented tray with an 80mm modular stem. (A) Strain in the full system mid coronal plane view. (B) Strain in the cancellous bone compartment mid coronal plane view. Black = > 3000 µε, White = < 50 µε

In the proximally cemented model the peak strain experienced is also above 7000 µε at 7217 µε however Fig 4.8 shows that this peak strain acts over a small area and most likely occurs during the loading phase, when deformation of the tibia causes the distal end of the stem to come into contact with the anterior wall of the cancellous bone and thus cause point loading at the stem - bone interface. (This phenomenon was seen in all the models investigated where the 80mm modular stem was added and not cemented, (Fig 4.21 and Fig 4.30)) Fig 4.9 shows that the high strain experienced in the cemented model acts over a much larger area of the cancellous bone. The results in Table 4.3 & 4.4 also show the difference in the strain distribution for these maximum strains experienced by both models. In the fully cemented model 1.05% of the
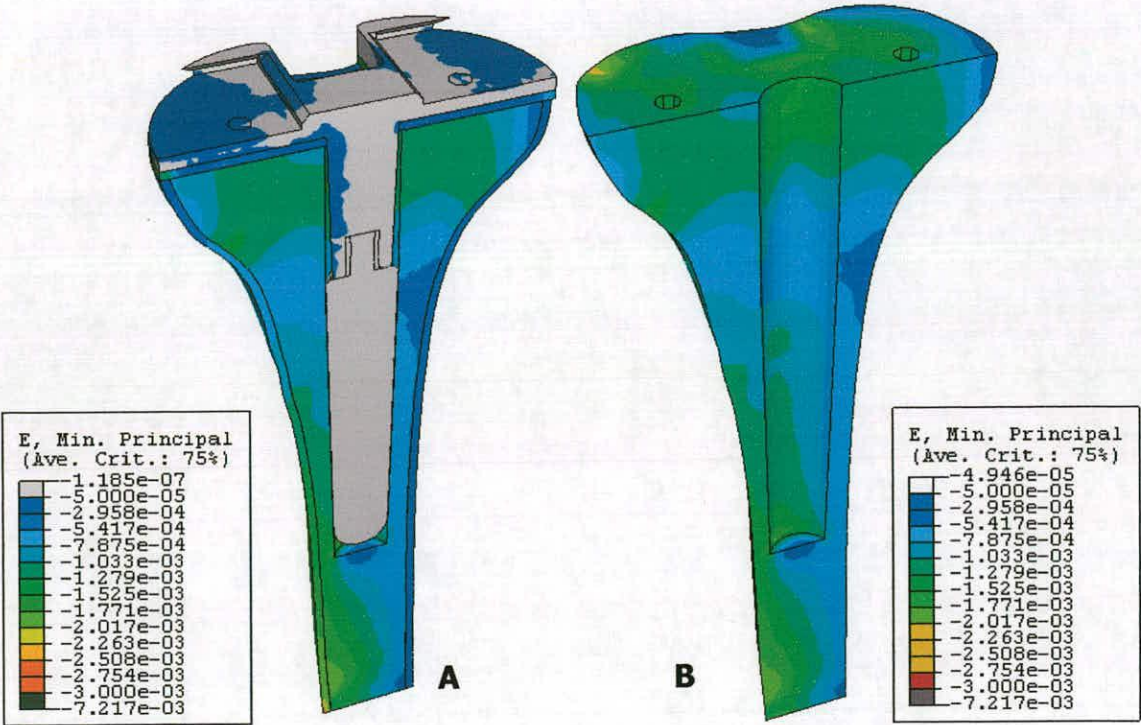

Fig. 4.7 Primary proximally cemented tray with an 80mm modular stem. (A) Strain in the full system mid coronal plane view. (B) Strain in the cancellous bone compartment mid coronal plane view. Black = > 3000 µε, White = < 50 µε.

cancellous tissue experienced strains greater than 3000 μE, with 0.05% experiencing strains greater than 7000 μE, in the proximally cemented model only 0.03% of cancellous tissue was loaded beyond 3000 με and although two elements registered a strain of over 7000 μE, this equated to none of the cancellous tissue experiencing a strain greater than 7000 με when calculated.

From these results it can be determined that the proximally cemented tray with an uncemented 80mm modular stem gives the best strain transfer to the cancellous bone when compared to the fully cemented model with an 80mm modular stem, however when the results for the trays without modular stems are taken into account we can conclude that the best method of fixation in the primary scenario based on the magnitude and patterns of strain experienced by the underlying cancellous bone is the proximally cemented tray without a modular 80mm stem.

E, Min. Principal
(Ave. Crit.: 75%)
-4.946e-05
-5.000e-05
-2.958e-04
-5.417e-04
-7.875e-04
-1.033e-03
-1.279e-03
-1.525e-03
-1.771e-03
-2.017e-03
-2.263e-03
-2.508e-03
-2.754e-03
-3.000e-03
-7.217e-03
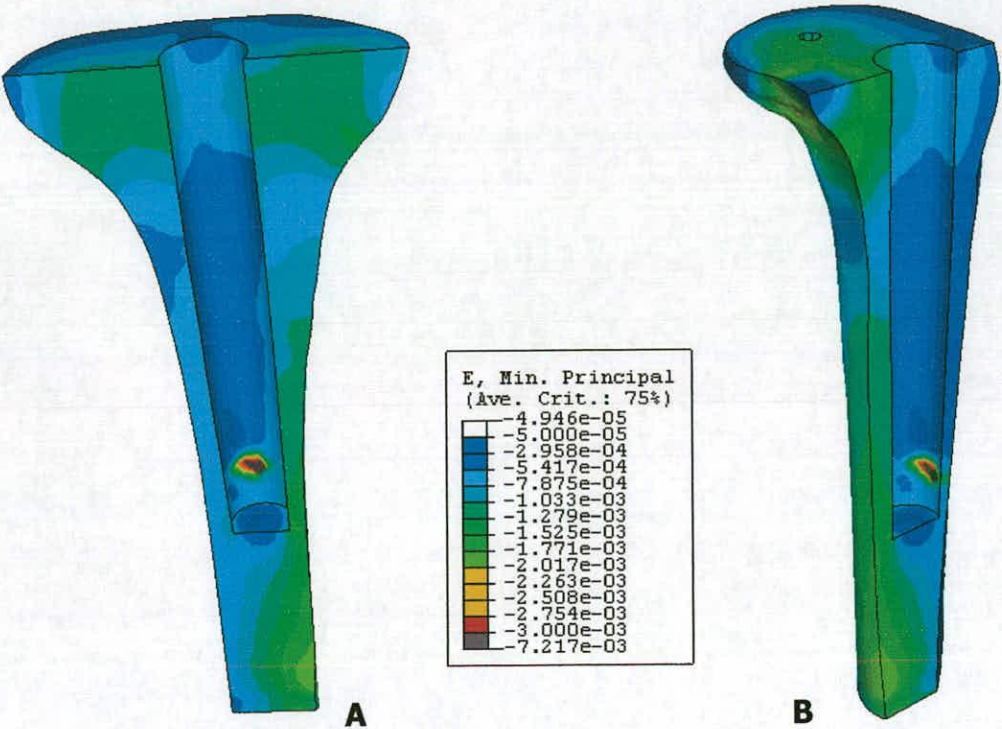
Fig. 4.8 (A) Posterior cut view of proximally cemented tray with an 80mm modular stem showing stem-cancellous point contact on anterior region. (B) Stem-cancellous point contact region a posterior-medial view. Black = > 3000 με, White = < 50 με
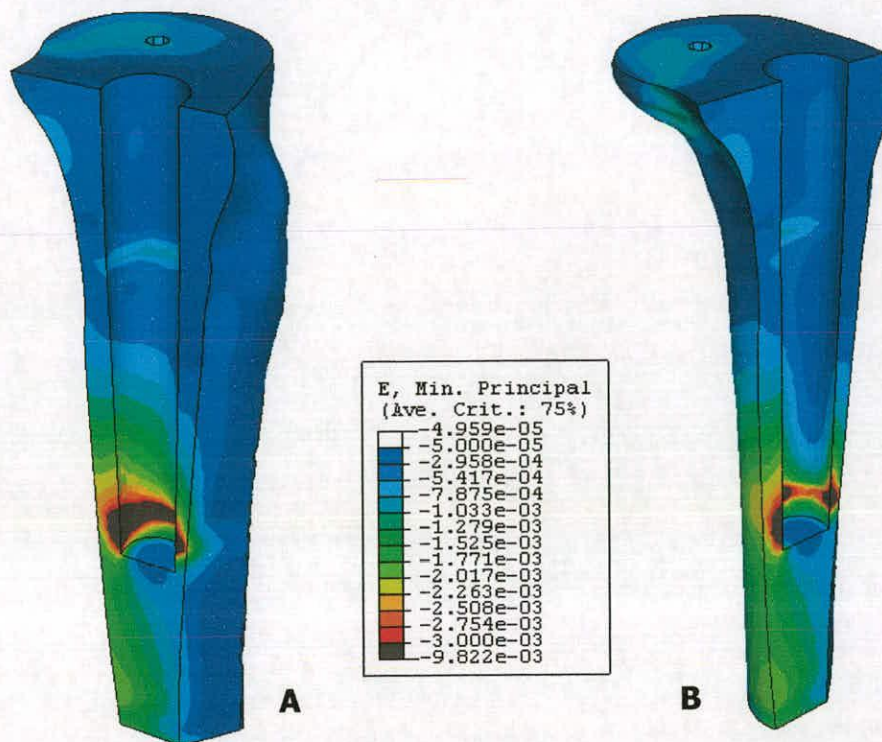
Fig. 4.9 (A) Medial cut view of fully cemented tray with an 80mm modular stem. (B) a posterior-medial cut view of fully cemented tray with an 80mm modular stem. Black = > 3000 με, White = < 50 με

experienced strains of 3000 με or greater, compared with 1.14% and 33.42% respectively in the fully cemented model (Table4.3 & 4.4). In the proximally cemented model the most excessive strain was found in the proximal posterior region of the graft and the distal anterior region of the cancellous bone at the non modular stem tip again caused by the stem tip contacting the cancellous bone due to the deformation within the proximal graft, (Fig 4.13 & 4.14).

Fig 4.10. T1 fully cemented tray with no modular stem, mid coronal plane views. (A) Strains within complete model. (B) Strains within the cancellous bone + bone graft. (C) Strains within the cancellous bone. Black = > 3000 με, White = < 50 με.

The high strain experienced in the proximal region of the graft could be down to the design of tibial tray used in this study. A primary tray was modeled which included a cut out in the posterior aspect of the tray to enable the surgeon to retain the PCL in primary cases. In revision cases however the PCL is rarely kept and thus a typical revision tibial tray design does not have the cut out section present, meaning that the graft would not be loaded in the same way as modeled here. The revision tibial tray would cover the graft fully and more of the load would be transferred through the bone's cortex rather than to the graft directly as occurred in this instance, thus the strain magnitudes and patterns experienced within the graft compartment may be altered in both the fully cemented and proximally cemented cases. In both the fully and proximally cemented models the strain pattern within the proximal portion of the cancellous

Fig 4.11. T1 fully cemented tray with no modular stem: strain within the cancellous bone compartment (A) medial view, (B) posterior-medial view. Black = > 3000 με, White = < 50 με

bone demonstrates the issues with using the primary tray for revision scenarios further as the both cancellous bone compartments exhibit high strain regions where the posterior cut out section of the tibial tray rests and transfers the load to the proximally resected surface. The rest of the proximal region in the cancellous bone was distributed evenly and the values remained within the range for healthy bone modeling and remodeling. However at the distal tip of the tray's non-modular stem in both models there is a strain concentration where the tray's stem point loads the cancellous bone due to the deformation that occurs within the graft and this leads to the point loading, which causes the high anterior strain.

From these results it can be concluded that in both the fully cemented and the proximally cemented models the strains transferred to the graft means that it is unlikely to incorporate fully, thus it would not be recommended to use a primary tibial tray in this scenario with either fixation method.

Fig 4.12. T1 fully cemented tray with no modular stem: strain within the bone graft compartment (A) mid coronal plane view, (B) medial view. Black = > 3000 με, White = < 50 με
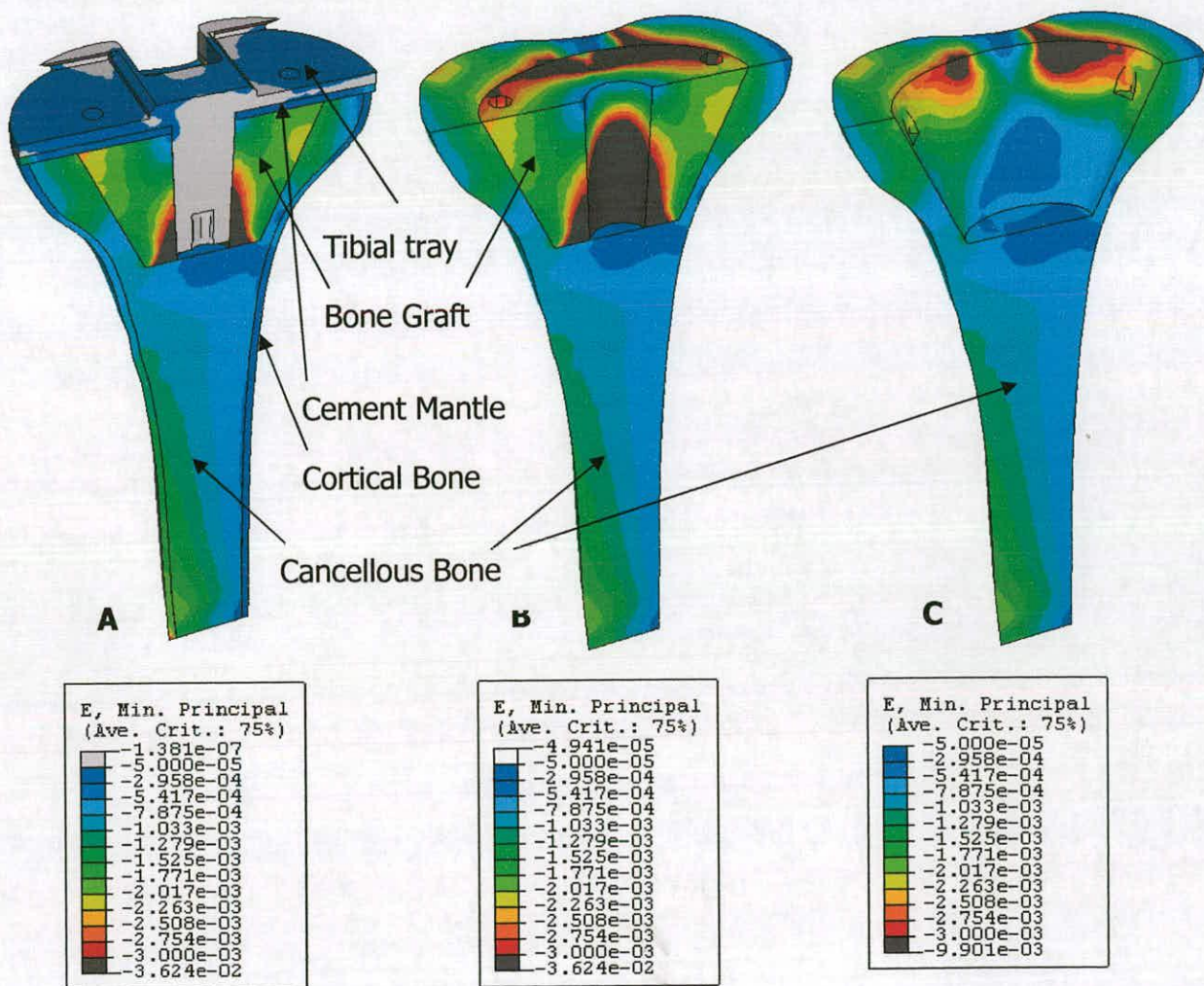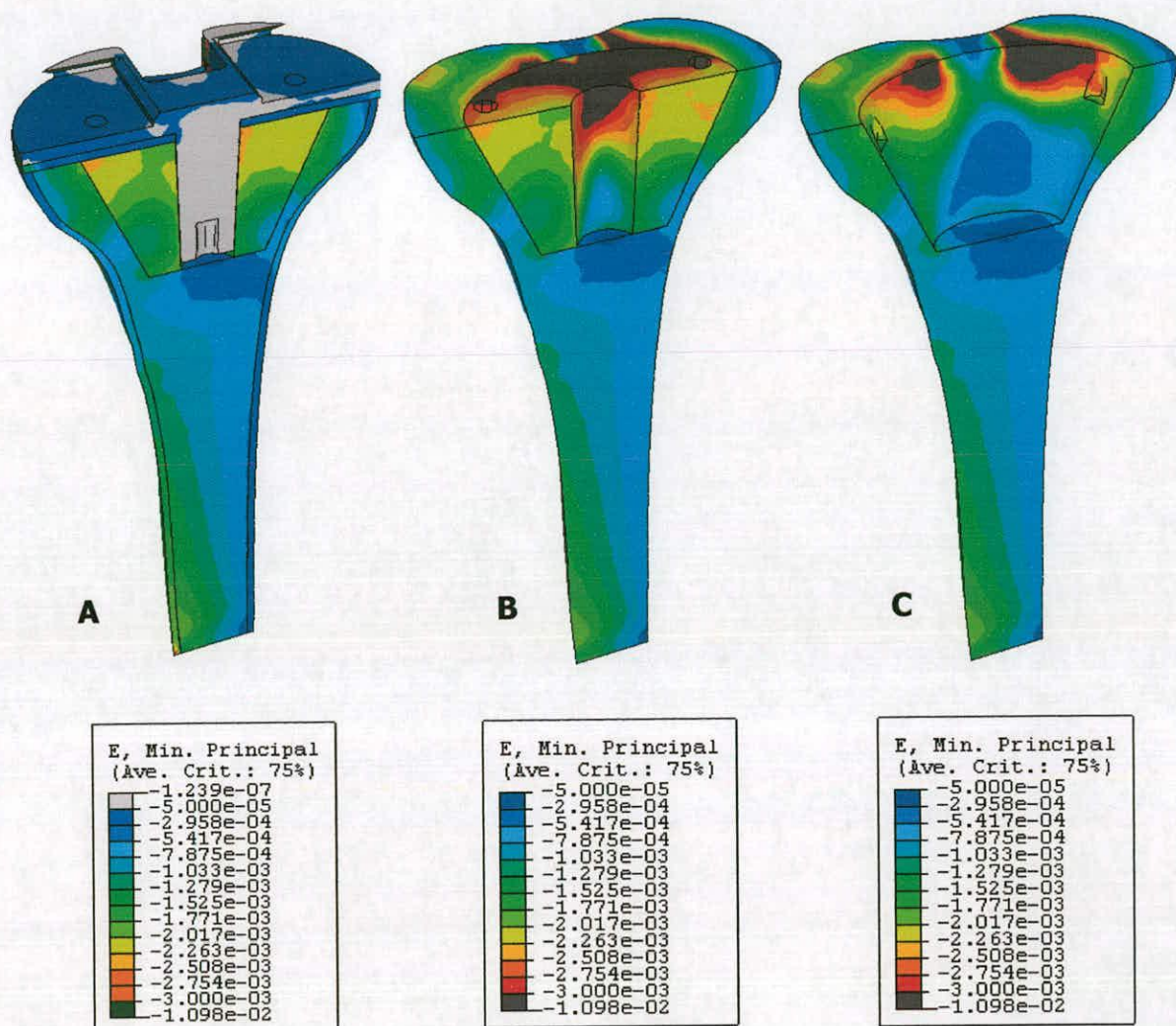
Fig 4.13. T1 proximally cemented tray with no modular stem, mid coronal plane views. (A)
Strains within complete model. (B) Strains within the cancellous bone + bone graft. (C) Strains
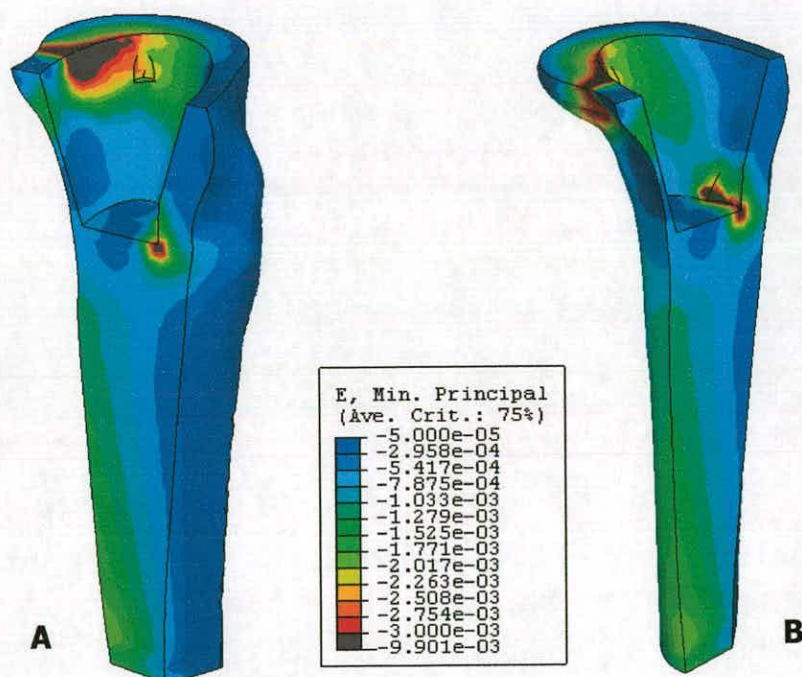within the cancellous bone. Black = > 3000 με, White = < 50 με.
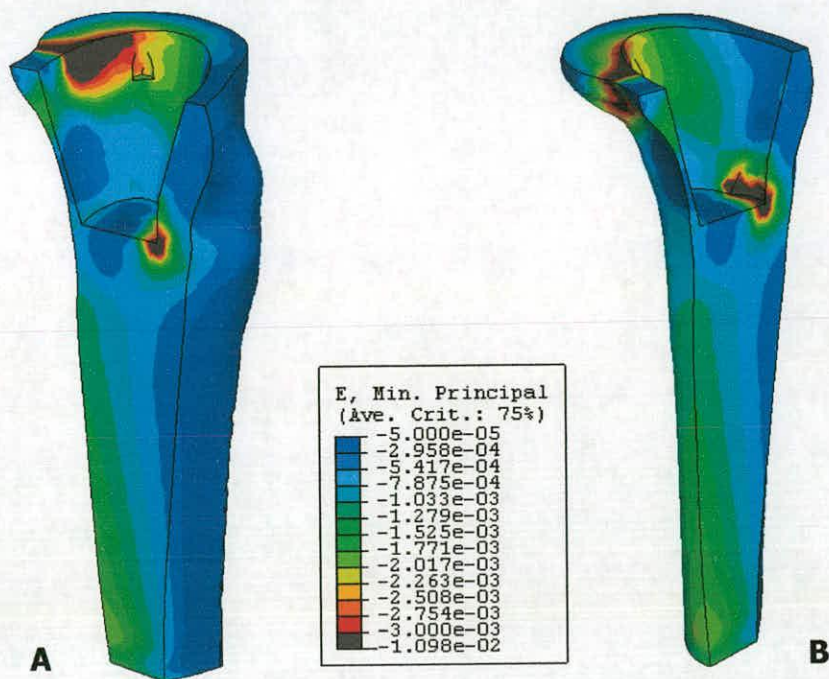
Fig 4.14. T1 proximally cemented tray with no modular stem: strain within the cancellous bone compartment (A) medial view, (B) posterior-medial view. Black = > 3000 με, White = < 50 με
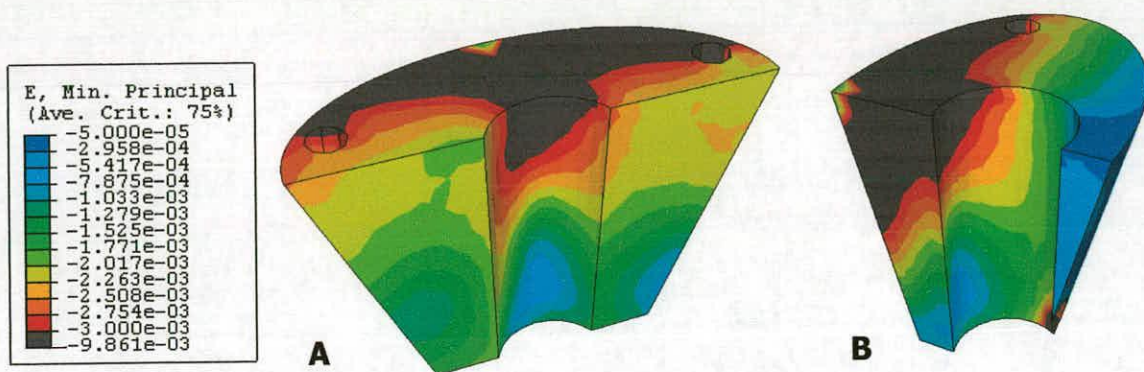
Fig 4.15. T1 proximally cemented tray with no modular stem: strain within the bone graft compartment (A) mid coronal plane view, (B) medial view. Black = > 3000 με, White = < 50 με.
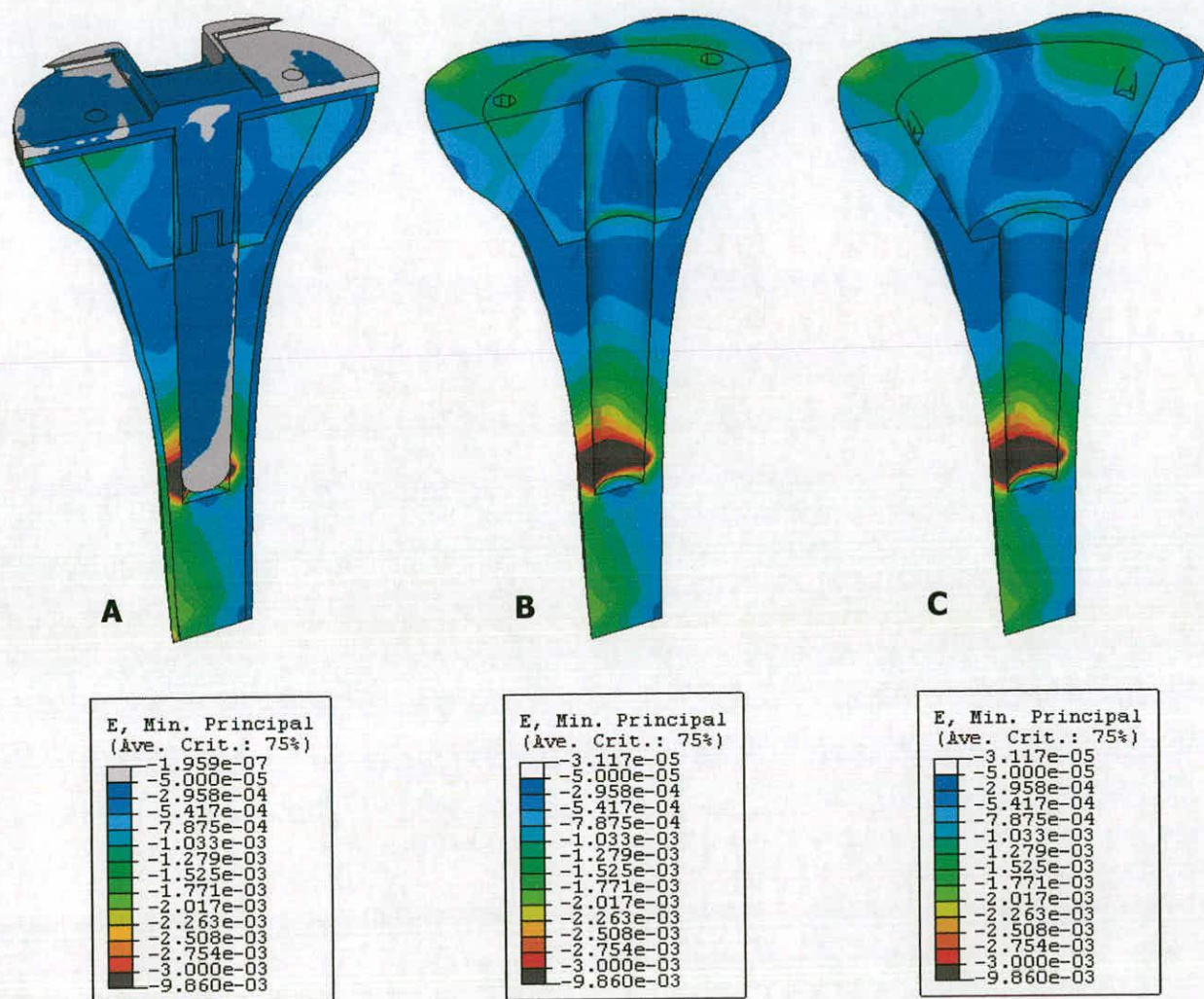
Fig 4.16. T1 fully cemented tray with an 80mm modular stem, mid coronal plane views. (A) Strains within complete model. (B) Strains within the cancellous bone + bone graft. (C) Strains within the cancellous bone. Black = > 3000 με, White = < 50 με
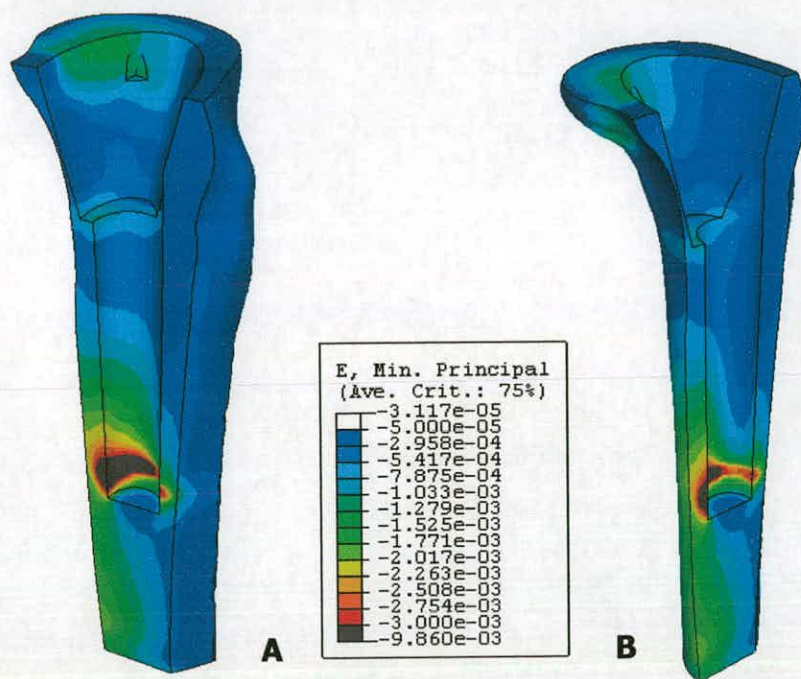
Fig 4.17. T1 fully cemented tray with an 80mm modular stem: strain within the cancellous bone compartment (A) medial view, (B) posterior-medial view. Black => 3000 µε, White = < 50 µε
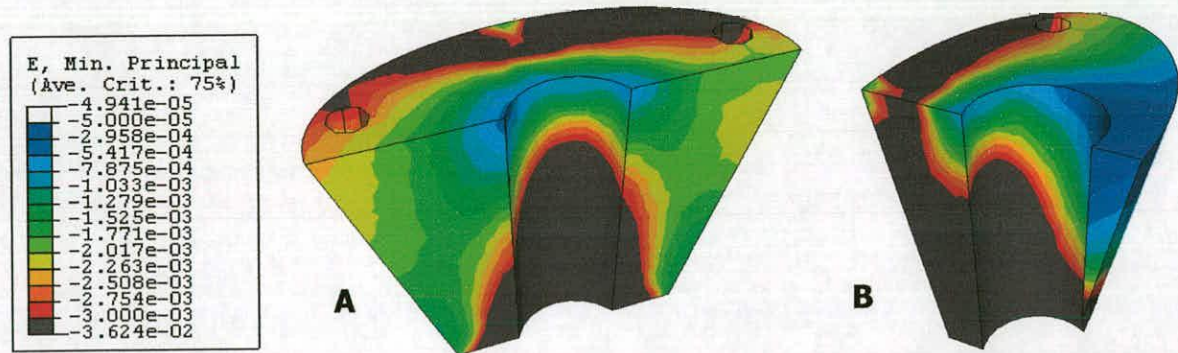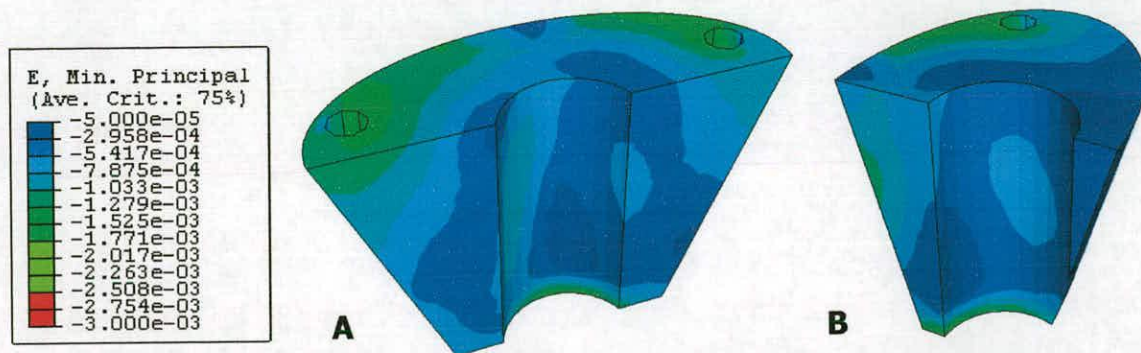

Fig 4.18. T1 fully cemented tray with an 80mm modular stem: strain within the bone graft compartment (A mid coronal plane view, (B) medial view. Black = > 3000 µε, White = < 50 µε

Figure 4.20 makes evident that proximally cementing the implant provides a more even strain distribution within the cancellous bone construct in the distal region. Figure 4.21 demonstrates there is not a region of strain concentration at the modular stem tip / cancellous bone interface, as seen in the fully cemented model, (Fig 4.16). There is a small region of high strain on the anterior wall distally and in the posterior proximal region of the cancellous bone compartment, with the maximum principal compressive strain reaching 6343 µE, (Fig 4.21) this could represent a pathological overload window
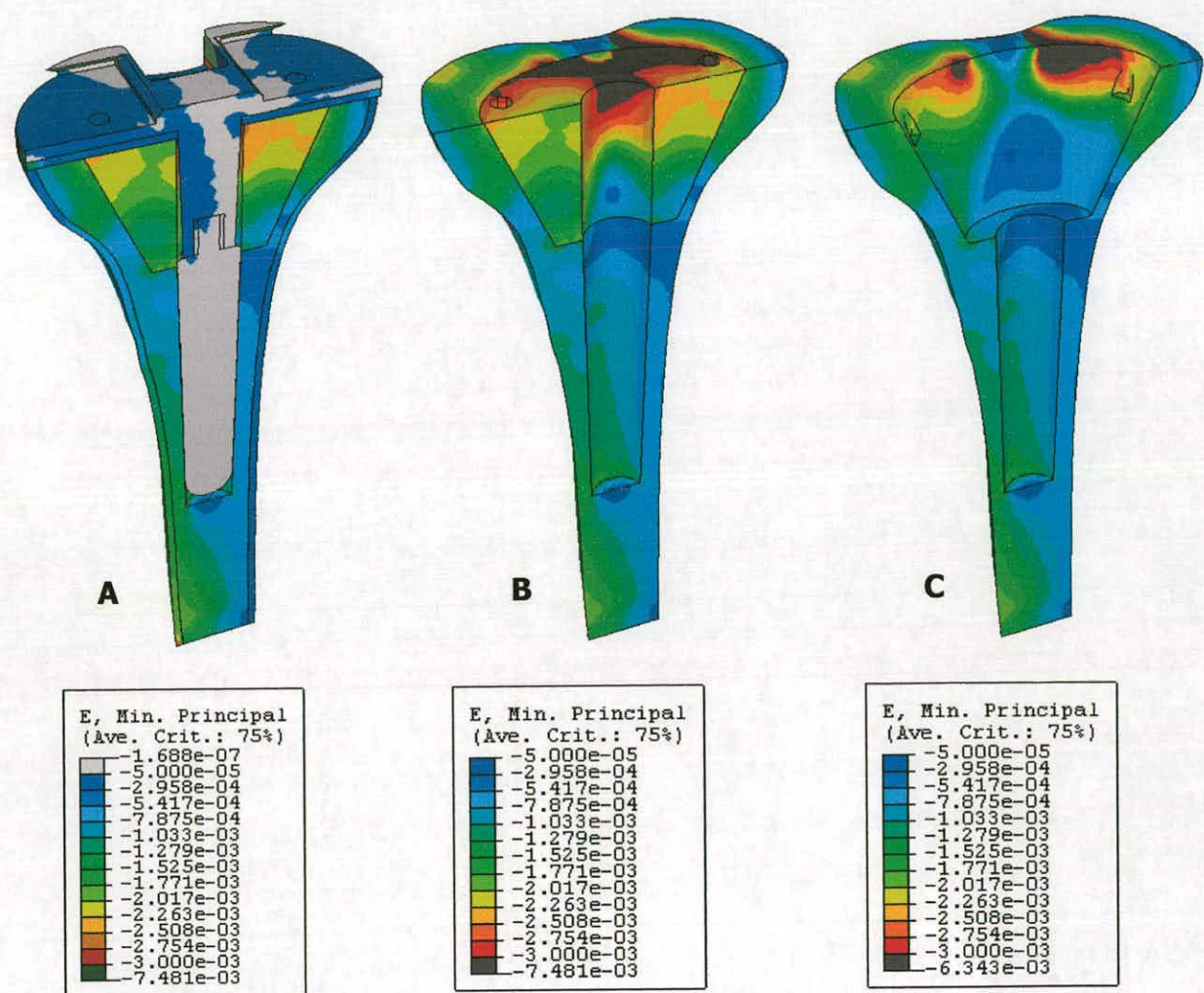
Fig 4.20. T1 proximally cemented tray with an 80mm modular stem, mid coronal plane views. (A) Strains within complete model. (B) Strains within the cancellous bone + bone graft. (C) Strains within the cancellous bone. Black = > 3000 µε, White = < 50 µε.
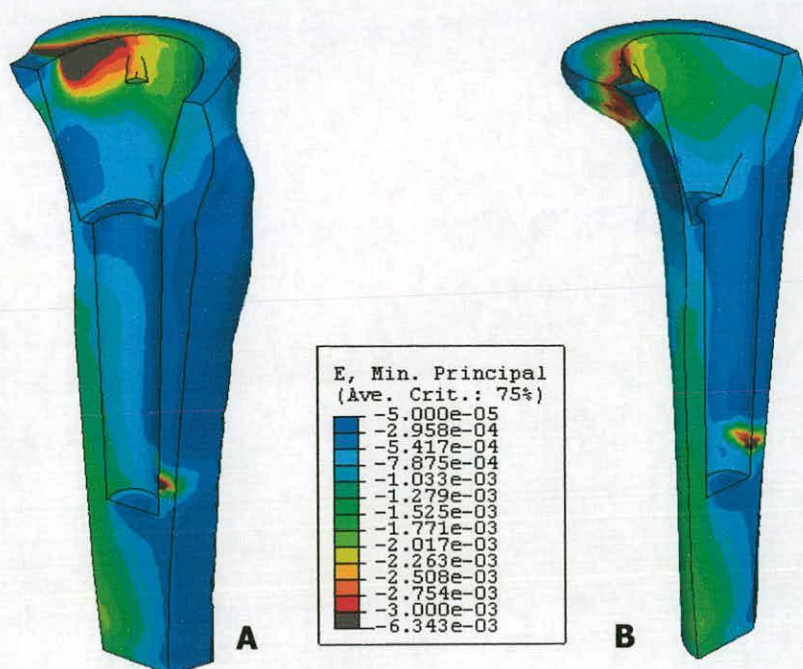
Fig 4.21. T1 proximally cemented tray with an 80mm modular stem: strain within the cancellous bone compartment (A) medial view, (B) posterior-medial view. Black = > 3000 με, White = < 50 με
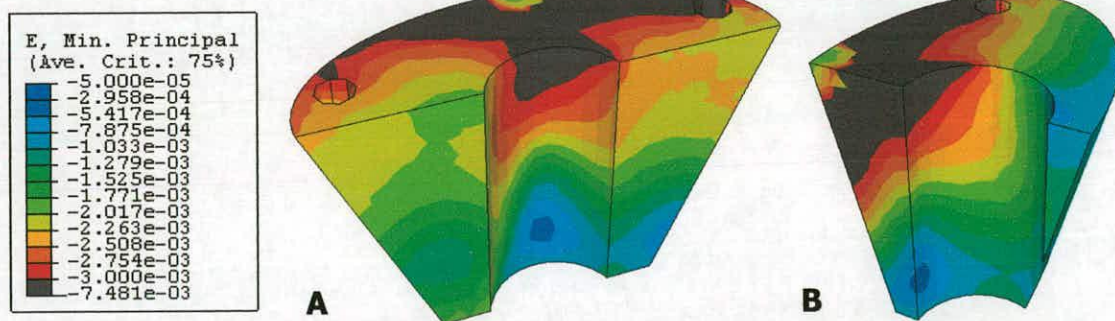
Fig. 4.22. T1 proximally cemented tray with an 80mm modular stem: strain within the bone graft compartment (A) mid coronal plane view, (B) medial view. Black = > 3000 με, White = < 50 με

225

Thus from these model simulations it can be seen that even when an augment is used without a modular stem the fixation technique which provides the best strain distribution in the underlying cancellous bone compartment is the proximally cemented method. These results hold true in the cases where the implants are fixed with a good cement mantle and good cortical contact is achieved for the entire prosthesis.

Fig. 4.23 T2A fully cemented tray with medial augment but no modular stem. (A) Strain in the full system) mid coronal plane view. (B) Strain in the cancellous bone compartment) mid coronal plane view. Black = > 3000 με, White = < 50 με

Fig. 4.24 T2A fully cemented tray with medial augment but no modular stem. (A) Strain in the complete cancellous bone posterior-medial view. (B) Strain in the cancellous bone compartment posterior-medial cut through view. (C) Strain in the cancellous bone compartment medial cut through view. Black = > 3000 µε, White = < 50 µε

Fig. 4.25 T2A proximally cemented tray with medial augment but no modular stem. (A) Strain in the full system) mid coronal plane view. (B) Strain in the cancellous bone compartment) mid coronal plane view. Black = > 3000 µε, White = < 50 µε

E, Min. Principal
(Ave. Crit.: 75%)
-5.000e-05
-2.958e-04
-5.417e-04
-7.875e-04
-1.033e-03
-1.279e-03
-1.525e-03
-1.771e-03
-2.017e-03
-2.263e-03
-2.508e-03
-2.754e-03
-3.000e-03
-3.342e-03

Fig. 4.26 T2A proximally cemented tray with medial augment but no modular stem. (A) Strain in the complete cancellous bone posterior-medial view. (B) Strain in the cancellous bone compartment posterior-medial cut through view. (C) Strain in the cancellous bone compartment medial cut through view. Black = > 3000 με, White = < 50 με
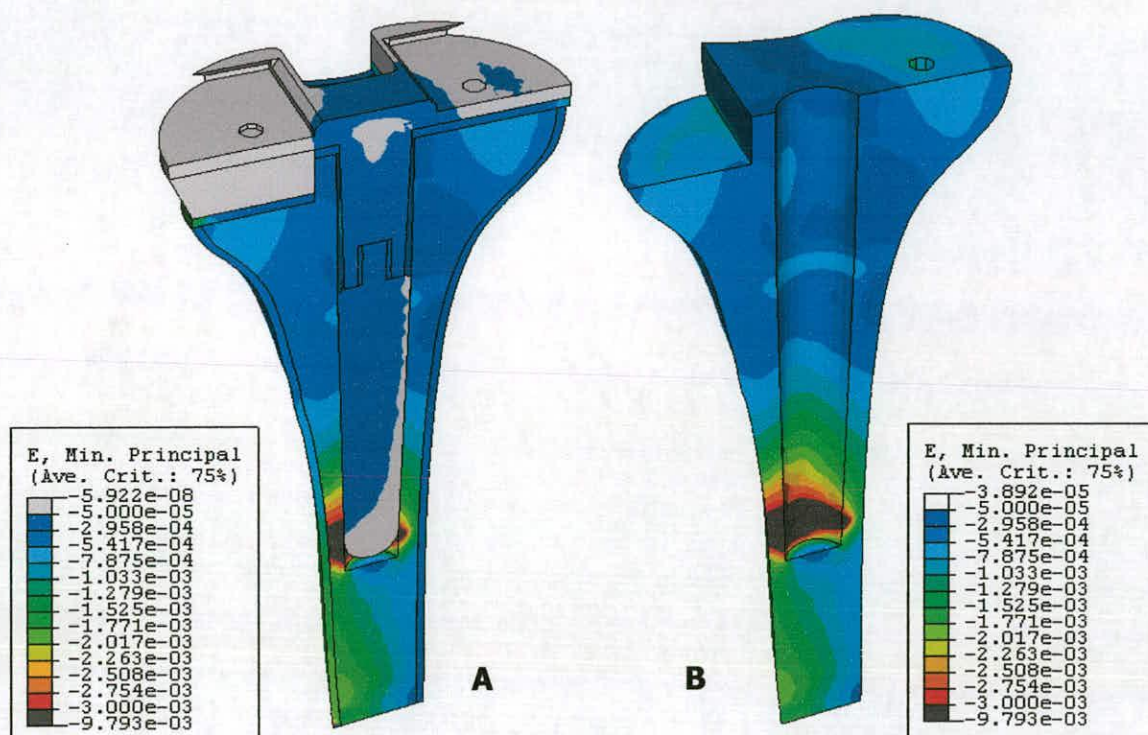
Fig. 4.27 T2A fully cemented tray with medial augment and an 80mm modular stem. (A) Strain in the full system) mid coronal plane view. (B) Strain in the cancellous bone compartment) mid coronal plane view. Black = > 3000 με, White = < 50 με

and only 0.02% experienced a strain greater than 3000 µE, (the strain at which a pathologic overload window could be defined), compared with 1.1% in the fully cemented model, (Table 4.3). As in the primary and the T1 investigations for the press fit modular stem model the region that felt these higher strains was small and confined to the distal anterior wall of the cancellous bone at the stem tip, (Fig. 4.30) this high region of strain most likely occurs due to the deformation of the bone in the loading phase bringing together the stem tip and the cancellous bone wall.

Comparing the fully cemented model with modular stem directly with the proximally cemented model with modular stem these model simulations presented suggest that the best strain distribution is achieved in the underlying

E, Min. Principal
(Ave. Crit.: 75%)
```
-3.892e-05
-5.000e-05
-2.958e-04
-5.417e-04
-7.875e-04
-1.033e-03
-1.279e-03
-1.525e-03
-1.771e-03
-2.017e-03
-2.263e-03
-2.508e-03
-2.754e-03
-3.000e-03
-9.793e-03
```
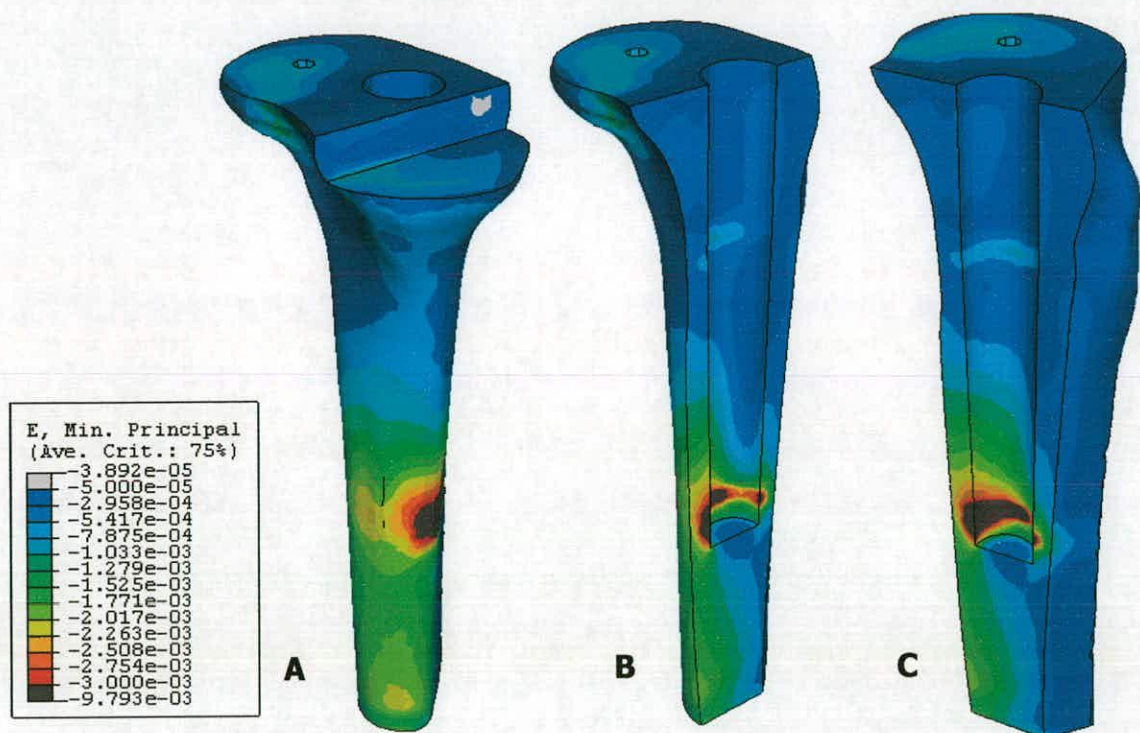
Fig. 4.28 T2A fully cemented tray with medial augment and an 80mm modular stem. (A) Strain in the complete cancellous bone posterior-medial view. (B) Strain in the cancellous bone compartment posterior-medial cut through view. (C) Strain in the cancellous bone compartment medial cut through view. Black = > 3000 με, White = < 50 με.

cancellous bone when the fixation technique employed is a proximally cemented tray with a press fit modular stem. When this technique is used less bone is loaded beyond 3000 με and below 50 με and the overall strain distribution within the bone is more advantageous with no region experiencing stress shielding. When the hybrid proximally cemented models with and without an 80mm modular stem are compared it is the proximally cemented model without the modular stem that gives the best strain distribution in the underlying bone. In both cases the strain distribution is even in the proximal and distal aspects of the cancellous bone with no regions of strain concentration that could cause excessive damage. However the maximum principal compressive strain is lower in the non modular stem model, 3342 με compared with 7745 με also less bone experienced loading beyond 3000 με and below 50 μE, (Table 4.3). Thus from
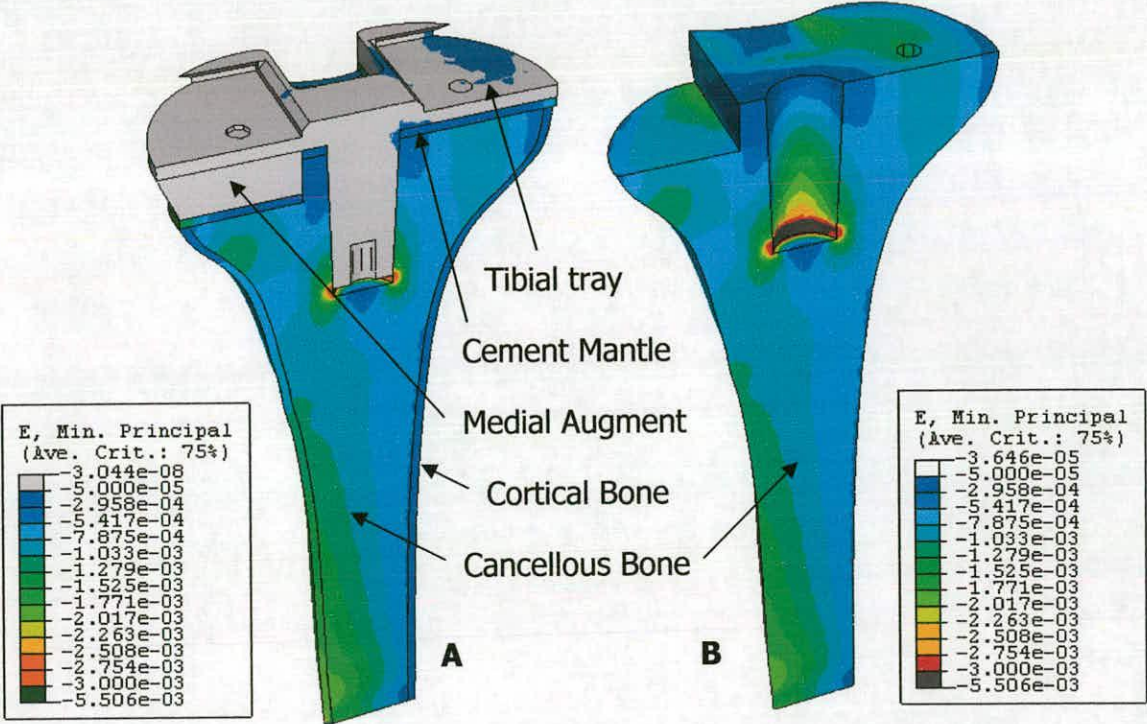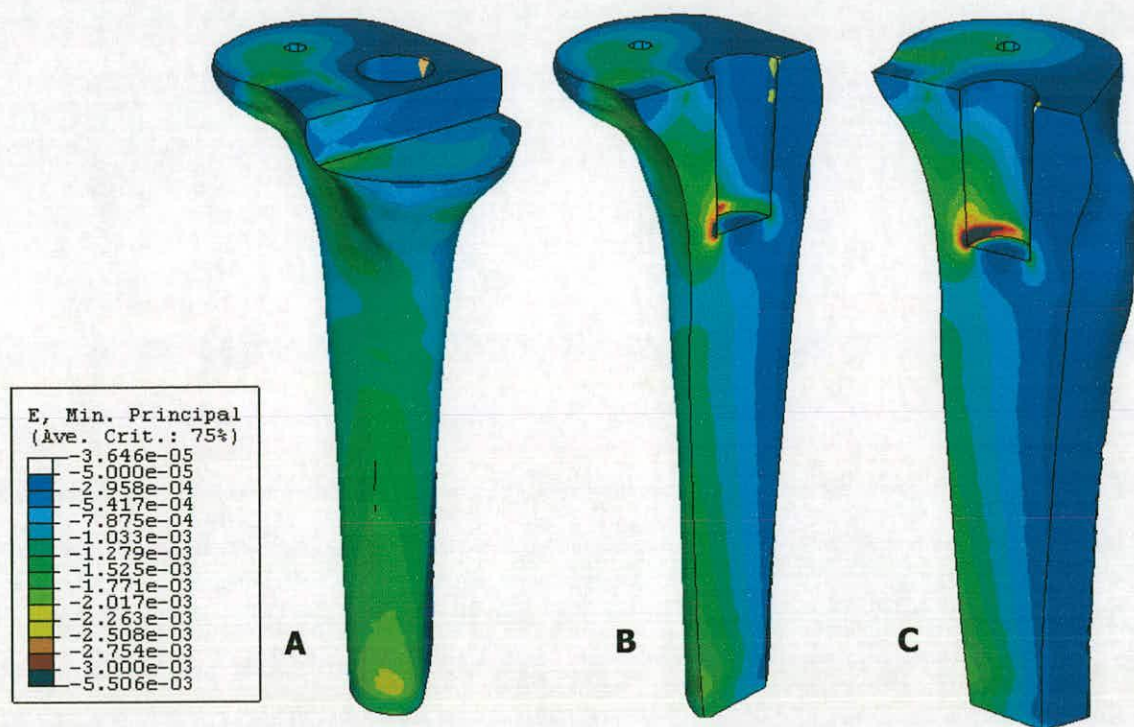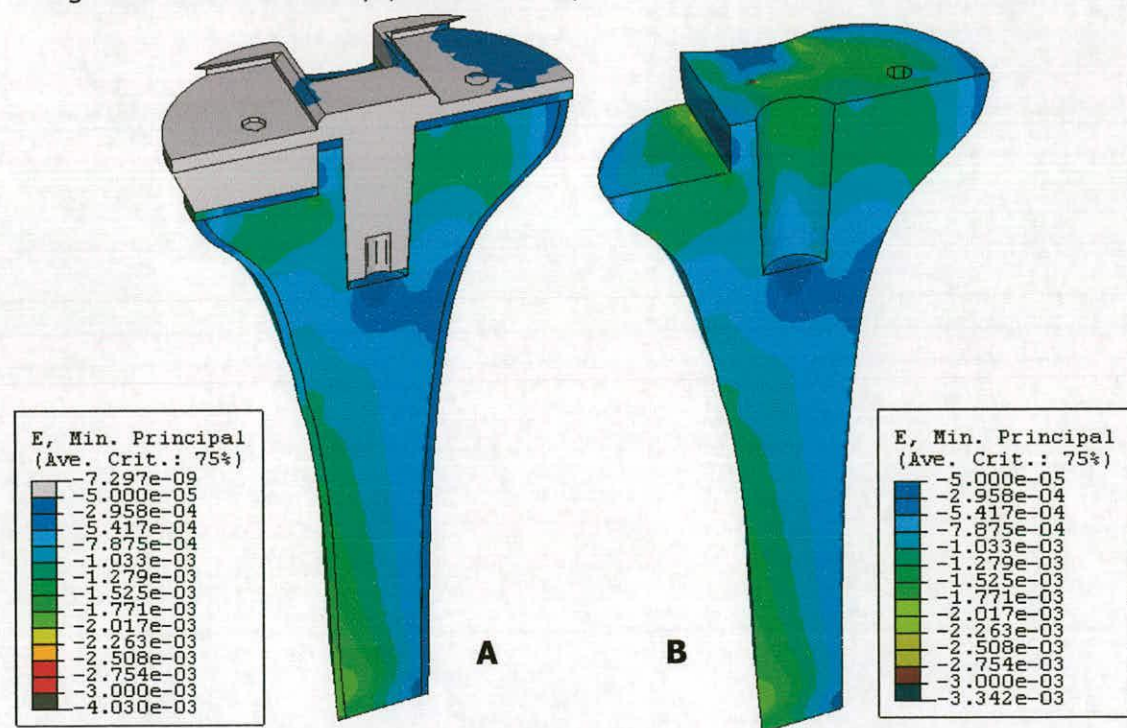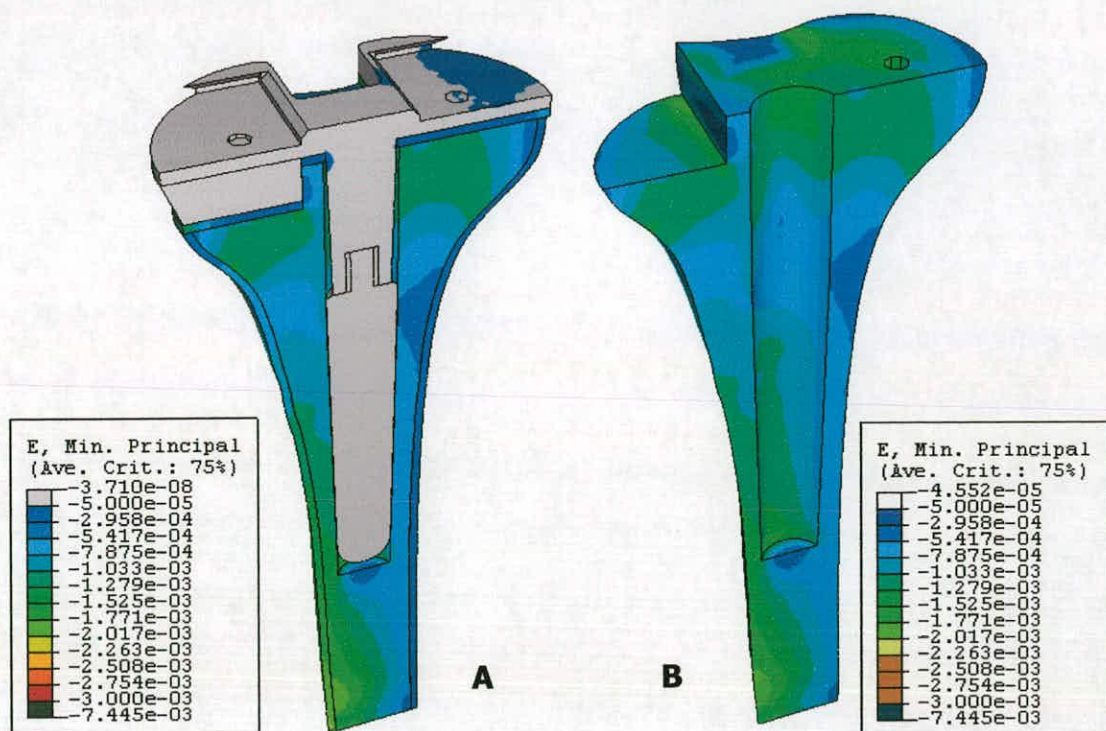
Fig. 4.29 T2A proximally cemented tray with medial augment and an 80mm modular stem. (A) Strain in the full system mid coronal plane view. (B) Strain in the cancellous bone compartment mid coronal plane view. Black = > 3000 µɛ, White = < 50 µɛ.

these simulations the optimal fixation technique based on strain distribution in the cancellous bone for a T2A revision with a 10mm medial augment is a proximally cemented tibial tray with no modular stem. Once again these results hold true in the cases where the implants are fixed with a good cement mantle and good cortical contact is achieved around the entire proximal rim of the tibial tray and augment as in this simulation should the cortex be deficient or a poor cement mantle occurs the strain distribution within the underlying cancellous bone may be altered and thus a different fixation technique may prove more beneficial.

E, Min. Principal
(Ave. Crit.: 75%)
-4.552e-05
-5.000e-05
-2.958e-04
-5.417e-04
-7.875e-04
-1.033e-03
-1.279e-03
-1.525e-03
-1.771e-03
-2.017e-03
-2.263e-03
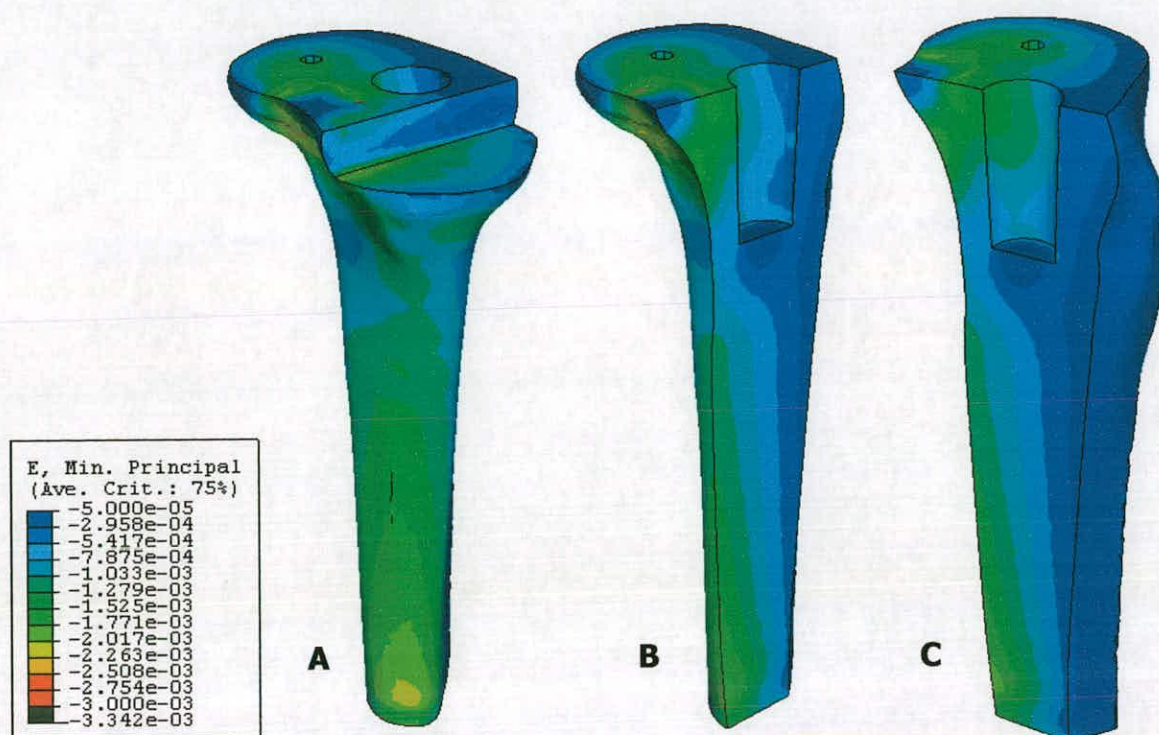-2.508e-03
-2.754e-03
-3.000e-03
-7.445e-03
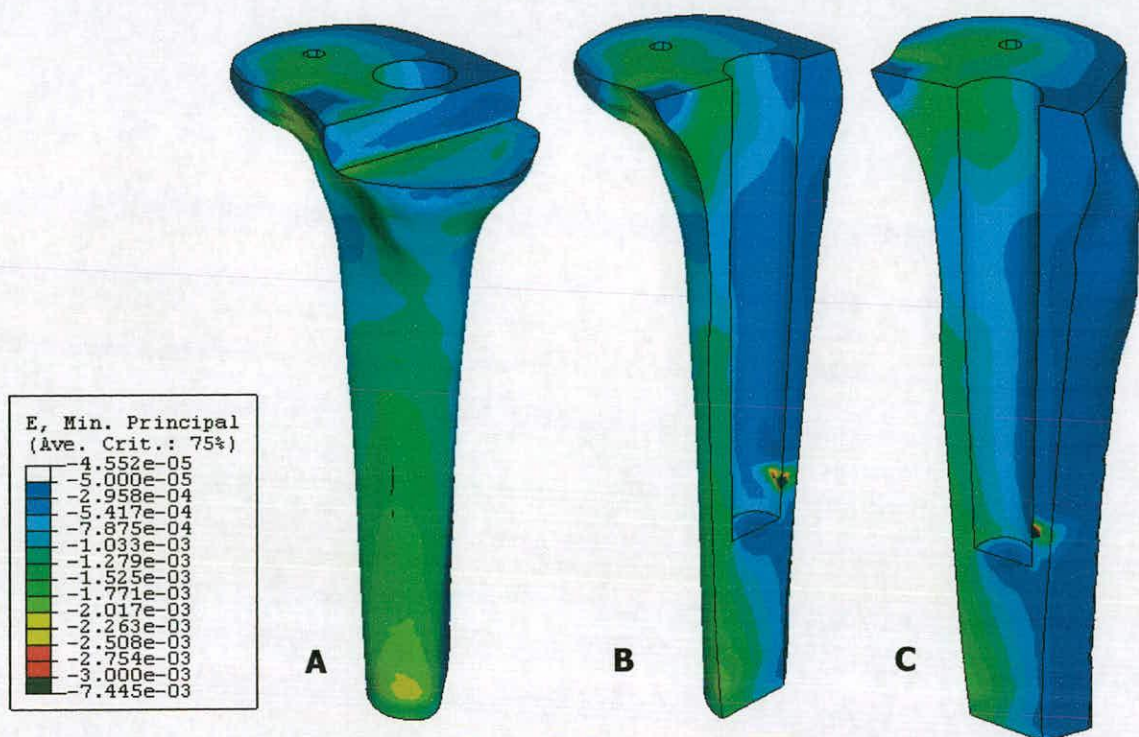
Fig. 4.30 T2A proximally cemented tray with medial augment but and an 80mm modular stem. (A) Strain in the complete cancellous bone posterior-medial view. (B) Strain in the cancellous bone compartment posterior-medial cut through view. (C) Strain in the cancellous bone compartment medial cut through view. Black = > 3000 με, White = < 50 με

The distal end of the tibia was rigidly constrained in all cases. Tied constraint conditions were assumed between the coincident surfaces of the cancellous and cortical bone. The interfaces between the metal tray/tibial blocks and the cement layer and between the cement layer and the tibial bone (both cortical and cancellous) were rigidly bonded using tied constraints. As mentioned previously it was assumed that 100% bony ingrowth had occurred at all metal – cancellous bone interfaces in the fully cemented models therefore these interfaces were also rigidly bonded.

The interfaces between the central and modular stems and the cancellous bone in the uncemented models were modeled with contact elements, with a 0.25 coefficient of friction[131].

4.3 RESULTS

To analyze the influence that the fixation technique, modular stems, augments and bone stock, (i.e. primary arthroplasty quality or revision arthroplasty bone quality) have on the strain patterns generated within the proximal cancellous bone, a fully cemented tibial prosthesis with and without an 80mm modular stem was created in three cemented tibial models, (Primary, T1 and T2A). These were compared against models where only the proximal surface of the tibia was cemented and the stems were left uncemented; this is known as hybrid fixation. The different models were compared by assessing the maximum principal compressive strain, the minimum principal compressive strain and the overall strain distribution within the cancellous bone. The stem – cancellous bone interface strains were examined for Primary, T1 and T2A fully cemented and proximally cemented tibial models.

For each analysis the maximum and minimum compressive principal strains and the number of elements within the cancellous bone or bone graft compartment experiencing a compressive strain greater than 3000 µε or less than 50 µε was calculated. The values of 3000 and 50 µε were chosen as these are the values reported by Frost that could define a pathologic overload window and a disuse window respectively. Strains greater than 3000 µε can cause woven bone drifts to form, excessive microdamage and suppress lamellar drifts. When strains stay below 50 µε bone remodeling units begin forming less bone than they resorb, causing bone density to decrease in that area. The results for the percentage of elements within the cancellous bone or bone graft compartments experiencing a compressive strain greater than 3000 µε and less than 50 µε are summarized for each model in Table 4.3. The results for the percentage of elements within the cancellous bone or bone graft compartments experiencing a compressive strain greater than 7000 µε, the reported compressive yield strain of trabecular bone are summarized in Table 4.4.

MODEL TYPE	No. of elements in cancellous bone or graft model	NO. OF ELEMENTS ABOVE 3000 µε	% OF ELEMENTS ABOVE 3000 µε	NO. OF ELEMENTS BELOW 50 µε	% OF ELEMENTS BELOW 50 µε
Primary: fully cemented no modular stem	102,350	129	0.13%	192	0.19%
Primary: proximally cemented no modular stem	102,350	0	0%	107	0.1%
Primary: fully cemented with 80mm modular stem	97,496	1022	1.05%	135	0.14%
Primary: proximally cemented with 80mm modular stem	97,496	31	0.03%	67	0.07%
T1: fully cemented no modular stem	87,095	442	0.51%	79	0.09%
T1: fully cemented no modular stem (graft)	22,128	7396	33.42%	13	0.06%
T1: proximally cemented no modular stem	87,095	617	0.17%	82	0.09%
T1: proximally cemented no modular stem (graft)	22,128	3264	14.75%	0	0%
T1: fully cemented with 80mm modular stem	84,476	991	1.17%	203	0.24%
T1: fully cemented with 80mm modular stem (graft)	19,917	0	0%	6	0.03%
T1: proximally cemented with 80mm modular stem	84,476	351	0.42%	80	0.09%
T1: proximally cemented with 80mm modular stem (graft)	19,917	2808	14.10%	0	0%
T2A: fully cemented no modular stem	99,880	128	0.13%	235	0.24%
T2A: proximally cemented no modular stem	99,880	5	0.01%	97	0.1%
T2A: fully cemented with 80mm modular stem	93,599	1033	1.10%	193	0.21%
T2A: proximally cemented with 80mm modular stem	93599	20	0.02%	102	0.11%

Table 4.3: percentage of elements within the cancellous bone or bone graft compartment experiencing a compressive strain greater than 3000 µε and less than 50 µε

MODEL TYPE	No. of elements in cancellous bone or graft model	NO. OF ELEMENTS ABOVE 7000 με	% OF ELEMENTS ABOVE 7000 με
Primary: fully cemented no modular stem	102,350	15	0.01%
Primary: proximally cemented no modular stem	102,350	0	0%
Primary: fully cemented with 80mm modular stem	97,496	49	0.05%
Primary: proximally cemented with 80mm modular stem	97,496	2	0%
T1: fully cemented no modular stem	87,095	6	0.01%
T1: fully cemented no modular stem (graft)	22,128	252	1.14%
T1: proximally cemented no modular stem	87,095	8	0.01%
T1: proximally cemented no modular stem (graft)	22,128	7	0.03%
T1: fully cemented with 80mm modular stem	84,476	44	0.05%
T1: fully cemented with 80mm modular stem (graft)	19,917	0	0%
T1: proximally cemented with 80mm modular stem	84,476	0	0%
T1: proximally cemented with 80mm modular stem (graft)	19,917	4	0.02%
T2A: fully cemented no modular stem	99,880	0	0%
T2A: proximally cemented no modular stem	99,880	0	0%
T2A: fully cemented with 80mm modular stem	93,599	48	0.05%
T2A: proximally cemented with 80mm modular stem	93599	4	0%

Table 4.4: Percentage of elements within the cancellous bone or bone graft compartment experiencing a compressive strain greater than 7000 με the reported yield strain of trabecular bone.

4.3.2 The T1 Bone Models

4.3.2.1 Fully cemented tibial tray with no modular stem v's proximally cemented tibial tray with no modular stem: T1 models.

In the fully cemented model the maximum principal compressive strain with in the morsalised bone graft compartment reached 36240 µE, (Fig. 4.10), with 1.14% of the graft experiencing strains greater than 7000 µε and 33.42% of the graft experiencing compressive strains exceeding 3000 µE, (Table. 4.3 & 4.4 respectively). These values demonstrate that a significant percentage of the graft experienced strains that were well above the yield strain of healthy cancellous bone and the strains occurring would be likely to cause high levels of plastic deformation within the bone graft. The level of plastic deformation that occurs in the graft will be linked however to the degree of impaction by the surgeon. Strains of this magnitude can cause woven bone drifts and suppress lamellar drifts making the incorporation of the bone graft more difficult and thus decreasing the stability of the revision construct and increasing the chances for further revision surgery. The strain values seen in the fully cemented model indicate that it is likely that there would be pathological overload in certain areas. The strain in the fully cemented tray was concentrated in the distal posterior area of the graft section (Fig. 4.12) and the distal anterior region of the cancellous bone at the non modular stem tip. This is most likely due to the deformation that occurs within the graft causing the stem to point load the bone, inducing the high anterior strain, (Fig. 4.11).

In the proximally cemented model the maximum strain in the morsalised bone graft was lower than the fully cemented model but it still reached a strain value of 10098 µE, (Fig. 4.15) which is still higher than the yield strain of healthy cancellous bone and again could lead to problems in the remodeling process. However the percentage of the graft that experienced these extreme strains was once again significantly lower than in the fully cemented model. In the proximally cemented model 0.03% of the graft felt strains in excess of 7000 µε and 14.75%

4.3.2.2 Fully cemented tibial tray with an 80mm modular stem v's proximally cemented tibial tray with an 80mm modular stem: T1 models.

Figure 3.16 shows that a fully cemented 80mm modular stem model transfers a greater proportion of the load experienced from the proximal area of the tibia to the distal region of the tibia at the modular stem tip creating a strain concentration in this area. The pattern for the cemented and stemmed T1 model is similar to that seen in Fig. 4.16 the primary fully cemented tray with an 80mm modular stem. The maximum principal compressive strain in the T1 fully cemented 80mm modular stem model reaches 9860 µɛ at the stem tip / cancellous bone interface, (Fig 4.17). This may mean that microdamage within the cancellous bone structure could occur in that region. Although the maximum principal strain is over the 7000 µɛ at the stem tip only 0.05% of the cancellous bone felt a strain in excess of 7000 µE, (Table 4.4) and 1.17% of the cancellous bone experienced a strain of 3000 µɛ or greater. Only 0.24% of the cancellous bone experienced strains below 50 µE, (Table 4.3). The strain distribution within the morsalised bone graft compartment however was uniform with the strain values staying well below what could define pathological overload, the maximum principal compressive strain reaching 2754 µɛ (Fig 4.18) Thus none of the graft compartment experienced strains which could be defined as a pathologic overload window and within the morsalised graft, only 0.03% of the graft experienced strains below 50 µE, (Table 4.3), a value which could define a disuse window and cause bone to be resorbed in that area. These results suggest that the cemented 80mm modular stem transfers a greater proportion of the load to the distal region of the bone, protecting the graft from excessive loads and strains, thus the graft has an increased chance of incorporating as the strains remain within the optimal remodelling window of 50 - 3000 µE.

However it is below the yield strain for normal cancellous bone, unlike the maximum principal strain calculated in the fully cemented 80mm modular stemmed model. In the proximally cemented model 0.42% of the cancellous bone was loaded beyond 3000 $\mu\epsilon$ and 0.09% was loaded below 50 μE, (Table 4.3), both values lower than the fully cemented cancellous compartment experienced. The morsalised bone graft construct in the proximally cemented stemmed model does however experience a higher amount of strain than in the fully cemented stemmed model. Figure 4.22 shows that an area in the proximal posterior region of the graft experiences strains as high as 7481 μE. This occurs in the region where the posterior aspect of the tray is in direct contact with the bone graft. Thus due to the poorer mechanical properties of the of the bone graft, compared with cancellous bone or cortical bone, the interface bone strains between the tray and the bone graft increase resulting in 14.1% of the graft being loaded above 3000 $\mu\epsilon$ (Table 4.3), with 0.02% being loaded beyond 7000 μE, (Table 4.4).

This does not occur in the fully cemented stemmed model as a greater proportion of the load is taken to the distal region of the tibia via the cemented stem. As discussed previously the strain distribution and magnitude may well alter if a revision style tibial tray was studied as a lower percentage of the graft would be loaded directly in the proximal region.From these results due to the fact the strains experienced in the morsalised bone graft region do not exceed 3000 $\mu\epsilon$ or drop below 50 $\mu\epsilon$, giving the graft the optimal chance for incorporation, and thus the best chance of achieving a stable revision construct. Fully cementing the tray with an 80mm modular cemented stem would be the recommendation based on these findings. This is despite the higher strain values experienced within the cancellous bone compartment in the fully cemented model when compared to the proximally cemented model. If properties of the graft were improved by increased degree of impaction by the surgeon or increased cement penetration levels, (increasing the stiffness of the graft in both cases). The results may vary from those found here.

4.3.3 The T2A Bone Models

4.3.3.1 Fully cemented tibial tray with no modular stem compared to cemented tibial tray with no modular stem: T2A models.

From Fig 4.23 it can be seen that the strain distribution for the T2A fully cemented tibial tray with no modular stem is similar to that for the primary fully cemented tibial tray with no modular stem in Fig 4.4. The larger strains were experienced by the cancellous bone at the distal tip of the non modular stem in both cases. It was hypothesised prior to testing that there would be increased strain experienced under the medial augment but from Fig 4.24 it can be seen that this is not the case and the strain on the proximally resected surface of the tibia is evenly distributed and within the 50-3000 $\mu\epsilon$ range. The maximum principal compressive strain experienced in the cancellous bone was 5506 μE, (Fig. 4.24), slightly less than that experienced in the primary scenario for the same model. 0.12% of the cancellous bone was loaded beyond 3000 $\mu\epsilon$ and 0.24% of the cancellous compartment experienced strains of below 50 μE, (Table 4.3). The area that experienced the low levels of strain occurred in the proximal region of the tibial tray's fixed stem perhaps suggesting that a small amount of stress shielding was occurring with the cement allowing more of the load to be transferred to the stem tip.

In the T2A proximally cemented tibial tray with no modular stem the strain distribution patterns were again similar to those witnessed in the primary version of the same model. No strain concentration occurred at the distal tip of the tibial trays fixed stem as was seen in the fully cemented models (Fig 4.25). Again from Fig 4.26 it can be seen that the strain magnitude and pattern is within the remodeling threshold over the resected proximal tibial surface even under the medial augment. The maximum principal compressive strain was 3342 μE, (Fig 4.26) and although this value is over the 3000 $\mu\epsilon$ value that could represent a pathologic overload window only 5 elements experienced a strain over 3000 $\mu\epsilon$ resulting in only 0.01% of the cancellous bone compartment, (Table 4.3).

4.3.3.2 Fully cemented tibial tray with an 80mm modular stem compared to cemented tibial tray with an 80mm modular stem: T2A models.

From comparing Fig.4.27 and 4.28 the fully cemented model with Fig 4.29 and 4.30, the proximally cemented model. It can be seen that the tibial tray with the fully cemented modular stem has the higher strains, and the poorer strain distribution throughout the cancellous bone structure when compared to the proximally cemented T2A model.

In the T2A with fully cemented modular stem model the strain is once again concentrated at the stem tip and the proximal region of the cancellous bone is shielded from experiencing some of the load with 0.21% of the cancellous bone loaded below 50 µE, (Table 4.3). The maximum principal strain experienced was 9793 µE, (Fig. 4.27) with 0.05% of the cancellous bone experiencing micro strains of over 7000, (Table 4.4), the yield strain for healthy cancellous bone. With 1.1% of the cancellous structure being subjected to loads above 3000 µE, (Table 4.3), this would suggest that a region of microdamage may well occur at the stem tip which could lead to instability issues as the life of the prosthesis progresses.

Within the cancellous bone structure for the proximally cemented tray with a press fit 80mm modular stem the strain distribution is evenly distributed in both the proximal and distal aspects of the cancellous compartment, (Fig. 4.29), unlike the fully cemented model (Fig. 4.27). The strain distribution on the resected surface of the tibia and directly under the medial augment lies within the region for healthy bone remodelling. The maximum principal compressive strain recorded within the cancellous bone was 7745 µε (Fig 4.30) however only 4 elements were loaded above 7000 µε which equated to 0% when calculated

4.4 DISCUSSION

Today's new revision knee systems are all designed to aid the surgeon with the challenges faced within the revision scenario, modern knee systems have the ability to attach medial and lateral augments to fill voids left by deficient bone stock and help in the restoration of the joint line. Modular revision knee systems also have the availability of modular stems of various lengths and diameters. These modular stems are used to facilitate joint alignment and the mechanical stability of the revised construct. It is now believed by many surgeons that initial stability of the prosthesis is a prerequisite for long term fixation and survivorship of the implant. Perillo-Marcone et al[115] showed that the degree of implant migration is dependent on the initial mechanical environment; in the revision situation it can prove difficult to obtain a sound mechanical environment due to bone loss and associated soft tissue laxity thus many surgeons advocate the use of intramedullary stems in patients undergoing revision TKA. Despite this little research has looked at the effects of intramedullary stems within the revision environment and how they might effect the vital biomechanical imperatives for natural bone remodeling, localized overloading of the bone at the stem bone interface or how the fixation technique will effect the strains in the underlying cancellous bone especially when augments or bone graft are incorporated into the structure along with a modular stem. This is despite the fact that these factors are known to be among those that can lead to loosening of the component and thus failure.

The objective of this study was to examine the cancellous bone strains generated in the implanted tibia for primary and revision scenarios investigating the effect of different fixation techniques, the use of modular augments and bone graft on the distribution of strain throughout the proximal tibia.

In the Primary model the proximally cemented tray with an uncemented 80mm modular stem provided the best strain transfer to the cancellous bone when compared to the fully cemented model with an 80mm modular stem. However when the results for the trays without modular stems were taken into account the best method of fixation in the primary scenario based on the magnitude and patterns of strain experienced by the underlying cancellous bone was the proximally cemented hybrid tray with no modular stem. When the trays were fully cemented both with and without a modular stem the maximum compressive strain was higher than the hybrid fixation. There were signs of stress shielding in the strain distribution patterns and a localized region of strain concentration at the distal end of the stem was present which could represent a zone of excessive microdamage leading to instability. In the primary hybrid model without a stem there was no noticeable stress shielding and none of the cancellous structure was loaded beyond 3000 $\mu\varepsilon$ and only 0.1% was loaded below 50 $\mu\varepsilon$, (Table 4.3) providing the optimal theoretical scenario for healthy bone turnover and long term biological fixation and survivorship of the prosthesis.

In the T1 models which included a compartment of morsalised bone graft in the proximal region of the cancellous bone, the fully cemented tray with a cemented 80mm modular stem provided the optimal strain distribution in the morsalised bone graft with the other modes of fixation creating less favourable strain patterns in the graft. With the fully cemented tray and modular stem the strains experienced in the morsalised bone graft region did not exceed 3000 $\mu\varepsilon$ or drop below 50 $\mu\varepsilon$ with the maximum compressive strain reaching 2754 μE, (Fig3.18), with the hybrid tray and modular stem creating strains in the proximal posterior region of the graft as high as 7481 $\mu\varepsilon$ (Fig.3.22) with 14.1% of the graft being loaded above 3000 $\mu\varepsilon$ (Tabel3.3) and 0.02% being loaded beyond 7000 μE, (Table 4.4). Thus the fully cemented tray with modular stem provided the graft with the optimal chance for incorporation based on the remodelling thresholds described by Frost and thus the best chance of achieving a long term stable revision construct. The strain distribution in the cancellous section generated

with the fully cemented tray and cemented modular stem however was not as favourable and produced higher strain values within the distal area of the cancellous bone compartment compared to the strains experienced with the proximally cemented tray and press fit modular stem model.

The higher strain distribution in the morsalised graft section associated with the two hybrid models studied could be associated with the shape of the tibial tray used in this study. A primary PCL retaining tray was modelled in this study, these styles of tray feature a posterior cut out slot designed to accommodate the PCL. Due to this posterior cut out being present the tray came into direct contact with the posterior section of the graft and thus loaded the graft directly. The poorer bone quality in the graft resulted in higher interface bone strains due to the lower Young's modulus value of the graft. In the fully cemented stem models this was less of an issue as a larger proportion of the load was transferred to the distal aspect of the cancellous bone. If a pure revision tray had been modelled, (the majority of which are PCL sacrificing trays and do not have a posterior cut out present), the tray would cover the graft more fully and a greater portion of the load would be transferred through the bones cortex, rather than to the graft directly as occurred with the PCL retaining tray modeled. Thus the strain magnitudes and patterns experienced within the graft compartment may be different to the ones calculated in this study.

From looking at the two T1 hybrid models (Fig 4.13 & 4.20) it can be seen that adding a press fit modular stem does not alter the strains experienced inside the morsalised graft greatly, with 14.75% of the graft loaded beyond 3000 µε when no modular stem is used and by adding an 80mm press fit modular stem it drops to only 14.1%, (Table 4.3). When the two fully cemented models are compared it can be seen that a fully cemented modular stem has a much greater impact upon the strain distribution experienced in the graft with 33.42% of the graft loaded beyond 3000 µε when no modular stem is used and by adding an 80mm cemented modular stem it drops to 0%, (Table 4.3). These results indicate that to protect the graft from excessive strains a cemented stem that bypasses the

repaired defect delivers the most favourable outcome in terms of strain distribution within the graft. As when the fixed stem on the tray was fully cemented and did not bypass the defect the strain in the graft was increased as the load carried to the distal end of the stem remained within the weaker graft, however when a longer cemented modular stem was used the load was carried to the stronger distal cancellous bone and the strain distribution in the graft became more favourable. Thus in this instance the phenomenon of stress shielding caused by the fully cemented stems aids the grafts incorporation initially. However in the long term as more of the graft incorporates the strain distribution and magnitudes may alter and become less favourable as seen in the primary model with a fully cemented modular stem.

When examining the T2A models with the 10mm medial augment once again the two hybrid proximally cemented models, one with and one without an 80mm modular stem provide the more favourable strain distribution throughout the cancellous bone compartment, when compared to the respective fully cemented T2A model. In the hybrid models the strain distribution is even in the proximal and distal aspects of the cancellous bone with no regions of strain concentration that could cause excessive damage. However the fully cemented T2A models exhibited strain concentration zones at the distal stem tip and signs of stress shielding in the proximal aspect of the cancellous bone was visible in the modular stem model and the model with no modular stem, (Fig 4.23 & 4.27). When the two hybrid models are compared it is the proximally cemented model without the modular stem that gives the best strain distribution in the underlying bone, (Fig 4.25 & 4.29). The maximum principal compressive strain is lower in the non modular stem model, 3342 $\mu\varepsilon$ compared with 7745 $\mu\varepsilon$; also less bone experiences loading beyond 3000 $\mu\varepsilon$ and below 50 μE, (Table 4.3). Thus from these simulations the optimal fixation technique based on strain distribution in the cancellous bone for a T2A revision with a 10mm medial augment is a proximally cemented tibial tray with no modular stem. Once again these results

hold true in the cases where the implants are fixed with a good cement mantle and good cortical contact is achieved around the entire proximal rim of the tibial tray and augment. This enables load to be transferred through the cortex as in this simulation. Should the cortex be deficient or a poor cement mantle achieved the strain distribution within the underlying cancellous bone may be altered and thus a different fixation technique may prove more beneficial.

The results presented here suggest that a stem is not always necessary in a simpler revision environment to achieve the best strain transfer from the prosthesis to the bone and indeed an argument could be made that adding a stem could increase the risk of future complications. In all the fully cemented stemmed cases a zone of strain concentration at the stem tip was observed, this sort of stress / strain concentration could facilitate increased bone hypertrophy at the stem tip leading to an increased risk of periprosthetic fracture. A zone of stress shielding in the proximal tibia was also noticeable when compared to the hybrid models. The alteration in strain and the potential alteration in bone remodelling linked to the prosthesis stem design and fixation could result in bone loss compromising the stability of the implant over time. The results of the study suggest that based on the strain magnitudes and distributions that there is a greater chance of bone loss associated with the use of a fully cemented tibial component as compared with a proximally cemented component, with or without a modular stem. In a biomechanical study Boorgeault et al, (1997) compared implant stability and proximal tibial cortex strain. No significant differences in micromotion were observed between components implanted with cemented or uncemented stems. Cemented stems however did significantly increase the strain relief in the proximal tibia relative to the uncemented stems. They commented an uncemented stem may be recommended to reduce proximal stress shielding and provide stable fixation. This in vitro cadaver study corroborates the findings of this current FE. study. Also by adding a modular component such as an 80mm stem you are introducing further possible modes of failure, such as fracture at the stem tray junction and pain at the stem tip which would not occur

with un-stemmed components. This author does not suggest that stems should not be used in revision surgery cases however from the results of this study it could be suggested that stems are not required simply because it is a revision that is being undertaken and that each case should be judged on the ability to achieve a solid stable initial fixation, with or without modular stems.

Direct comparisons with other finite element work from the literature is difficult and should be tempered by the differences in geometry of the bone and prosthesis, bone properties and loading conditions of the individual models. Studies in the past have reported on Von Mises stress values however it is now believed that the strain experienced by the cancellous bone is a more significant factor on the remodelling behaviour of the bone thus in this study the principal compressive strains experienced by the bone are reported rather than the Von Mises stresses. The finite element model of the proximal tibia described in this thesis provides a comprehensive approach to strain analysis of the tibia. The model incorporates a realistic three-dimensional geometry of the tibia and bone properties which are more physiologically representative than previous two-dimensional studies. The difference between the axis symmetric two-dimensional tibia geometries reported in the past and the three dimensional asymmetric geometry used in this series is expected to produce different strain results within the tibial bone again making direct comparisons difficult. Nyman et al[141] reported that long stemmed TKA caused bone loss in the proximal regions of the tibia and that press fit stems had the greatest amount of bone loss with cemented stems causing the least amount of bone loss. The results reported by Nyman et al[141] disagree with the findings of this study. This present study found that cemented stems caused greater stress shielding of the proximal region of the tibia and higher concentration of strain at the stem tip than press fit hybrid stems. Nyman et al's study was carried out with a two-dimensional model and this may explain the differences in results. The results presented here agree with Askew and Lewis[126] and Murase et al[35], who noted that the maximum compressive stresses occurred beneath the cemented central stem.

Only a few non finite element studies have attempted to document the effects of total knee arthroplasty on bone remodelling and bone density. Levitz et al[142], revealed an average 36.4% proximal tibial bone loss eight years after total knee arthroplasty. This finding links to those of this study suggesting that the strain alteration within the proximal tibia caused by total knee arthroplasty may contribute to bone resorption and hence aseptic loosening over time. Lonner et al[49], reported decreased bone densities under the medial and lateral plateaus using DEXA scans in the fully cemented stemmed tibial tray group compared with the unstemmed group, similarly in the primary and T2A models investigated in this study the fully cemented tray's provided the greater potential for stress shielding and bone loss due to strain overloading of the bone at the stem tip. Brooks et al[19], and Bourne and Finlay[65], used arrays of strain gauges to quantify the stress changes associated with stemmed tibial components, concluding that there was a marked reduction in stress measured in all locations proximal to the stem tip. This agrees with the alteration in the strain distribution patterns seen in the primary, T2A and T1 models where when a fully cemented primary stemmed tray and modular stemmed tray was implemented the strain in the proximal tibia was reduced in magnitude and the strain at the stem tip intensified when compared to the equivalent hybrid model.

Due to the added complexity of removing fully cemented long stemmed tibial components, should revision surgery become necessary for any reason in the future the popularity of hybrid fixation has increased. Hass et al report good short term results for this technique however eight patients out of sixty seven did observe pain at rest and mild pain with walking. Barrack et al[47] also report pain that was localised to the diaphyseal portion of the tibia at the stem tip. The stemmed hybrid models presented in this thesis could provide an answer to why patients experience pain at the stem tip. In all three model scenarios investigated the hybrid tray with an 80mm modular stem caused a small area of high strain in the anterior region of the cancellous bone at the stem tip, (Fig. 4.8

provides an example of such localised strain concentration). This occurred due to the deformation of the tibial bone in the loading phase causing the bone and stem tip to come into contact and transfer high loads over a very small area, which may result in pain for the patient. Barrack et al[47] also reported an incidence of pain in patients with fully cemented modular stems, however the pain was generally less severe and occurred only during activity, this could be due to the fact that high strains at the stem tip in the fully cemented models with an 80mm modular stem were distributed over a larger surface area compared to the press-fit modular stems. Pain at the end of the stem is thought to be clinically significant as there is a lower patient satisfaction and clinical score in patients with press fit stems that experience pain. Although the results of the models presented do not fully explain why or confirm that there is an increased incidence of pain at the stem tip with press-fit stems compared with fully cemented stems (as the models used would require further validation), the results presented could provide an insight to this phenomenon when used in conjunction with clinical data. The incidence with pain at the stem tip with press-fit stems could also be connected with stem malalignment and direct stem - cortical contact which does not occur with fully cemented stems and individual patient anatomy

Long modular stems were found to add no additional benefit to the initial strain distribution and strain transfer within the proximal tibia in the T2A revision scenario model and thus the finding suggested that no modular stem would be required. However short stems such as the fixed stem on the tibial tray have been associated with less consistent alignment, (Parsley et al, 1998). Thus to avoid malalignment of the tibial component it is suggested to use long intramedullary stems to make the appropriate resections of the tibia to accept the revision component and then the surgeon is free to use a hybrid or cemented short stem dependant on surgical preference. Again the use of a long modular stem may be required to provide stability and reduce micromotion but the results presented only take account of strain distribution.

The strain magnitude and distribution results for the T1 models agree with the findings of Toms et al[101] in that a long modular stem provides the best fixation when bone graft is used to repair a proximal tibial defect. Toms et al reported that long stemmed trays migrated 4.5 times less than short stemmed trays, this correlates with the findings of this study, where the short stemmed trays caused strains above that of the yield strain of healthy cancellous bone, these high strains could cause the graft to deform and resorb accelerating the migration of the tibial tray. However Toms et al[101] only examined press fit stems and although they may provide optimal results in terms of initial stability this study showed that cemented long stems provide better results for the proximal graft in terms of strain distribution and magnitudes.

There are a number of limitations with the study described which should be borne in mind when reflecting on the data presented. This study attempts only to be a comparative study of the initial compressive strain distribution conditions due to changes in fixation and prosthesis design and does not attempt to predict the performance of fixation or implant design in individual patients due to interface strains. To be predictive a wider range of tibial bone geometries and boney properties would have to be included as the optimal configuration in one patient may be suboptimal in another.

The cortical and cancellous bone was assumed to be isotropic, homogenous and linear elastic, where strictly considered cortical and cancellous bone exhibits anisotropic, hetrogenous and viscoelastic properties. Although the isotropy assumption for all materials used in this study can be considered justified as it has been reported that the isotropy assumption has little effect on models in which loading along the long axis of the bone is dominant[134], Rakotomanana et al[124], reported that an isotropic model of the implanted proximal tibia tended to overestimate the axial compressive stress by up to 40% when compared to an anisotropic model. Thus the percentage of cancellous bone loaded beyond 3000

$\mu\varepsilon$ and being at risk of pathologic overload may have been over estimated in the results described here. Although Rakotomanana's study reported that bone and interface stress behaviour in the proximal tibia is significantly different when transversely isotropic bone is introduced, his study was carried out using two-dimensional models and thus the exact values given may not be directly comparable with a three dimensional model. In fact Au et al[121] used a three dimensional model to investigate the effects of anisotropy and in their FE model anisotropic bone increased Von Mises stresses and predicted that cancellous bone stresses near the resected surface would increase by 100% and increase by 30 -50 % as you travelled distally when compared to the isotropic model. Thus the percentage of cancellous bone loaded beyond 3000 $\mu\varepsilon$ and being at risk of pathologic overload may have been under estimated by assuming isotropic cancellous bone, given that the three dimensional tibial geometry used in the Au et al study is more representative of the geometry used in the study reported here.

The cancellous bone in the models presented was modelled as a homogeneous region but Goldstein et al[143], showed the proximal tibia to be heterogeneous, with regions of high strength beneath the centres of each tibial condyle as only one value was used for the modulus of the cancellous bone in these models and it was similar to the higher values reported by Goldstein et al[143] the risk of resected tibial surface experiencing excessive strains may have been underestimated, particularly in the T2A cases where the strength of the resected tibial surface may play more of a role. Au et al also reported increased von Mises stress levels in the more proximal cancellous bone when hetrogenity was incorporated into the model.

The loading condition presented in this study was bi-condylar and representative of a physiological load within the knee however it only represented normal gait loading in the stance phase near full extension. Determining the optimal configuration of fixation and implant on the basis of a single load case is

inadequate especially when the point of loading continually moves in the knee throughout flexion and extension. This limitation exists in all static analyses such as finite element analysis. Muscle and ligament forces were also omitted from this study in order to simplify the models.

Each of the assumptions described above were present in all of the finite element models investigated, adding a systematic error to all the results. Therefore although the actual magnitude of the predicted strains may not be as precise as those occurring naturally, the relative differences seen between prosthetic combinations and each of the methods of fixation should remain constant. To improve the results of future work any further models should attempt to improve upon the limitations described above.

4.5 CONCLUSION

This study supports the contention that the use of cemented modular stems in primary TKA and simple revision TKA scenarios such as the T2A model investigated here, reduces the strains experienced in the proximal tibia and causes excessive strains within the distal cancellous bone at the stem tip. This may result in bone resorption and thus aseptic loosening of the implant. Although press-fit stems do not seem to cause as significant stress shielding of the proximal tibia or cause large strain concentration in the distal region they do cause localised areas of high strain at the stem tip, (which may be linked to patient pain and discomfort) which the trays without a modular stem do not. It was found that for primary TKA and revision TKA requiring augmentation primary tibial trays proximally cemented provided the optimal fixation in terms of strain distribution when good cortical contact was achieved. This study however does support the use of stems for revision cases requiring bone impaction grafting of the tibia if it is extensive and a primary tray stem will not bypass the defect adequately. It was found that a cemented long modular stem provided the best strain distribution within the proximal graft when compared to the press fit long modular stem. Although the use of a central modular stem may enhance component stability, providing resistance to lift off and shear, it may come at a long term price when strain patterns within the cancellous structure are taken into account.

Chapter 5

Summary of Findings and Future Work

5.1 SUMMARY OF FINDINGS

The results presented within chapter two showed that in a primary and revision T2A TKA scenario it is preferable to use a tibial tray with no modular stem fixed to the bone via a hybrid cement mantle, ensuring sound contact between the tray and the cortical rim. Cemented implants with no modular stem were found to have better initial fixation compared to all uncemented implants, (even those with an 80mm modular stem), thus the addition of a modular stem does not offer the stabilizing benefits of cement. Secure fixation of the tibial tray can be better achieved by a cement mantle of 2-3mm. Small errors in resection of the proximal tibia lead to large micromotions in the uncemented trays tested.

The results presented within chapter three showed that in a primary and revision T2A TKA scenario the addition of a press-fit or fully cemented 80mm modular stem offers no added translational or rotational stability to the tibial tray in all three planes. Suitable stability is achieved via a tibial tray with no modular stem using hybrid cement fixation. The addition of a press-fit or fully cemented modular stem did not reduce the micromotion experienced by the tray in the x, y or z direction in the primary and T2A revision groups. When compared to the tibial tray with no stem and hybrid cement fixation. However in the T1 group where the proximal bone stock was of poor quality a fully cemented tibial tray with an 80mm modular stem significantly increased the migrational and inducible displacement stability of the construct in all three planes when compared to the tibial tray with no stem and hybrid cement fixation, suggesting that in the presence of poor proximal bone quality and in the presence of proximal bone impaction grafting a long cemented modular stem which by-passes the defect and provides intramedullary fixation in the higher quality distal cancellous bone should be used to provide the most stable construct.

In Chapter four when the strain distribution rather than initial stability was examined the study supported the contention that the use of cemented modular

stems in primary TKA and simple revision TKA scenarios such as the T2A model, reduced the strains experienced in the proximal tibia and caused excessive strains within the distal cancellous bone at the stem tip. The excessive strains found may result in bone resorption and thus aseptic loosening of the implant. Although press-fit stems do not seem to cause as significant stress shielding of the proximal tibia or cause large strain concentration in the distal region they do cause localised areas of high strain at the stem tip, (which may be linked to patient pain and discomfort) which the trays without a modular stem do not. It was found that for primary TKA and revision TKA requiring augmentation primary tibial trays proximally cemented provided the optimal fixation in terms of strain distribution when good cortical contact was achieved. The results in chapter four however did support the use of stems for revision cases requiring bone impaction grafting of the tibia. It was found that a cemented long modular stem provided the best strain distribution within the proximal graft when compared to the press fit long modular stem.

5.2 SIX DEGREE OF FREEDOM FUTURE WORK

The Edinburgh Orthopaedic Engineering Centre is currently using the system designed for this experimental series to investigate varying lengths and diameters of stem to see the effect they play in providing improved initial stability to the tibial tray in three planes. The new experimental series is looking at the how the degree of bone impaction and the density of the graft in the T1 group effects the stability of the construct. The tests are also being carried out over two million cycles so that the data can be compared directly with in vivo RSA measurements that have been published in the data.

5.3 FINITE ELEMENT ANALYSIS FUTURE WORK

Future projects have come about as a direct result of this project. The new project sets out to incorporate pre-op data from dexa scans to provide and look at how varying levels of bone quality effect the mechanical environment and the strain transfer in the proximal tibia with different implant designs.

The next phase of the project will also look at the under side design of the tibial tray and compare a central post design with the fin designs of many new prosthesis systems. The FE model will continue to be developed to include the femur and muscle and ligament attachments. The hope is then to be able to carry out patient specific analysis prior to surgery in an attempt to provide the best mechanical environment for the revised construct.

References

1. Scottish Arthroplasty Project Annual Report 2004. 2004:1-80.

2. Emmerson KP, Moran CG, Pinder IM. Survivorship analysis of the Kinematic Stabilizer total knee replacement: a 10- to 14-year follow-up. *J Bone Joint Surg Br 1996;78-3:441-5.*

3. Ranawat CS, Luessenhop CP, Rodriguez JA. The press-fit condylar modular total knee system. Four-to-six-year results with a posterior-cruciate-substituting design. *J Bone Joint Surg Am 1997;79-3:342-8.*

4. Ranawat CS, Flynn WF, Jr., Saddler S, Hansraj KK, Maynard MJ. Long-term results of the total condylar knee arthroplasty. A 15-year survivorship study. *Clin Orthop Relat Res 1993-286:94-102.*

5. Weir DJ, Moran CG, Pinder IM. Kinematic condylar total knee arthroplasty. 14-year survivorship analysis of 208 consecutive cases. *J Bone Joint Surg Br 1996;78-6:907-11.*

6. Font-Rodriguez DE, Scuderi GR, Insall JN. Survivorship of cemented total knee arthroplasty. *Clin Orthop Relat Res 1997-345:79-86.*

7. Heck DA, Melfi CA, Mamlin LA, Katz BP, Arthur DS, Dittus RS, Freund DA. Revision rates after knee replacement in the United States. *Medical Care 1998;36-5:661-9.*

8. Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM. Insall Award paper. Why are total knee arthroplasties failing today? *Clinical Orthopaedics & Related Research 2002-404:7-13.*

9. Gofton WT, Tsigaras H, Butler RA, Patterson JJ, Barrack RL, Rorabeck CH. Revision total knee arthroplasty: fixation with modular stems. *Clinical Orthopaedics & Related Research 2002-404:158-68.*

10. Cameron HU, Hunter GA. Failure in total knee arthroplasty: mechanisms, revisions, and results. *Clin Orthop Relat Res 1982-170:141-6.*

11. Bryan RS, Rand JA. Revision total knee arthroplasty. *Clin Orthop Relat Res 1982-170:116-22.*

12. Ranawat CS, Boachie-Adjei O. Survivorship analysis and results of total condylar knee arthroplasty. Eight- to 11-year follow-up period. *Clin Orthop Relat Res 1988-226:6-13.*

13. Insall JN, Dethmers DA. Revision of total knee arthroplasty. *Clin Orthop Relat Res 1982-170:123-30.*

14. Nilsson KG, Karrholm J, Ekelund L, Magnusson P. Evaluation of micromotion in cemented vs uncemented knee arthroplasty in osteoarthrosis and rheumatoid arthritis. Randomized study using roentgen stereophotogrammetric analysis. *Journal of Arthroplasty 1991;6-3:265-78.*

15. Mjoberg B. Loosening of the cemented hip prosthesis. The importance of heat injury. *Acta Orthop Scand Suppl 1986;221:1-40.*

16. Collier JP, Mayor MB, Surprenant VA, Jensen RE, Surprenant HP, Kidd K. Interfaces between host and uncemented femoral hip prostheses. *Acta Orthop Belg 1993;59 Suppl 1:106-15.*

17. Pilliar RM, Lee JM, Maniatopoulos C. Observations on the effect of movement on bone ingrowth into porous-surfaced implants. *Clinical Orthopaedics & Related Research 1986-208:108-13.*

18. McKellop H, Ebramzadeh E, Niederer PG, Sarmiento A. Comparison of the stability of press-fit hip prosthesis femoral stems using a synthetic model femur.[erratum appears in J Orthop Res 1991 Nov;9(6):933]. *Journal of Orthopaedic Research 1991;9-2:297-305.*

19. Brooks PJ, Walker PS, Scott RD. Tibial component fixation in deficient tibial bone stock. *Clinical Orthopaedics & Related Research 1984-184:302-8.*

20. Elia EA, Lotke PA. Results of revision total knee arthroplasty associated with significant bone loss. *Clin Orthop Relat Res 1991-271:114-21.*

21. Haas SB, Insall JN, Montgomery W, 3rd, Windsor RE. Revision total knee arthroplasty with use of modular components with stems inserted without cement. *Journal of Bone & Joint Surgery - American Volume 1995;77-11:1700-7.*

22. Kraemer WJ, Harrington IJ, Hearn TC. Micromotion secondary to axial, torsional, and shear loads in two models of cementless tibial components. *J Arthroplasty 1995;10-2:227-35.*

23. Lee RW, Volz RG, Sheridan DC. The role of fixation and bone quality on the mechanical stability of tibial knee components. *Clin Orthop Relat Res 1991-273:177-83.*

24. Moreland JR. Mechanisms of failure in total knee arthroplasty. *Clin Orthop Relat Res 1988-226:49-64.*

25. Rosenberg AG, Barden R, Galante JO. A comparison of cemented and cementless fixation with the Miller-Galante total knee arthroplasty. *Orthop Clin North Am 1989;20-1:97-111.*

26. Vince KG, Insall JN, Kelly MA. The total condylar prosthesis. 10- to 12-year results of a cemented knee replacement. *J Bone Joint Surg Br 1989;71-5:793-7.*

27. Walker PS, Greene D, Reilly D, Thatcher J, Ben-Dov M, Ewald FC. Fixation of tibial components of knee prostheses. *J Bone Joint Surg Am 1981;63-2:258-67.*

28. Walker PS, Hsu HP, Zimmerman RA. A comparative study of uncemented tibial components. *J Arthroplasty 1990;5-3:245-53.*

29. Bourgeault S, Chareancholvanich K, Lew W. Does a central stem effect bone strain and the stability of a cemented tibial tray in primary and revision TKA. *Trans Orthop Res Soc.* Vol. 22, 1997:635.

30. Lombardi AV MT, Gunderson R. Surface-cementation of the tibial component in total knee arthroplasty. *Proceedings 65th Annual Meeting of the American Academy of Orthopaedic Surgeons 1998.*

31. Fehring TK, Odum S, Griffin WL, Mason JB, Nadaud M. Early failures in total knee arthroplasty. *Clin Orthop Relat Res 2001-392:315-8.*

32. Ryd L, Toksvig-Larsen S. Early postoperative fixation of tibial components: an in vivo roentgen stereophotogrammetric analysis. *Journal of Orthopaedic Research 1993;11-1:142-8.*

33. Ryd L, Albrektsson BE, Carlsson L, Dansgard F, Herberts P, Lindstrand A, Regner L, Toksvig-Larsen S. Roentgen

stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. *Journal of Bone & Joint Surgery - British Volume 1995;77-3:377-83.*

34. Fukuoka S, Yoshida K, Yamano Y. Estimation of the migration of tibial components in total knee arthroplasty. A roentgen stereophotogrammetric analysis. *Journal of Bone & Joint Surgery - British Volume 2000;82-2:222-7.*

35. Murase K, Crowninshield RD, Pedersen DR, Chang TS. An analysis of tibial component design in total knee arthroplasty. *J Biomech 1983;16-1:13-22.*

36. Bertin KC, Freeman MA, Samuelson KM, Ratcliffe SS, Todd RC. Stemmed revision arthroplasty for aseptic loosening of total knee replacement. *Journal of Bone & Joint Surgery - British Volume 1985;67-2:242-8.*

37. Bartel DL, Burstein AH, Santavicca EA, Insall JN. Performance of the tibial component in total knee replacement. *Journal of Bone & Joint Surgery - American Volume 1982;64-7:1026-33.*

38. Frost HM. A 2003 update of bone physiology and Wolff's Law for clinicians. *Angle Orthod 2004;74-1:3-15.*

39. Harada Y, Wevers HW, Cooke TD. Distribution of bone strength in the proximal tibia. *Journal of Arthroplasty 1988;3-2:167-75.*

40. Engh GA, Herzwurm PJ, Parks NL. Treatment of major defects of bone with bulk allografts and stemmed components during total knee arthroplasty. *Journal of Bone & Joint Surgery - American Volume 1997;79-7:1030-9.*

41. Ghazavi MT, Stockley I, Yee G, Davis A, Gross AE. Reconstruction of massive bone defects with allograft in revision total knee arthroplasty. *Journal of Bone & Joint Surgery - American Volume 1997;79-1:17-25.*

42. Bugbee WD, Ammeen DJ, Engh GA. Does implant selection affect outcome of revision knee arthroplasty? *Journal of Arthroplasty 2001;16-5:581-5.*

43. Albrektsson BE, Ryd L, Carlsson LV, Freeman MA, Herberts P, Regner L, Selvik G. The effect of a stem on the tibial component of knee arthroplasty. A roentgen stereophotogrammetric study of uncemented tibial components in the Freeman-Samuelson knee arthroplasty. *Journal of Bone & Joint Surgery - British Volume 1990;72-2:252-8.*

44. van Loon CJ, Buma P, de Waal Malefijt MC, van Kampen A, Veth RP. Morselized bone allografting in revision total knee replacement--a case report with a 4-year histological follow-up. *Acta Orthop Scand 2000;71-1:98-101.*

45. Lim LA, Trousdale RT, Berry DJ, Hanssen AD. Failure of the stem-condyle junction of a modular femoral stem in revision total knee arthroplasty: a report of five cases. *Journal of Arthroplasty 2001;16-1:128-32.*

46. Barrack RL. Modularity of Prosthetic Implants. *J Am Acad Orthop Surg 1994;2-1:16-25.*

47. Barrack RL, Rorabeck C, Burt M, Sawhney J. Pain at the end of the stem after revision total knee arthroplasty. *Clinical Orthopaedics & Related Research 1999-367:216-25.*

48. van Lenthe GH, Willems MM, Verdonschot N, de Waal Malefijt MC, Huiskes R. Stemmed femoral knee prostheses: effects of prosthetic design and fixation on bone loss. *Acta Orthop Scand 2002;73-6:630-7.*

49. Lonner JH, Klotz M, Levitz C, Lotke PA. Changes in bone density after cemented total knee arthroplasty: influence of stem design. *J Arthroplasty 2001;16-1:107-11.*

50. Yoshii I, Whiteside LA, Milliano MT, White SE. The effect of central stem and stem length on micromovement of the tibial tray. *Journal of Arthroplasty 1992;7 Suppl:433-8.*

51. Stern SH, Wills RD, Gilbert JL. The effect of tibial stem design on component micromotion in knee arthroplasty. *Clinical Orthopaedics & Related Research 1997-345:44-52.*

52. Gunston FH. Polycentric knee arthroplasty. Prosthetic simulation of normal knee movement. *J Bone Joint Surg Br 1971;53-2:272-7.*

53. Engh GA, Ammeen DJ. Bone loss with revision total knee arthroplasty: defect classification and alternatives for reconstruction. *Instructional Course Lectures 1999;48:167-75.*

54. Wolff J. Das Gesetz der Transformation der Knochen (Hirchwild Berlin, 1892); translated as The Law of Bone Remodeling (trans. Maquet, P & Furlong,R) (Springer Berlin, 1986). *1892.*

55. Huiskes R, Ruimerman R, van Lenthe GH, Janssen JD. Effects of mechanical forces on maintenance and adaptation of form in trabecular bone. *Nature 2000;405-6787:704-6.*

56. Frost HM. Perspectives on Artifical Joint Design. *Journal of Long-Term Effects of Medical Implants 1992;2-1:9-35.*

57. Recker RR, Davies KM, Hinders SM, Heaney RP, Stegman MR, Kimmel DB. Bone gain in young adult women. *Jama 1992;268-17:2403-8.*

58. Smith HP, Jr., Meli RJ, Copenhaver WE, Stewart JS. Computerized tomography body scanning in a community hospital. *J Fla Med Assoc 1978;65-10:823-5.*

59. Gie GA, Linder L, Ling RS, Simon JP, Slooff TJ, Timperley AJ. Impacted cancellous allografts and cement for revision total hip arthroplasty. *J Bone Joint Surg Br 1993;75-1:14-21.*

60. Friedlaender GE. Bone grafts. The basic science rationale for clinical applications. *Journal of Bone & Joint Surgery - American Volume 1987;69-5:786-90.*

61. Prolo DJ. Biology of bone fusion. *Clin Neurosurg 1990;36:135-46.*

62. Burr DB, Schaffler MB, Yang KH, Lukoschek M, Sivaneri N, Blaha JD, Radin EL. Skeletal change in response to altered strain environments: is woven bone a response to elevated strain? *Bone 1989;10-3:223-33.*

63. Frost HM. A brief review for orthopedic surgeons: fatigue damage (microdamage) in bone (its determinants and clinical implications). *J Orthop Sci 1998;3-5:272-81.*

64. Fehring TK, Peindl RD, Humble RS, Harrow ME, Frick SL. Modular tibial augmentations in total knee arthroplasty. *Clinical Orthopaedics & Related Research 1996-327:207-17.*

65. Bourne RB, Finlay JB. The influence of tibial component intramedullary stems and implant-cortex contact on the strain distribution of the proximal tibia

following total knee arthroplasty. An in vitro study. *Clinical Orthopaedics & Related Research 1986-208:95-9.*

66. Peters CL, Craig MA, Mohr RA, Bachus KN. Tibial component fixation with cement: full- versus surface-cementation techniques. *Clinical Orthopaedics & Related Research 2003-409:158-68.*

67. Henley MB, Meier M, Tencer AF. Influences of some design parameters on the biomechanics of the unreamed tibial intramedullary nail. *J Orthop Trauma 1993;7-4:311-9.*

68. Cristofolini L, Viceconti M. Mechanical validation of whole bone composite tibia models. *Journal of Biomechanics 2000;33-3:279-88.*

69. Szivek JA, Thomas M, Benjamin JB. Characterization of a synthetic foam as a model for human cancellous bone. *J Appl Biomater 1993;4-3:269-72.*

70. Martens M, Van Audekercke R, Delport P, De Meester P, Mulier JC. The mechanical characteristics of cancellous bone at the upper femoral region. *J Biomech 1983;16-12:971-83.*

71. Carter DR, Spengler DM. Mechanical properties and composition of cortical bone. *Clin Orthop Relat Res 1978-135:192-217.*

72. Fung Y. In: Bone and Cartilage Biomechanics-Mechanical Properties of Living Tissues, Springer, New York. *1980:383-415.*

73. Buhler DW BU, Lippuner K, Jaeger P, Nolte LP. Three-dimensional primary stability of cementless femoral stems. *Clinical Biomechanics 1997;12-2:75-86.*

74. Shimagaki H, Bechtold JE, Sherman RE, Gustilo RB. Stability of initial fixation of the tibial component in cementless total knee arthroplasty. *Journal of Orthopaedic Research 1990;8-1:64-71.*

75. Peters CL, Craig MA, Mohr RA, Bachus KN. Tibial component fixation with cement: full- versus surface-cementation techniques. *Clin Orthop Relat Res 2003-409:158-68.*

76. Miura H, Whiteside LA, Easley JC, Amador DD. Effects of screws and a sleeve on initial fixation in uncemented total knee tibial components. *Clinical Orthopaedics & Related Research 1990-259:160-8.*

77. Schmalzried TP, Szuszczewicz ES, Northfield MR, Akizuki KH, Frankel RE, Belcher G, Amstutz HC. Quantitative assessment of walking activity after total hip or knee replacement. *J Bone Joint Surg Am 1998;80-1:54-9.*

78. Collier JP, Mayor MB, Surprenant VA, Surprenant HP, Dauphinais LA, Jensen RE. The biomechanical problems of polyethylene as a bearing surface. *Clinical Orthopaedics & Related Research 1990-261:107-13.*

79. Harrington IJ. A bioengineering analysis of force actions at the knee in normal and pathological gait. *Bio-Medical Engineering 1976;11-5:167-72.*

80. Morrison JB. The mechanics of the knee joint in relation to normal walking. *Journal of Biomechanics 1970;3-1:51-61.*

81. Reilly D, Walker PS, Ben-Dov M, Ewald FC. Effects of tibial components on load transfer in the upper tibia. *Clinical Orthopaedics & Related Research 1982-165:273-82.*

82. Kuster MS, Wood GA, Stachowiak GW, Gachter A. Joint load considerations in total knee replacement. *Journal of Bone & Joint Surgery - British Volume 1997;79-1:109-13.*

83. Dahlkvist NJ, Mayo P, Seedhom BB. Forces during squatting and rising from a deep squat. *Eng Med 1982;11-2:69-76.*

84. Andriacchi TP, Andersson GB, Fermier RW, Stern D, Galante JO. A study of lower-limb mechanics during stair-climbing. *Journal of Bone & Joint Surgery - American Volume 1980;62-5:749-57.*

85. Jasty M, Bragdon CR, Schutzer S, Rubash H, Haire T, Harris WH. Bone ingrowth into porous coated canine total hip replacements. Quantification by backscattered scanning electron microscopy and image analysis. *Scanning Microsc 1989;3-4:1051-6; discussion 6-7.*

86. Toksvig-Larsen S, Ryd L, Lindstrand A. Fixation of the tibial component in knee arthroplasty after six weeks. *International Orthopaedics 1995;19-2:89-93.*

87. Fehring TK, Griffin WL. Revision of failed cementless total knee implants with cement. *Clin Orthop Relat Res 1998-356:34-8.*

88. Branson PJ, Steege JW, Wixson RL, Lewis J, Stulberg SD. Rigidity of initial fixation with uncemented tibial knee implants. *Journal of Arthroplasty 1989;4-1:21-6.*

89. Bert JM, McShane M. Is it necessary to cement the tibial stem in cemented total knee arthroplasty? *Clinical Orthopaedics & Related Research 1998-356:73-8.*

90. Volz RG, Nisbet JK, Lee RW, McMurtry MG. The mechanical stability of various noncemented tibial components. *Clinical Orthopaedics & Related Research 1988-226:38-42.*

91. Luring C, Perlick L, Trepte C, Linhardt O, Perlick C, Plitz W, Grifka J. Micromotion in cemented rotating platform total knee arthroplasty: cemented tibial stem versus hybrid fixation. *Arch Orthop Trauma Surg 2006;126-1:45-8.*

92. Maher SA, Prendergast PJ, Lyons CG. Measurement of the migration of a cemented hip prosthesis in an in vitro test. *Clinical Biomechanics 2001;16-4:307-14.*

93. Maher SA, Prendergast PJ. Discriminating the loosening behaviour of cemented hip prostheses using measurements of migration and inducible displacement. *Journal of Biomechanics 2002;35-2:257-65.*

94. Speirs AD, Slomczykowski MA, Orr TE, Siebenrock K, Nolte LP. Three-dimensional measurement of cemented femoral stem stability: an in vitro cadaver study. *Clinical Biomechanics 2000;15-4:248-55.*

95. Elting JJ, Mikhail WE, Zicat BA, Hubbell JC, Lane LE, House B. Preliminary report of impaction grafting for exchange femoral arthroplasty. *Clin Orthop Relat Res 1995-319:159-67.*

96. Giesen EB, Lamerigts NM, Verdonschot N, Buma P, Schreurs BW, Huiskes R. Mechanical characteristics of impacted morsellised bone grafts used in revision of total hip arthroplasty. *J Bone Joint Surg Br 1999;81-6:1052-7.*

97. Ullmark G, Hovelius L. Impacted morsellized allograft and cement for revision total knee arthroplasty: a preliminary report of 3 cases. *Acta Orthop Scand 1996;67-1:10-2.*

98. Bradley GW. Revision total knee arthroplasty by impaction bone grafting. *Clinical Orthopaedics & Related Research 2000-371:113-8.*

99. Heyligers IC, van Haaren EH, Wuisman PI. Revision knee arthroplasty using impaction grafting and primary implants. *J Arthroplasty 2001;16-4:533-7.*

100. Benjamin J, Engh G, Parsley B, Donaldson T, Coon T. Morselized bone grafting of defects in revision total knee arthroplasty. *Clinical Orthopaedics & Related Research 2001-392:62-7.*

101. Toms AD, McClelland D, Chua L, de Waal Malefijt M, Verdonschot N, Spencer Jones R, Kuiper JH. Mechanical testing of impaction bone grafting in the tibia: initial stability and design of the stem. *J Bone Joint Surg Br 2005;87-5:656-63.*

102. Jazrawi LM, Bai B, Kummer FJ, Hiebert R, Stuchin SA. The effect of stem modularity and mode of fixation on tibial component stability in revision total knee arthroplasty. *Journal of Arthroplasty 2001;16-6:759-67.*

103. Berzins A, Sumner DR, Andriacchi TP, Galante JO. Stem curvature and load angle influence the initial relative bone-implant motion of cementless femoral stems. *J Orthop Res 1993;11-5:758-69.*

104. Dunlop D. Mechanical properties of bone impaction grafting. *PhD Thesis, Edinburgh University 2001.*

105. Kuiper J, Richardson, JB, Soliman A, Cheah, K. Stability of impaction-grafted hip and knee prostheses: surgical technique, implant design and graft compaction. *In: Delloyce C, Bannister, G eds. Impaction bone grafting in revision arthroplasty. New York: Marcel Decker 2004:75-94.*

106. Harrington IJ. Static and dynamic loading patterns in knee joints with deformities. *Journal of Bone & Joint Surgery - American Volume 1983;65-2:247-59.*

107. Conditt MA, Parsley BS, Alexander JW, Doherty SD, Noble PC. The optimal strategy for stable tibial fixation in revision total knee arthroplasty. *J Arthroplasty 2004;19-7 Suppl 2:113-8.*

108. Nazarian DG, Mehta S, Booth RE, Jr. A comparison of stemmed and unstemmed components in revision knee arthroplasty. *Clin Orthop Relat Res 2002-404:256-62.*

109. Albrektsson BE, Carlsson LV, Freeman MA, Herberts P, Ryd L. Proximally cemented versus uncemented Freeman-Samuelson knee arthroplasty. A prospective randomised study. *Journal of Bone & Joint Surgery - British Volume 1992;74-2:233-8.*

110. Hilding MB, Yuan X, Ryd L. The stability of three different cementless tibial components. A randomized radiostereometric study in 45 knee arthroplasty patients. *Acta Orthopaedica Scandinavica 1995;66-1:21-7.*

111. Ryd L. Micromotion in knee arthroplasty. A roentgen stereophotogrammetric analysis of tibial component fixation. *Acta Orthopaedica Scandinavica. Supplementum 1986;220:1-80.*

112. Ryd L, Albrektsson BE, Herberts P, Lindstrand A, Selvik G.
Micromotion of noncemented Freeman-Samuelson knee prostheses in gonarthrosis. A roentgen-stereophotogrammetric analysis of eight successful cases. *Clinical Orthopaedics & Related Research 1988-229:205-12.*
113. Ryd L, Lindstrand A, Stenstrom A, Selvik G. Porous coated anatomic tricompartmental tibial components. The relationship between prosthetic position and micromotion. *Clinical Orthopaedics & Related Research 1990-251:189-97.*
114. Grewal R, Rimmer MG, Freeman MA. Early migration of prostheses related to long-term survivorship. Comparison of tibial components in knee replacement. *Journal of Bone & Joint Surgery - British Volume 1992;74-2:239-42.*
115. Perillo-Marcone A, Ryd L, Johnsson K, Taylor M. A combined RSA and FE study of the implanted proximal tibia: correlation of the post-operative mechanical environment with implant migration. *J Biomech 2004;37-8:1205-13.*
116. Lewis PL, Brewster NT, Graves SE. The pathogenesis of bone loss following total knee arthroplasty. *Orthop Clin North Am 1998;29-2:187-97.*
117. Li MG, Nilsson KG. The effect of the preoperative bone quality on the fixation of the tibial component in total knee arthroplasty. *Journal of Arthroplasty 2000;15-6:744-53.*
118. Jee WS, Li XJ. Adaptation of cancellous bone to overloading in the adult rat: a single photon absorptiometry and histomorphometry study. *Anat Rec 1990;227-4:418-26.*
119. Jee WS, Li XJ, Schaffler MB. Adaptation of diaphyseal structure with aging and increased mechanical usage in the adult rat: a histomorphometrical and biomechanical study. *Anat Rec 1991;230-3:332-8.*
120. Beaupre GS, Orr TE, Carter DR. An approach for time-dependent bone modeling and remodeling--theoretical development. *J Orthop Res 1990;8-5:651-61.*
121. Au AG, Liggins AB, Raso VJ, Amirfazli A. A parametric analysis of fixation post shape in tibial knee prostheses. *Med Eng Phys 2005;27-2:123-34.*
122. Beaupre GS, Vasu R, Carter DR, Schurman DJ. Epiphyseal-based designs for tibial plateau components--II. Stress analysis in the sagittal plane. *J Biomech 1986;19-8:663-73.*
123. Garg A, Walker PS. The effect of the interface on the bone stresses beneath tibial components. *J Biomech 1986;19-12:957-67.*
124. Rakotomanana RL, Leyvraz PF, Curnier A, Heegaard JH, Rubin PJ. A finite element model for evaluation of tibial prosthesis-bone interface in total knee replacement. *J Biomech 1992;25-12:1413-24.*
125. Vasu R, Carter DR, Schurman DJ, Beaupre GS. Epiphyseal-based designs for tibial plateau components--I. Stress analysis in the frontal plane. *J Biomech 1986;19-8:647-62.*
126. Askew MJ, Lewis JL. Analysis of model variables and fixation post length effects on stresses around a prosthesis in the proximal tibia. *J Biomech Eng 1981;103-4:239-45.*
127. Walker PS, Hajek JV. The load-bearing area in the knee joint. *J Biomech 1972;5-6:581-9.*

128. Heiner AD, Brown TD. Structural properties of a new design of composite replicate femurs and tibias. *J Biomech 2001;34-6:773-81.*

129. Miyoshi S, Takahashi T, Ohtani M, Yamamoto H, Kameyama K. Analysis of the shape of the tibial tray in total knee arthroplasty using a three dimension finite element model. *Clinical Biomechanics 2002;17-7:521-5.*

130. Perillo-Marcone A, Barrett DS, Taylor M. The importance of tibial alignment: finite element analysis of tibial malalignment. *Journal of Arthroplasty 2000;15-8:1020-7.*

131. Taylor M, Tanner KE, Freeman MA. Finite element analysis of the implanted proximal tibia: a relationship between the initial cancellous bone stresses and implant migration. *Journal of Biomechanics 1998;31-4:303-10.*

132. Rho JY. An ultrasonic method for measuring the elastic properties of human tibial cortical and cancellous bone. *Ultrasonics 1996;34-8:777-83.*

133. Phillips AT, Pankaj, Usmani AS, Howie CR. The effect of acetabular cup size on the short-term stability of revision hip arthroplasty: a finite element investigation. *Proc Inst Mech Eng [H] 2004;218-4:239-49.*

134. Huiskes R, Janssen, JD, Sloof, TJ. A Detailed comparison of experimental and theoretical stress analysis of a human femur. In: Proceedings of the joint ASME-ASCE Applied Mechanics Fluids Engineering and Bioengineering Conference AMD. *1981;45:211-34.*

135. Pugh JW, Rose RM, Radin EL. Elastic and viscoelastic properties of trabecular bone: dependence on structure. *J Biomech 1973;6-5:475-85.*

136. Cowin S. Bone mechanics handbook, 2nd Edition. *CRC Press Boca, Florida 2001.*

137. Ding M, Danielsen CC, Hvid I. Bone density does not reflect mechanical properties in early-stage arthrosis. *Acta Orthop Scand 2001;72-2:181-5.*

138. Li B, Aspden RM. Material properties of bone from the femoral neck and calcar femorale of patients with osteoporosis or osteoarthritis. *Osteoporos Int 1997;7-5:450-6.*

139. McCalden RW, McGeough JA, Court-Brown CM. Age-related changes in the compressive strength of cancellous bone. The relative importance of changes in density and trabecular architecture. *J Bone Joint Surg Am 1997;79-3:421-7.*

140. Viceconti M, Baleani M, De Lollis A, Toni A. An FEA-based protocol for the pre-clinical validation of custom-made hip implants. *J Med Eng Technol 1998;22-6:257-62.*

141. Nyman JS, Hazelwood SJ, Rodrigo JJ, Martin RB, Yeh OC. Long stemmed total knee arthroplasty with interlocking screws: a computational bone adaptation study. *J Orthop Res 2004;22-1:51-7.*

142. Levitz CL, Lotke PA, Karp JS. Long-term changes in bone mineral density following total knee replacement. *Clin Orthop Relat Res 1995-321:68-72.*

143. Goldstein SA, Wilson DL, Sonstegard DA, Matthews LS. The mechanical properties of human tibial trabecular bone as a function of metaphyseal location. *J Biomech 1983;16-12:965-9.*

Appendix 1

Conference Presentations and Posters

Conference Presentations & Posters

A.J. McLean, A.T.M. Phillips, J.A. McGeough, A.H.R.W. Simpson, and C.R. Howie. Finite element modeling of revision total knee replacements: analysis of modular stem length and the effect on initial cancellous bone stresses. *Computer Methods in Biomechanics and Biomedical Engineering*, Antibes, France, 2006

P. Pankaj, A.T.M. Phillips, K.W. Taylor, F.P. May, C.R. Howie, A.J. McLean, and A.S. Usmani. Constitutive modelling of morsellised cortico-cancellous bone. *Computer Methods in Biomechanics and Biomedical Engineering*, Antibes, France, 2006

P. Pankaj, A.T.M. Phillips C.R. Howie, A.J. McLean, A.H.R.W. Simpson. Quantifying the behaviour of morsellised cortico-cancellous bone. *Bone Research Society*, Southampton, 2006
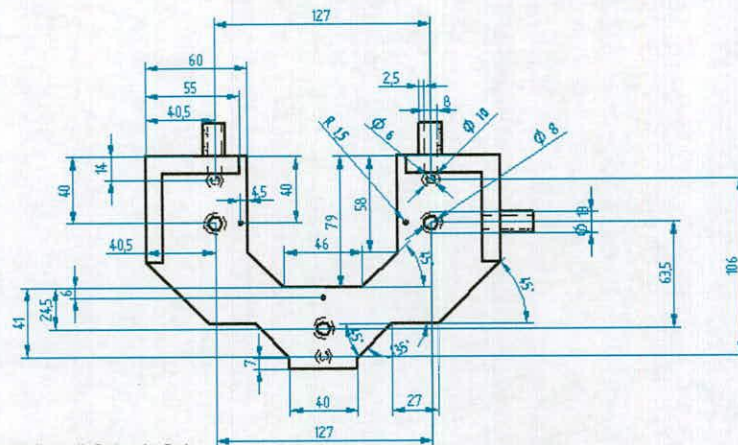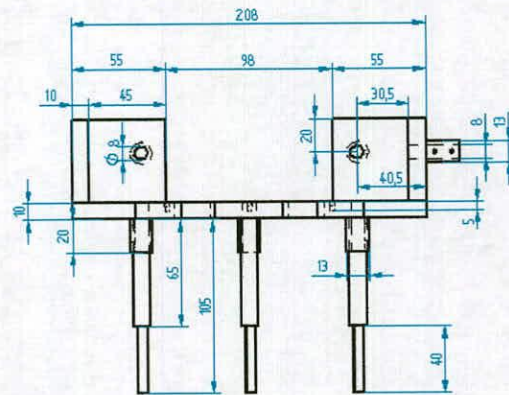Proceedings to be published in the Journal of Bone and Joint Surgery (British)

A.T.M. Phillips, K.W. Taylor, F.P. May, C.R. Howie, Pankaj, A.J. McLean, and A.S. Usmani. The elastic behaviour of morsellised cortico-cancellous bone: the importance of impaction technique. *British Hip Society*, Wrightington, 2005
Proceedings published in the Journal of Bone and Joint Surgery (British)

A.J. McLean, J.A. McGeough, A.H.R.W. Simpson, and C.R. Howie. Modular Stems and Backside Tray Design; the effect they have on the fixation of tibial components in total knee arthroplasty. *Computer Aided Production Engineering*, Melbourne, 2005

A.J. McLean, J.A. McGeough, A.H.R.W. Simpson, and C.R. Howie. Initial Fixation of the Tibial Tray in Revision Total Knee Arthroplasty. *IMechE Knee Arthroplasty Conference*, London, 2005

Appendix 2

Design Drawings

All dimensions in mm

Scale 1 : 2

Alastair McLean
tel: 0131 242 6296
e-mail :
A.J.McLean-1@sms.ed.ac.uk

REV	DESCRIPTION	DATE	APPROVED

	NAME	DATE
DRAWN	Alastair	10/08/04
CHECKED		
ENG APPR		
MGR APPR		

SOLID EDGE
EDS-PLM SOLUTIONS

TITLE
LVDT Bracket Holder

SIZE A3	DWG NO		REV

FILE NAME: LVDT bracket.dft

| SCALE: | WEIGHT: | SHEET 1 OF 1 |

UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN MILLIMETERS
ANGLES ±X.X°
2 PL ±X.XX 3 PL ±X.XXX

Edinburgh Orthopaedic Engineering Centre

	NAME	DATE
DRAWN	Alastair	10/18/04
CHECKED		
ENG APPR		
MGR APPR		

SOLID EDGE
EDS PLM SOLUTIONS

TITLE
Locating Pins

SIZE A4	DWG NO		REV

UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN MILLIMETERS
ANGLES ±XX°
2 PL ±XXX 3 PL ±XXXX

FILE NAME: locating pins.dft

SCALE	WEIGHT:	SHEET 1 OF 1

Edinburgh Orthopaedic Engineering Centre

132

65

5

28.5

10

23

12.5

20

20

5

2.5

2.5

42.5

35

12.5

106

12

R 52.5

Ø 55

127

75.5

67.5

Ø 20

Ø 10.5

25

20

Edinburgh Orthopaedic Engineering Centre

REVISION HISTORY			
REV	DESCRIPTION	DATE	APPROVED

151

20

7.5

11.5

75.5

7.5

M5

All holes not
dimensioned are M5

Scale 1 : 1

All dimensions in mm

Alastair McLean

A.J.McLean-1@sms.ed.ac.uk
Tel 0131 242 6296

SOLID EDGE
EDS-PLM SOLUTIONS

	NAME	DATE
DRAWN	Alastair	10/08/04
CHECKED		
ENG APPR		
MGR APPR		

TITLE
Tibial Bone Ring

UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN MILLIMETERS
ANGLES ±XX°
2 PL ±XXX 3 PL ±X.XXX

SIZE A3 DWG NO REV

FILE NAME: tibial bone ring.dft

SCALE: WEIGHT: SHEET 1 OF 1

Engineering drawing — Tibial target ring

Top view dimensions: 127, 63.5, 25, R 15?, 107

Right view dimensions: 63.5, R 15?, 10, 5, 3.4, 5

Front/plan view dimensions: 127, 66, 29, 45, 14, R 10, Ø 5, 75, 88, 5, 63.5, 12.5, 8.5, 45