

Biomechanical Analysis of Fixation and Bone Remodelling of Total Knee Replacement

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*“To solve a biomechanical problem, find and try to
copy how Nature solved it”*

Harold M. Frost, 1986

Dedicated to
my Father, who passed away one month before I
embarked on my Ph.D journey,
my Mother,
and my Wife.

ABSTRACT

Long-term survivorship of a total knee replacement (TKR) relies on the strength of bone around the implant and its initial stability. Aseptic component loosening caused by mechanical factors is a recognised failure mode for knee prostheses. Bone resorption due to “stress-shielding” of the stiff stemmed implants will potentially lead to weakened bone strength, and presents a challenge for revision TKR surgery. The aim of this study was to develop analytical methodologies for the investigation of fixation performance of TKR, and to gain a better understanding of the prosthetic design requirements, addressing two major mechanical problems of *bone remodelling* and *aseptic loosening*.

Patient-specific finite element (FE) modelling incorporated with a strain-adaptive bone remodelling theory was used to simulate bone remodelling responses of the post-operative tibial fixation. The choice of cementing technique was found to influence the remodelling behaviour; cemented fixation—modelled as a firm anchorage of the prosthesis onto the bone, was predicted to induce greater stress-shielding effect consequently leading to severe proximal bone resorption; for a fixation relying on biological attachment of bony ingrowth—modelled as a less firmly anchored bone-prosthesis interface, lesser proximal bone resorption was predicted.

The consideration of bone remodelling in FE simulations for fixation analyses is paramount as it influenced the risk prediction of aseptic loosening between prosthesis designs. The cement tensile stresses and bone-prosthesis interface micromotions predicted were different prior to and after bone adaptation. FE predictions of the MIS mini-keel and standard stemmed prosthesis fixations after simulating six months of bone adaptation correlated well with the RSA measurements at a similar period.

A modified in-vitro technique of measuring bone-prosthesis relative micromotion was developed for relating initial stability of the cemented and cementless (press-fit) tibial prostheses fixations to late aseptic loosening. The developed computational and in-vitro methods should be applicable to other joint replacements.

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CHAPTER 1. INTRODUCTION

1.1. Background

Biomechanics is the science that studies the effects of forces on biological tissues, organs and organisms, in relation to biological and medical problems. It is a branch of the engineering discipline of Mechanics. Applied research in biomechanics uses existing biomechanical knowledge to improve the living lifestyle of human beings. In biomechanics research, it can be sub classified as *biosolid* or *biofluid* (Bronzino 1995). Biofluid mechanics involves the study of fluid behaviour in a human biological system. Biosolid mechanics involves the study of solid behaviour of a human musculoskeletal system, where it can be further divided into 3 sub fields namely i) bone/soft-tissue mechanics, ii) orthopaedic biomechanics, and iii) musculoskeletal biomechanics. In the medical field of total joint replacement (TJR), orthopaedic biomechanics concepts are used to enhance the understanding of the mechanical behaviour of these prosthetic joints. With it, new designs of the prosthesis and surgical techniques can be developed to prolong the prosthesis survivorship and improve its functionality.

Total Knee Replacement (TKR) is a surgical procedure for the treatment of severe arthritis of the knee, where the cartilage in a patient's knee is replaced. Images of knee joints before and after TKR are shown in Fig. 1.1. It is also commonly known as *Total Knee Arthroplasty* (TKA). Patients who undergo TKR are mainly elderly people who suffer from *Osteoarthritis* (OA) or *Rheumatoid Arthritis* (RA), a degenerative condition indicating inflammation and then destruction of a joint that causes pain and swelling which could affect a person's daily life. With the trend of aging population around the world, there has been a large increase in the number of TKA performed each year. It has inevitably resulted in a rise in the number of cases for revision surgery. Although the rate of failure of TKR is low (approximately 5-10%), it is reported that more than 30,000 knee replacement are revised yearly in the United States (Kurtz et al. 2007). Many long term clinical studies have found that TKR has excellent survivorship of about 10 to 15 years (Scuderi et al. 1989; Vessely et al. 2006; Furnes et al. 2007), with the failure frequency increasing after 10 years (Levit

et al. 1995). In the past, a knee replacement operation was commonly performed only on elderly patients (age 60 years old and above), in view of the prosthesis survivorship. With the advances in surgical techniques and prosthesis technology, more and more younger patients (below the age of 50 years old) are receiving TKR treatment. This patient group is generally more active and functionally more demanding after the surgery. As such, prostheses implanted today need to be more durable and able to survive longer.

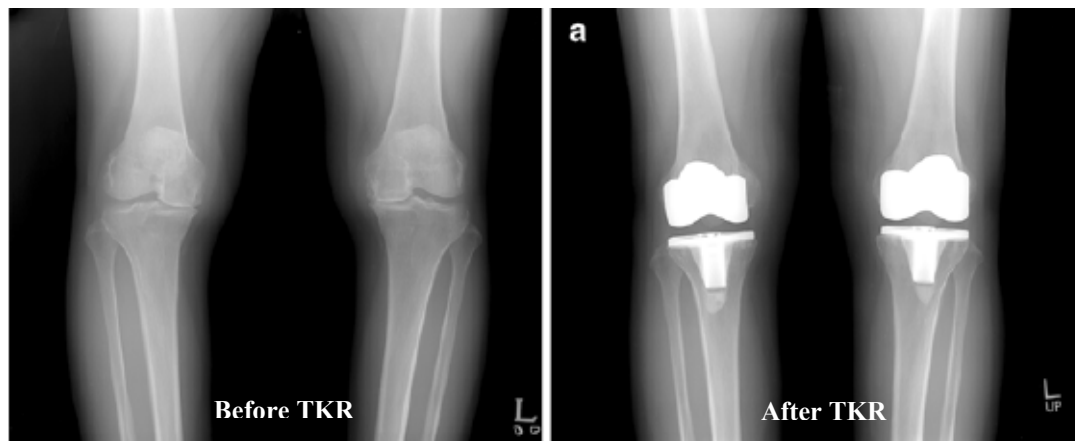


Figure 1.1: X-ray images of the knee joints - before and after TKR.

The *minimally invasive surgery* (MIS) approach for total knee replacement, which involves a shorter incision length for implant placement (tibial trays with shorter and wider keel) compared to the conventional approach, is gaining interest in the orthopaedic community. The MIS approach is driven by its potential clinical advantages such as less post-operative pain, reduced blood loss, more rapid recovery and return of functionality, and shorter hospitalisation period. A typical MIS tibial prosthesis features two broad mini-keels (see Fig. 1.2), with the stem extension as a “dropped-down” option for extra fixation stability. Although the MIS technique have shown early promises (Cheung et al. 2008), its long-term fixation performance is unclear compared to the standard stemmed design that has remarkable survivorship. Conflicting design trends were noted in biomechanical analyses of the stemmed versus stemless MIS prostheses (Coleman et al. 2006; Bartel & Gunsallus 2007). Hence, a better understanding of the mechanical responses of these new prostheses is crucial.



Figure 1.2: MIS mini-keel tibial prostheses with “drop-down” stem extension.

TKR is a successful surgical operation with an excellent survival rate at 10 to 15 years of more than 90% (Stern & Insall 1992; Schai et al. 1998; Furnes et al. 2007), and of some greater than 95% (Malkani et al. 1995; Khaw et al. 2002; Berend et al. 2004; Gioe et al. 2004; Vessely et al. 2006; Hardeman et al. 2006). The most common problems leading to revision surgery are aseptic component loosening and polyethylene wear, follow by fracture failure (bone or prosthesis) and instability (Cameron & Hunter 1982; Windsor et al. 1989; Sharkey et al. 2002; Gioe et al. 2004; Saleh et al. 2006). In 212 consecutive TKR revisions performed, Sharkey et al. (2002) reported that the primary causes of failure were aseptic loosening (24.1%) and polyethylene wear (25%). And Saleh et al. (2006) reported polyethylene wear (24.5%) and tibial loosening (22.2%) as the main modes of mechanical failure in primary TKA. Aseptic loosening or wear was the cause of revision in 40.8% of patients with a TKR (Gioe et al. 2004). Of the ninety-four failed knee prostheses, six cases were revised due to wear debris and thirty-nine cases revised due to component loosening (Cameron & Hunter 1982). Of these, seven and thirty-two were femoral and tibial failures respectively. 3032 primary TKR cases (cemented with patellar resurfacing) were reported to the Norwegian Arthroplasty Register from 1994 to 2004, and the number of revisions due to component loosening (femoral/tibial), polyethylene wear and periprosthetic fracture were fifty-two, twenty-two and nine respectively (Furnes et al. 2007).

To achieve a strong fixation, a bone cement mantle made of *polymethylmethacrylate* (PMMA) is often used to anchor the prosthesis onto the bone. However the bone cement is a brittle material, prone to fatigue failure and is a poor transmitter of tensile and shear stresses (Rosenberg and Galante 1993). If the bone cement fatigues, it can lead to late aseptic loosening (Jasty et al. 1991; Lewis 1997) and a revision operation is necessary. Cementless fixation, which relies on bony ingrowth onto the prosthesis,

has gained popularity in recent years in addressing the concern of cement fatigue. Cementless prosthesis survival at 10 years of 95.6-97.1% were reported (Khaw et al. 2002; Hardeman et al. 2006). In a cementless fixation, the prosthesis is porous-coated to allow bone to grow into the pores so that in the course of time the two surfaces will be held together securely. A prerequisite for bone ingrowth is intimate contact between the prosthesis and bone with minimum interface motion post-operatively. In independent canine studies, it was found that the maximum interface micromotion that would allow bone ingrowth was 20-50 μ m (Pilliar et al. 1986; Burke et al. 1993; Jasty et al. 1997a). Therefore, a small or no interface movement is required for a good cementless fixation. Pre-clinical assessment of the interface micromotion of new cementless prosthesis design is necessary as part of the process to ensure long-term TKR performance.

After TKR, the mechanical loading conditions of the knee are altered due to the implantation of the prosthesis. The relatively high stiffness of the prosthesis causes most of the load to be transferred through the prosthesis rather than the bone - a phenomenon commonly known as “stress-shielding”. This results in the tibia and femur being subjected to lesser compressive stresses (and strains). According to Wolff’s law (1986), it effectively leads to remodelling of the bone (resorption). This has deleterious effects because it predisposes the prosthesis to loosen, and any revision surgery will have to be based on a weakened bone foundation. Complications and difficulties of revision arthroplasty as a result of absence of solid bone stock have been reported (Mintzer et al. 1990; Rand 1991a; Whiteside 1993; Levitz et al. 1995; Lonner et al. 2001; Soininvaara et al. 2004), and the management of bone loss remains a challenge for revision TKR procedures (Lotke et al. 2006; Backstein et al. 2006; Mulhall et al. 2006).

Clinically, bone resorption can be determined by measuring the bone composition using the *Dual Energy X-ray Absorptiometry* (DEXA) technique. A DEXA scan is a non-invasive method that measures the areal Bone Mineral Density (BMD, g/cm²). It is the current “gold standard” for bone density quantification. The BMD is also closely related to the mechanical bone strength (Petersen et al. 1996; An 2000). When the bone density decreases, the strength of the bone will decrease. As a result, it will lead to formation of weakening bone zones, loss of prosthesis-bone support,

breakdown of the intimate bond between cement and bone, and eventually component migration/loosening and bone fracture (Freeman et al. 1982; Carlsson et al. 1983; Lonner et al. 2001; Davis et al. 2005; Carlsson et al. 2006). The above described problems are caused partly by a lack of knowledge as to the optimum length needed for the prosthesis stems, as well as related prosthesis design and fixation technique factors. There is a need to develop analytical methodologies for the investigation of fixation performance and bone remodelling after TKR.

The *finite element method* (FEM) computational technique has been widely used in engineering fields for the investigation and understanding of the physics of behaviour and failure in engineering problems. In the field of orthopaedic biomechanics, the FEM has been employed to study the stress/strain behaviour in the bone surrounding a prosthesis (Bartel et al. 1982; Lewis et al. 1982; Tissakht et al. 1996; Au et al. 2005; Swider et al. 2006), periprosthetic bone remodelling (van Lenthe et al. 1997; van Lenthe et al. 2002; Barink et al. 2003; Nyman et al. 2004; Bitsakos et al. 2005), prosthesis-bone interface micromotion (Keja et al. 1994; Tissakht et al. 1995; Hashemi & Shirazi-Adl 2000), and wear performance of the prostheses such as the *polyethylene* (PE) insert (Liau et al. 2002). In any total joint replacement survivorship study of a new prosthesis (or improved version of existing design) or modified surgical technique, it needs at least 10 to 15 years follow-up before meaningful results are obtained. Potential failures (if any) will begin to surface 1-2 years after surgery. After analysing the failures, prosthesis design or surgical technique will then be rectified for it to be used in future patients. However for the existing patients, the possibility of them returning for revision surgery for failed TKR may be very high if there was inadequate pre-clinical evaluation. The FEM is a good assessment tool for pre-clinical analysis whereby faults can be determined and characterised at the design stage, and rectifications be made before clinical implementation. When the response of the bone to prostheses (stress/strain, bone density and interface micromotion) are simulated accurately, design features of the prostheses (stem length/diameter, slope/shape of the keel etc) and surgical techniques (amount of bone resected, varus/valgus deformity correction, cemented/cementless, varus/valgus malalignment etc) can be evaluated and the effects of these features can be studied parametrically.

There are 3 analytical approaches for performing biomechanical investigations in total joint replacement, namely *in-vivo (clinical or animal)*, *in-vitro (experimental)* and *computational (in-silico)*.

In clinical follow-up studies, bone resorption is evident with diversity in the bone loss regions surrounding the femoral and tibial components (Petersen et al. 1995; Levitz et al. 1995; Lonner et al. 2001; Soininvaara et al. 2004; Petersen et al. 2005; Miura et al. 2005; Abu-Rajab et al. 2006). This is largely dependent on the prosthesis design and fixation technique used by individual surgeons, which result in different stress shielding and load transfer patterns in the periprosthetic bone. Lonner et al. (2001) found a significant bone loss under the medial and lateral tibial plateau with the unstemmed Miller-Galante tibial prosthesis induced a lower BMD reduction than the Press-Fit Condylar prosthesis with a 4-cm central stem. Both prostheses were implanted with cement. Bone loss in the anterior distal femur region was found to be highly significant after 2 years, with the cementless fixation experiencing lesser bone resorption than the cemented one (Seki et al. 1999). For revision TKR performed due to loosening, there were more cementless TKR cases than cemented (Ryd et al. 1995; Fehring et al. 2001/2003). In a ten-year follow up study, Khaw et al. (2002) however reported equally good survival of the press-fit condylar TKR regardless of the cement technique. Tibial component migration measured by *Roentgen Stereophotogrammetric Analysis* (RSA) was observed to be higher for the cementless over the cemented fixation (Albrektsson et al. 1992; Ryd et al. 1995). On the other hand, femoral component rotation determined by RSA did not differ between the cemented and hydroxyapatite-coated (cementless) prosthesis types over time (Uvehammer et al. 2007). Radiolucency studies revealed that cemented tibial prostheses had fewer zones with radiolucent lines (clinical indication of loosening) than the uncemented group (Winemaker et al. 1998; Bassett 1998; Collins et al. 1991). In addition, inclusion of a metal back and a 110mm stem to the standard polyethylene component (cementless) significantly reduced both component migration and inducible displacement over two years (Albrektsson et al. 1990).

Laboratory-based in vitro bone strain measurements (Reilly et al. 1982; Bourne & Finlay 1986; Whiteside & Pafford 1989; Seki et al. 1998; Jazrawi et al. 2001; Bottlang et al. 2006) and prosthesis migration measurements (Walker et al. 1981;

Volz et al. 1988; Branson et al. 1989; Yoshii et al. 1992; Seki et al. 1997; Stern et al. 1997; Jazrawi et al. 2001) on human cadaver knees have been conducted extensively to assess the performance of different prosthesis designs and fixation techniques. Bourne & Finlay (1986) measured a reduction in strain of the cadaveric tibiae cortex due to stress-shielding by a stemmed cemented component (which will lead to cortical bone resorption of the proximal tibia), and discouraged the use of stemmed prostheses in clinical practice. Jazrawi et al. (2001) also reported a similar trend of decreased proximal tibial strain as the stem length and diameter were increased. In the same study, micromotion was measured for cemented and cementless tibial components which were stemless, or had short (75mm) or long (150mm) stems. A trend of lower micromotion of cemented fixation and of longer stem was evident. Subsidence of the tibial trays with a long stem was found to be significantly lower than the short stem or stemless groups (Yoshii et al. 1992).

In computational analysis, strain-adaptive bone remodelling theory has been applied in conjunction with the FEM for the prediction of the change in BMD after TKR. Higher bone loss in the femoral component was predicted for the stemmed over the unstemmed design, thick over a thin stem, and cemented over the cementless fixation (van Lenthe et al 2002). A long stem tibial component was predicted to decrease the proximal bone strain by 30-50% (Rawlinson et al. 2005). In preventing fracture failure of the proximal bone, a low stress level at the tibial plateau is desirable and could be achieved by using a metal-backed tibial tray with pegs instead of using an all-PE tibial component without pegs (Bartel et al. 1982). In modelling a cementless unstemmed tibial component with four pegs, the micromotion at the bone-prosthesis interface was predicted to be highest at the edge of the tray (Tissakht et al. 1995). This micromotion site coincided with the findings in clinical studies of similar prostheses where a high occurrence of radiolucent lines was observed at the edge of the tray (Hsu et al. 1995; Berger et al. 2001).

From the biomechanical studies illustrated above, critical conflicting design requirements for TKR are noted:

- i) Stemmed versus unstemmed - a stemmed prosthesis provides stability (lower micromotion and lower stress in the proximal cancellous bone) after operation,

however stress-shielding in the bone will be prominent. A shorter stem helps in preserving proximal bone stock, but long-term loosening is a concern.

ii) Cemented versus cementless - a cemented fixation provides immediate stability post-operation, with less occurrence of loosening failure leading to revision surgery, but bone loss in the long-term is a concern. While a cementless fixation reduces the possibility of bone resorption, failure due to loosening is undesirable.

iii) Reduction in tibial stress – if a stem is used to transfer load distally, it will minimise the chance of early compressive bone fracture, but then the stress-shielding effect may lead to bone resorption.

Although the design trends and requirements are known, no design optimisation has been done. The push for longevity in primary TKR could be achieved with better prosthesis designs, improved surgical techniques and most importantly a comprehensive understanding of the failure mechanisms of these prostheses. Computational and experimental analyses are useful for pre-clinical assessment of new and modified prosthesis designs and fixation techniques. This research project involved the development of computational modelling methods and in-vitro techniques for the analysis of fixation after TKR. The methods should be able and intend to i) provide explanations of mechanical related problems observed in TKR (such as stress-shielding and aseptic component loosening), ii) determine the root causes for failures, iii) predict the relative risk of fixation failure for new surgical techniques and prosthesis designs, and iv) implement prosthesis design changes/modifications to improve the performance of TKR. The computational models will be a useful tool for the design and analysis of prosthesis fixation to bone, and the methods should be applicable to all joint replacements.

1.2. Objectives and Scope

The objective of this research project was to develop analytical methods (computational/simulation models and in-vitro techniques) for the investigation of fixation performance after TKR, addressing the two major mechanical problems of *bone remodelling* and *aseptic component loosening*. It is essential for the developed tools to be able to:

- i) perform bone remodelling simulations and to investigate aseptic loosening (cemented and cementless fixations) after TKR,
- ii) provide biomechanical explanations for TKR failures and of the load transfer mechanisms between prostheses and bones,
- iii) optimise patient-specific (or problem-specific) prosthesis design.

The aim was to gain a better understanding of the design requirements in order to lead to knee prostheses and their fixation stems that will last longer and preserve the patients bone better. Ultimately, the surgeon should be able to select a suitable configuration of prosthesis design (type and size) and fixation technique (e.g. cemented or cementless), and implement surgical corrections (e.g. valgus/varus alignment) for optimal fixation performance based on each patient's pre-operative condition.

The tibial component of knee prostheses was selected for this study instead of the femoral component. The reason being that aseptic loosening and radiolucencies have occurred predominately in the tibial components of the knee prostheses (Hsu et al. 1995; Malkani et al. 1995; Duffy et al. 1998; Berger et al. 2001), while loosening and existence of radiolucent zones for the femoral components occurred less frequently (Colley et al. 1978; King & Scott 1985; Nilsson et al. 1995; Haas et al. 1995).

Numerous investigations on the impact of tibial component designs have been conducted, however they have separated the study of aseptic loosening and stress-shielding, while these phenomena are inter-related in-vivo. When the proximal bone resorbs due to stress-shielding around a stiffer prosthesis, a decrease in the bone strength will result in the formation of weakening bone zones and loss of bone-prosthesis support which can have a consequential effect on component loosening. In the other instance, loosening and component migration will alter the loading condition and load distribution in the periprosthetic bone, that may lead to further bone remodelling. It has been indicated that periprosthetic bone loss can be accelerated if the component is loose (Harris 2006). It is thus essential to investigate a novel method for fixation analysis to be performed in a unified manner so that the effects of prosthesis design features can be characterised optimally.

The uniqueness of the research included; i) quantitative analysis and explanation of stress-shielding and component loosening phenomena in TKR using the finite element method and bone remodelling computer algorithms, ii) FE simulations of the bone-prosthesis interface micromotions during gait and the influence on these of the bone remodelling process, iii) unified FE analysis and evaluation of bone resorption and aseptic loosening, iv) optimisation of the conflicting design requirements in relation to bone remodelling and loosening, v) characterisation of fixation performance of the new MIS mini-keel tibial prostheses, vi) correlation of patient-specific FE modelling predictions to tibial component migration, vii) exploring a modified technique for bone-prosthesis relative micromotion measurement (in-vitro) for a comparative study of the initial stability between the cemented and cementless (press-fit) tibial component fixations.

The scope of the project covered computational, in-vitro and in-vivo studies. The MSC Marc commercial finite element software (MSC.Marc 2005, MSC Software Corporation, Santa Ana, California, USA) was used for computational analyses. FE models for the tibia and femur were created based on CT images, and the prostheses were inserted virtually at the appropriate positions with the advice of the surgeons. Physiological joint loads were then prescribed. Predictions of the stresses and strains, bone mineral density and interface micromotion were used for analysis. Parametric studies of prosthesis designs on the fixation performance of the tibial components were conducted and parameters influencing the accuracy of FEM results were investigated. New codes were developed and written in the strain-adaptive bone remodelling algorithm to capture the bone-prosthesis interface micromotion as the bone remodelled due to its altered load conditions. The FE models were validated with in-vitro tests using cadaveric tibiae and a prospective in-vivo study performed in the Singapore General Hospital (SGH), Singapore. The in-vitro work involved the measurements of bone strains and bone-prosthesis relative movement with the use of cadaveric tibiae. A novel technique was explored to measure the initial stability of a tibial fixation and relating it to late aseptic loosening of the tibial fixations. The in-vivo study was conducted in collaboration with the Department of Orthopaedic Surgery, SGH. Forty patients were recruited for the purpose of comparing the fixation performance of the MIS mini-keel tibial prostheses with the conventional stemmed design. Component migration (translation and rotation) at intervals of six, twelve,

eighteen and twenty-four months were to be measured by RSA. Statistical analysis was performed to assess the fixation performance of different prosthesis designs.

1.3. Structure of the Thesis

This thesis is structured into nine chapters. The first four chapters provide an overall view of the total knee replacement and its related biomechanical studies. The subsequent four chapters detail the biomechanical analyses performed in this project for the investigation of bone resorption and component loosening in TKR.

Chapter One consists of the introduction. Chapters Two details the mechanical properties and remodelling processes of the bone. Chapter Three provides a description of the biomechanics of the knee, the requirements of total knee replacement and its clinical aspects. Chapter Four outlines the literature review on the biomechanical (engineering) analyses for total knee replacement.

Finite element analysis of the fixation of the tibial component of knee prostheses and the key developments of the computational models are detailed in Chapter Five. The developed models were then used for the study of the MIS mini-keel tibial prosthesis fixation as described in Chapter Six. The in-vivo study and validation of the FE predictions with RSA measurements are also detailed in this chapter. Chapter Seven discusses the factors and parameters that would influence the FE models and predictions. The in-vitro cadaveric study of the tibial prosthesis fixation is outlined in Chapter Eight.

Chapter Nine concludes the current study and provides proposals for the future work.

CHAPTER 2. BONE: ITS MECHANICAL PROPERTIES AND REMODELLING PROCESSES

2.1. Composition and Structure of Bone

Bone is an important and dynamic tissue in the human body, which continually models and remodels due to the forces acting on it (Hall 2004). It serves two critical mechanical functions of, i) providing a rigid skeletal framework to support and protect the internal organs and body tissues, ii) forming a system of rigid levers that can be moved by forces from the attaching muscles. The major mineral constituents of the bone are calcium carbonate, calcium phosphate, collagen and water. Calcium carbonate and calcium phosphate constitute approximately 60-70% of the dry bone weight, and are the primary determinants of the bone stiffness (modulus) and its compressive strength. Collagen is a protein that provides flexibility and contributes to the bone's tensile strength. The remaining 25-30% of bone is made up of water. The bone tissue can be classified into two categories depending on its porosity, or the percentage of the bone volume that is occupied by non-mineralised tissue. If the percentage falls within 5-30% (i.e. low porosity), the bone is termed as cortical (or compact). If the percentage is relatively high of 30% to greater than 90%, the bone is termed as cancellous (also called trabecular or spongy bone). The cancellous bone has a honeycomb structure with mineralised vertical and horizontal bars known as trabeculae. The spaces between the trabeculae are filled with marrow and fat (see Fig. 2.1).

In a long bone (Fig. 2.1), the cortical bone forms most of the diaphysis (centre portion, roughly cylindrical in shape) and the thinner surfaces of the other areas. The cancellous bone is located mainly in the epiphyses and metaphyses of the long bone, and forms the interior of all other bones. The outer surface of the bone is covered by a dense connective tissue called the periosteum, which contains blood vessels and nerves. The inner surface of the medullary cavity (or canal) is lined with a thinner connective tissue membrane called the endosteum. The periosteum and endosteum contain osteoblasts (bone-forming cells) that are responsible for bone growth, as well

as repair and remodelling of the bone. The endosteum also contains osteoclasts (giant multinucleated bone cells) which are responsible for the resorption of bone.

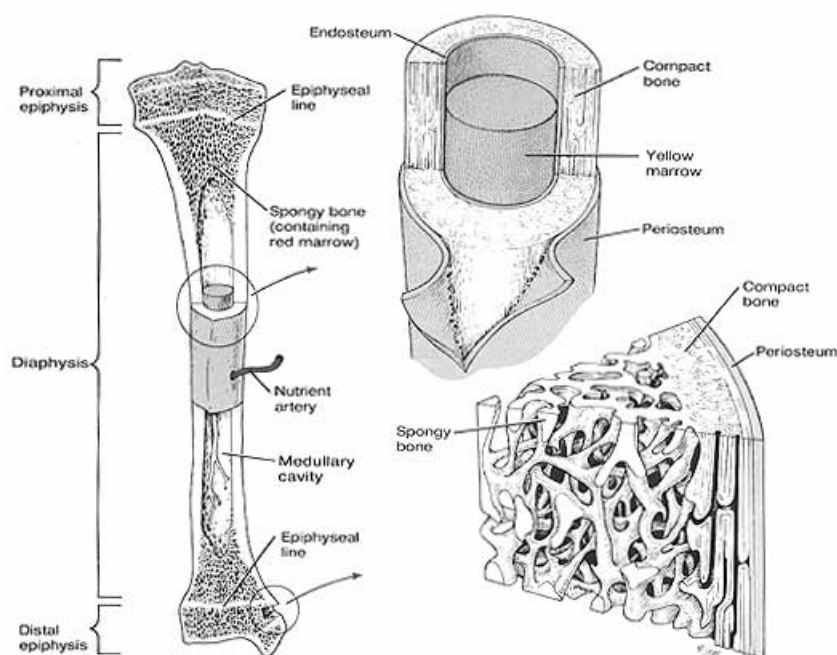


Figure 2.1: Macro structures of the bone (from “Basic Medical Anatomy”, Spence 1990).

Rho et al. (1998) highlighted the importance of the hierarchical structure of bone in relation to its mechanical properties. They noticed that the mechanical properties of bone varied at different levels and structures. The levels collectively are, i) the macrostructure: cortical and cancellous bone, ii) the microstructure (from 10 to 500 μ m): Haversian systems, osteons, single trabeculae, iii) the sub-microstructure (1–10 μ m): lamellae, iv) the nanostructure (from a few hundred nanometers to 1 μ m): fibrillar collagen and embedded mineral, and v) the sub-nanostructure (below a few hundred nanometers): molecular structure of constituent elements, such as mineral, collagen, and non-collagenous organic proteins. This hierarchically organized structure (see Fig. 2.2) has an irregular, yet optimized, arrangement and orientation of the components, making the material of bone heterogeneous and anisotropic. As Rho et al. (1998) noted, degenerative diseases of bone such as osteoporosis and osteoarthritis may be influenced by the microstructures of different levels. If some diseases (or syndromes) are contained at specific level(s), they may become easier for a treatment to be found. It is also possible to isolate the physical scale where the most clinically relevant changes in the bone quality originate (Hernandez & Keaveny

2006). The classic mechanical studies of bone have been mainly at the macro and micro structural levels. This relatively new and closely linked hierarchical structure of bone reveals that new research is needed at the sub-micro and beyond levels to advance the understanding of the bone.

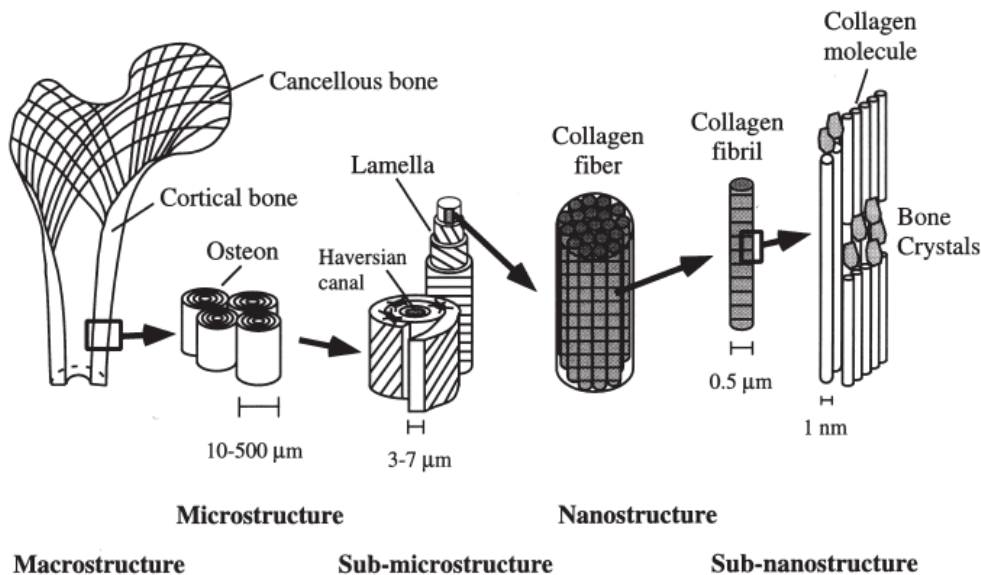


Figure 2.2: Hierarchical structural organisation of bone (from Rho et al. 1998).

2.2. Mechanical Properties of Bone – Cortical and Cancellous

The porosity of bone influences the mechanical characteristics of the tissue. With a higher mineral content, the cortical bone is stiffer and able to withstand greater stress. The cancellous bone, which is less dense and weaker, however it is able to undergo more strain before failure. Mechanical properties of bone can be measured using traditional mechanical test methods like uniaxial tensile or compressive testing, 3- or 4-point bending, and torsion test. More sophisticated techniques like micro and nanoindentation, and acoustic tests are employed for cancellous bone and bone at a microstructural level (Turner & Burr 2001).

Anisotropic and Heterogeneous Properties of Bone

The mechanical properties of the cortical and cancellous bones are anisotropic in nature (Galante et al. 1970; Williams & Lewis 1982; Keaveny & Hayes 1993). The strength and elastic modulus (E) are dependent on its orientation with the orthogonal

axes: i) superior-inferior (SI), ii) anterior-posterior (AP), and iii) medial-lateral (ML). Usually the properties along the AP and ML directions for the cortical bone are similar, i.e. transverse isotropic, but not necessary for the cancellous bone. Modulus and strength for the cortical bone are highest along the SI direction (0° , longitudinal), lowest at the AP/ML direction (90° , transverse), and intermediate values with angles between 0° and 90° (An 2000). For the cancellous bone, it is anisotropic based on its trabecular morphology (Keaveny & Hayes 1993; van Rietbergen et al. 1995). The apparent modulus of cancellous bone in the SI direction was found to be about 2.5 times larger than in the AP direction in a human long bone, and the AP value is higher than the ML direction (Ciarelli et al. 1991). From testing a single human proximal tibial epiphysis bone, Williams & Lewis (1982) found the cancellous bone structure is approximately transverse isotropic (average modulus values, $E_{\text{transverse1}}=51.0\text{MPa}$, $E_{\text{transverse2}}=37.2\text{MPa}$, and $E_{\text{longitudinal}}=227.4\text{MPa}$). Note that these properties are the apparent values for the porous trabecular structure as a whole, not the actual material properties of the bone material of individual trabeculae.

The cortical and cancellous regions of bones are also mechanically heterogeneous, and their properties are anatomically site dependent. For example, in a detailed study performed by Goldstein et al. (1983) on the human proximal tibia, they found that the moduli of the cancellous bone at different locations within the same metaphysis can differ by 100 times. In testing the cortical bone of bovine tibias by Pope & Outwater (1974), the elastic modulus and strength were found to be highest at the mid-diaphysis, and decreased gradually at the epiphyses (see Fig. 2.3). The properties are highly anisotropic at the mid-diaphysis (large variation between longitudinal, radial and circumferential orientations) and almost isotropic at the epiphyses. When tested on a microstructural level (cross-section $100\text{-}170\mu\text{m}$) using 3-point bending test, the mean elastic moduli are 1.15GPa , 4.59GPa and 5.44GPa for the subchondral, cancellous and cortical bone tissues respectively (Choi et al. 1990). In a survey of published data by Goldstein (1987), he concluded that the mechanical properties of bone are largely dependent on anatomical sites.

Elastic Modulus and Yield Strength for Bone

A wide range of the elastic modulus and yield strength for cortical and cancellous have been reported. The elastic modulus and strength of the cortical bone can vary from 5-34.3GPa and 35-295MPa respectively, depending on the type of mechanical tests and the anatomical sites and orientation of test specimens. The values of modulus and strength for cancellous bone are 10-1570MPa and 1.5-38MPa respectively (An 2000). Guo (2001) reported the elastic modulus for cortical bone to be 17.4GPa and 9.6GPa in the longitudinal and transverse directions of the long bone respectively. Keaveny & Hayes (1993) noted that the modulus of cancellous bone could vary from 20-5000MPa.

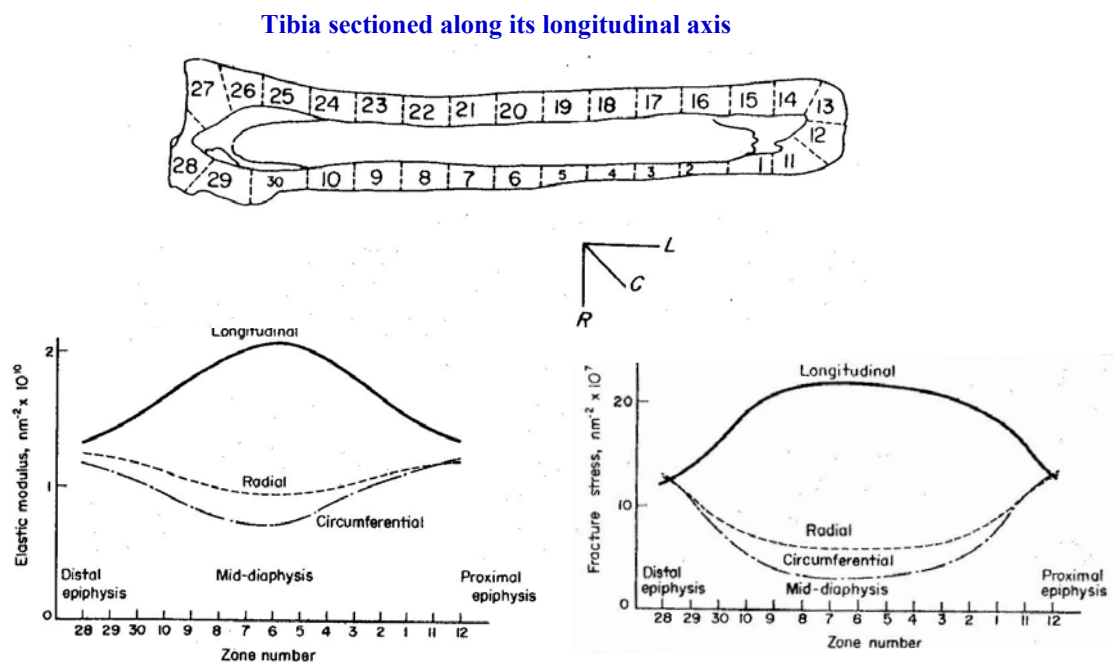


Figure 2.3: Variation of modulus and strength with locations in the tibia (from Pope & Outwater 1974).

Stiffness and Strength in Relation to Apparent Density

There is a strong correlation between the mechanical properties of bone (cortical and cancellous) and its apparent density (ρ), with various relationships determined over the years. In the early 1970's, Galante et al. (1970) reported a linear relationship between the strength and apparent density of cancellous bone. In using human tibia

and bovine femur cancellous bone specimens with and without marrow, Carter & Hayes (1977) established their strain rate dependent relationship where the elastic modulus is proportional to the cube of the apparent density, and the strength (S) is proportional to the square of the apparent density:

$$E = 3790 \varepsilon^{\bullet 0.06} \rho^3 \quad \text{--- (2.1)}$$

$$S = 68 \varepsilon^{\bullet 0.06} \rho^2 \quad \text{--- (2.2)}$$

where E is in MPa, and ρ in g/cm^3 . Carter and Hayes explained that because the compositions, true tissue densities, and microscopic material properties of cancellous and cortical bone are similar, cortical bone can be considered as a denser cancellous bone. Thus by analysing the cancellous bone test data with reference to the values for the mechanical behaviour of cortical bone (some of which were of bovine specimens) reported in the literature, the developed expressions can be extended for cortical bone. These empirical relationships are anatomically site independent, and have been adopted in many bone related studies (Kerner et al. 1999; van Lenthe et al. 2002; Perillo-Marcone et al. 2004; Bitsakos et al. 2005; Turner et al. 2005). In the late 1980's, Rice et al. (1988) however questioned the validity of the Carter and Hayes relationships. They argued that the data of human and different species cannot be combined to form interspecies mechanical properties relationships, as their analysis showed a statistically distinct difference of modulus and strength between human and bovine cancellous bones. In addition, they also argued that the properties of cortical bone cannot be extrapolated from cancellous bone data, and disagreed that cortical bone is a “densified” cancellous bone. They found instead that both the elastic modulus and strength were proportional to the square of apparent density. Using an ultrasonic technique to determine the modulus of bone, Rho et al. (1995) established another set of modulus-density relationships at different anatomical sites for the 3 orthogonal axes of SI, ML and AP. Some of the expressions are as below:

$$E = -3.842 + 0.013\rho \quad (\text{cortical bone, SI axis}) \quad \text{--- (2.3)}$$

$$E = 0.51\rho^{1.37} \quad (\text{proximal tibia cancellous bone, SI axis}) \quad \text{--- (2.4)}$$

$$E = 0.82\rho^{1.47} \quad (\text{distal femur cancellous bone, SI axis}) \quad \text{--- (2.5)}$$

where E is in GPa and MPa for cortical and cancellous bone respectively, and ρ in kg/m^3 .

Morgan et al. (2003) also demonstrated the site-specificity of the modulus-density relationships with a power law relationship for the proximal tibia:

$$E = 15520\rho^{1.93} \quad \text{--- (2.6)}$$

where E is in MPa, and ρ in g/cm^3 . A number of different studies have also been conducted to relate strength to density for the tibial cancellous bone (Odgaard et al. 1989; Hvid et al. 1989; Linde et al. 1989). Although there are many different linear and power relationships for cancellous bone, their predictive power is negligible since the range of apparent density exhibited is usually quite small (Hvid et al. 1989; Keaveny & Hayes 1993). Cortical bone has an average apparent density of approximately 1.9g/cm^3 , and the cancellous bone ranges from $0.14\text{--}1.10\text{g/cm}^3$ (An 2000).

The apparent density values of bone can be derived from *Computed Tomography* (CT) scan data. A linear correlation between the CT number, or *Hounsfield Units* (HU), and apparent density was established for vertebral bone (Cann & Genant 1980; McBroom et al. 1985) and proximal tibial bone (Hvid et al. 1989). With the modulus-apparent density relationships available, the mechanical properties of bone can be determined in a non-invasive way.

Viscoelastic Behaviour of Bone

It is known that bone exhibits viscoelastic behaviour (Sasaki 2000; Lakes 2001), which has an influence on material performance. The mechanical behaviour of the bone varies with the rate at which it is loaded. The bone can sustain a higher load when loads are applied at higher rates. A change in strain rate produced a larger change in yield strength than the elastic modulus (Nordin & Frankel 2001). Thus the loading rate is clinically important because it will influence the stress patterns in bone of different patients and it is the stresses on the bone which affect the durability of the fixation of joint replacements. However, very few investigations to characterise bone viscoelastic properties have been conducted as compared to the vast literature on elastic modulus, strength and density (Rimnac et al. 1993; Bowman et al. 1994; Bowman et al. 1998; Moore et al. 2004; Norman et al. 2006). It would be beneficial

for viscoelastic constitutive equations to be developed and eventually incorporated into FE models to study the effect of viscoelasticity on mechanical responses of bone and prosthesis-related issues. Limited viscoelastic FE modelling of bone has been attempted (Shultz et al. 2006).

2.3. Mechanical Properties of Tibia and Femur

Based on the review of published data, Goldstein (1987) observed a wide range of modulus and yield strength values for the cancellous bone in the proximal tibia and distal femur. For the proximal tibia, the modulus and yield strength ranged from 1.4-552MPa and 0.2-116MPa respectively. For the distal femur, the modulus and yield strength were 7.6-2942MPa and 0.56-66.2MPa respectively. A summary of mechanical properties based on the current author's own review is listed in Table 2.1.

Two particular sets of results are highlighted. Behrens et al. (1974) characterised the yield strength of the cancellous bone at the femur and tibia, and compared the difference between healthy and arthritic knees. There was a wide variation in the bone strength from both the healthy and arthritic knee specimens (heterogeneous). For the healthy knees, the average compressive strength was 20.25MPa and 17.72MPa for the femur and tibia respectively. The bone was found to be stronger on the medial side than on the lateral (both femur and tibia). For the arthritic knees, the overall strength was lower than the healthy ones. For those with marked varus or valgus deformity, the femoral bone on the highly stressed condyle was stronger than normal, while the off-loaded condyle was comparatively weaker. Goldstein et al. (1983) performed a detailed mechanical characterisation of five human proximal tibias. Cancellous bones cubes were obtained at four different levels of the tibia (10mm intervals), and across the tibial plateau. The compressive moduli were found to vary from 4 to 430MPa, and the average values as a function of location are shown in Fig. 2.4. Across the plateau, the bone was stiffer at the medial/lateral condyles (loading-bearing areas) and less stiff at the intercondylar area. Along the longitudinal axis, the stiffness of the bone reduced distally. Similarly, bone strength decreased with depth from the resected surface of the proximal tibia and distal femur (Hvid 1988). These observations are in agreement with Wolff's law of bone remodelling where the bone strength will

increase with the applied functional force. A linear relationship was found between the yield strength and elastic modulus (Goldstein et al. 1983):

$$\text{Yield Strength} = 0.0265 \times \text{Elastic Modulus} \quad \text{--- (2.7)}$$

These mechanical properties have since been widely used in many FEM studies on knee joint (Murase et al. 1983; Vasu et al. 1986; Tissakht et al. 1995; Hashemi & Shirazi-Adl 2000; Iesaka et al. 2002).

Table 2.1
Summary of mechanical properties for tibia and femur bones

Authors	Site / Type	Test Method	Properties
Tibia (cancellous):			
Behrens et al. 1974	Human femoral condyles and tibial plateaus 10 fresh autopsy knees	0.785cm ² indenter	Average (range): Strength (Femur) = 20.25MPa Strength (Tibia) = 17.72MPa
Carter & Hayes 1977	Human tibial plateau	Uniaxial compression	E = 10-500MPa Strength = 1.5-50MPa
Williams & Lewis 1982	Human proximal tibia epiphysis Single human bone, dried, defatted, rewetted	Compression test ran at strain rate 0.005 s ⁻¹	Average (range): E (longitudinal) = 227.4MPa (44.7-475.7MPa) E (transverse 1) = 51.04MPa (8.3-130.3MPa) E (transverse 2) = 37.23MPa (9.0-84.1MPa)
Goldstein et al. 1983	Human tibia metaphysis 5 fresh autopsy tibias	Uniaxial compression	Range: E = 4-430MPa Strength = 0.0265 × E
Ashman et al. 1989	Human proximal tibias 3 fresh autopsy tibias	Ultrasonic technique	Range: E = 340-3350MPa
Linde et al. 1990	Human proximal tibial epiphysis 5 fresh autopsy knees	0.5% strain controlled non-destructive compression	Average (range): E (SI) = 267MPa (67-734MPa) E (ML) = 84MPa (17-493MPa) E (AP) = 83MPa (18-481MPa)
Femur (cortical):			
Reilly & Burstein 1975	Human femur	Uniaxial tension and compression	Average : E (longitudinal) = 17.0GPa E (transverse) = 11.5GPa Strength (long., tension) = 133MPa Strength (long., comp) = 193MPa Strength (trans., tension) = 51MPa Strength (trans., comp) = 133MPa
Cuppone et al. 2004	5 pairs of human femurs	3-point bending test	E = 18600 ± 1900MPa

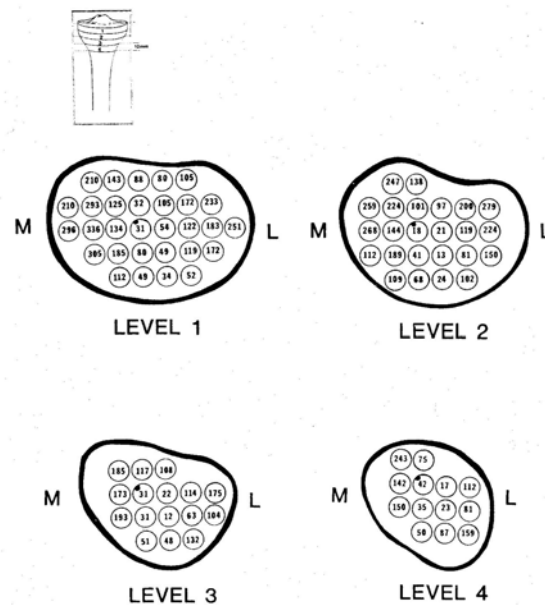


Figure 2.4: Elastic moduli (MPa) as a function of location in the proximal tibia (from Goldstein et al. 1983).

2.4. Bone Remodelling Nature and its Related Theories

In 1892, Julius Wolff (a German scientist and anatomist) published his famous law on bone remodelling that the alteration of the internal architecture and external form of the bones occurs as a consequence of primary changes in the stresses (or strains) of the bones (Wolff 1986). In another words, the law indicates that the bone mass (or strength) will increase or decrease as the functional forces acting on the bone increase or decrease. The bone modelling and remodelling processes, which include apposition and resorption, are directed by the osteocytes—cells that are embedded in bone that are sensitive to changes in the flow of interstitial fluid through the pores resulting from strain on the bone (Hall 2004). In response to a detected strain change, the osteocytes will trigger the actions of osteoblasts (bone-forming cells) and osteoclasts (bone-resorbing cells). A predominance of osteoblastic activity will result in an increase of bone mass (hypertrophy), while osteoclastic activity dominance will result in a reduction of bone mass (atrophy). When the rate of the two activities is balanced, the structural integrity of bone remains unchanged while the turnover of material continues.

Based on the above conceptual observations and actual biological behaviour, it was hypothesised that the basic structure and mass of the bone is dependent on its mechanical loading histories, i.e. the amount of strain change, in a nonlinear manner as shown in Fig 2.5 (Carter 1984). Normal physiological activities are required to maintain a level of normal bone mass, wherein the bone tissue is fairly unresponsive to changes in load histories. It is termed as “*dead zone*” by other researchers. When the strain exceeds the normal activity range due to severe loading, bone mass will increase. However immobilisation can lead to severe bone loss. The hypothesis also suggests that the bone mass gain with normal activities will stabilise when a bone reaches maturity.

The phenomenon of bone remodelling is a complex biological process which is dependent on genetic, hormonal, metabolic, age-related factors as well as functional requirements. Several bone remodelling theories (or mechanical models) have been formulated to explain Wolff’s law and the functional adaptation of bone quantitatively. The general concept of a bone remodelling theory is an adaptive feedback control process of the bone, shown schematically in Fig. 2.6 (Hart 2001). The bone is subjected to external forces and converted to internal loads, thereby inducing stresses and strains. The sensors in the control process will detect these mechanical responses and the transducers will convert them into cellular responses triggering the remodelling potential. This potential will cause osteoblast/osteoclast activity leading to bone formation and resorption. A normal load condition will lead to homeostatic equilibrium with no change in bone morphology. An abnormal load will result in gradual change of the bone shape and/or density. As such, the stresses and strains in the bone will change, again affecting the remodelling potential. This process will continue until the structure has adapted sufficiently, the feedback signal will diminish and further change in shape and density will be stopped. To model the adaptive process, there must be some mechanical features which are measurable, called the *stimulus*, to activate the bone response. Cowin (1984) argued that the stimulus should be strain and not stress, as strain is a primary and direct measurable physical quantity representing a deformation whereas stress is secondary and being computed indirectly. Hart et al. (1984b) defined strain as the stimulus, and other forms of mechanical stimulus used include strain energy (Fyhrie & Carter 1986;

Huiskes et al. 1987; Harrigan & Hamilton 1992), strain rate (Lanyon 1984) and damage-based (Prendergast & Taylor 1994; Doblaré & García 2001).

Two other aspects to be considered in a bone remodelling theory are *site dependence* (or *site specificity*) and *time dependence* (Hart 2001). It is clear that different bones provide different mechanical functions and thus are subject to different loads. For instance the tibia is a major load-bearing bone whereas the radius is only subjected to functional load like carrying things or playing sports. The adaptation response of the osteoblasts and osteoclasts at these 2 bones may be different. It is even stated that the biological environments of the periosteal and endocortical surfaces of the same bone could be different, both in terms of the “remodelling equilibrium” values and the speed of the cell-mediated adaptive responses (Hart 2001). This would have a significant impact on the bone remodelling models whether different parameters are needed for different anatomical sites, or if it is reasonable to assume that the response is site independent. A family of hypothetical bone remodelling curves (similar to Fig. 2.5) was drawn to suggest that no single curve is applicable for all bones or in all regions of a single bone (Beaupré et al. 1990a). As of to date, some degree of site dependence is assumed in most remodelling theories. For *time dependence*, it is necessary to account for how long it will take for a bone to decrease or increase by a specific amount of density. At present, it remains a challenge for the bone remodelling theories to predict whether a change of bone morphology will take place within weeks or months. More readings on bone remodelling theories can be found in the Chapter written by Richard Hart (Hart 2001). Among the many established theories, two which are of “strain-based” stimulus, will be described in detail here. These two theories are quasi-static, thus the effects of loading rate, viscoelasticity and inertia were not considered.

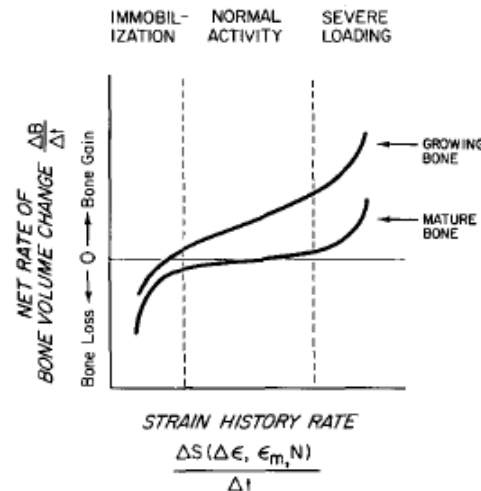


Figure 2.5: Hypothesis of relationship between bone strain history and its remodelling rate (from Carter 1984).

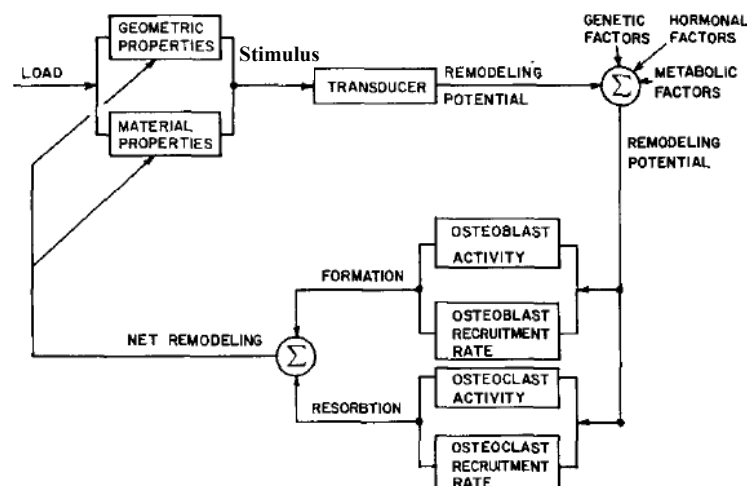


Figure 2.6: Schematic diagram for adaptive feedback control process of the bone (from Hart 2001).

Beginning from 1976, Cowin and his associates (Cowin & Hegedus 1976; Hegedus & Cowin 1976; Cowin & Nachlinger 1978; Cowin & van Buskirk 1978; Cowin & Firoozbakhsh 1981) developed the “*Theory of Adaptive Elasticity*” (AE) progressively to describe the remodelling behaviour of cortical bone where an elastic material adapts its structure to applied loading. This is a comprehensive phenomenological theory based on linear elasticity theory enhanced by additional constitutive equations that allow for changes in the density (thus stiffness) and external shapes of the cortical bone. According to Frost (1964), bone remodelling can be divided into two classes of either internal or external (surface) remodelling. For *internal remodelling*, the bone is

only able to adapt to its density (or a change in volumetric porosity). For *external remodelling*, the bone can only deposit or resorb on a bone surface (i.e. on the periosteal and endosteal surfaces resulting in geometry change). Constitutive remodelling rate equations are then formalised to relate the rate of bone tissue deposition and resorption to the mechanical stimulus (Cowin 1993; Juo et al. 1995). An internal remodelling rate equation specifies the rate of change of bone density ρ at each point “X” in the bone tissue as a function of density at point “X” and the change in bone remodelling stimulus at point “X”:

$$\frac{\partial \rho}{\partial t}(X) = f(\rho(X), \text{change in stimulus at } X) \quad \text{--- (2.8a)}$$

$$\text{or} \quad \frac{\partial \rho}{\partial t}(X) = A [S(X) - S_0(X)] \quad \text{--- (2.8b)}$$

where A is a remodelling constant, S is the actual stimulus, and S_0 is the reference stimulus at homeostatic equilibrium. The external remodelling rate equation specifies the velocity V of the remodelling bone surface at a surface point “X” as a function of the change in bone remodelling stimulus at surface point “X”:

$$V(X) = f(\text{change in stimulus at the surface } X) \quad \text{--- (2.9a)}$$

$$\text{or} \quad V(X) = B [S(X) - S_0(X)] \quad \text{--- (2.9b)}$$

where B is another remodelling constant.

The remodelling rate equations can be site specific if they depend on the specific anatomical site of point “X” where it is to be applied. The mechanical stimulus used is strain tensor for the concept of AE. This AE theory can also be supplemented to simulate cancellous bone remodelling behaviour (Hart 2001), with complexity involved however. The theory of AE was implemented in finite element modelling to study strain-induced remodelling in long bone (Hart et al. 1984a).

Noting that the AE theory neglected the influence of strain history effects on cortical bone remodelling rate, and the difficulty in applying it to cancellous bone due to lack of accountability for the adaptation of the direction of the materials anisotropy to load, Carter and his associates progressively established another bone remodelling theory for cancellous bone based on a “*self-optimisation*” principle of a material (Carter &

Hayes 1977; Fyhrie & Carter 1986; Carter 1987; Carter et al. 1987a; Carter et al. 1987b). Fyhrie & Carter (1986) developed a unified theory to relate the change in trabecular orientation and apparent density of cancellous bone with applied stress. The mechanical stimulus chosen was strain energy density with the assumption that the bone has the goal of optimising its stiffness using the least material. By assuming bone to be a self-optimising material, it will try to align its trabecular orientation with the principal stress directions. After the alignment, its apparent density will be proportionate to an “effective stress”. In this way, both the bone architecture and the change of bone mass can be predicted. The above is also termed the *Bone Maintenance Theory*. Recognising the importance of repeated loading of the bone with different loading conditions and widely varying number of loading cycles, a general method of defining the daily load history within the bone maintenance theory was introduced (Carter et al. 1987a). The stimulus required to activate the bone response is defined as a function of the strain energy density, loading cycles and apparent density:

$$S^* \propto \frac{1}{\rho^k} \sum_{day} n_i U_i^k \quad \text{--- (2.10)}$$

where U is the strain energy density, i is the number of different loading conditions, n is the number of loading cycles, and k is a constant. By assuming the stimulus is constant everywhere, the bone apparent density can be approximated as:

$$\rho \propto [\sum n_i U_i^k]^{1/k} \quad \text{--- (2.11)}$$

Similar forms to Eqs 2.10 and 2.11 were also defined for stress (“effective stress”) and fatigue damage stimuli. The “load history bone maintenance” theory was expanded into a time-dependent remodelling theory for internal and external remodelling suitable for both cortical and cancellous bone, and accounting for the bone surface area available for osteoblastic and osteoclastic activities (Beaupré et al. 1990a/1990b). A general idea was proposed by Lekszycki (1999) to combine both the theories of adaptive elasticity and bone maintenance. The approach was a simplified one-dimensional case to introduce a possible method of deriving the adaptation laws by means of optimisation methods being used in structural optimisation. However further investigation was needed to apply the approach to real tissue behaviour.

Bone remodelling has a significant impact on TKR. Stress-shielding due to implantation of a metallic prosthesis will result in the loss of bone mass. It will have an adverse effect on the stability of the prosthesis and eventually its long-term fixation reliability. Bone-adaptive theories can be formulated into finite element codes for the analyses of periprosthetic bone remodelling in clinical cases, in order to perform “pre-clinical” trials. The use of bone-adaptive remodelling FE algorithms for periprosthetic bone remodelling study in TKR will be discussed in Chapter 4.

2.5. Summary

From the great variation in the properties and complicated behaviour of bone, factors such as anatomic sites, species, age, loading directions should be specified when describing its mechanical properties. In the current study, the mechanical properties of the tibia are of particular importance as they will affect the accuracy of the FE results generated. The detailed heterogeneous elastic moduli determined by Goldstein et al. (1983) and the CT based HU-density-modulus relationships were used for the FE modelling.

CHAPTER 3. THE KNEE, TOTAL KNEE REPLACEMENT AND ITS CLINICAL ASPECTS

3.1. Anatomy and Biomechanics of the Knee

3.1.1. Anatomy of the Knee

The knee is the largest human synovial joint. It is made up of 3 major bones, the *femur*, *tibia* and *patella* joined together by ligaments and muscles (see Fig 3.1). It consists of two articulating joints namely the *tibiofemoral* (TF) and *patellofemoral* (PF) joints. The tibiofemoral joint is a dual condyloid articulation between the medial and lateral condyles of the tibia and femur, constituting the main joint of the knee. The patellofemoral joint is an articulation between the patella and the femur. There are many ligaments (connective tissue from bone to bone) crossing the knee joint providing its stability. The *anterior cruciate ligament* (ACL) and *posterior cruciate ligament* (PCL) limit the forward and backward sliding of the femur on the tibia plateau during knee flexion and extension, and limit hyperextension. The *medial collateral ligament* (MCL) and *lateral collateral ligament* (LCL) prevent the abduction-adduction motion at the knee. They are also called the tibial and fibular collateral ligaments respectively. The triangularly shaped patella glides along the trochlear groove of the femoral condyles, being held in place by the patellar ligament and the quadriceps tendon (a connective tissue between muscle and bone). At the end of the proximal tibia and distal femur, the articulating surfaces are covered by a thin layer of *articular cartilage*. It is a special type of dense white connective tissue typically 1-5mm thick. The articular cartilage serves 2 main purposes, i) it spreads loads at the joint over a wide area so that stress at any contact point between the bones is reduced, ii) it allows movement of the articulating bones with minimal friction and wear. Two fibrocartilagenous structure known as the *menisci* are firmly attached to the tibial plateau. The menisci help in distributing the load at the knee over a larger surface area and absorbing shock during impact, bearing as much as an estimated 45% of the total load when walking. The knee joint is crossed by many muscles that assist in its movement. They are the *quadriceps* (*rectus femoris*, *vastus lateralis*, *vastus*

medialis & vastus intermedius), *hamstrings* (*semitendinosus*, *semimembranosus* & *biceps femoris*), *sartorius*, *gracilis*, *popliteus*, *gastrocnemius*, and *plantaris*. The functions of the different muscles will be described in the next section. The above anatomical descriptions are extracted mainly from Hall (2004).

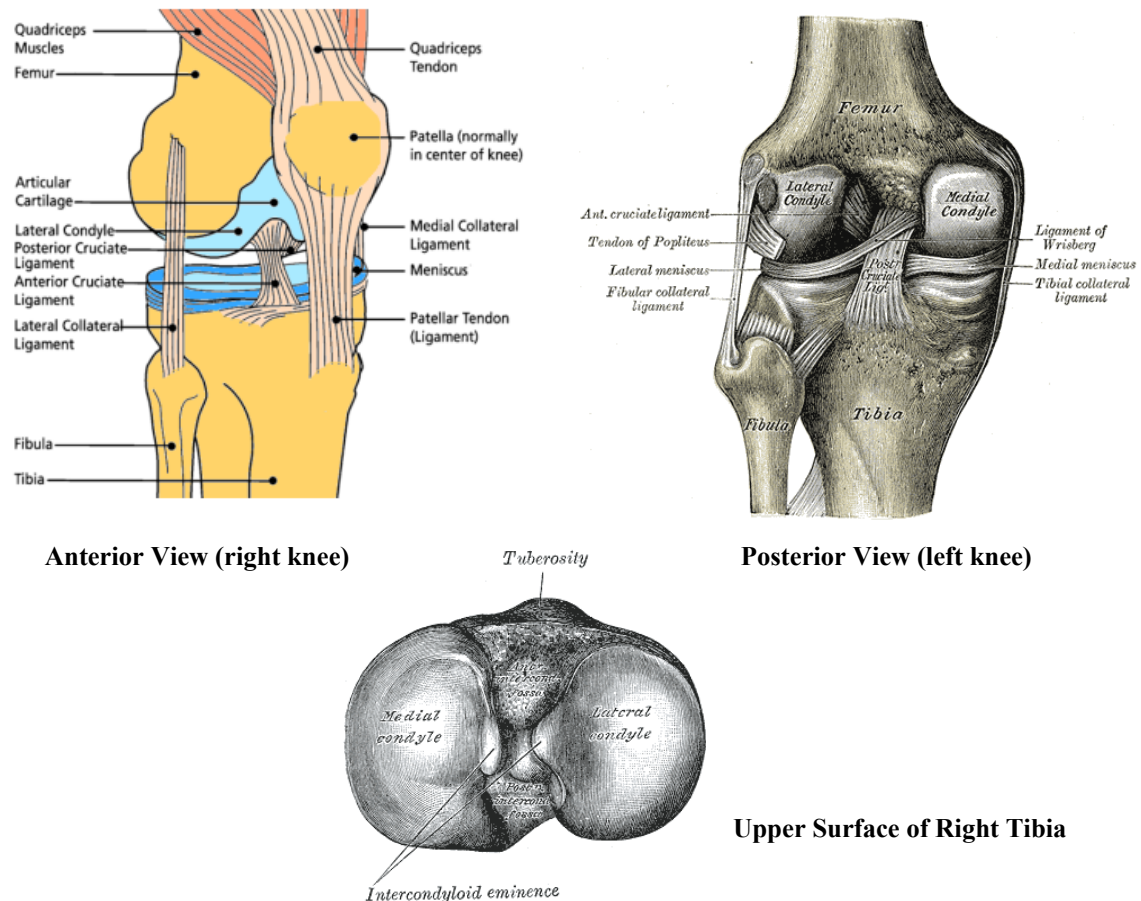


Figure 3.1: Anatomy of the knee joint (the anterior view is from <http://www.conformis.com>, June 2009; the posterior and upper surface views are from Gray 1918).

3.1.2. Biomechanics of the Knee

The knee joint has six degrees of freedom (DOF) for movement (Fig. 3.2), with *flexion* and *extension* (in the sagittal plane) being the primary movements. The knee joint is classified as a modified *hinge joint* as the movement is mainly restricted to only one plane (sagittal) by the connecting ligaments, with some lateral and rotation allowed (see Fig. 3.3). The knee is extended by the quadriceps muscles, and flexion is caused by hamstrings and assisted by gracilis, sartorius, gastrocnemius and plantaris. The flexed joint can be rotated internally-externally independently of the flexion and

extension by the muscles which attach at the sides of the joint. Biceps femoris is the main external rotator of the tibia; sartorius, gracilis, semitendinosus and semimembranosus are internal rotators of the tibia. The main joint movement is a combination of rolling, sliding and rotation of the femoral condyles over the tibial plateaus (Kapandji 1987). When the knee is extending, the femoral condyles roll forward and slide backward on the tibial condyles, and the points of contact with the tibia move steadily forward on the femoral condyles. There is also a backward translation of the femoral medial condyle such that the tibia rotates externally while extending. The extension is completed by a sudden external rotation of the tibia which *locks* the knee joint. This is also referred as the “*screw-home*” position of the knee. Fig. 3.4a shows the tibial-femoral contact points with knee flexion (Andriacchi et al. 1986). As the knee is flexed, the rolling motion that predominates early in flexing ($0-20^\circ$) produces posterior translation of the TF contact points. The contact on the lateral side moves posteriorly much more than the medial side during early flexion of $0-20^\circ$, because the lateral femoral condyle is rolling on a larger radius than the medial. After 20° , sliding motion of both condyles begins. In an unloaded cadaveric knees test where forces on the knee and soft tissues of the ligaments, menisci and muscles were not considered (Freeman & Pinskerova 2005), the medial contact point hardly moved antero-posteriorly from $0-120^\circ$ (Fig. 3.4b).

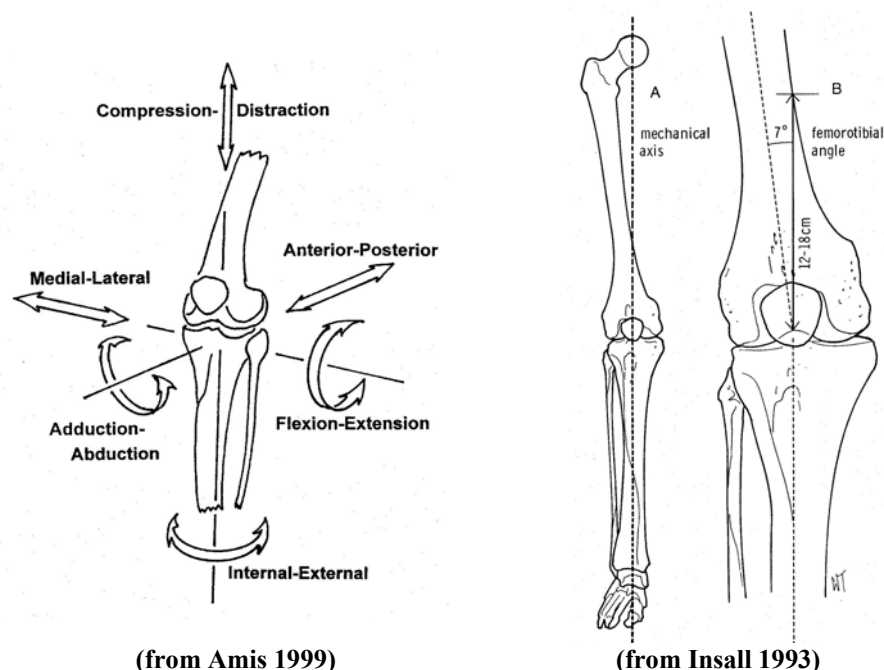


Figure 3.2: 6 DOF for movement of the knee joint and its mechanical axis.

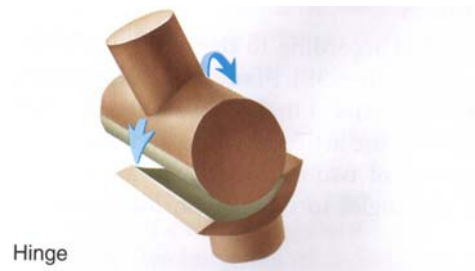


Figure 3.3: Modified hinge joint type of the knee joint.

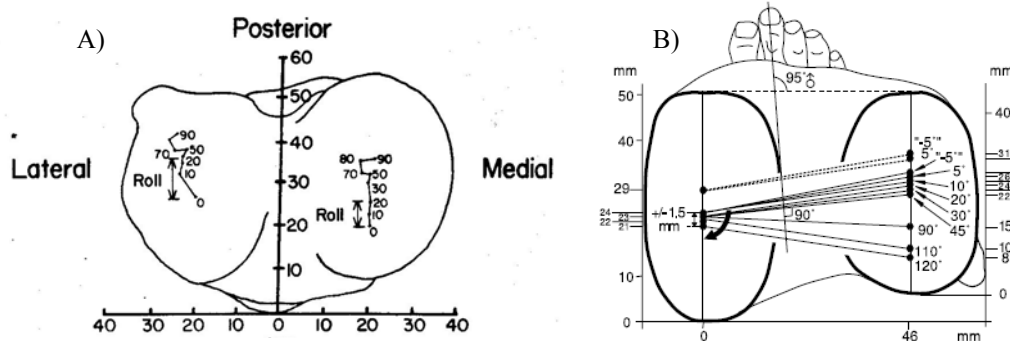


Figure 3.4: Tibial-femoral contact points during flexion: a) from Andriacchi et al. 1986, b) from Freeman & Pinskerova 2005.

The mechanical axis of the leg (Fig. 3.2) is formed by a line that passes from the centre of the hip through the centre of the knee into the centre of the ankle joint (Insall 1993). Due to the offset created by the femoral neck, a valgus angle of 7° is formed between the femoral and tibial shafts. The transverse axis of the knee joint forms a 3° and 10° angle with the axes of the tibial and femoral shafts respectively. With this arrangement, more body weight is distributed medially than laterally in each knee when a person is standing (Insall 1993). At walking, it was found that the dominance of adduction moment in the knee over a gait cycle (see Fig. 3.5) has led to a higher resultant force on the medial compartment as the adduction increases (Andriacchi 1993). Therefore approximately 70% of the load across the knee joint acts on the medial compartment of the knee during walking (Morrison 1970; Hurwitz et al 1998; Shelburne et al. 2006). Schipplein & Andriacchi (1991) also showed that the adduction moment during walking not only shifted the knee joint load medially, it caused the knee joint to open laterally. This might have led to a disastrous problem for the stability of the knee joint, however is resisted by lateral muscle forces (F_m in sagittal plane) and axial load acting about the medial joint contact (see Fig. 3.6). The quadriceps and gastrocnemius muscles were found to offer the most resistance to knee adduction by developing large forces (hence exerting large abduction moments)

during the stance phase of normal gait (Shelburne et al. 2006). An axial internal-external torque was also generated in the knee joint during walking and other activities. However this rotation moment acting on the knee joint is quite small and probably does not play a substantial role in loading the knee during walking (Andriacchi et al. 1986). A 10Nm torque (internal rotation of the tibia) was determined during walking which would be balanced by the MCL acting in tension (Morrison 1970).

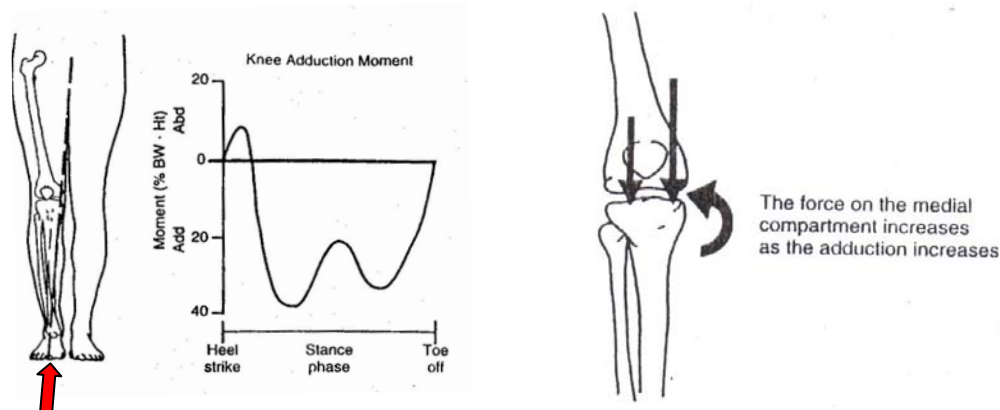


Figure 3.5: Adduction moment during walking and force distribution in the medial-lateral compartments (from Andriacchi 1993).

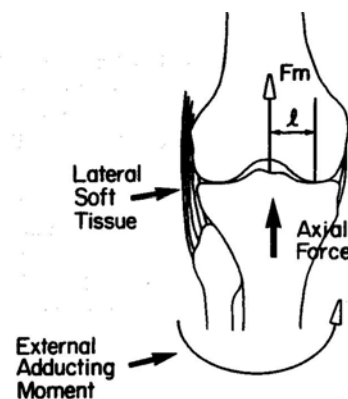


Figure 3.6: Resisting of the adducting moment by muscle forces and axial load (from Schipplein & Andriacchi 1991).

The force acting on the knee joint has been investigated by many. The maximum joint force during walking was found to be 2-4 times body weight—BW (Morrison 1970; Kuster et al. 1997; Taylor et al. 2004; Shelburne et al. 2006), with peak joint force registered shortly after heel-strike at about 15% (contralateral toe-off) of a gait cycle (Schipplein & Andriacchi 1991; Shelburne et al. 2006). Forces acting in the AP and ML shear directions were generally smaller than the vertical joint force, equalling to 0.5 times BW (Taylor et al. 2004) and 0.26 times BW (Morrison 1970) respectively.

Forces through the knee joint are considerably larger, of 5.4 times BW in stair climbing (Taylor et al. 2004) and 8 times BW (Kuster et al. 1997) in downhill walking. Muscle and ligament forces acting on the knee were also determined by Morrison (1970). With 12 normal adults aged 18-38 years-old (3 females, 9 males), a greatest muscle force of 1802N was calculated. The mean maximum forces developed in the quadriceps femoris, hamstrings and gastrocnemius were 743N, 1201N and 1041N respectively. The mean maximum forces acting on the ACL, PCL, MCL and PCL were 156N, 330N, 62N and 263N respectively. The force acting on the knee joint in normal gait is a sum of the ground reaction force (GRF) and net muscle force (NMF), and the NMF contributes at least 70% of the total joint force (Kuster et al. 1997; Shelburne et al. 2006).

3.2. Total Knee Replacement and its Long-Term Requirements

Total knee replacement involves a surgical procedure for the treatment of severe arthritis of the knee joint. It is one of the most successful of all surgical operations with a survival rate of more than 90% between 10 to 15 years (Stern & Insall 1992; Malkani et al. 1995; Ritter et al. 2001). With its success over the past 30 years in relieving pain and restoring mobility in patients associated with arthritis, the current challenge lies in improving post-operative functionality and fixation longevity. In mechanical terms, the assessment of TKR can be twofold, i) kinematics – looking at the range of motion, patient satisfaction, knee scoring, pain level etc, and ii) kinetics – looking at bone loss (stress-shielding), loosening (component migration), wear (shear and load history), and fracture (material strength). The long-term success of TKR is dependent on proper restoration of the mechanical axis and soft tissue balance, and any misalignment with large valgus/varus deformity should be corrected before or at the time of the surgery.

Typical images of an intact knee before operation and after TKR are shown in Fig. 3.7, and an X-ray image of a patient with TKR is shown in Fig. 3.8. The detailed surgical procedure could be found in the website listed (http://jri-oh.com/kneesurgery/Knee_index.asp, April 2007). TKR uses specially designed components made of high strength and biocompatible materials to replace the worn out cartilage surfaces of the knee. The femoral component is usually made of Cobalt-

Chromium alloy (CoCr) and the tibial component is usually made of Titanium alloy (Ti-6Al-4V). The polyethylene insert (*ultra-high molecular weight polyethylene*, UHMWPE) is placed in between the metal components to provide articulation. The undersurface of the patella is cut flat and covered with another polyethylene component. The components are attached to the bone with a specialized polymer called *polymethylmethacrylate* (PMMA), also referred to as “bone cement”. Alternatively, cementless fixation can be adopted by porous-coating the undersurface of the components, which allows bone ingrowth into the pores to form a secure interface.

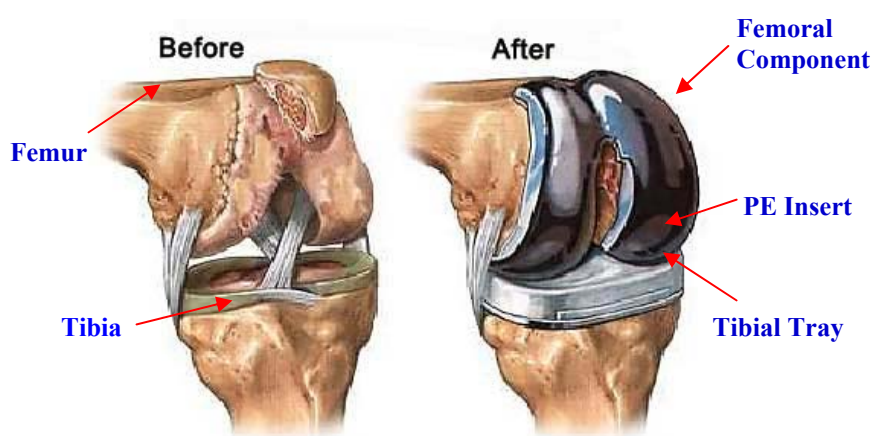


Figure 3.7: Before and after of a TKR.

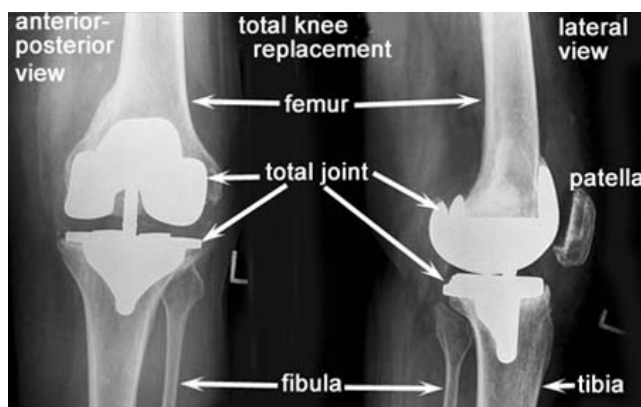


Figure 3.8: X-ray image of a TKR.

Over 70,000 (78356 in total in 2008) primary TKR were undertaken in the United Kingdom (UK) yearly (<http://www.njrcentre.org.uk>, June 2009). The figure was even higher in the United States (US), with 450,000 primary TKR cases performed in 2005 (Kurtz et al. 2007). It is projected that the number of revision TKR in the US will grow from the current 38,300 in 2005 to 268,200 in 2030! This constitutes to a rise in

revision rate from 8% to 14.5% in 2030. This increase in numbers is alarming for the healthcare sector to prepare for the demand in revision surgery which is usually performed by more senior and experienced surgeons due to its complicated procedures. It requires many years of surgical experience for a surgeon to be well-trained for revision surgery. In addition, due to the great success of TKR, which was predominately reserved for elderly patients (above 60 years old) in the past, there are now more younger patients (below the age of 50 years old) receiving TKR treatment. This patient group is generally more active and functionally more demanding after the surgery, and a more durable TKR fixation is needed to meet their lifestyle. These factors have pushed for a need to enhance the longevity of primary TKR, where it can only be achieved with better prosthesis designs, improved surgical techniques and most importantly a comprehensive understanding of the failure mechanisms of these prostheses. Combining both medical and engineering concepts is essential to develop enhanced design tools and analytical methodologies for achieving these goals. It is desirable that the current study will be able to play a contributing role in enhancing the survival of TKR in patients.

3.3. Variations in Fixation Techniques and Prosthetic Designs

Cemented vs Cementless

Fixation of prostheses is more commonly performed using bone cement to provide a *mechanical* attachment of the prosthesis to the bone. Cementless fixation relies on *biological* attachment of prosthesis onto bone through osseointegration. As a generally accepted practice (Rosenberg and Galante 1993), cemented fixation is recommended for less active patients usually of age > 70 (lower chance of cement failure), or patients with compromised bone stock. Cementless fixation is usually reserved for younger, heavier and more functionally demanding patients aged 60 and below, where the chance of cement failure is higher. (Rosenberg and Galante 1993; Duffy et al. 1998). The *hybrid* cementing technique involves cementing only the undersurface of the tibial tray and leaving the stem uncemented. One advantage of this cementing technique is the ease of prosthesis removal during revision surgery where the stem is not anchored firmly to the adjacent bone.

The osseointegration process requires a balance of sufficient loading, so that stress alteration is minimised, avoiding stress shielding and bone remodelling, and sufficient stability for minimum interface motion postoperatively. Fibrous connective tissues will invade the pore spaces if bone ingrowth does not occur (Rosenberg and Galante 1993). Fibrocartilaginous or mineralised cartilage tissue formation has been attributed to excessive interface motion or gaps between the bone and the porous surface (Turner et al. 1989; Branson et al. 1989). For cementless fixation, bony ingrowth is required rather than fibrous tissue formation at the prosthesis interface to ensure secure fixation.

Mechanically, it is desirable to minimise tensile and shear loading at the bone-prosthesis interfaces. The requisites for bone ingrowth are i) appropriate porous structure, ii) minimum interface motion post-operatively, and iii) intimate contact between the prosthesis and bone. A pore size of 150-400 μ m is optimal for fixation strength, between 400-800 μ m the strength of fixation is lowered, probably due to lesser void space for bone to grow (Rosenberg and Galante 1993). A maximum interface micromotion of 20 μ m, 28 μ m and 50 μ m allowable for bone ingrowth were determined by Burke et al. (1993), Pilliar et al. (1986) and Jasty et al. (1997a) from independent canine studies respectively. Fibrous tissues were formed with excessive movement of 150 μ m or more (Pilliar et al. 1986), and a mixture of bone and fibrous tissue ingrowth was found with 40 μ m interface motion (Burke et al. 1993). Between the porous-coated surface and bone, gaps of 1.5mm (Cameron et al. 1976) and 2-3mm (Bobyn et al. 1981; Rosenberg and Galante 1993) were bridged with new bone for loaded and unloaded settings respectively.

Prosthesis Features - Central Stem and Fixation Pegs

The main functions of the central stem are to resist bending and torsion loads acting on the prosthesis, and to prevent tilting and rocking of the tray due to eccentric loads. The central stem also increases the available metal surface for fixation and its shear resistance (Lewis et al. 1982). Long intramedullary stems are used in revision surgery to supplement fixation of the components at the diaphyseal bone regions when weak metaphyseal bone support is found (Stern & Insall 1992). However load transfer of the long stem would inevitably lead to (or more) proximal bone resorption, and the

concern raised would be what is the optimal stem length for a compromise between stability and stress-shielding. A smooth stem without provision for bone ingrowth does not have the ability to transfer axial load, and the entire axial load will be transmitted proximally (Whiteside 1993). These observations will be shown in the subsequent FE modelling results.

Fixation pegs added at sides of the prosthesis (see Fig. 3.9) are primarily to enhance initial fixation stability, especially for the cementless prostheses. With the pegs providing additional anchorage of the tibial tray to the lateral/medial compartments of the tibial plateau, tray tilting can be prevented further. The inclusion of pegs to a stemmed prosthesis will reduce stresses in the proximal cancellous bone, which will be shown by current FE modelling results in Chapter 5. In some prosthetic designs, the central stem is replaced by a number of fixation pegs so that proximal stress-shielding effect can be eliminated. However its capability for preventing tilting and rocking of the tray may be compromised.

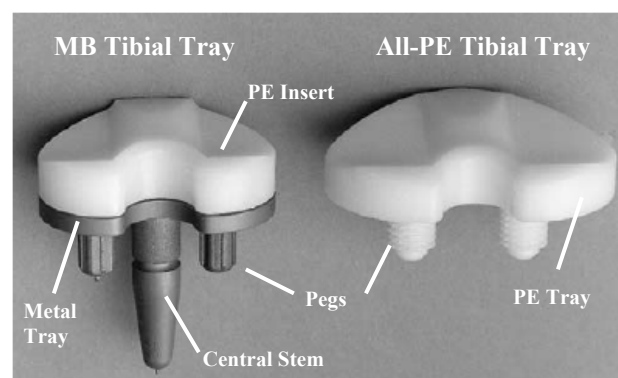


Figure 3.9: Freeman-Samuelson tibial components – inclusion of fixation pegs, central stem and the variation of metal-backed and all-PE trays (from Adalberth et al. 2001).

All-Polyethylene versus Metal-Backed Tibial Trays

The main drivers for the introduction of *metal-backed* (MB) tibial trays (Fig. 3.9) are load distribution across the tibial plateau, load transfer distally thereby relieving high stresses proximally (Lewis et al. 1982; Bartel et al. 1982; Reilly et al. 1982; Murase et al. 1983), modularity with the use of extended stems and augments (especially for bone stock deficient), and the ability for porous coating in provision for bony ingrowth. The benefits of the *all-polyethylene* (all-PE) tibial components (Fig. 3.9)

include no backside wear of the PE, increased PE thickness and lower cost. However, the low bending resistance of the PE stem is a concern (Reilly et al. 1982). Caution is needed for converting an all-PE prosthesis to MB type; in order to obtain an identical thickness to the all-PE component, the PE insert thickness has to be reduced or additional tibial bone has to be resected (Gioe & Bowman 2000). Either alternative has consequential effects. The reduced PE thickness will see TKR revised earlier due to wear failure (Schai et al. 1998). Because the strength of the tibial cancellous bone decreases distally, additional resection of the bone will result in the tibial tray resting on a weaker bone bed which may have a risk of future bone fracture. A FE study comparing on the stress/strain responses between all-PE and MB trays is presented in Chapter 5.

PCL-Retaining (CR) versus PCL-Sacrificing (PS) Prostheses

One of the functions of the cruciate ligaments, in addition to providing static stability, is to impose certain movements on the joint surfaces relative to one another. The PCL is considered by many to cause the femoral condyles to glide and rotate posteriorly on the tibial articular surface as the knee is flexed (Insall 1993). The removal of the PCL in TKR surgery was proposed by Freeman et al. (1977) for soft tissue release in varus or valgus deformity cases, and to provide extensive exposure of the posterior capsule for the correction of angular deformities. The arguments for and against the two different types of prosthesis are many (Insall et al. 1993; Rand 1991b). The reasons for CR are i) helps to maintain the joint line, ii) greater range of flexion (assists in femoral rollback to allow increased motion), iii) posterior stability, iv) ligament control of horizontal forces, and v) near-normal gait. While the reasons against CR are i) difficult technique for soft tissues balancing, ii) seesaw effect, iii) subluxation, and iv) increased wear. The reasons for PS are i) correction of deformity, ii) simpler technique to facilitate soft tissue balancing and surgery, and iii) increased mobility. Lastly the reasons against PS are i) posterior tibial subluxation due to loss of PCL, ii) increased stress on the bone-cement interface, and iii) more bone needs to be resected (for the cam to be in place).

The main difference between the CR and PS prostheses lies in the femoral component where an intercondylar box exists for the PS version (refer to Fig. 3.10). The large

bulk of the metal block will result in a considerable amount of stress-shielding at the distal femur. Thus greater bone resorption is anticipated in the PS version. Saari et al. (2006) reported greater bone loss (-38%) in the anterior distal femur with a posterior stabilised prosthesis than using a CR prosthesis (-15% to -28%) at 5 years.

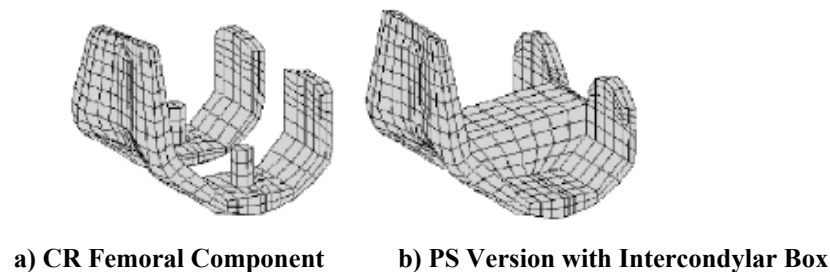


Figure 3.10: Femoral components for the CR and PS prostheses.

3.4. Clinical Observations and Failures in TKR

3.4.1. Bone Resorption

The evaluation of bone resorption can be performed by Roentgenography, using plain radiographs (qualitatively) or bone densitometry (quantitatively). The use of radiographs is less accurate and the interpretation of results is usually person-dependent. Bone densitometry allows the *bone mineral density* (BMD) or *bone mineral content* (BMC) to be quantified physically. The *Dual Energy X-ray Absorptiometry* (DEXA) is currently the “gold standard” for bone density quantification in clinical practice. A DEXA scan is a non-invasive method where the image produced is a planar projection and measures an integral of the cortical and cancellous bones. The physical property measured is termed the areal Bone Mineral Density (g/cm^2). *Quantitative Computed Tomography* (QCT) is another technique which measures volumetric BMD (g/cm^3), and allows a separate analysis of the cortical and cancellous bones. Due to the high radiation dose, the use of QCT for bone density quantification is less common than DEXA. More details on specific operations of DEXA and QCT can be found in the textbook edited by Grainger & Allison (1997).

There are two major concerns related to bone resorption after TKR. Firstly, the weakened bone foundation will lead to potential failure by component loosening and

bone fracture. Bone resorption observed below the anterior flange of the total condylar femoral component at 5 years after operation can lead to component loosening failure (Vince et al. 1989). Secondly, it leads to complications in revision surgery. When bone loss is encountered during revision surgery, complicated procedures like the use of modular augments, stem extensions, autograft or allograft bone supplementation, cement supplementary as “filler”, a customised device, or even a combination of these modalities are involved. And it is usually performed by a senior surgeon. In the fifty-six revision TKR performed by Whiteside (1993), all knees had major bone loss in the femur and tibia, and bone allografting and complicated pre-surgical preparation were needed. The majority of them had failed due to aseptic loosening. There is a critical need to manage bone loss after TKR, to reduce the risk of TKR failure and avoid excessive bone loss prior to revision.

Bone resorption after TKR is evident. Bone loss was detected preoperatively and intraoperatively in 77.6% of the 98 revision TKRs performed (Mulhall et al. 2006). Major bone loss was found under the anterior aspect of the distal femur (Abu-Rajab et al. 2006), with 27% decrease in BMD after cemented/less TKR at 2 years (max of 74% bone loss individually). Significant periprosthetic bone loss of 22% at 12 months after surgery was found behind the anterior flange of the cemented femoral component (van Loon et al. 2001). The BMD decreased from 9.2-21.5% in both the tibia and femur at 9 months (Karbowski et al. 1999). At 14-17 years post-surgery, bone loss was found in 21% and 17% of the tibial and femoral components of the Miller-Galante I prostheses respectively (Goldberg and Kraay 2004). While there were cases of no statistically significant difference in change of BMD between cemented vs cementless fixations (Li and Nilsson 2000; Abu-Rajab et al. 2006), Seki et al. (1999) reported more bone loss for prostheses fitted with cement than prostheses relying on bony ingrowth. Bone resorption was generally found under the tibial plateau and at the anterior aspect of the distal femur.

The rate of bone remodelling was examined. Seitz et al. (1987) reported a bone loss rate of 1.5% per month (range 0.4-3.6%) soon after knee implantation, which was more pronounced up to 6 months, and the bone density stabilised after 1 year. In the proximal tibia fitted with a stemless prosthesis (cemented/less), BMD decreased by 13% during the initial 3 months but regained its initial level after 2 years (Li and

Nilsson 2000). Soininvaara et al. (2004) found an average decrease in BMD of 17.1% (12.1-22.8% range) at 12 months in the femoral bone after cemented TKR, and found that bone loss occurred most rapidly during the first 3 months (decrease of 11.1-14.9%). The rate of bone loss then diminished after 6 months, and bone loss continued to 12 months. Unlike most bone resorption studies, Bohr & Lund (1987) reported bone gain in their investigation instead. Following cementless PCA (Porous Coated Anatomic, Howmedica) prosthesis implantation, the bone density in the proximal tibia was found to increase significantly by about 15% during the first 6 months postoperatively, gradually increasing to 1 year (although not significantly), and eventually stabilised after 2 years. The bone gain observed can be due to the weight bearing activities that began 3 weeks after operation; a high loading strain history may stimulate bone formation. The above findings revealed that bone resorption usually occurred soon after prosthesis implantation (less than two years).

Long-term bone remodelling may reveal different trends. Anterior distal femur bone loss was found in most of the cemented TKAs by radiography, with bone loss visible at 3 months and stabilized at 2 years after the operation (Cameron et al. 1987). Levitz et al. (1995) reported a fluctuating trend of BMD level after TKR. The BMD dropped by 10% at 6 months but returned to its post-operative level at 1 year. At 8 years, a decrease of 36.4% BMD was found with a rate of bone loss of 5.2% per year. Bone loss was observed at the proximal tibia (under the tibial tray medially/laterally). At 2 years after porous-coated stemless TKR, the BMD at the anterior flange of the femoral prosthesis decreased by 36% but the BMD at the bone region proximal to the fixation pegs was increased by 22% (Petersen et al. 1995). With another group of patients where bone density was measured only once at 3-8 years, their BMD level was found to be similar to the first group at 2 years. This led the authors to suggest that bone loss occurred only up to 2 years with no further decrease in BMD after 3-8 years. Nevertheless the authors acknowledged that patients in the second group were mainly men with a mean age approximately 20 years younger. Thus the long-term bone loss trend remains uncertain.

Discussion

There is no clear indication from a review of the literature specifying which anatomical sites are more prone to bone resorption. Thus the bone loss regions have now been mapped out from the surveyed literature (refer to Fig. 3.11). From all the papers reviewed, the percentages (of the total) reported for the distal femoral and tibial plateau bone loss are 65% and 35% respectively. In those reported for the distal femur, 40% of the total was reported behind the anterior distal femoral flange and 8% of the total behind the posterior distal femoral flange. There have been some exceptions to the mapping; i) no bone loss behind the anterior distal femoral flange for a press-fit femoral prosthesis with no provision for bone ingrowth, and bone gain at the distal posterior part instead (Seki et al. 1999), ii) the BMD remained unchanged behind the posterior flange of a porous-coated femoral component (Petersen et al. 1995), and iii) increase in BMD in the proximal tibia at 2 years, with an uncemented prosthesis (Bohr and Lund 1987; Petersen et al. 2005).

The tibial plateau being a natural load-bearing site, the joint force acting on it would be borne by the tibial component after implantation. Bone resorption will occur if stress is reduced (stress-shielding) in the proximal tibia, which may result from load transmission along a fixation stem. One reason for bone loss at the anterior distal femur could be due to off-loading of the patellar compression force. After TKR, the patellar pressure is no longer applied locally to the anterior femoral condyles directly but is shielded by the femoral component. This patellofemoral contact force was estimated to be up to 4600N or 6.5 times of a normal body weight (Huberti & Wayes 1984). As such, great stress-shielding occurs at the anterior distal femur.

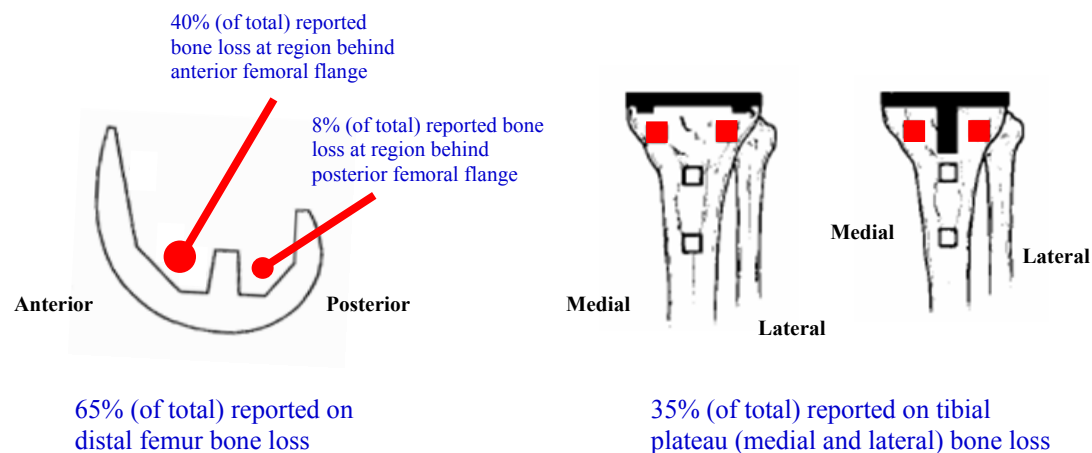


Figure 3.11: Bone loss mapping in the femur and tibia.

The bone resorption rate and trend after TKR can be classified as below:

- Short-term (3-12 months) - significant bone loss occurred.
- Mid-term (1-3 years) - bone loss did not progress further. Some even returned to post-operative level.
- Long-term (> 5 years) – unclear, mixed trends of declining or stable BMD

Early bone loss could be due to operative trauma, post-operative immobilization, and altered mechanical loading. The lack of bone loss progression after 1-3 years may be due to increased stress levels in the knee joint with some new state of bone remodelling equilibrium under altered loading conditions which reflect the patient returning to a more active life. The bone remodelling response after 5 years is largely dependent on the individual patient's lifestyle and health conditions, or even the type of prosthesis implanted.

3.4.2. Prosthesis Aseptic Loosening

One of the most common mechanical problems leading to revision of TKR is aseptic loosening (Cameron and Hunter 1982; Lee et al. 1991; Gioe et al. 2004; Furnes et al. 2007), accounting for up to 22% of revision cases (Saleh et al. 2006) as a result of component migration (Bertin et al. 1985; Windsor et al. 1989) and malalignment (Moreland 1988; Sharkey et al. 2002; Berend et al. 2004). A lack of bone ingrowth in cementless fixation is also a common cause of component loosening (Goldberg and Kraay 2004). Risks of component loosening can be assessed by radiographic means

(qualitatively) and Roentgen stereophotogrammetric analysis (quantitatively). The following discussion outlines the two assessment techniques and their related clinical results.

Radiography

In TJR, radiographs are examined in order to identify radiolucent lines at the interface of bone and cement or prosthesis. A *radiolucent line* (RLL) is a site that allows the passage of X-rays or other radiation (i.e. not radiopaque), indicating a debonding of either the cement-bone or cement-prosthesis interface which represents a risk of component loosening. Radiolucency is used for the identification of component loosening (King and Scott 1985; Vince et al. 1989; Duffy et al. 1998), and can add insights into the cause of long-term loosening failure and fixation longevity (Wright et al. 1990b; Gioe et al. 2007). The presence of thick (width > 2mm), progressive and/or completely circumferential RLLs about the prosthetic components suggests potential loosening, and is usually associated with symptoms, poor clinical results and possible failure (Freeman et al. 1982; Ecker et al. 1987; Malkani et al. 1995). Generally, non progressive radiolucencies of 2mm (width) or less have been reported to have little clinical significance (Ritter et al. 1981; Gioe & Bowman 2000; Gioe et al. 2007), but they are not a good sign.

With no immediate ingrowth of the bone into the prosthesis after a cementless TKR, radiolucency is usually assessed a period of time after operation to cater for bone ingrowth. The occurrence of RLLs will indicate no sign of bony ingrowth, or the formation of fibrous tissues (Cooke et al. 2006). *Radiodense lines* (RDL) are usually formed when there is an excessive movement between the bone and prosthesis. A prosthesis can be classified as stable with bone ingrowth if no or minimal radiosclerotic lines are observed. *Radiosclerotic lines* (RSL) are defined as radiodense lines that run along the surface contour of the prosthesis but are separated from it by a radiolucent zone (or line) of varying thickness (Kawamura et al. 2001).

The radiographic TKR evaluation system developed by the Knee Society (Ewald 1989) is commonly used for uniform reporting of radiolucency results between different institutions and different prosthesis designs. Fig. 3.12 illustrates the different

zonal assignment for the tibia, femur and patella. Most RLLs have been noted at the bone-cement interface (Freeman et al. 1982; Ecker et al. 1987; Vince et al. 1989; Stern & Insall 1992; Ritter et al. 1994). Some of the possible causes of RLL occurrence are i) failure to pressurise cement tightly against the bone, ii) thermal necrosis from the exothermic polymerisation of the acrylic cement, and iii) interface micromotion between the cement and bone (Ecker et al. 1987). Zonal analysis revealed that radiolucency occurred more frequently at the edges of the tibial trays (AP view zones 1 & 4, lateral view zones 1 & 2), with few or none observed at the stem or peg tips (Ritter et al. 1981; Ecker et al. 1987; Hanssen et al. 1988; Vince et al. 1989; Stern & Insall 1992; Hsu et al. 1995; Malkani et al. 1995; Duffy et al. 1998; Berger et al. 2001). Comparatively, there were lesser radiolucent zones observed around the femoral components. When it occurred, it resided mainly in zones 1, 2 and 4 (Stern & Insall 1992; Hsu et al. 1995; Bassett 1998; Goldberg and Kraay 2004) with fewer in zones 3 and 5 (Wright et al. 1990a/1990b; Malkani et al. 1995).

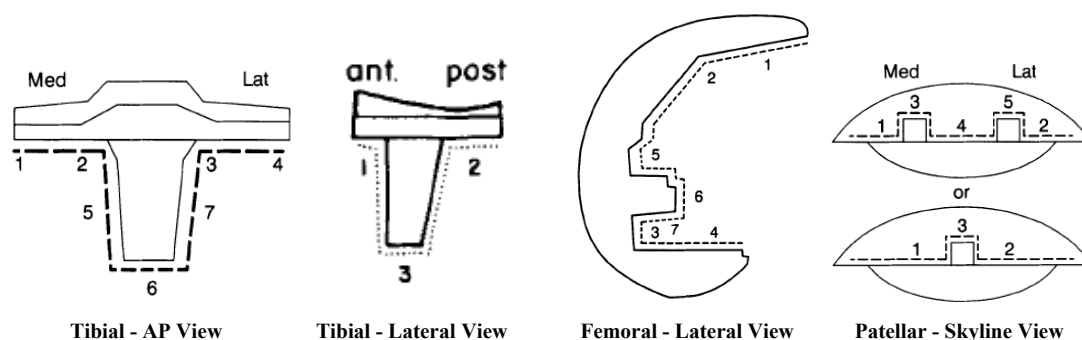


Figure 3.12: Zonal assignment of the knee society radiographic TKR evaluation system (Ewald 1989).

Lesser radiolucencies were found at the femoral components (3%) than tibial trays (16%); 3 cemented and 1 cementless for the femoral components, and 9 fully cemented and 15 hybrid cementing cases for the tibial prostheses (Schai et al. 1998). Most of the RLLs were located underneath the edge of the tibial trays. Examination of the cemented posterior stabilised prosthesis (all-PE tibial tray) at 9 to 13 years post-operation showed that 49% and 5% of the tibial and femoral components had some radiolucent lines around them. The number of revision cases due to tibial component loosening was twice of femoral components (Stern and Insall 1992). In contrast to the above, there were more femoral components demonstrated radiolucency than tibial components at 2 years for CR cemented prostheses implanted by Ritter et al. (1981).

All RLLs observed were incomplete and less than 1mm in width. These findings suggest that RLLs around tibial components will outgrow their femoral counterpart in long-term. For Kinematic I TKR (CR, MB type, Howmedica) at 5-9 years post-operatively, RLLs were found in 45% and 35% of the cemented tibial components of OA and RA patients respectively, though the difference was not significant (Wright et al. 1990a).

For cementless TKR the absence of radiosclerotic lines suggested better early stability of the tibial component, which is an indication of improved survival rate against loosening failure (Winemaker et al. 1998). With 2-year follow-up, Winemaker et al. reported RSL formation in 14 out of 15 cementless tibial stems. Also at 2 years, Whiteside (1993) observed a very large proportion of RSL around his operated femoral and tibial stems. Nevertheless, the radiolucent zones were all less than 1mm thick. With an average follow-up of 18 months, Bertin et al. (1985) found 54% of knees had RSL and 24.3% had RDL firmly apposed to the prosthesis in the entire outline of the femoral/tibial stems. At 5 years after the porous-coated anatomic total knee prosthesis was implanted, Kim (1990) reported good fixation and excellent clinical results despite RDL visible at the bone-prosthesis interfaces of the tibial components.

Relation of Radiolucency Occurrence with Component Loosening

In a comparative study by Fehring et al. (2003), TKR with cemented stems were more radiographically stable than press-fit cementless stems. 10% of the cementless TKR were revised due to loosening but none of the cemented group. There was a significantly higher survival rate for cemented PFC prostheses (94%) compared to the cementless group (72%) at 10 years in terms of loosening failure (Duffy et al. 1998). Significantly lesser RLLs were observed for the cemented tibial components (41%) than the cementless group (86%), which also had a higher number of tibial components being considered as radiographically loose and being revised. Tibial components with complete, circumferential RLLs were revised for loosening (Vince et al. 1989). Although 7.1% of the cementless fixations had radiolucencies (compared to none for the cemented fixations), subjective and functional TKR scores were not statistically different for all cementless knees (Bassett 1998). The author commented

that excellent clinical results can be obtained with cementless TKR with proper patient selection.

Roentgen Stereophotogrammetric Analysis

Roentgen Stereophotogrammetric Analysis (RSA) is a widely adopted quantitative method for evaluating prosthesis motion in total joint and total knee replacements (Ryd et al. 1987; Önsten et al. 1998; Ryd et al. 1990; Adalberth et al. 2001; Hyldahl et al. 2005a/2005b; Saari et al. 2006b; Uvehammer et al. 2007). It is also known as *Radiostereometric Analysis*. Roentgen stereophotogrammetry is an accurate technique for measuring the 3-dimensional position of an object (Kärrholm et al. 2006). This technique was developed by Göran Selvik (a Swedish mathematician and anatomist) in 1972 in Lund, Sweden, and was applied to evaluate relative skeletal motion and fixation of implanted devices (Selvik 1989).

In TKR, the RSA technique primarily measures the *relative movements* (or micromotion) between the prosthesis and bone. For measurement, tantalum bead markers of typical size 0.8-1.0mm in diameter are inserted into the prosthesis (or cement layer in some cases) and the bone. Post-operative and follow-up radiographic images are captured for the AP and lateral views (see Fig. 3.13) in a calibration cage. The tantalum markers in the prosthesis and bone are then grouped as separate “rigid bodies”, and the relative movement (in six degrees of freedom - translation and rotation) between them can be calculated using customised trigonometric computer programs. Very commonly, the component migration in the vertical axis (i.e. subsidence and/or lift-off displacements) and *maximum total point motion* (MTPM) are reported. The MTPM is defined as the vector translation (directionless) of the prosthetic marker with the most pronounced movement (Ryd et al. 1987).

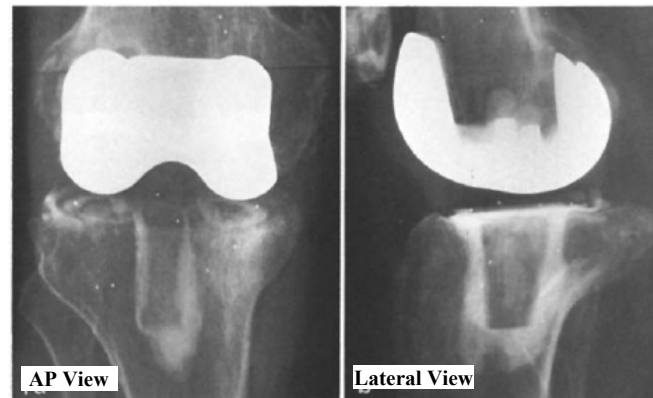


Figure 3.13: Radiographic images with tantalum markers (from Ryd et al. 1987).

There is evidence showing that early migration of knee (Grewal et al. 1992; Ryd et al. 1995) and hip prostheses (Freeman & Plante-Bordeneuve 1994; Kärrholm et al. 1994; Walker et al. 1995) will lead to long-term aseptic loosening failure, regardless of cemented or cementless fixations. Grewal et al. (1992) determined that tibial prosthesis groups with higher RSA migration measured at one year corresponded to a lower survivorship at 5 years. Ryd et al. (1995) followed up TKR patients with different prosthesis types and cement techniques for 10 years. Of the 14 cases revised due to loosening, 12 had MTPM migration level (3.3mm) at 2 years one standard deviation above the non-revised group (1.1mm) (statistically significant). This indicated a predictive power of 85% where RSA measured migration at 2 years can be used to identify the risk of loosening failure. For hip prostheses, components that migrated 2.6mm or more at 2 years only had a 5% chance of survival (Kärrholm et al. 1994; Walker et al. 1995). In another study, a limit of 1.2mm/year during first 2 years post-operative predicted late loosening with a specificity of 86% and a sensitivity of 78% (Freeman & Plante-Bordeneuve 1994).

Ryd et al. (1990/1995) reported that mechanical loosening of tibial prostheses was faster in the early post-operative period, with migration (MTPM) of about 1mm registered in the first year. The rate slowed down subsequently with migration reaching 1.5mm after 10 years. In separate studies of the PCA tibial (Ryd et al. 1990) and Miller-Galante I femoral (Nilsson et al. 1995) components, migration in the early phase (first few weeks to 3 months post-operative) was more prominent for the cementless prostheses. This could be due to the less stable initial fixation of the cementless prosthesis (whereas a cemented prosthesis is securely fixed by the

cement). In the intermediate phase (1 to 2 years post-operative), the cemented prostheses migrated more this time round. In the later phase (2-4 years), migration of the cementless prostheses ceased while the cemented prostheses continued to progress. In the author's view, this migration trend could be attributed to bone remodelling after TKR. Stress-shielding in the cemented fixation would lead to bone resorption and hence the bone strength reduced progressively. As a result, the fixation became less secure over time and the prostheses migrated continuously. On the other hand for the cementless fixation, lesser extent of stress-shielding was experienced (FE modelling shown in Chapter 5) and bone remodelling equilibrium can be achieved much earlier by the intermediate phase. Although migration of the cementless prostheses stabilised soon after operation, the large magnitude of movement in the early phase still poses a long-term loosening risk.

Discussion

From the literature surveyed, close to 70% of the studies focused on loosening and radiolucency of the tibial components. It was noted that loosening of a femoral component with cemented or cementless fixation is very rare, and occurs less frequently than of the tibial component (Colley et al. 1978; King and Scott 1985; Nilsson et al. 1995). There have also been comparative less radiolucent zones observed around the femoral than the tibial components. A few reasons can be offered. Firstly, the "clamped shape" of the femoral component allows tighter gripping (hence lesser interface movement) around the distal femoral bone compared to the "sitting" position of the tibial component on the tibial plateau. Secondly, a greater compressive strength of bone in the distal femur than proximal tibia (Colley et al. 1978) could contribute to better fixation stability. Thirdly, the low occurrence of RLLs around femoral components can be partly attributed to the difficulty in visualizing the lucencies at the bevel and flange surfaces of the femoral component. King and Scott (1985) related femoral component loosening to inadequate contact and structural support of the posterior flange of the femoral components resulting from inaccurate surgical cuts, poor cementing or deficient bone stock.

Although threshold levels for early migration in predicting late aseptic loosening have been determined, for example the MTPM level at 2 years for tibial prostheses should

not be greater than one standard deviation above the MTPM of a well-fixed group of components, and hip components not migrating more than 2.6mm at 2 years, it may only be applicable to specific groups of prostheses. With new and improved prosthesis designs and surgical techniques, new threshold levels may need to be established, which the author envisages to be even tighter.

3.5. Summary

Bone resorption after TKR is evident in many clinical cases. Significant bone loss sites are at the distal femur (65%) and proximal tibial plateau (35%). The latter site is mainly due to the load at knee joint being shielded by the stem of the tibial prosthesis. Stress-shielding at the anterior distal femur could be due to off-loading of the patellar compression force. Aseptic loosening and radiolucencies occurred predominately in the tibial components. It is commonly cited that weakened bone support due to bone resorption is the one of the main reasons for component migration.

The trends and patterns of bone resorption and aseptic component loosening are largely dependent on prosthetic designs and fixation techniques used. Although bone loss is more prominent in the distal femur, it is surprising to note that femoral component loosening is comparatively rare. This remains a question to be answered. Although cementless fixations are more prone to loosening failure than cemented cases, the cemented fixations may result in more proximal stress-shielding and thus bone loss. From the good results of cementless TKR (Ortholoc I prosthesis) with survivorship of 94% at 10 years reported by Whiteside (1994), it seems that the option of cementless fixation over cemented may be favourable, although most TKR are fixed using cement.

CHAPTER 4. BIOMECHANICAL (ENGINEERING) ANALYSES FOR TOTAL KNEE REPLACEMENT – A REVIEW

4.1. Introduction

Biomechanical analysis of a total joint replacement can be divided into three approaches, namely i) in-vivo (clinical), ii) in-vitro (experimental), and iii) computational (in-silico). While in-vivo studies and in-vitro test processes are lengthy and can be costly if a large sample size of subjects or specimens is needed, computational study is time and cost efficient as multiple models of different designs can be created simultaneously and solved using a single computer. Specific details of the use of the finite element method for fixation analysis will be discussed in Chapter 5. This chapter outlines a literature review of the analyses of stress-shielding (load transfer mechanism), bone remodelling and aseptic loosening of total knee replacement.

4.2. Stress Shielding and Bone Resorption

Computational Study

Stress-shielding and load transfer mechanisms in the tibia were first explained in detail by Vasu et al. (1986) using the FEM. In an intact tibia subjected to a bi-condylar load, stresses were transferred from the subchondral bone through the cancellous bone to the metaphyseal shell. These stresses were mainly compressive. When a short stemmed tibial prosthesis was implanted, the compressive stresses were directed towards the central stem. The stresses underneath the tray were reduced due to load transferred distally by the stem, with high stresses found in the bone at the stem tip and closer to the metaphyseal cortex. Bone densification was observed clinically in these high stress regions (Bertin et al. 1985; Whiteside & Pafford 1989). When using a stemless prosthesis with fixation pegs, stresses at the periphery of the plateau were reduced greatly with intensification of stress at the ends of the pegs. Stress-shielding of the proximal epiphyseal cancellous bone was not observed. For the

stemless prosthesis fixation, the stress levels were very close to those of the intact knee.

Stress analysis revealed that the cemented tibial stem helped to transfer the load distally, while the tibial tray distributed the stresses over the tibial plateau (Bartel et al. 1982). As the stem length increased, the amount of load borne by the prosthesis increased (hence stress-shielding) and lowered the shear stresses along the stem (Askew & Lewis 1981; Murase et al. 1983). Lower compressive stresses were found underneath the tibial tray (bone-cement interface, cancellous bone) of the metal-backed design than its all-PE counterpart, thereby helping to reduce the risk of cement and bone fracture (Lewis et al. 1982; Bartel et al. 1982, Murase et al. 1983). However the tensile stresses caused by the component tilting were higher, which may lead to interface separation, and stress relief may result in bone resorption. The inclusion of fixation pegs to a stemmed tibial prosthesis (cemented) lowered the cortical bone stresses below the joint line by 40%, and greatly reduced the cancellous bone stress underneath the tibial tray by 75%. But it had minimal effect on the cortical and cancellous bone more distally, and on the cement layer (Au et al. 2005). In applying a uni-condylar load (medially) in a cementless tibial model, contact stresses at the bone-prosthesis interface were lowered when pegs were added to the stemless tray (Hashemi & Shirazi-Adl 2000). Besides the high stiffness prosthesis stem being the primary cause for distal load transfer, it was shown that different loading conditions at the plateau surface also influenced the stress-shielding phenomenon considerably (Au et al. 2007). Under a medial axial load of 3000N and 10Nm varus moment, a stem augment of length 75mm (hybrid cement technique – cement underneath the tray but cementless at stem) generated 30-50% proximal cancellous bone strain decrease compared to a cemented short stem (Rawlinson et al. 2005). In this case, although the bone fracture risk could be minimised, bone resorption may lead to component loosening.

In a cemented femoral component (with or without a stem), severe stress-shielding (>90%) in the distal cancellous bone region was noted as most of the load was transmitted upwards in shear through the anterior and posterior flanges to the cortical bone (Walker et al. 1982). The femoral stem length was found to have little effect on load transfer from the distal end, only to alter the distal femoral bone stress when it

was longer than 90mm. When the anterior and posterior flanges were uncemented, stress-shielding of 25-50% had occurred. These have revealed a different stress-shielding characteristic of the femoral component; the “clamped shape” gripping of the femoral component around the distal bone dominated the stress-shielding effect compared to the stem, where most load was being transferred to the bones at the superior areas of the anterior and posterior flanges, rather than to the bone at the tip of the stem. The result was that bone hypertrophy was observed in these regions (Spittlehouse et al. 1999) instead of the stem tip regions in the tibia (Bertin et al. 1985, Whiteside & Pafford 1989). The anterior distal corner of the femur was found to be most vulnerable to stress-shielding (Tissakht et al. 1996).

A strain-adaptive bone remodelling FE algorithm was used to investigate the effect of a femoral stem (PFC, Johnson & Johnson) on bone resorption (van Lenthe et al. 1997). For a stemless prosthesis with an intercondylar box, bone loss was observed at the anterior part of the distal femur, where the rate of loss was greater at the lateral side and for the cemented fixation. The bone loss rate was also faster when the cement was fully bonded to the prosthesis (25% in 1.5 yr, 50% in 3.5 yrs) than when the interface was unbonded (25% in 1.75 yr, 50% in 5 yrs). Densification was predicted in the bone near the proximal anterior flange, with the unbonded case having a larger area of bone gain than the bonded interface. This showed that more load was being transmitted across the unbonded interface, rather than through the bone (to distally). In a more recent study (van Lenthe et al. 2002), more bone loss was predicted around a stemmed prosthesis (than the stemless/unboxed design) and with a thicker stem. In tackling severe bone loss at the distal anterior femur, a cemented femoral component with a debonded inner side of the anterior flange was suggested to reduce bone resorption (Barink et al. 2003). The difficulty in surgical implementation remains a challenge however.

In coupling a damage- and disuse-based remodelling theory and FE modelling, substantial bone loss in the first few weeks and gradual decrease in bone loss from 6 months to 5 years were predicted in the proximal tibia after implantation (Nyman et al. 2004). The finding was consistent with clinical studies where most bone loss occurs in the early life of TKR. By implementing the bone maintenance theory to simulate a porous-coated short pegs stemless tibial prosthesis (assuming good bony

ingrowth with a bonded interface), increased bone density at the ends of the pegs with decreased density of bone directly underneath the tray was observed (Orr et al. 1990).

In-Vitro Study

The strain experienced in the proximal tibia and distal femur is proportional to the load borne by the knee joint. In TKR where the load is transferred through the metallic prosthesis rather than the bone, the tibia and femur will be subjected to less compressive strain (and stress). A cemented stemmed tibial component resulted in strain reduction of the tibial cortex, which may lead to cortical resorption of the proximal tibia, so Bourne & Finlay (1986) discouraged the use of stemmed prostheses. In the same study, it was also found that the removal of cortical rim support for the tibial prosthesis resulted in marked reduction of proximal cortical strains, suggesting that more load was being transferred to the cancellous bone instead. A similar observation was made by Reilly et al. (1982). As a result a lack of support from the cortical rim may lead to bone collapse, where the prosthesis would be prone to sinkage or loosening.

In testing a cementless stemmed tibial fixation (Whiteside and Pafford 1989), low strains were measured around the proximal cortex of the tibia and corresponded to peripheral atrophy seen in the clinical Roentgenographic study. The high strains were recorded at the metaphyseal cortex adjacent to the stem tip with hypertrophy of cancellous bone observed around the region. These reflected closely the FE modelling by Vasu et al. (1986). Prostheses should be designed to apply load in compression to ensure bone hypertrophy and avoid shear or tensile failure of the interface between the porous surface and base metal.

In a parametric study performed by Jazrawi et al. (2001), the proximal tibial bone strain was reduced by 7-18% when the cementless stem was cemented (undersurface of tray cemented in both cases). Strains for cemented fixation were further reduced with an increase in stem length, complementing the results of Bourne & Finlay (1986). However, no significant changes in proximal bone strain were noted when designs for cementless fixation were varied (stem length/diameter, stemless). A larger

strain reduction of 30-50% was determined by Seki et al. (1997) when a cementless short stem was cemented (undersurface of the tray was cemented for both cases).

With off-centre loading of the tibial plateau (bending moments induced), the strain was larger by about 10 times for the all-PE stem over the metal stem (Reilly et al. 1982). This had created large bending stresses in the cement and higher shear stresses at the bone-prosthesis interface in the all-PE fixation. Higher compressive stresses would also be induced in the bone directly underneath the loaded compartment for the less stiff PE tray, where radiolucency has been observed (Gioe & Bowman 2000, Rodriguez et al. 2001). Pressure sensors were placed in between the femoral component and tibial tray (Fig. 4.1) to study the effect of prosthesis malalignment (Werner et al. 2005). Varus/valgus angulation of the PE insert resulted in an uneven load distribution in the lateral/medial tibial compartments. Bone loss will be a concern in the off-loaded compartment.

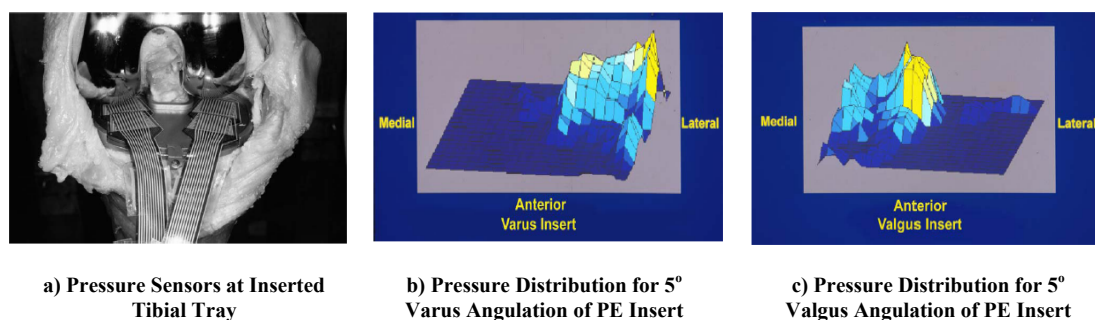


Figure 4.1: Pressure measurement in tibial tray – varus/valgus malalignment study (from Werner et al. 2005).

Strains were measured at the cortex and cancellous bone of the distal femur (Seki et al. 1998). The cortical strains were found to be higher when the femur was fitted with a cemented prosthesis compared to a cementless one. However the strains in the cancellous bone were higher for the cementless fixation. This concurred with the modelling results by Walker et al. (1982) that load transfer occurred along the anterior/posterior flanges to the cortex when the femoral prosthesis was cemented. For the cementless prosthesis, the bone-prosthesis anchored interface was less firmed thus more load was being transmitted across the bevel surface of the prosthesis to the cancellous bone thereby inducing higher compressive strains.

In-Vivo Study

As the evaluation period is lengthy for clinical studies, and it is more logistically and labour intensive, fewer biomechanical studies have been reported. A decrease of BMD in the distal femur was found for different prosthesis types at 2 years post-operatively (Seki et al. 1999). With the Genesis femoral prostheses fitted with cement, the largest BMD decrease was 57% compared to 28% reduction of the porous-coated components, followed by 20% decrease of the Miller-Galante cementless wire-mesh components. The greatest bone loss site was at the distal anterior flange of the femoral component for all three groups. On the other hand, when the Mark-II prostheses were implanted by press-fitting with no provision for bone ingrowth, an increase in the BMD was found at the distal posterior flange of the femoral component. The above observations agreed well with the FEM and experimental studies reported earlier. Load transfer was most prominent for the firmly anchored interface formed by cement. A bone-prosthesis interface with bony ingrowth resulted in a less firm anchorage which only enabled some amount of load transfer, where more load was transmitted from the prosthesis to the adjacent bone. A smooth surface without cement fixation had the least anchorage strength thus almost no load was transferred away distally but all was transmitted across the prosthesis. The smooth flange surface may however allow invasion of polyethylene wear debris into the bone-prosthesis interface leading to a higher risk of subsequent osteolysis (Whiteside & Pafford 1989).

Bone densities in the proximal tibia for cemented stemmed and stemless prostheses were compared at an average of 94 months (minimum of 84 months) post-operatively (Lonner et al. 2001). The bone densities under the medial and lateral plateaus in the stemmed group were significantly reduced as compared with the unstemmed group ($P < 0.001$).

93% of the cementless TKR patients had radiographic evidence of distal cancellous hypertrophy at the distal femur, where the posterior bevel surface appeared to have denser bone formation than the anterior (Whiteside and Pafford 1989). The bone hypertrophy resulted from the high load transmission across the bevel surface of the prosthesis to the cancellous bone.

4.3. Aseptic Loosening

Computational

Taylor & Tanner (1997) suggested that aseptic loosening was triggered by a mechanical rather than biological process, and that fatigue failure of cancellous bone would lead to component migration. The initial cancellous bone stress obtained from FE modelling was correlated with clinical data; higher bone stresses were predicted for cementless fixations than cemented and corresponded to greater migration and lower survivorship (Taylor et al. 1998; Perillo-Marcone et al. 2004). By press-fitting a stemless all-PE tibial tray with pegs, the bone stress was about 16% higher than a cementless stemmed metal-backed tibial tray with pegs (Taylor et al. 1998). The tibial tray size effect was investigated by Murase et al. (1983). With an all-PE tray with a stem, there was little difference of the proximal cancellous bone stresses between a wider tray that overlaid the cortex or a smaller tray which rested only within the cancellous bone bed. However for a metal-backed component, the stresses induced by a narrow tray resting entirely on the cancellous bone were higher than for the wider tray with cortical support.

Minimal movement between the prosthesis and the adjacent bone enhances the bone ingrowth process and hence its fixation strength against long-term loosening. The bone-prosthesis *interface micromotion* has been modelled to assess the likelihood of osseointegration. Interface micromotion was predicted to be largest at the peripheral regions of the tibial tray (Rakotomanana et al. 1992; Keja et al. 1994; Tissakht et al. 1995; Hashemi and Shirazi-Adl 2000), thereby bony ingrowth at the periphery of the tray may be hindered. In modelling a medial uni-condylar loading of a cementless tibial prosthesis, micromotion at the horizontal surface of the plateau of 33.5µm and 21.8µm were predicted for the stemless and stemless/with pegs prostheses respectively (Hashemi and Shirazi-Adl 2000). A 35% reduction of the micromotion by the inclusion of pegs was noted. Taking the criterion of 28µm allowable micromovement, bone ingrowth would occur only for the stemless/pegs design whereas fibrous tissues would be formed for the stemless prosthesis. In separate investigations, higher micromotions of 50µm (Rakotomanana et al. 1992) and 90-101µm (PCA prosthesis, Keja et al. 1994) were predicted for the stemless/with pegs

prostheses. For their designs, it was inferred that fibrous tissues would form at the bone-prosthesis interface.

The influence of design variations was also studied. The increase in stem length had a negligible effect on the micromotion at the interface underneath the tibial tray, but resulted in a substantial increase along the stem (Shirazi-Adl and Ahmed 1989). In the same study, it was found that the inclusion of a circumferential flange resulted in a reduction of micromotion at both the undersurface of the tray and along the stem. When the short pegs of the tibial tray fitted by press-fitting were replaced by screws, micromotion at the tray-bone interface was reduced significantly (Tissakht et al. 1995). It was expected as the threads of the screws provided a much stronger anchorage to the bone than the flat surfaces of the pegs. Surprisingly, micromotion predicted at the tray side of a cemented fixation was higher than for a cementless case, which was in opposite trend to the current and many other reported studies (Rakotomanana et al. 1992).

In-Vitro Study

Various loading conditions have been applied to different cemented tibial prosthesis designs to assess its stability (Walker et al. 1981). With the vertical and shear AP loads, a 2-peg stemless tibial tray (either all-PE or MB) generated the least component movement. With vertical and rotational loads, the MB tibial tray (with a stem or pegs) showed the least movement. And in varus (or valgus) loading, designs with 2 pegs displaced the least as the pegs provided direct support to the off-centred load.

A cemented fixation produced better initial stability (less component motion and migration) than the cementless, and the prosthesis stability increased with stem length for the cementless fixation (Stern et al. 1997). However the long cemented stems did not help in enhancing initial fixation. Based on this, Stern and his associates suggested that cement has a great stabilising effect on fixation—the cement filled the gaps between the prosthesis and bone, thus distributed stresses more evenly and resulted in better prosthesis stability. They further commented that stem extensions may be unnecessary for most routine primary cemented TKAs. The impact of

cemented stem length was however in contrast to the study of Jazrawi et al. (2001) where a longer stem resulted in lower tray motion. This discrepancy could be due to the different stem length used: Stern et al. used 40 and 75mm and Jazrawi et al. used 75 and 150mm. A longer stem (say > 100mm) may be needed to enhance initial fixation stability. Therefore the recommendation of Stern and his associates could be invalid in the presence of poor proximal bone stock where a longer stem is needed to provide cortical bone engagement distally.

With a porous-coated stemless tibial tray with pegs implanted with and without cement onto cadaver specimens and loaded centrally with a cyclic force varying from 10-2000N, significantly ($P < 0.05$) greater motion at the bone-tray interface was registered for the cementless prosthesis than the cemented case (Branson et al. 1989). A maximum motion of 290 μ m was recorded for the cementless prosthesis versus 100 μ m for the cemented prosthesis. These results showed that for either a stemless or stemmed (from Stern et al. 1997) tibial prosthesis, cemented fixation provides better initial stability.

Volz et al. (1988) tested different configurations of tibial prostheses that were porous-coated (underneath the tray and on pegs surfaces only) for bone ingrowth fixation from different manufacturers. The most secure fixation was achieved by the configuration of a central stem with 4 cancellous screws (AMK design) positioned peripherally in 4 quadrants of the tibial plateau (tray lift-off < 100 μ m). The use of an enlarged central stem with peripheral rectangular slots for cancellous bone engagement (Whiteside design) generated the second lowest tray lift-off (~200 μ m). The stemless configurations with either a 2-peg (PCA design) or 4-peg (MG design) produced the highest tray movement (lift-off > 500 μ m).

In an off-centre load testing for cementless components with pegs, the lowest subsidence and contra lift-off were observed for the long stem group, followed by the short and stemless groups (Yoshii et al. 1992). This is what could be expected and is opposite to the findings of Stern et al. (1997) noted above. With hybrid cementing, the motion of the tibial tray decreased with increased stem length and diameter (Jazrawi et al. 2001). With the tray undersurface being cemented, although the tray micromotion value for the cemented stem was lower than with a cementless stem

(either short or long), the difference was not significant (Seki et al. 1997). With 10° tibial internal and external rotations, proximal cortical bone strain with a mobile-bearing prosthesis was decreased by 22-33% compared to a fixed-bearing prosthesis (Bottlang et al. 2006). As such, the mobile-bearing prosthesis was able to tolerate axial rotation better by transferring lesser shear strain to the prosthesis-bone interface thereby helpful in deferring aseptic implant loosening.

In-Vivo Study

Post-operative occurrence of RLL at the bone-cement interface was employed to compare different cement injection techniques. Ritter et al. (1994) found that proper preparation of the cancellous bone and pressurization of the cement reduced the initial occurrence of a RLL.

RSA was also employed to study the effects of prosthetic design variations on clinical performance. The addition of a cementless metal-backed tray with a long stem to an all-PE insert tibial component reduced the MTPM migration from 2.4mm to 1.3mm at 2 years (Albrektsson et al. 1990). CR tibial prostheses were found to register higher MTPM migration than the PS type (0.6mm versus 0.49mm respectively) (Saari et al. 2006a). Ryd et al. (1990/1995) reported that cementless tibial prostheses migrated significantly more than the cemented group at first and the tenth year (migration: cementless – 1.7mm at 1 year, ~2.7mm at 10 year / cemented – 0.7mm at 1 year, ~1.2mm at 10 years). A similar increase in migration of cementless tibial prostheses over the cemented group was observed by Albrektsson et al. (1992) and Önsten et al. (1998). However no difference in the migration at 2 years between cemented and cementless femoral components was found by Nilsson et al. (1995). No difference in rotations of the femoral components between cemented and hydroxyapatite-coated prostheses at 2 years was noted (Uvehammer et al. 2007).

Hyldahl et al. (2005a/2005b) evaluated the fully and hybrid cementing techniques on the performance of all-PE and MB tibial prostheses. The central stem was of an “I-beam” shape instead of cylindrical. When only the undersurface of the tibial tray was cemented, the all-PE group was significantly more stable in AP and varus/valgus tilts than the MB group. The MB components also demonstrated an increase in MTPM

migration. In the case when the entire prosthesis was cemented (tray surface and stem), no statistical differences were found in rotations and translations between all-PE and MB groups. The observed trends were attributed to the different rigidity between polyethylene and metal. However that factor alone cannot convincingly explain the comparable performance between the fully cemented all-PE and MB groups. In the author's view, in hybrid cementing where the stem (either PE or metal) is not cemented, minimal joint load was transferred distally by the stem. Similar level of load would be transmitted to the resected bone bed for the all-PE and MB prostheses. As more bone resection was required for the MB tibial tray to maintain the same thickness of PE, the metal tray would rest on a weaker bone support (Hvid 1988). Therefore a less stable fixation was anticipated leading to higher component migration. When the tray and stem were fully cemented, the metal stem resulted in a greater load transfer to the distal region thereby reducing the stress level in the bone underneath the tray which was of lower mechanical strength. In this way, fixation stability for both the all-PE and MB prostheses would be comparable and hence no difference in migration was observed.

4.4. Bone Remodelling Finite Element Algorithms

Numerous bone remodelling theories and mechanical models have been developed over the years to explain and quantify the relationships between mechanical loads and bone morphology. These mathematical models have been incorporated into FEM codes to simulate bone morphologies (Carter et al. 1989; Beaupré et al. 1990; Weinans et al. 1992a) and the bone remodelling responses after prosthesis implantation (Orr et al. 1990; Weinans et al. 1992b; McNamara et al. 1997; Doblaré & García 2001). Most of these bone-adaptive algorithms evolved in the late 1970's, 1980's and early 1990's (Cowin & Hegedus 1976; Cowin & van Buskirk 1978; Hart et al. 1984a; Fyhrie and Carter 1986; Huiskes et al. 1987; Harrigan and Hamilton 1992; Prendergast and Taylor 1994). Since the late 1990s, research work was mainly focused on improving the developed algorithms such as incorporating simultaneous density and anisotropy (Jacobs et al. 1997) and extension of the adaptive-elasticity theory to include bone microdamage as a stimulus (Ramtani and Zidi 2002). Efforts on validating these FE models with clinical results were also explored (Kerner et al. 1999; Bitsakos et al. 2005; Turner et al. 2005). More recently, "energy and damage"

based theory (Levenston & Carter 1998), “damage-repair” based theory (Doblaré & García 2001) and viscoelastic (Bařotto et al. 2006) bone remodelling models have been proposed.

In Chapter 2.4, various bone remodelling theories are discussed. The implementation of the FE algorithms is elaborated here. Huiskes et al. (1987) developed the strain-adaptive bone remodelling finite element algorithm based on an alternative formulation of the theory of AE, using the *strain energy density* (SED) as a feedback control variable or mechanical stimulus (instead of using a strain tensor alone). The SED is defined as:

$$U = \frac{1}{2} \epsilon_{ij} \sigma_{ij} \quad \text{--- (4.1)}$$

where σ_{ij} and ϵ_{ij} are the local stress and strain tensors respectively. The driving force for adaptive activity to take place is the difference between the actual SED, U , and a homeostatic equilibrium SED, U_n , i.e. $(U - U_n)$. As shown in Fig. 4.2, the algorithm accounted for a threshold level (“ s ”) where the bone remodelling process will not be active, similar to the “*dead zone*” suggested by Carter (1984). Bone will remodel only when the driving force exceeds or is lower than the threshold level. The remodelling response is assumed to be linear, and the slope “ C ” is the remodelling rate. Hence the internal remodelling rate equation is:

$$\frac{dE}{dt} = \begin{cases} C_e (U - (1 + s)U_n), & U > (1 + s)U_n \\ 0, & (1 - s)U_n \leq U \leq (1 + s)U_n \\ C_e (U - (1 - s)U_n), & U < (1 - s)U_n \end{cases} \quad \text{--- (4.2)}$$

where E is the elastic modulus at the point concerned, and C_e is the remodelling rate for elastic modulus change. A similar formula can be used for external remodelling whereby dX/dt , the rate of surface growth perpendicular to the surface, is expressed in the same form as Eq 4.2, and C_e is replaced by C_x . In FEM, U and U_n are expressed per element. The remodelling objective can be “site specific” or “non site specific”. The site specific approach assumes that the bone in a particular location in the knee post TKR strives to equalise its actual SED U to the value in the same location of the intact knee (i.e. before the prosthesis had been implanted), U_n . Thus two FE models are needed for the site specific approach, so that U_n could be obtained from a

reference model of an intact knee, and U is obtained for the model of the knee with TKR. If a non site specific approach is selected, U_n will be set as a constant. This remodelling program was then integrated into FEM codes using commercial software *Marc*, schematically illustrated in Fig. 4.3. To determine the geometrical and material changes, the remodelling rates are integrated using forward Euler integration with a constant time step Δt . For internal remodelling, the change in elastic modulus in each step follows from ($s=0$):

$$\Delta E^i = E^i(t + \Delta t) - E^i(t) = \Delta t C_e \left\{ U^i(t) - U_n^i \right\}, \quad 1 \leq i \leq n \quad --- (4.3)$$

where n is the number of elements. For external remodelling, the relocation of the surface points perpendicular to the surface in each step follows from ($s=0$):

$$\Delta X^j = X^j(t + \Delta t) - X^j(t) = \Delta t C_x \left\{ U^j(t) - U_n^j \right\}, \quad 1 \leq j \leq m \quad --- (4.4)$$

where m is the number of surface nodal points concerned. For internal remodelling, the SED is evaluated per element, averaging the values in the element integration points. In the case of external remodelling the SED is evaluated at the surface nodal points.

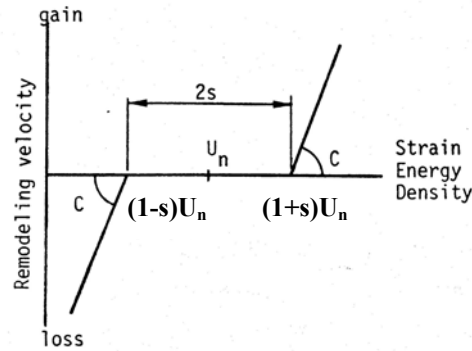


Figure 4.2: Linear strain-adaptive bone remodelling relationship (from Huiskes et al. 1987).

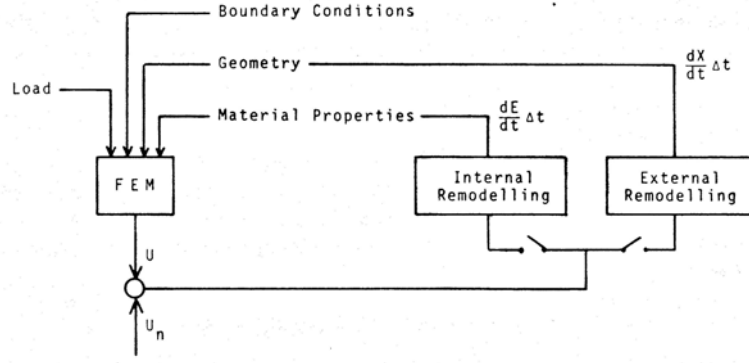


Figure 4.3: Schematic representation of the adaptive remodelling program integrated with finite element codes (from Huiskes et al. 1987).

In a continuation work, a new stimulus of strain energy density per unit of bone mass, $S = U/\rho$, was defined (Weinans et al. 1992a/1992b). It can be obtained in a continuum model by dividing SED by the apparent density ρ . An alternative adaptive response was proposed, showing the nonlinearity of bone resorption and formation (see Fig. 4.4). The mathematical relation for the nonlinear internal remodelling is:

$$\frac{d\rho}{dt} = A \{ S - (1+s)S_n \}^2 \quad \text{if } S > (1+s)S_n \quad \text{--- (4.5)}$$

$$\frac{d\rho}{dt} = 0 \quad \text{if } (1-s)S_n \leq S \leq (1+s)S_n \quad \text{--- (4.6)}$$

$$\frac{d\rho}{dt} = A \{ S - (1-s)S_n \}^3 \quad \text{if } S < (1-s)S_n \quad \text{--- (4.7)}$$

where A is a time constant, and S_n is at homeostatic equilibrium or the reference stimulus. The exponents for bone apposition and resorption are taken to be 2 and 3 respectively to reflect the finding that resorption occurs more progressively than apposition (Parfitt 1983). Similarly with the linear remodelling equation, Eqs 4.5-4.7 are solved by forward Euler integration with a constant time steps Δt in the FEM computer procedure. The density change per time step is calculated from:

$$\Delta\rho = \Delta t A \{ S - S_n (1 \pm s) \}^\alpha$$

$$\text{if } S > (1+s)S_n \quad \text{or} \quad S < (1-s)S_n \quad \text{--- (4.8)}$$

where α takes the value 2 or 3. After each time step, the elastic modulus of the bone is adapted to a new value in relation to Eq 2.1 ($E = 3790\rho^3$) which the strain rate is taken as 1.0 s^{-1} .

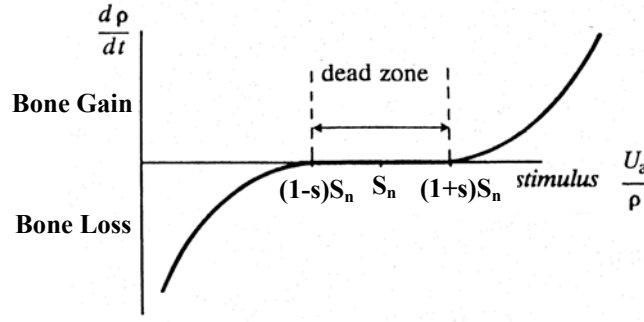


Figure 4.4: Nonlinear strain-adaptive bone remodelling relationship (Weinans et al. 1992).

Finite element algorithms are also being written for the “load history bone maintenance” theory developed by Carter and his associates for computational simulations (Carter et al. 1989). It uses “effective stress” σ_{eff} as the alternative form of stimulus, and the local apparent density of cancellous bone is approximated by the relationship:

$$\rho = K \left(\sum_{i=1}^c n_i \sigma_{eff,i}^M \right)^{(1/2M)} \quad --- (4.9)$$

$$\sigma_{eff} = \sqrt{2EU} \quad --- (4.10)$$

where c = discrete loading conditions, i = specific loading condition, n = number of loading cycles, and K, M = constant (E = elastic modulus, U = strain energy density). As the bone density changes during remodelling, the elastic modulus is calculated as a power function of the apparent density per Eq 2.1 ($E = 3790\rho^3$). Thus in the FE model, the bone elements are adapted with new density and modulus after each iterative step. These adjusted elemental values will be used for the next iterative calculations.

For both the strain-adaptive (linear/nonlinear) and “load history bone maintenance” bone remodelling FE algorithms, a range of allowable density has to be set, usually of $0\text{g/cm}^3 < \rho < 1.7\text{-}1.9\text{g/cm}^3$. This means that the bone can only vary its density between zero and density of the cortical bone. The iterative bone remodelling process will continue until the bone has fully adapted to the mechanical changes and no further change in shape or density will occur.

The strain-adaptive bone remodelling FE algorithms are applicable to both the cortical and cancellous bones (Weinans et al. 1992a), and were validated with animal

experiments (Weinans et al. 1993) and human clinical studies (Kerner et al. 1999; Bitsakos et al. 2005) on periprosthetic bone remodelling. The “load history bone maintenance” FE algorithm was able to predict the distribution of cancellous bone density and trabecular orientation successfully in an adult proximal femur (Carter et al. 1989).

4.5. Summary

The proportion of computational work seems to correlate with clinical studies; at the knee there are more bone remodelling FE studies on the distal femur, while the focus of stress and interface micromotion analysis in relation to aseptic loosening are on the proximal tibia. As discussed in the previous chapter, clinical loosening of femoral components is uncommon even though the likelihood of bone resorption in the distal femur is high. The tibial components continue to become loosened, with deficient bone stock at revision surgery. Haas et al. (1995 B5) reported aseptic loosening of the tibial component as the most common cause of failure, accounting for 23% of the 76 revision TKR cases performed. In contrast, only 5% of the revised cases were due to femoral component loosening. These observations strongly suggest the existence of different failure mechanisms (and bone response maybe) between the tibial and femoral components, which may result from different loading patterns in the proximal tibia and distal femur, different modes and strengths of fixation due to components shape and design, and different anatomical functions etc.

Conflicting stress/strain responses and inconsistent optimal design factors were noted between the many biomechanical studies reported. This is mainly due to the differences in model geometries, material properties assignment, loading conditions and experimental setup, regions of investigation, and even discrepancy between 2D and 3D FE models. A relationship between bone remodelling and component migration is also apparent. It is thus hoped that by implementing bone remodelling algorithms in the FEM studies of bone-prosthesis interface micromotion and component loosening failure (including cemented fixation), FE modelling can provide greater understanding of these phenomena.

CHAPTER 5. FINITE ELEMENT MODELLING OF THE FIXATION OF TIBIAL COMPONENTS OF THE KNEE PROSTHESES

5.1. Background

The computational finite element method (FEM) was first employed in the study of orthopaedic biomechanics in 1972 to analyse the mechanical behaviour of a femur (Brekelmans et al. 1972). Nowadays, FEM has been used extensively for stress analyses of the bones and soft tissues, investigation of joint replacements and fracture, and the study of the musculoskeletal systems. In the area of knee joint mechanics, the FEM studies include knee and soft tissues mechanics, bone remodelling, component loosening, component failure, biomaterials wear and fixation designs evaluation. Geometrical representation of the FE models was generally *two-dimensional* (2D) before the mid 1990s. With the advances in computational capabilities (much faster processing speed and huge memory space available) in recent years, patient-specific *three-dimensional* (3D) models could be created from CT images making the entire computational evaluation more realistic. In a 3D model, full geometric effects of the bone and prosthesis can be captured and detailed heterogeneous mechanical properties can be assigned on an element-by-element basis (Hopkins et al. 2004; Abdul-Kadir et al. 2008; Perillo-Marcone et al. 2004; Sawatari et al. 2005).

The main objective of this research was to develop computational finite element models for the study of tibial fixation performance in relation to bone remodelling and component loosening after TKR. In the current study, 2D axisymmetric models were used for a preliminary parametric study to understand the fundamental mechanisms of stress-shielding. The 3D modelling was then employed for a more detailed analysis of bone resorption and aseptic loosening of the tibial fixation. These FE results were correlated to in-vitro and in-vivo studies documented in literature.

This chapter first outlines the procedures of creating a FE model of the tibial prosthesis fixation, implementation of strain-adaptive bone remodelling in FE

simulations, and the assessment criteria for aseptic loosening in cemented and cementless fixations. Detailed analyses of i) parametric study of the tibial prosthesis designs, ii) bone remodelling after tibial prosthesis implantation (cemented and cementless), and iii) bone-prosthesis interface micromotion for cementless tibial fixation are presented subsequently.

5.2. Finite Element Modelling of the Tibial Prosthesis Fixation

The procedure and steps of creating a 3D patient-specific FE model are described in Fig. 5.1.

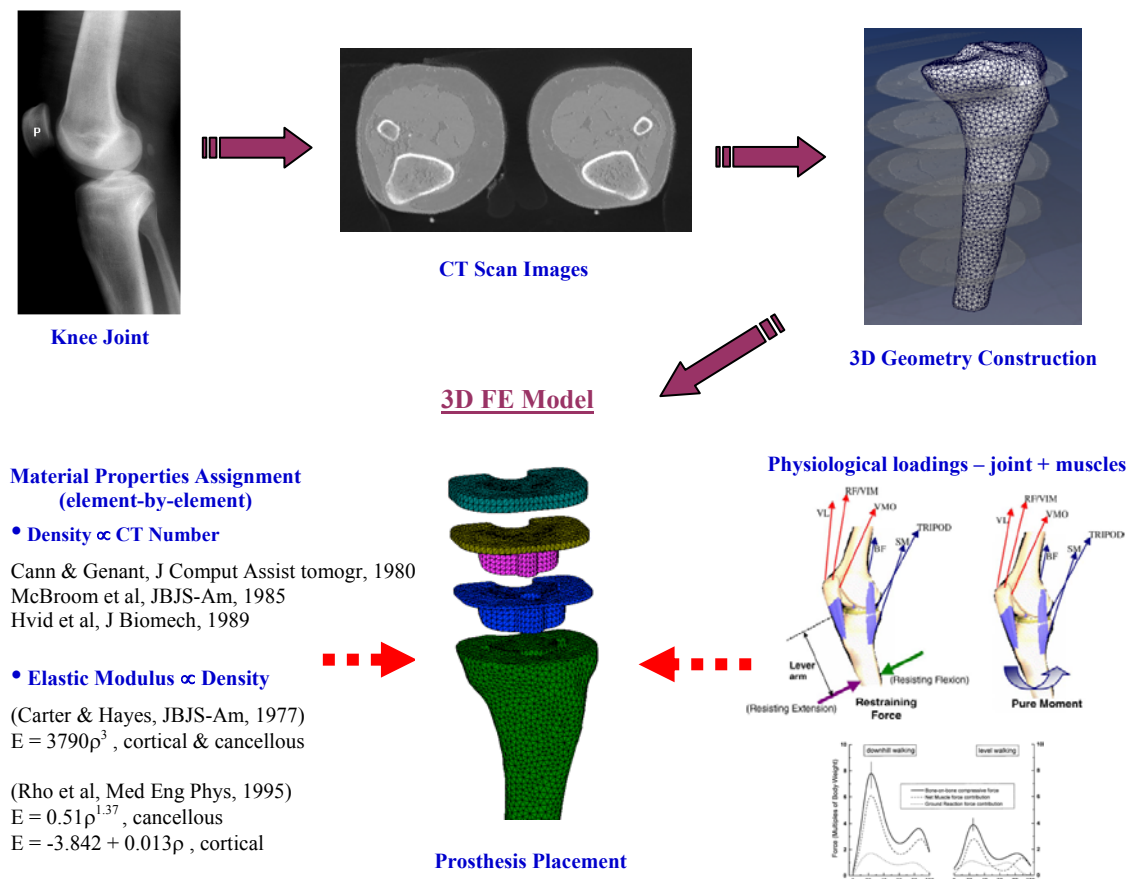


Figure 5.1: Creation of 3D FE models for tibial prosthesis fixation.

The CT scanned images of the patient's tibia were obtained first. They were processed by *Amira* (Amira 2.2, Mercury Computer Systems Inc., Chelmsford, MA, USA), a 3D visualisation and volume modelling software, to reconstruct the 3D geometry from slices of the CT images. The 3D tibial geometry was then imported to Mentat (Marc pre-processing meshing tool) for a virtual resection of the proximal tibia. It was

followed by placing the prosthesis virtually and its position verified by an experienced orthopaedic surgeon. With the prosthesis in place, the bone was then meshed with finite elements. The anatomically site dependent and heterogeneous elastic moduli of the bone were assigned on an element-by-element basis. A linear relationship between the apparent density of the bone and the CT number (or Hounsfield number) was first established (Cann and Genant 1980; McBroom et al. 1985; Hvid et al. 1989). The elastic modulus of every finite element was then computed by the equation proposed which relates the apparent density of the bone to the modulus (Carter and Hayes 1977; Rho et al. 1995). Lastly, physiological loadings representing the joint and muscles forces during gait were applied to the FE model.

Material Properties Assignment of the Bone

Proper definition of bone material properties plays an important role in generating an accurate FE model. Human bone displays anisotropic and heterogeneous characteristics, and its density (hence elastic modulus) is anatomically site dependent. Due to the complexity of anisotropic property assignment (involving 21 elastic constants), most of the FEM studies assumed either isotropic (Walker et al. 1982; Keja et al. 1994; Taylor et al. 1998; Barker et al. 2005), orthotropic (Askew and Lewis 1981; Au et al. 2005/2007) or transverse isotropic (Williams and Lewis 1982; Rakotomanana et al. 1992; Simon et al. 2003) for a simplified representation of the bone property. Assignment of bone as isotropic in FE modelling has generated good predictions in stress (Tissakht et al. 1996; Perillo-Marcone et al. 2004; Zalzal et al. 2006), bone remodelling (Kerner et al. 1999; van Lenthe et al. 2002; Bitsakos et al. 2005), and micromotion (Keja et al. 1994; Hashemi and Shirazi-Adl 2000; Glyn-Jones et al. 2006) studies. Small differences in von Mises stress and nodal displacement were found between isotropic and orthotropic bone material properties assignment for a femur FE model (Peng et al. 2006). But this was not true when anisotropy was considered in bone-prosthesis models. Models with orthotropic bone predicted higher cancellous bone and lower cortical bone stresses (Au et al. 2005), and also higher bone stress underneath the tibial tray but lower shear stresses along the stem (Askew and Lewis 1981). When isotropy was replaced by transversely isotropic properties, stresses at the bone-prosthesis interface were significantly reduced by 20 to 50% (Williams and Lewis 1982). It has been demonstrated that

when bone heterogeneity was correctly accounted for in FE models, anisotropy of the bone would not have much effect on the stress distribution (Askew and Lewis 1981; Hayes et al. 1982; Baca et al. 2008). It was also suggested that modelling of the heterogeneity in bone density is more crucial than accounting for complex bone anisotropy. The reason for this being that the elastic modulus of bone varies with density to a power factor of 2 to 3, whereas the maximum change in modulus along different axes is only about 2-3 times (Galante et al. 1970; Linde et al. 1990; Ciarelli et al. 1991). With these reasons, it is believed that heterogeneity has a more important role than anisotropy in bone behaviour. Also, linear elasticity of the bone was assumed to be valid at physiological loading rates (Pugh et al. 1973). Thus elastic, isotropic and heterogeneous material properties of bone were considered in the current project.

Strain-adaptive Bone Remodelling

In the bone remodelling analysis, the strain-adaptive bone remodelling algorithm adopted by Huiskes and his associates (outlined in Chapter 4.4) (Huiskes et al. 1987; Weinans et al. 1993; van Lenthe et al. 1997), Kerner et al. (1999) and Bitsakos et al. (2005) was used. The algorithm and its computer implementation in *Fortran* was being developed at the Orthopaedic Research Laboratory, Institute of Orthopaedics, University of Nijmegen, Netherlands. It was further enhanced by Jan Kerner, Charalampos Bitsakos and the author (PhD students, Biomechanics Section). Full details of the algorithms and implementation into FEM codes are described by Jan Kerner (1999) and Charalampos Bitsakos (2005) PhD dissertations in the Biomechanics Section, Mechanical Engineering Department, Imperial College London. The algorithm is based on internal modelling and is site dependent, and the internal remodelling rate is defined by Equation 4.2. The time (t) is given in units of one month. The strain energy density per unit of bone mass, $S = U/\rho$ (U = strain energy density, ρ = apparent density), was used as a mechanical stimulus to regulate the linear remodelling process. Two FE models were created for the site specific approach where S_{ref} would be obtained from the reference model of an intact bone, and S_{op} obtained from the model of the bone with prosthesis implanted (Fig. 5.2a). The S of every element in all locations was generated for two situations of i) intact

bone (reference, S_{ref}) and ii) operated bone (with prosthesis, S_{op}) based on the loading in daily activities.

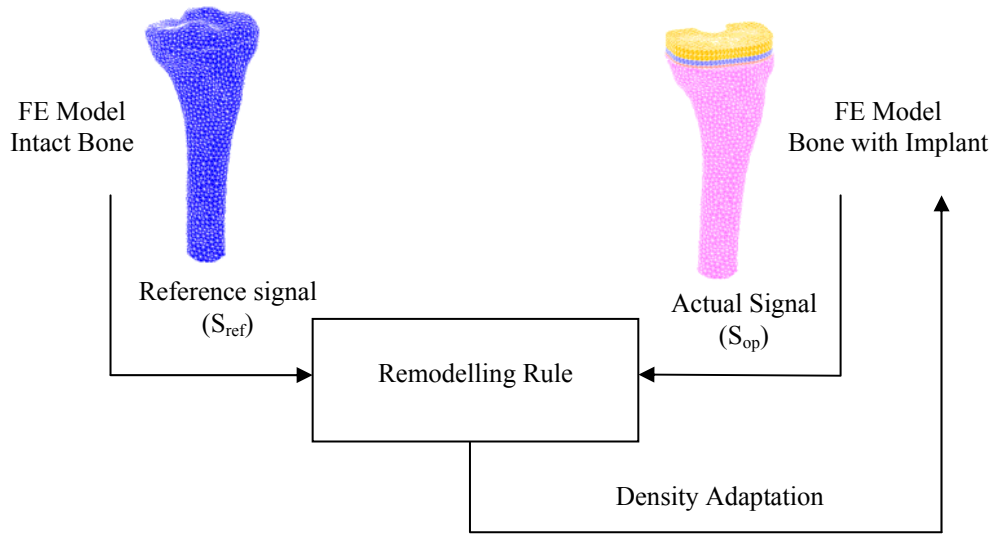


Figure 5.2a: Schematic representation of the strain-adaptive bone remodelling algorithm implemented in FE simulations of tibial prosthesis fixations.

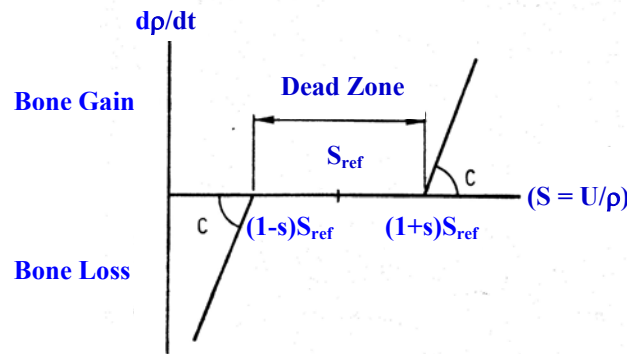


Figure 5.2b: Bone remodelling rule - relationship between bone apposition/resorption and S (U/ρ).

In each time step of the simulation, S_{op} was compared with S_{ref} against the remodelling rule in Fig. 5.2b. A “dead zone” was defined with a threshold level “ s ” set at 0.75 where there would no bone loss or gain. This threshold level has been shown to generate realistic bone remodelling results after hip (Huiskes et al. 1992; Kerner et al. 1999) and femoral knee (van Lenthe et al. 1997; Barink et al. 2003) prosthesis implantation. If $S_{op} > (1+s)S_{ref}$, bone would be formed (apposition). And if $S_{op} < (1-s)S_{ref}$, bone would resorb. At the end of each time step, the density of each element would be adapted to a new value (either increased, decreased or unchanged), and the bone in that particular location would gain or lose part of its density. At the start of the next time step, the elastic modulus of each element would be updated with a new value according to the pre-defined modulus-density relationship (Eqs 2.1, 2.3 to

2.6). The strain-adaptive remodelling simulation continues until the operated bone has fully adapted to the mechanical changes produced by the prosthesis or the SED of the operated bone matches with the intact bone, i.e. an “equilibrium” state has been reached. The Poisson’s ratio was assumed to remain constant throughout the simulation.

Aseptic Loosening (Cemented Fixation)

The behaviour and responses of the materials at the bone-prosthesis interface are important factors possibly causing aseptic loosening. It has been suggested that fatigue failure of the supporting cancellous bone could lead to component migration and eventual loosening (Taylor and Tanner 1997). A retrieval study revealed that bone cement failure could be another detrimental factor for late aseptic component loosening (Jasty et al. 1991; Lewis 1997), and that the primary cement failure mechanism is fatigue (Topoleski et al. 1990). Bone-cement interface failure was also normally observed in loosened tibial prostheses (Rakotomanana et al. 1994; Ramaniraka et al. 2000), and so a strong interfacial strength between the bone and cement is essential for long-term reliability against loosening (Arola et al. 2006; Mann et al. 2008). The initial stress levels extracted from FE models based on the immediate post-operative state were used as an indicator for long-term fatigue failure. Stresses of the cancellous bone underneath the tibial tray predicted from FEM have been used to assess the relative risk of TKR component loosening (Taylor et al. 1998; Perillo-Marcone et al. 2004), however the risk ratio did not correlate well with clinical survivorship data (Taylor et al. 1998). For a cemented tibial fixation, the cement stresses were found to be insensitive to the shape of the stem (Au et al. 2005), and high tensile cement stresses were experienced close to the stem (Shrivastava et al. 1982). Shear stresses predicted at the bone-cement interface along the stem had been shown to decrease with increasing stem length (Askew and Lewis 1981), showing a positive correlation with lower prosthesis movement for tibial trays with a longer stem (Jazrawi et al. 2001). It was proposed in this study that by considering the failure parameters of cancellous bone stress (or strain), cement stress and bone-cement interfacial shear stress collectively in FE analyses, the relative risk of component loosening could be better assessed.

Aseptic Loosening (Cementless Fixation)

The cementless fixation, an alternative to the cemented technique, relies on bony ingrowth onto the porous surfaces of the prosthesis thereby providing a biological attachment. Minimal movement between the prosthesis and the adjacent bone enhances the bone ingrowth or osseointegration process. With the porous-coated prosthesis directly in contact with the bone by press fitting, the bone-prosthesis interface was modelled as unbonded and contact surfaces were defined between them with an appropriate coefficient of friction assigned. Similar contact modelling approach was used by other researchers (Tissakht et al. 1995; Hashemi and Shirazi-Adl 2000; Barink et al. 2003). The bone-prosthesis interface micromotion was computed based on an algorithm developed by Dr Andrew Hopkins (Post-Doctoral Fellow, Biomechanics Section), which was based on the immediate post-operation condition where bony ingrowth has not occurred. The threshold of interface micromotion, below which bone ingrowth was likely to occur, was set at **50 μ m** in the current study (see Chapter 3.3).

The use of gap elements (Shirazi-Adl and Ahmed 1989; van Lenthe et al. 1997; Bitsakos et al. 2005) and surface-to-surface contact elements (Keja et al. 1994; Rakotomanana et al. 1994; Taylor et al. 1998; Simon et al. 2003) are other ways of modelling the contact interfaces between bone and prosthesis in cementless fixation. Gap elements are not suitable for large shear motion or slipping (Zachariah and Sanders 2000), and micromotion prediction using surface-to-surface contact elements was found to be much more accurate than the gap elements (Viceconti et al. 2000). In performing contact analysis, the numerical objectives are to detect the motion of the bodies, apply a constraint to avoid penetration, and apply appropriate boundary conditions to simulate the frictional behaviour (MSC Marc Manual 2005). It involves the solving of a constrained minimisation problem where the constraint is ‘no penetration’, and the use of either the technique of the Lagrange multiplier or the Penalty method was found not to produce appreciable differences in the FE prediction of interface micromotion (Bernakiewicz and Viceconti 2002).

5.3. Stress Analysis for Parametric Study of Tibial Prosthesis Designs

5.3.1. Introduction

As described in the preceding chapters, critical conflicting design requirements for tibial prosthesis fixation are observed: prosthetic designs favourable in terms of minimising component migration have an adverse effect on proximal stress-shielding, thus leading to bone resorption. With fixation studies on component loosening and stress-shielding carried out separately where in reality these mechanisms interact, the impact of different tibial prostheses on fixation performance cannot be captured fully. Fixation analysis needs to be performed in a unified manner so that the effects of prosthesis design features can be characterised optimally. In addition, although both the bone or bone-cement interface fatigue have been suggested to induce long-term aseptic loosening, it remains unclear which mechanical phenomenon is prevailing to cause loosening failure.

The objectives of this study were to characterize the influence of tibial prosthesis design features on proximal stress-shielding and component loosening, and to examine the stresses in the cancellous bone and bone-cement interface underneath the tibial tray. This preliminary parametric study was limited to a simplified geometry that would be capable of demonstrating the consequent trends in the results for a wide range of prosthesis designs and, therefore, identify the specific designs of interest for more detailed analyses.

5.3.2. Materials and Methods

Two-dimensional axisymmetric FE models were used to represent a section of the mid coronal plane of the tibia with a prosthesis implanted (Fig. 5.3). The tibia represented a mid-size human knee with a medial-lateral (ML) width of 74mm. The FE model was created using linear isoparametric quadrilateral and triangular elements, with approximately 2500 elements for all prosthetic designs. The tibial model consisted of the tibial bone (cortical and cancellous), tibial tray, polyethylene (PE) insert and polymethylmethacrylate (PMMA) cement. The heterogeneous material properties of the bone were modelled with six sections of different modulus

(cortical diaphyseal, cortical metaphyseal, cancellous epiphyseal/proximal, cancellous metaphyseal 1 & 2, and cancellous diaphyseal). Linear elastic behaviour was assumed for all materials. The tibial tray was made of Titanium alloy, and properties of all materials are listed in Table 5.1. Moduli for the diaphyseal and metaphyseal cortical bone were taken as 17GPa (Reilly and Burstein 1975) and 5GPa (Taylor et al. 1998) respectively, and the cancellous bone sections from values reported by Goldstein et al. (1983). The cement mantle thickness was 2mm all round the tibial tray and stem. A joint load of 2100N (3 times normal body weight) was applied at the condyle positions on the tibial tray. The axisymmetric boundary condition was prescribed by $U_x=0$, and the tibia was assumed to be rigidly fixed distally with $U_x=U_y=0$, both shown in Fig. 5.3.

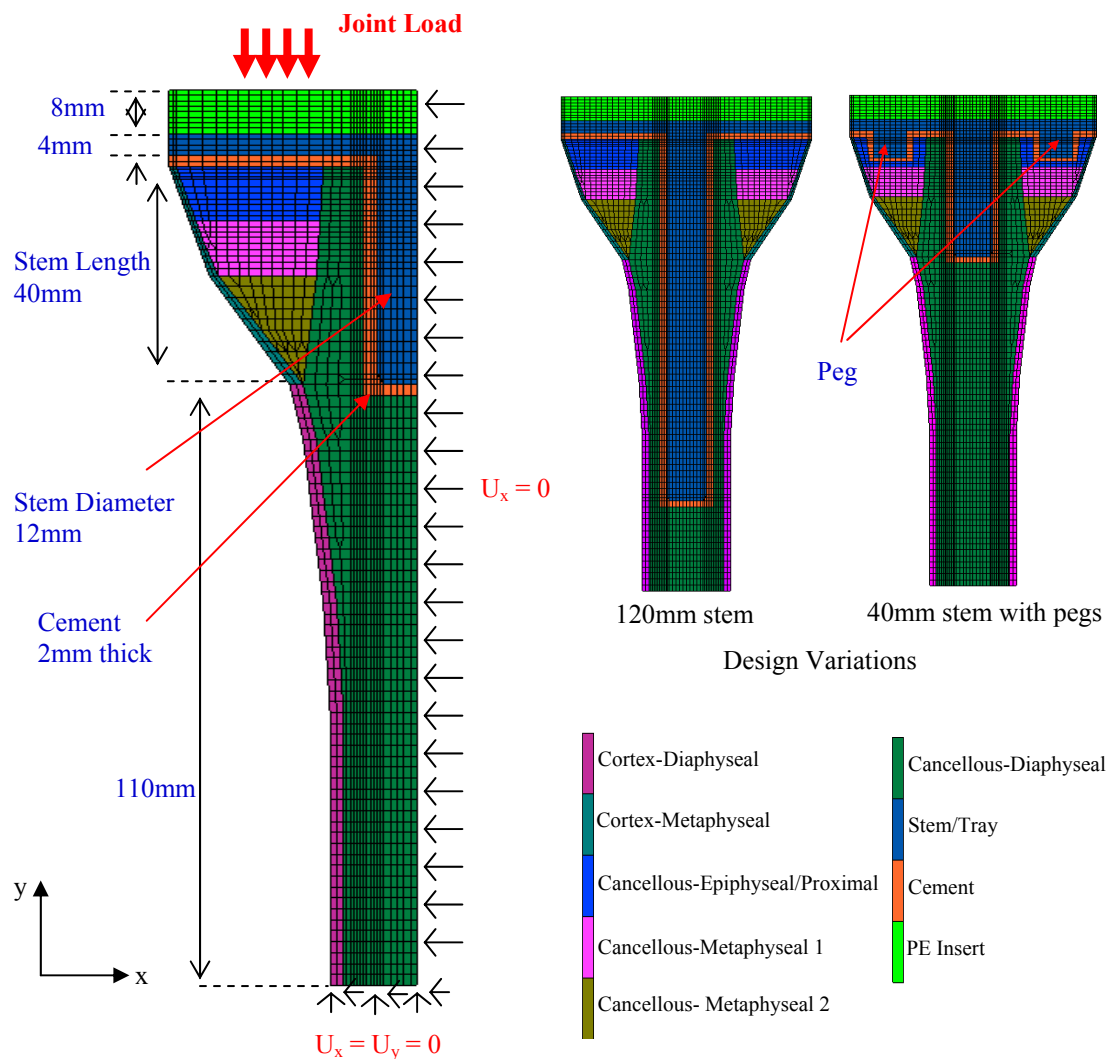


Figure 5.3: 2D axisymmetric FE models of the tibia and tibial prosthesis.

Table 5.1
Material properties of the tibia and tibial prosthesis

Material	Elastic Modulus (MPa)	Poisson's Ratio
Diaphyseal cortical bone	17000	0.3
Metaphyseal cortical bone	5000	0.3
Cancellous epiphyseal/ proximal bone	400	0.3
Cancellous metaphyseal bone 1	320	0.3
Cancellous metaphyseal bone 2	300	0.3
Cancellous diaphyseal	100	0.3
Cement (PMMA)	2000	0.23
PE	1000	0.3
Stem/Tray (Titanium alloy)	110000	0.33

The tibial prosthesis design variations being investigated are described in Table 5.2. The prosthesis with a 40mm stem (design C) with dimensions shown in Fig. 5.3 formed the baseline reference for comparison. Clinically, tibial trays with a short stem (for instance 40mm) are usually used in primary TKR. It is when the surgeon feels that the native bony support of an individual patient is inadequate for implant stability that an alternative prosthesis design like a longer stem or fixation pegs will be used. The effect of prosthesis material stiffness was investigated with three different elastic moduli: i) 110GPa (Titanium alloy, current baseline), ii) 200GPa (Cobalt Chromium, CoCr), and iii) 17GPa (“bone compatible” material). The impact of cement thickness was also analysed. For a stemmed prosthesis to be fitted using bone cement, the tibia was assumed to be reamed with a hole 4mm larger than the stem diameter giving a cement mantle 2mm thick. However in some situations such as revision surgery, or porotic bone in the patient’s tibia where more bone removal is needed for a firmer bone-cement engagement, the tibia is reamed to an even larger diameter, giving a thicker cement layer. In this case, the overall prosthetic structural stiffness will increase with the additional amount of cement (cement is stiffer than the surrounding cancellous bone). The increased structural stiffness was also evaluated to determine if it would result in further stress-shielding in the proximal bone. A firm interlock fixation is formed with the use of cement, hence the interfaces of the cement with the bone and prosthesis were modelled as perfectly bonded.

Table 5.2
Design variations of the tibial prosthesis used in the study

Design	Design Configurations		Pegs
	Stem length (mm)	Stem diameter (mm)	
A	Stemless	Stemless	No
B	Stemless	Stemless	Yes
C*	40	12	No
D	40	12	Yes
E	40	16	No
F	70	12	No
G	120	12	No
H	Similar to “C” but it is an all-polyethylene tibial tray and stem		
C1	Similar to “C” - stem/tray stiffness reduced to 17GPa		
C2	Similar to “C” - stem/tray stiffness increased to 200GPa		
C3	Similar to “C” - cement thickness increased to 4mm		
F1	Similar to “F” - stem/tray stiffness reduced to 17GPa		
F2	Similar to “F” - stem/tray stiffness increased to 200GPa		

* Design C is the baseline reference for comparison

To study the effect of design variation on proximal stress-shielding, the strain energy density (SED) was used as a mechanical stimulus for bone remodelling (Huiskes et al. 1987). For each prosthesis design, the averaged SED in the “cancellous-epiphyseal” bone region (see Fig. 5.3) was extracted and compared to the reference value (SED_{ref}) of the pre-operative intact tibia. The stress-shielding signal was defined as $(SED - SED_{ref})/SED_{ref}$, where a negative value indicated a likelihood of bone resorption. The minimum principal (compressive) stress in the cancellous bone at the resected surface, as well as the shear stress along the bone-cement interface underneath the tibial tray, were examined to evaluate the relative risk of component loosening between different prosthesis designs. The risk ratios of cancellous bone fatigue failure (bone stress/bone fatigue strength) and bone-cement interface fatigue failure (interfacial shear stress/bone-cement interface fatigue strength) were also determined to see if a dominant factor for loosening failure could be identified. For a modulus of 400MPa for the epiphyseal cancellous bone underneath the tray, fatigue failure after 1 million cycles has been reported for an apparent stress level of 3.57MPa (Michel et al. 1993). For the bone-cement interface, an apparent fatigue strength of 3.2MPa was reported for a similar number of test cycles (Arola et al. 2006).

5.3.3. Results

Stress-shielding and stress/strain distribution in the tibia after prosthesis implantation

The von Mises stress (MPa) distribution in the cancellous bone in the tibiae with stemless, short- and long-stemmed prostheses shown in Figs. 5.4 and 5.5 illustrates the stress-shielding phenomenon and the general bone response after implantation of a metallic prosthesis. For the stemless design, joint forces were transmitted distally through the epiphyseal cancellous bone to the metapophyseal regions, causing high compressive stresses (Fig. 5.4a). When a stemmed prosthesis was implanted, the joint load was transferred through the stem distally thereby relieving the proximal bone stress (Fig. 5.4b). Similar stress distribution and magnitudes have been reported (Vasu et al. 1986). Further increase in the stem length transferred more of the joint load to the distal diaphyseal cancellous bone. As a result of this change in the load pathway, the bone around the distal part of the fixation stems experienced higher stresses (Fig. 5.4c). The stresses in the cancellous bone along the tibia (dotted line) are shown in Fig. 5.5. The bone stresses in the proximal region were highest for design A, and decreased with the addition of a stem with increasing length. The cancellous bone stress generally increased from proximally to distally, reaching a maximum at the stem tip, showing the load transfer capability of a cemented stem. The longer the stem, the higher the stresses around its tip.

The predicted strain energy densities in the proximal tibia (averaged in the “cancellous-epiphyseal” bone region) and stress-shielding signals for different prosthesis designs are shown in Fig. 5.6. The stress-shielding signals were negative in value for all designs, indicating that the proximal bone of the operated tibia was subjected locally to lower SED compared to the pre-operative tibia thus leading to a likelihood of bone resorption. The possibility of bone resorption was estimated to be 50-70% for the stemless designs and the use of an all-polyethylene (all-PE) tibial tray and stem, and increased to 80-92% for the stemmed (and longer stem and larger in diameter) tibial trays.

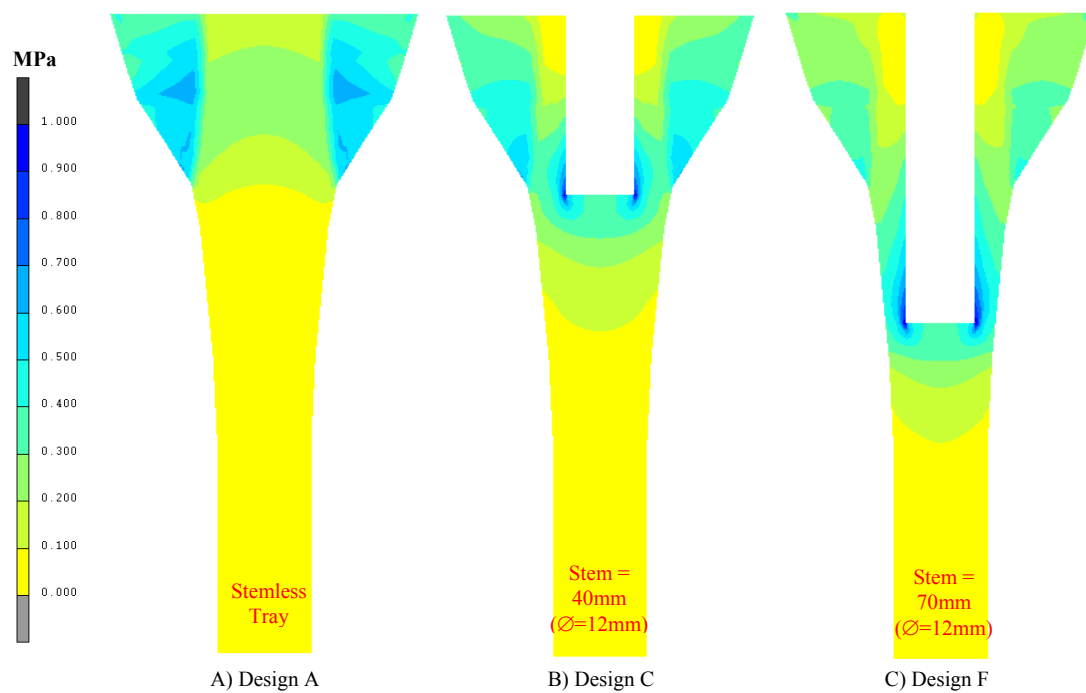


Figure 5.4: Von Mises stress (MPa) distribution in the cancellous bone of the tibia upon loading.

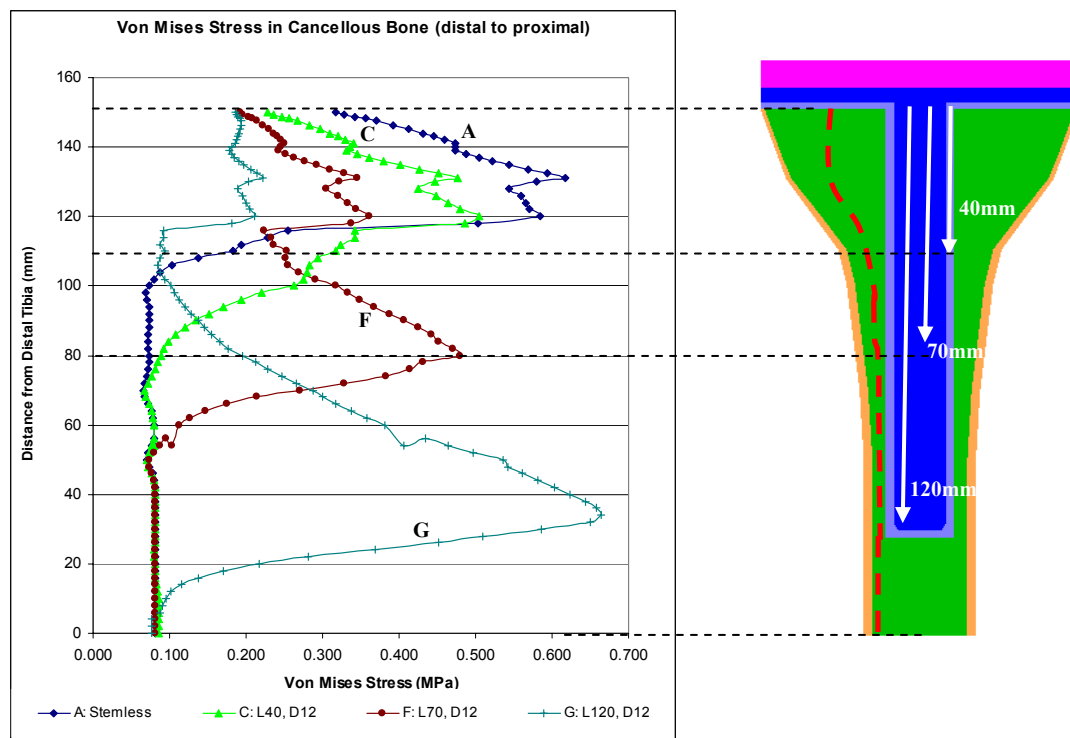


Figure 5.5: Von Mises stress plots along the tibia cancellous bone (red dotted line as shown from distal to proximal). L = stem length (mm) and D = stem diameter (mm).

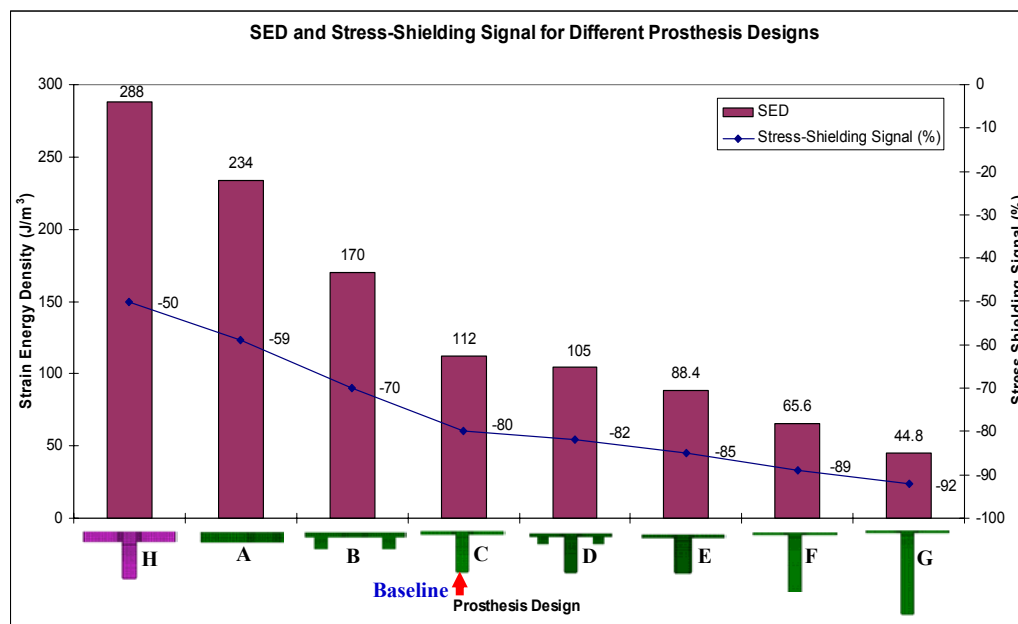


Figure 5.6: Influence of prosthesis designs on strain energy density (extracted from the proximal “cancellous-epiphyseal” bone region) and stress-shielding signal in the proximal bone.

Proximal cancellous bone stresses and bone-cement interfacial shear stresses

The mean minimum principal (compressive) stress in the cancellous bone at the resected surface and the peak bone-cement interfacial shear stress were used as failure parameters to assess the likelihood of aseptic loosening between different designs. Fig. 5.7 shows that stresses in the supporting cancellous bone underneath the tibial tray were reduced with the inclusion of long stems as the proximal load was transferred distally. Conversely, removal of the stem led to the mean compressive stress rising 52% in relation to the standard 40mm fixation stem design, and a relative 59% increase in bone stress when the metal tray with 40mm stem was replaced by the polyethylene material. The addition of fixation pegs reduced the mean compressive stress, by 46% in relation to the flat tray (A versus B) and by 41% for the 40mm stem design (C versus D). A consequence of this was a 30% increase in the stresses in the bone below the tip of the fixation feature. A similar trend was observed for the bone-cement interfacial shear stresses with variation in fixation geometry (Fig. 5.8), although smaller changes in relation to the standard 40mm stem design were found. An exception was noted for the all-PE tibial prosthesis (design H), where the interfacial shear stress decreased by 57% relative to design C.

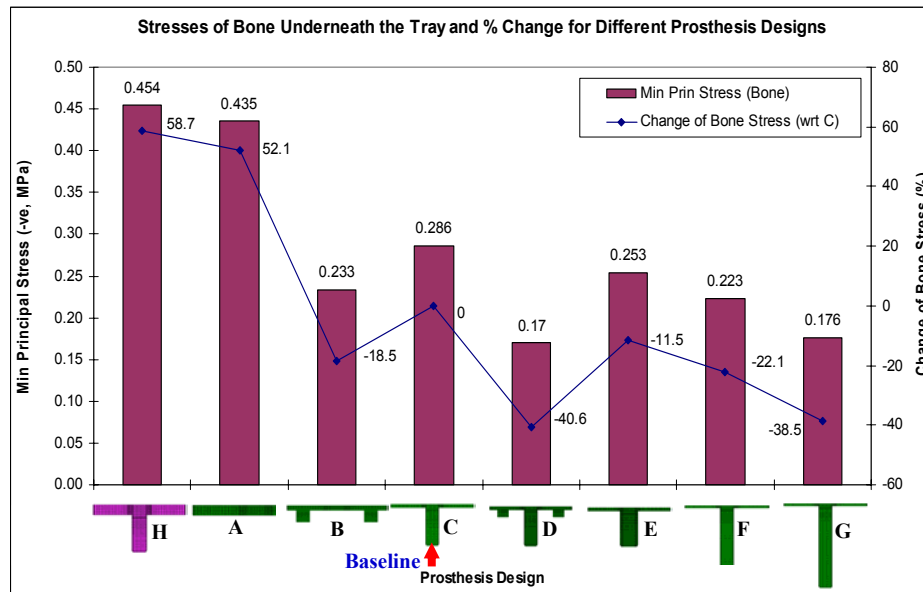


Figure 5.7: Effects of prosthesis designs on minimum principal (compressive) stresses in the cancellous bone.

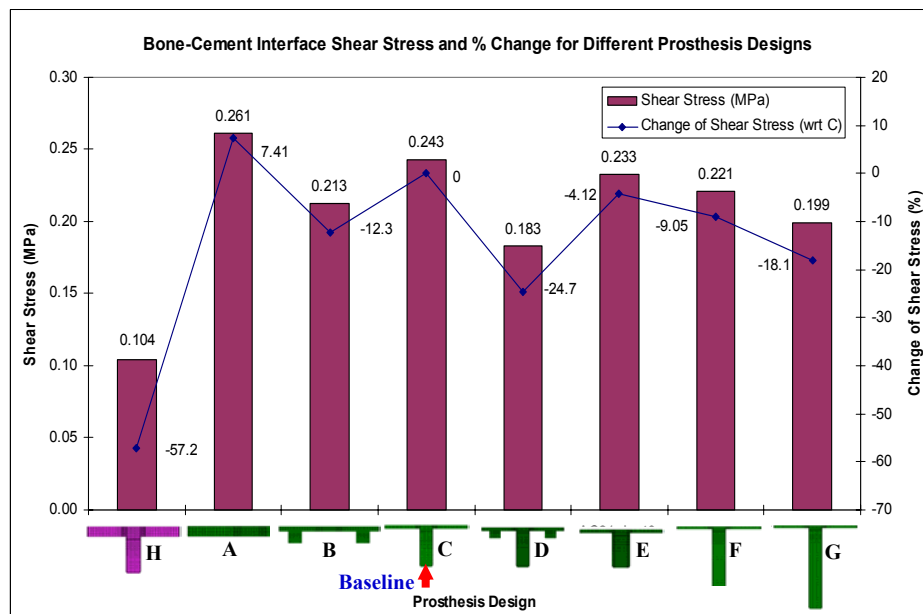


Figure 5.8: Effects of prosthesis designs on bone-cement interfacial shear stresses.

Fig. 5.9 shows the risk ratios of cancellous bone fatigue failure and bone-cement interface fatigue failure against different fixations. The trend and risk ratio are quite comparable between the two failure parameters for the metal-backed tibial tray fixations. However for the all-PE tibial prosthesis, risk ratio of the bone-cement

interface failure dropped, which was in opposite trend to the rise of risk ratio for bone fatigue failure.

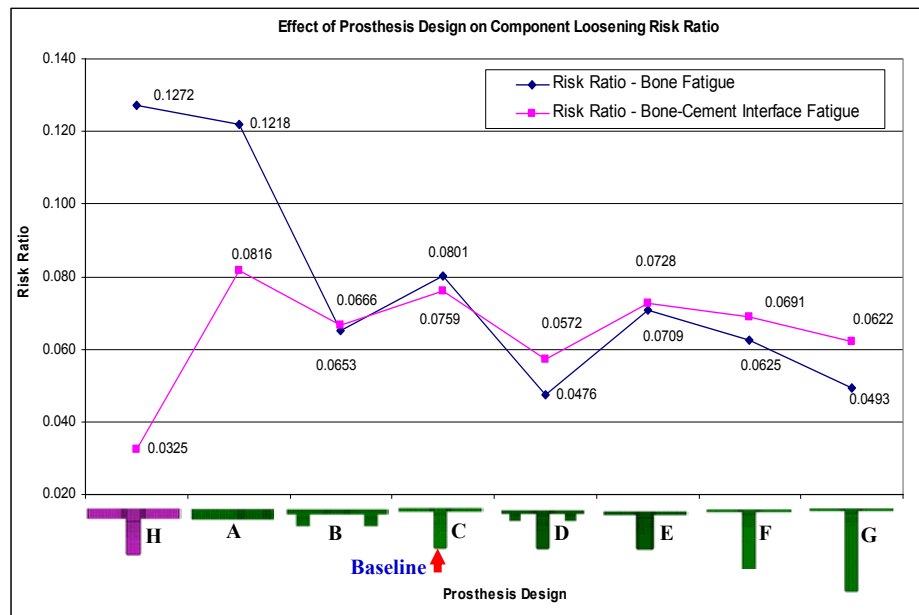


Figure 5.9: Risk ratios for cancellous bone fatigue failure and bone-cement interface fatigue failure.

Effects of prosthesis material stiffness

The effects of changing the stiffness of the prosthesis material on stress-shielding and component loosening for tibial prostheses of 40 and 70mm stem length are reflected in Fig. 5.10. The “bone compatible” material resulted in 49-89% higher SED in the proximal bone than the Titanium alloy (for both short and long stems), and thus was favourable for minimising stress-shielding. It had also reduced the bone-cement interfacial shear stresses by 22-28% but increased the compressive stresses in the cancellous bone marginally (22-37%). The change in the stress responses between the CoCr and Titanium stems were less drastic. The SED related bone resorption in the proximal tibia, was decreased by less than 14%. The compressive bone stresses at the cut tibial surface were reduced by 3-8%, and the bone-cement interfacial shear stresses were increased by 3-9%.

The influence of cement mantle thickness

It was found that for the design changes studied that included reaming a 20mm diameter bone cavity, there were relatively small effects on the relative risk of aseptic loosening (Fig. 5.11). When the cement layer increased from 2 to 4mm thick, the SED in the proximal bone was reduced by 16%.

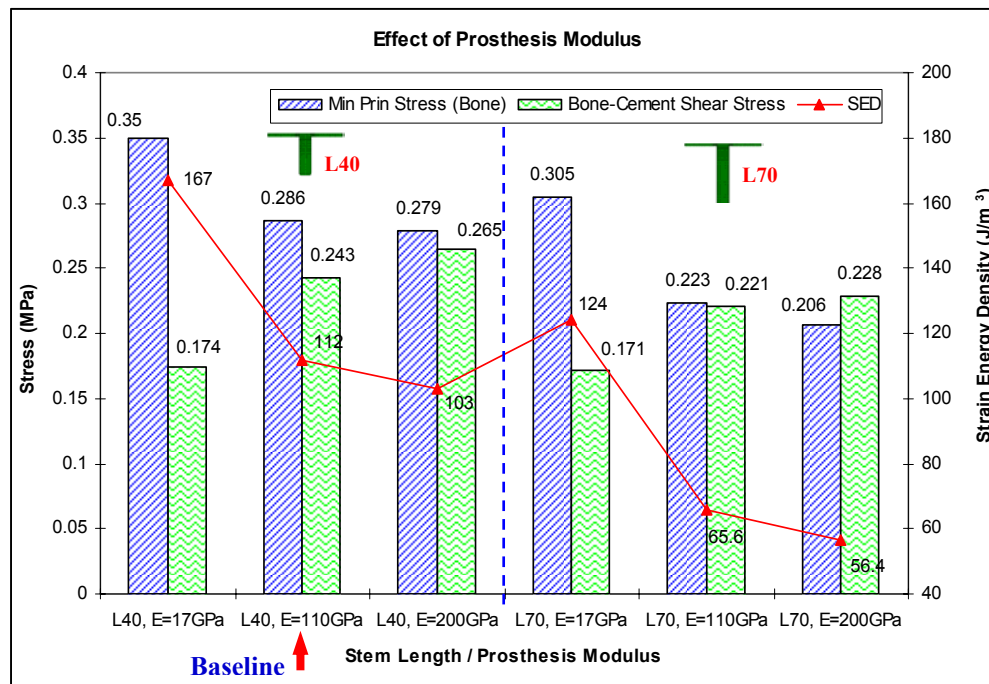


Figure 5.10: Effect of prosthesis material moduli on fixation stress responses.

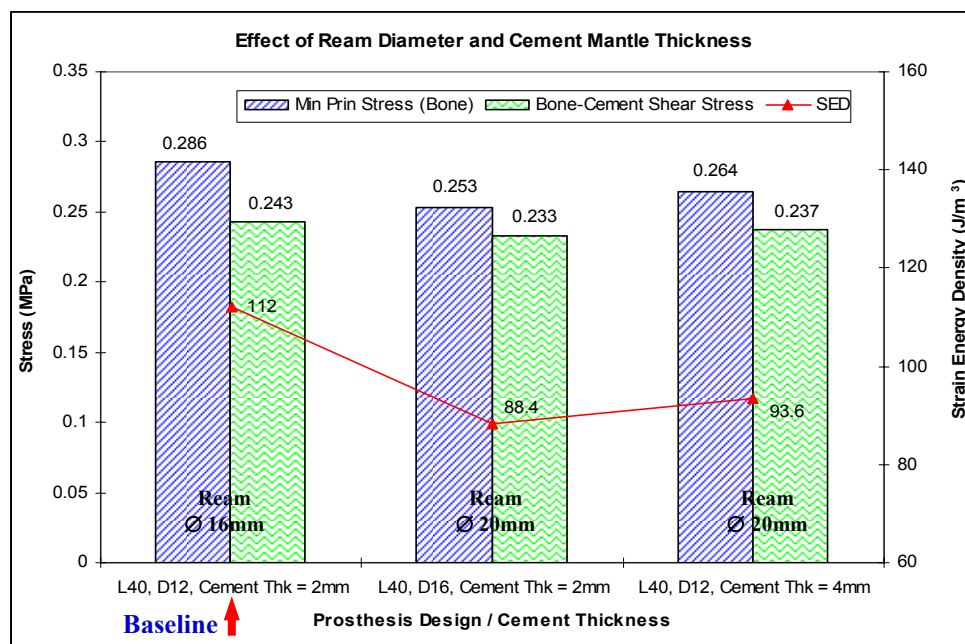


Figure 5.11: Effect of cement mantle thickness on fixation stress responses.

5.3.4. Discussion

In this study, an axisymmetric finite element model of the tibial prosthesis with linear elastic, isotropic and heterogeneous bone properties was used for characterising the influence of tibial prosthesis design features on fixation performance. The 2D FE models were chosen to reduce the many man-hours needed to create and develop the models, and to enable a parametric study that was capable of demonstrating the consequent trends in the results for a wide range of prosthesis designs. The current stress responses predicted using the 2D models were in agreement with other 3D modelling studies, and axisymmetric models have been shown to provide reliable and valuable design trends (Murase et al. 1983; Shirazi-Adl and Ahmed 1989; Barker et al. 2005). Some specific limitations in the current modelling methodology should be discussed. Firstly, the 2D model was not able to capture the full geometrical effects of the prostheses (such as flange and pegs). Secondly, the anatomical site-dependent elastic modulus of the bone was not fully represented by the 2D model. However the current method of dividing the tibia into cortical and cancellous segments of different elastic moduli gave a fairly good representation of the stiffness variation across the tibia. The discontinuity in stresses at approximately 118mm level of the tibia (Fig. 5.5) was caused by the change in material stiffness over two cancellous bone segments. Thus it is advisable to map the detailed heterogeneous mechanical properties of the bone from clinical CT data on an element-by-element basis, where a smooth transition of material stiffness could be obtained. Thirdly, the current joint load only acts in the axial direction. The 30/70 proportion of physiological load in the lateral/medial condyles and shear components were not accounted for, nor were the actions of muscles and tendons that attach to the proximal tibia. Together with the irregular tibia shape and non-circular tibial plateau, the 30/70 lateral/medial load distribution and shear forces may alter the stress responses of the tibia/prosthesis structure. Regardless of these limitations, the trends of stress responses were in agreement with the 3D FE studies available in the literature (Bartel et al. 1982; Au et al. 2005; Au et al. 2007), and the load-transfer phenomenon predicted correlated with tibial strain measurements (Bourne and Finlay 1986) and bone density scans (Lonner et al. 2001) which have shown that the stress-shielding effect was more significant with stemmed prostheses (and longer stems).

In the present work, the optimal design features for improved component fixation were clearly shown to have a negative influence relative to stress-shielding. If fixation security alone had been studied, this would have led to a recommendation to include longer fixation stems. Conversely, if the study had examined stress-shielding, it would have led to very minimal fixation features or a PE component being recommended. Thus, despite the 2D simplification, the analysis of both stress-shielding and fixation security in one combined study has led to novel insights in tibial component fixation design. It appears that the best overall approach would be to choose a prosthesis design which has relatively small fixation features. This study also presented the mechanisms of proximal stress-shielding after tibial prosthesis implantation. In addition, the relative risks of bone resorption and component loosening between different tibial fixations were assessed, with the risk ratios of cancellous bone and bone-cement interface fatigue failures reported.

Bone resorption in the proximal tibia after tibial prosthesis implantation

The current approach used strain energy density as a parameter to predict the likely bone resorption behaviour. Strain-adaptive bone remodelling theory (Huiskes et al. 1987; Weinans et al. 1992b) has been incorporated into finite element analysis for bone remodelling investigations after hip (Kerner et al. 1999; Bitsakos et al. 2005) and femoral knee (van Lenthe et al. 2002; Barink et al. 2003) prosthesis implantation. FE modelling in the current study predicted 80% SED decrease in the proximal bone when a 40mm stem prosthesis was implanted in the intact tibia, but a bone adaptation simulation estimated a global bone resorption of 15% of the tibial bone density at 1-year after TKR (Rakotomanana 2001). This suggests the need for further work, to link bone remodelling theory to clinical bone density data.

Component loosening assessment using cancellous bone stress and bone-cement interfacial shear stress

The current FE models simulated the situation of the tibial prosthesis immediately after operation, where the interfaces of bone-cement and prosthesis-cement were securely bonded. Clinical analysis has shown that radiolucent lines occur more frequently underneath the tibial trays, with few or none observed at the stem or peg

tips (Ecker et al. 1987; Hannsen et al. 1988; Hsu et al. 1995). Thus only the cement layer underneath the tray was used for assessing the effect of prosthesis design changes on the likelihood of bone-cement interfacial failure.

The cancellous bone stresses and bone-cement interfacial shear stresses predicted in the current study were low compared to the threshold level of fatigue failure, hence the risk ratios were also low (<15%). This could be due to the stress magnitudes not being predicted precisely by the 2D FE models, or a higher joint load is needed to generate higher stresses to trigger fatigue response. The peak load acting on the knee joint can go up to 3.9 times body weight (BW) during level walking or even 6 times BW during stair descent (Kuster et al. 1997), while a nominal joint load of 3 times BW was used in this study. With the bone stresses and bone-cement interfacial shear stresses generated by a lower load being normalised with its fatigue strength, the risk ratios computed would reasonably be valid for relative comparison of fatigue performance between the cancellous bone and bone-cement interface. Fig. 5.9 suggests that with metal-backed tibial trays, fatigue of either the cancellous bone or the bone-cement interface is similarly likely as a cause of long-term aseptic loosening. For the all-PE tibial prosthesis, fatigue of the supporting cancellous bone could be the dominating factor for inducing loosening failure in the long run. This can be explained by the reduced load transfer capability of the less stiff polyethylene stem, leading to the increase in compressive stress at the supporting cancellous bone. Also the all-PE prosthesis would be more compliant with bone deformation due to its lower stiffness, hence a lower bone-cement interface shearing could be expected.

The large differences in the cancellous bone stress between different fixation geometries were not reflected by similarly large changes in the bone-cement interfacial shear stress, and the magnitudes differed (Figs. 5.7 & 5.8). For instance, increasing the stem of the tibial tray from 40mm to 70 or 120mm resulted in 22-38% decrease in the supporting bone stress but only 9-18% reduction in bone-cement shear stress. This suggests that should a surgeon vary his choice of tibial prosthesis, the stresses in the underlying supporting cancellous bone would have a greater influence on fixation performance than would the smaller change in cement stress. The cement mantle was modelled as a solid layer, whereas the reality is that it will be at least partly porous. The porosity is dependent on the preparation techniques, and affects the

cement's fatigue performance (Gates et al. 1984; Murphy and Prendergast 2000). However it was anticipated that the results obtained in this study would be adequate for comparative analysis between prosthesis designs.

There are only limited in-vivo and in-vitro parametric studies reporting the effect of design change on cemented tibial component loosening, probably due to the additional logistical and financial commitments required. Lower tibial prosthesis movement and subsidence were reported for tibial trays with a longer stem (Yoshii et al. 1992; Jazrawi et al. 2001), and the trends generated by the current FE models matched with these observations. More detailed studies may allow more exact relationships between the stresses in bone and cement interface and the fixation performance to be derived.

Effect of tibial prosthesis design features on fixation performance

The risk assessment for component loosening between different prosthesis designs was relative to the baseline design C (stem length = 40mm, stem diameter = 12mm). The design features for improved component fixation were shown to have a negative influence on stress-shielding. The risk ratios of component loosening (Fig. 5.9) decreased with the increase of the stem length/diameter (designs E, F & G) and increased with the removal of the stem (design A). However the reverse trend was observed for stress-shielding. Risk ratios were also lowered by 18-46% with the inclusion of fixation pegs to the short stem (design D versus C) and stemless (design B versus A) tibial trays, suggesting that fixation pegs help to distribute and off-load stresses in the proximal bone below the tray. The stemless tibial tray with fixation pegs (design B) was found to be a possible alternative for the baseline design C, as both the risks in component loosening and stress-shielding were potentially reduced. Clinical results for this design were encouraging with a survivorship of 90% at ten years reported (Parker et al. 2001) and component migration was comparable to other stemmed tibial prostheses (Ryd et al. 1990). Bone density of the proximal tibia fitted with this prosthesis type was decreased by 13% after 3 months post-operatively, and regained to the initial post-operative level at 2 years (Li and Nilsson 2000).

A distinctive trend was noted earlier for the all-PE tibial design (H) – the possibility of loosening due to cancellous bone fatigue failure was much greater than its metal-backed counterpart (design C), but the likelihood of bone-cement interface fatigue failure was considerably reduced. With the stress-shielding signal approximately 40% lower than the metal-backed design, the slower bone resorption rate could counter the negative impact of bone fatigue. These observations may account partly for all-PE tibial components having comparable survival rate with metal-backed trays (Najibi et al. 2003; Gioe et al. 2007) if not better (Rodriguez et al. 2001), and higher occurrence of radiolucencies around the metal-backed than all-PE tibial prosthesis (Gioe et al. 2000; Rodriguez et al. 2001).

Using 3D FE modelling with orthotropic and heterogeneous bone properties (Au et al. 2007), a tibial prosthesis with elastic modulus similar to the surrounding cancellous bone was found to increase stress levels in the proximal bone region (hence a higher loosening risk). The “bone compatible” tibial prosthesis results reported in this work agrees with that of earlier work. Conversely, the change in stress responses caused by introducing a stiffer prosthesis (CoCr) in place of the Titanium alloy was less drastic, suggesting that the influence of the prosthesis modulus reduces when its value is much larger than the bone. Similar observations were made between Titanium alloy and CoCr materials in strain-adaptive bone remodelling studies for femoral knee (Barink et al. 2003) and hip (Weinans et al. 2000) prostheses.

5.4. Bone Remodelling after Tibial Prosthesis Implantation

5.4.1. Introduction

Proximal tibial bone resorption due to stress-shielding of the stiff implanted prosthesis is a clinical concern, where the formation of weakening bone zones and loss of bone-prosthesis support can have a consequential effect on component loosening. It also presents a challenge for revision TKR procedures. Fully cemented (cement applied at both tibial tray and stem) (Lonner et al. 2001; Abu-Rajab et al. 2006), hybrid cementing (Schai et al. 1998; Adalberth et al. 2001) or cementless (Hofmann et al. 2001; Whiteside 2001) fixation techniques may be chosen. The influence of these different fixation techniques on proximal tibial bone resorption remains unclear due to the paucity of studies in the literature. A trend of increased proximal tibia stress-shielding was observed in-vitro for the cemented over the cementless fixation, however that was not statistically significant (Jazrawi et al. 2001). Bone loss in-vivo at two years in the distal femur after femoral implantation was found to be lower for the cementless than the cemented fixation (Seki et al. 1999). In computational bone remodelling studies of the femoral component fixation, it was found that bone resorption was less extensive when the interfaces between the cement and prosthesis were debonded as compared to when the interfaces were bonded (van Lenthe et al. 1997; Barink et al. 2003). A direct comparison of bone resorption between the cemented and cementless tibial fixations has not been investigated. In cemented fixation, the load transfer capability of the uncemented stem could be lower if it was cemented or polished. While sufficient osseointegration increases the fixation strength of the cementless fixation, a greater extent of bone ingrowth into the porous-coated surfaces of the prosthesis was anticipated to induce greater distal load transfer thus leading to proximal bone resorption.

The objectives of this study were to investigate bone remodelling in the proximal tibia after prosthesis implantation between different fixation techniques, and to suggest the preferred choice of fixation techniques for preserving the bone stock and maintaining essential fixation stability.

5.4.2. Materials and Methods

The three-dimensional FE tibial fixation models were built based on the CT images of the Visible Human Project (VHP) female left tibia. The proximal segment of the bone 150mm long was modelled as linear elastic and isotropic, with a Poisson's ratio of 0.3. The heterogeneous property of the bone were defined by mapping the CT greyscale number to the elastic modulus of each bone element based on a linear relationship between the CT number and bone apparent density (ρ) (Abdul-Kadir et al., 2008; Hopkins et al., 2004), and the elastic modulus assigned by $E = 3790\rho^3$ (Carter and Hayes, 1977). The tibial component was built based on a generic commercial design. The proximal tibia was virtually resected at 8mm below the lateral articulating surface of the tibial plateau. The tibial tray size was then dimensioned to provide a maximum coverage of the resected surface, with medial/lateral width of 74mm, anterior/posterior depth of 46mm, and a thickness of 4mm. The central stem length was 40mm with a diameter of 12mm. The tibial tray was made of Titanium alloy, with an elastic modulus of 110GPa and Poisson's ratio of 0.33. The polyethylene insert was 8mm thick, with elastic modulus of 1GPa and Poisson's ratio of 0.3. Fig. 5.12 shows the FE models of the tibial fixations with different cementing techniques.

Five different cementing cases were modelled: i) *fully cemented* – cement was applied over the entire prosthesis, ii) *hybrid cementing* – cement was applied only at the undersurface of the tibial tray leaving the stem uncemented, iii) *cementless no ingrowth* – porous-coated tibial prosthesis assuming the worst scenario that no bony ingrowth has occurred, iv) *cementless partial ingrowth* – porous-coated prosthesis assuming a realistic amount of bony ingrowth occurrence, v) *cementless fully ingrowth* – porous-coated prosthesis assuming the best scenario that bone ingrowth had occurred into the entire prosthesis surface.

All the interfaces were modelled as bonded where bone cement was applied. For the cementless cases, the bone-prosthesis and bone-stem interfaces with no bony ingrowth were unbonded. These unbonded interfaces were modelled by defining contact between them, and the friction between the surfaces coming into contact was

modelled with Coulomb's friction. The tibial prosthesis was considered to be porous-coated with beads and a coefficient of friction of 0.6 between the bone and prosthesis was assigned (Rancourt et al. 1990; Hashemi et al. 1996). The regions of bone ingrowth for the "partial ingrowth" case were determined by analysing the zonal area of the prosthesis with interface micromotion lower than 50 μ m where osseointegration is likely (to be explained in the next section). For this specific tibial prosthesis design, it was predicted that osseointegration would occur at 33% of the prosthesis surface area (tray and stem), thus the nodes at these bone-prosthesis interfaces were bonded. As for the "fully ingrowth" case, all the nodes at the bone-prosthesis interfaces were bonded. For the hybrid cementing case, a friction coefficient of 0.1 was defined at the unbonded bone-prosthesis interface. In all cases, the PE was modelled as bonded to the tibial tray. The entire FE model consisted of approximately 35,000 tetrahedral elements, and the convergence tolerance was set at 1%. The tibia was rigidly fixed at the distal end.

The strain-adaptive bone remodelling algorithm described in Section 5.2 was incorporated in the FEM to predict the change in apparent bone density with time after joint replacement. Three different physiological knee joint load conditions corresponding to 0% and 15% of the walking gait cycle (Shelburne et al. 2006), and 25% of the stair climbing cycle (Zhao et al. 2007) were prescribed in the FE model to mimic the subject's daily activities (Table 5.3). The AP shear loads were obtained from Taylor et al. (2004), and acted in the posterior direction. The body weight (BW) was taken as a nominal 70kg. The loads were applied at the tibial-femoral contact points (shown in Fig. 5.12b) according to the different angles of knee flexion (Andriacchi et al. 1986). As the knee flexed, the loading point in the lateral compartment moved more posteriorly than in the medial compartment.

The results of bone remodelling after joint replacement and the change in apparent density of the bone over a period of sixty months are presented for three levels (in the transverse plane): at the tibial resected surface, at mid-stem and at stem tip. The sixty months duration was chosen because clinical studies found no further decrease in BMD after three to five years of knee joint replacements (Mintzer et al. 1990, Petersen et al. 1995, Saari et al. 2007). The apparent density of the bone at each level

was computed by averaging the apparent densities of all elements in the particular transverse plane.

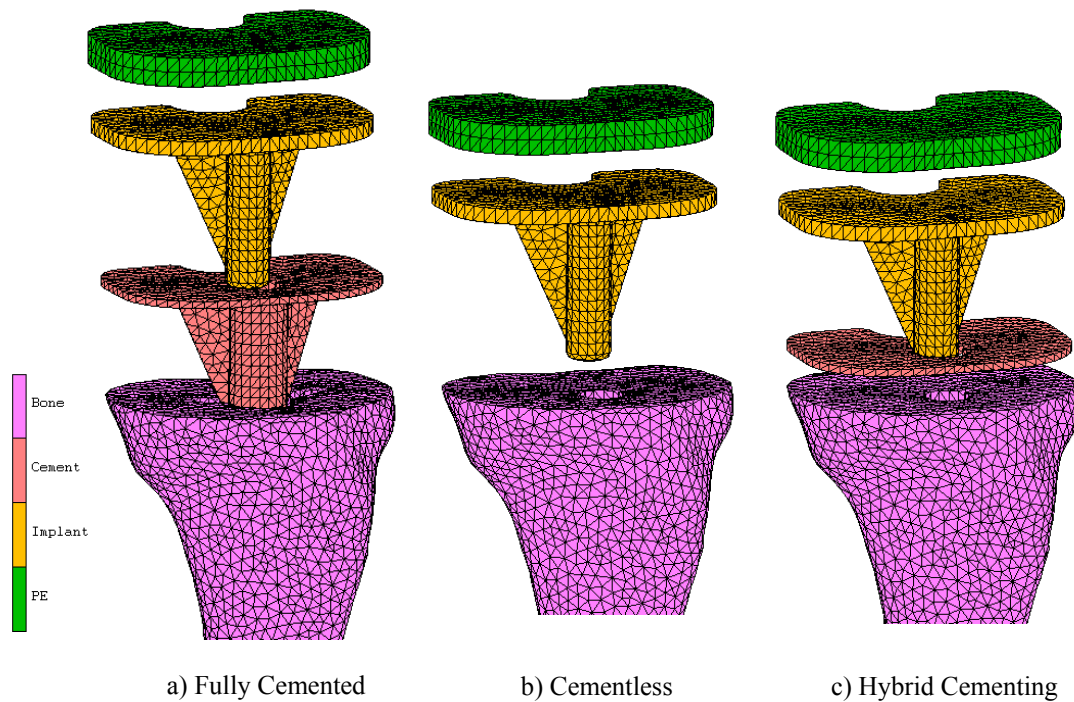


Figure 5.12a: FE models of the tibial fixation for different cementing techniques.

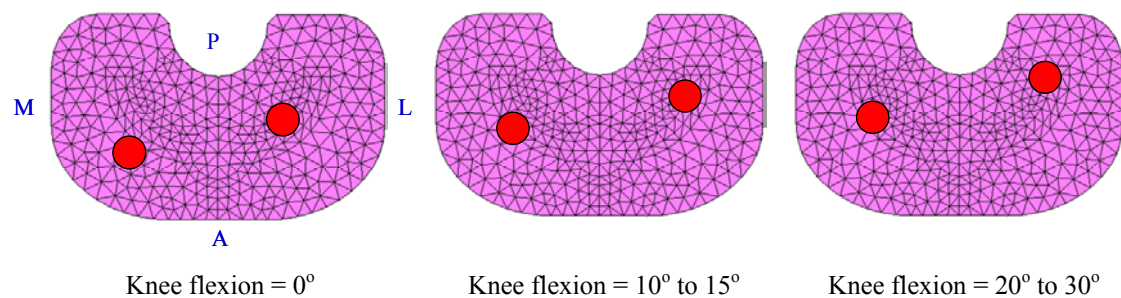


Figure 5.12b: Loading points on the FE models (PE insert) at different knee flexion angles.

Table 5.3
Joint load configurations for bone remodelling simulations

No	Load Case	Load (xBW)			Knee Flexion Angle (deg)
		Medial	Lateral	AP	
1	0% gait (heel strike)	0.9	0.19	0.1	0
2	15% gait (contra toe-off)	2.3	0.46	0.08	16
3	25% stair climbing	2	1.5	1.3	32

5.4.3. Results

Bone remodelling of the proximal tibia after prosthesis implantation and the change in bone apparent density with time at various levels are illustrated in Fig. 5.13. At the tibial resected surface, the fully cemented and fully ingrowth cases were predicted to induce the largest amount of proximal bone resorption (26-29% at 60 months). It was followed by the partial ingrowth case (17%). The cementless (no ingrowth) and hybrid cementing cases experienced the least bone resorption (11%).

At the mid-stem level (20mm below the resected surface), bone resorption was observed for the fully cemented, fully ingrowth and partial ingrowth cases, though of a lower extent than at the resected surface. Bone densification was predicted for the cementless and hybrid cases instead. This could be due to the loads from the flange of the stem which acted directly on the adjacent bone (see contour plots in the next figure).

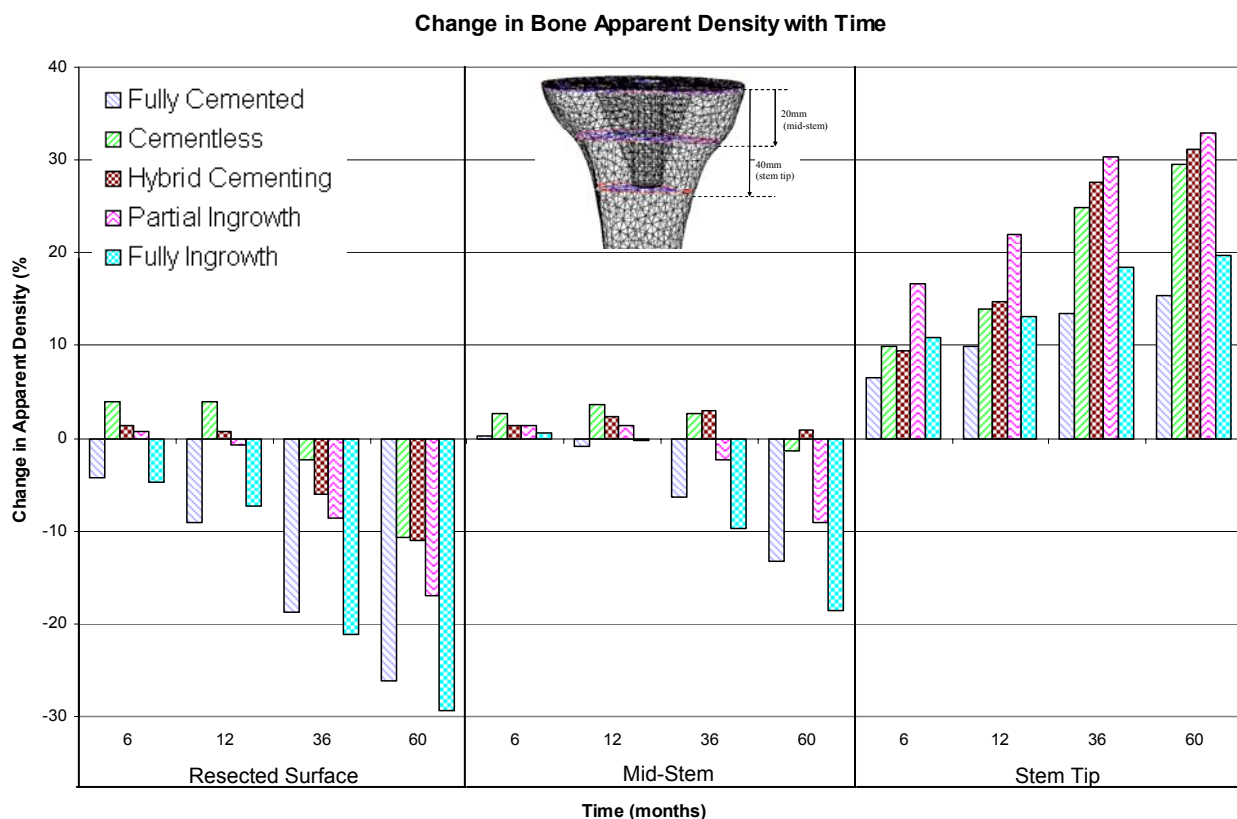


Figure 5.13: Predicted change in apparent densities over time.

At the stem tip region (40mm below the resected surface), bone densification was predicted for all the five cases, showing the load transfer capability of the 40mm stemmed tibial prosthesis. Bone deposition has been observed clinically in these regions (Bertin et al. 1985; Whiteside and Pafford 1989).

The predicted regions of bone resorption and densification after bone remodelling in the transverse plane at the tibial resected surface and various levels below for all the fixation cases are shown in Figs. 5.14a & b. At the tibial resected surface in Fig 5.14a, severe proximal bone resorption for the cementless fixation (time = 36 months) occurred almost two to three times slower in duration than the fully cemented fixation (time = 12 months). Greater bone resorption was predicted to occur at the medial condyle for both the cemented and cementless fixations. It was mainly due to the higher joint load acting on the medial side that was being shielded by the metallic tibial prosthesis (i.e. greater stress-shielding effect at the medial side). Bone densification was observed at the lateral condyle (anterior to the flange) for the cementless case, indicating that some amount of the joint load was transmitted across the tibial tray to the underlying bone. At five years post-operation, a much larger proportion of bone resorption was predicted for the cemented than the cementless fixation at the resected surface and the region 10mm underneath. At the mid-stem level, a global cortical bone resorption was predicted at the antero-medial side for the fully cemented case. Further down the resected surface (at 30mm level) and at the stem tip, bone densification was predicted. It indicated that the joint load acting at the tibial tray was transferred distally by the cemented stem. For the cementless fixation, localised bone densification at the periprosthetic regions was observed from the mid-stem level and below. Load transfer distally by shear stresses along the uncemented stem was anticipated to be minimal. Thus bone densification predicted in these regions could be due to the direct contact between the flange and stem tip with the adjacent bone.

The bone remodelling patterns predicted for the hybrid cementing, partial ingrowth and fully ingrown cases are shown in Fig. 5.14b. Similar to the cementless (no ingrowth) fixation, severe proximal bone resorption began to occur only after 30 months post-operatively for the hybrid and partial ingrowth cases. For the fully ingrown case, severe bone resorption occurred 18 months after implantation of the

tibial prosthesis (bone density plot at 18 months not shown). It was observed that severe proximal bone resorption occurred only at the medial condyle of the tibial plateau for the hybrid cementing fixation, in contrast to both condyles for the fully cemented fixation. And bone in the medial condyle resorbed at a slower rate compared to the fully cemented case. The bone remodelling pattern predicted for the partial ingrowth cementless fixation was similar to the case where no ingrowth could occur, but with a greater amount of proximal bone resorption. With the bone-prosthesis interfaces fully bonded for the fully ingrown cementless fixation, the absence of the cement layer led to a prediction of slightly greater bone resorption proximally and at mid stem, and greater bone densification towards the stem tip when compared to the fully cemented case. With the uncemented stem for the hybrid cementing and partial ingrowth cases, bone densification at the stem tip regions was expected to result from the direct contact between the stem tip and the adjacent bone.

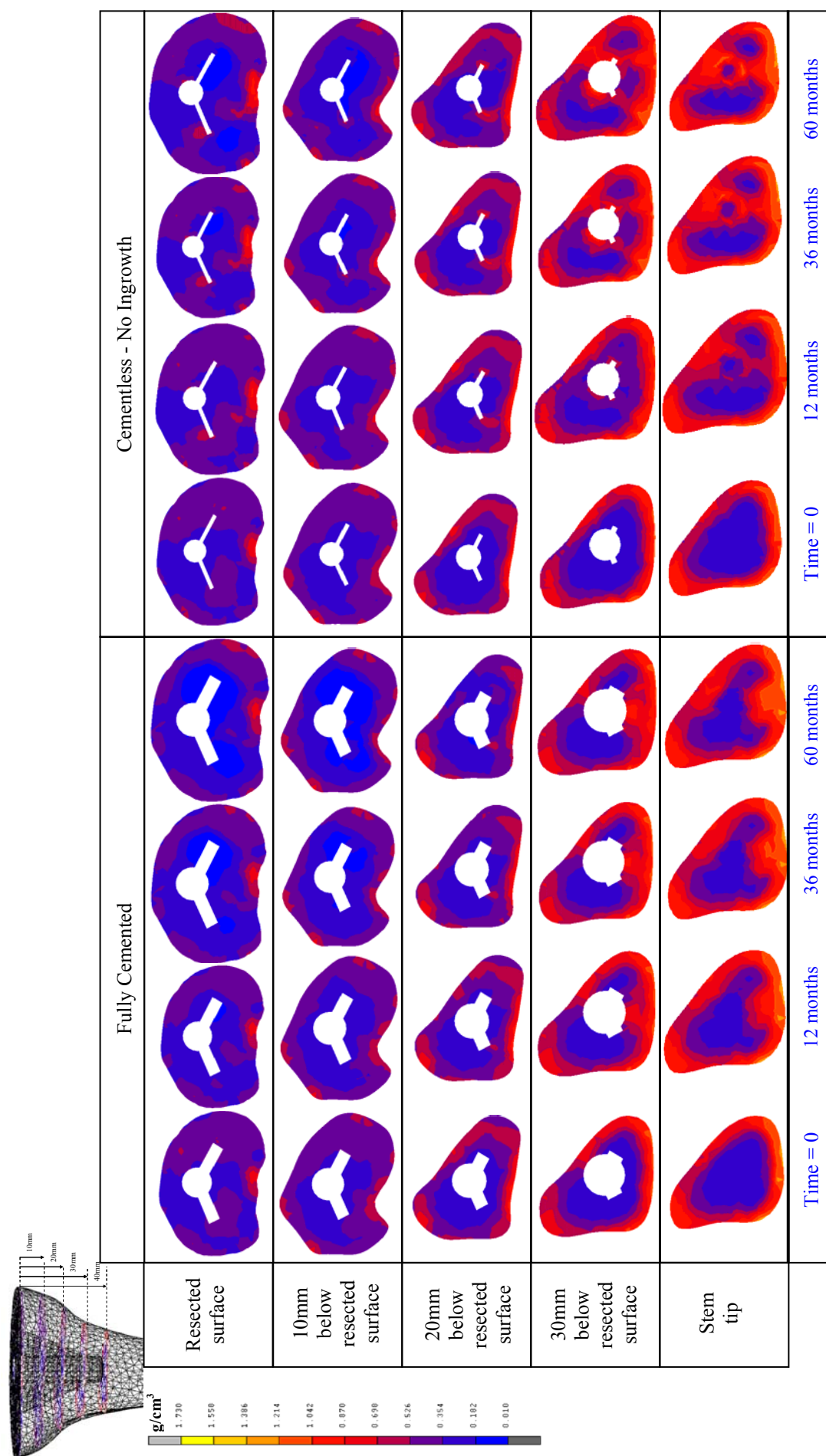


Figure 5.14a: Bone apparent density plots showing the regions of predicted bone resorption and densification in the transverse plane at the tibial resected surface and various levels below for the fully cemented and cementless cases.

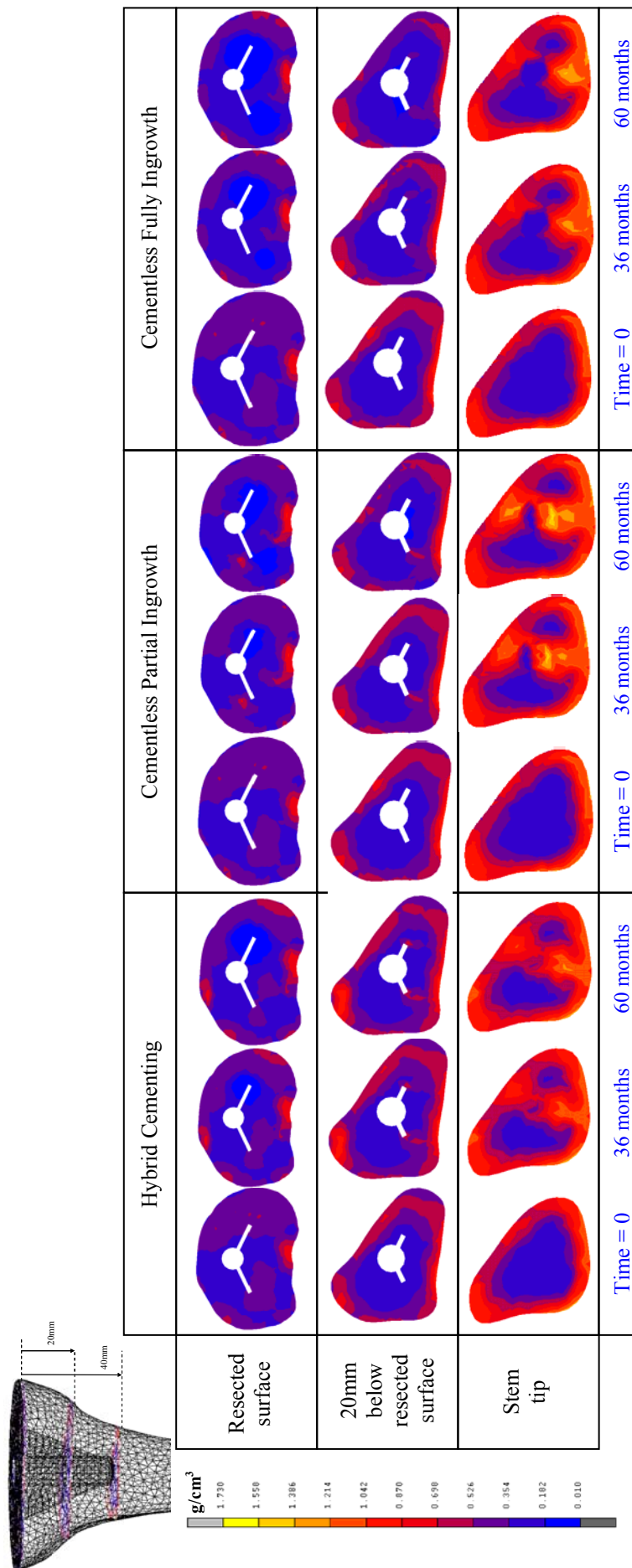


Figure 5.14b: Bone apparent density plots showing the regions of predicted bone resorption and densification in the transverse plane at levels of the tibial resected surface, mid-stem and stem tip for the hybrid cementing, partial ingrowth and fully ingrowth cases.

5.4.4. Discussion

In this study, bone remodelling in the proximal tibia after prosthetic implantation with different cemented and cementless fixation techniques was investigated by finite element simulations. A direct validation of the bone remodelling predictions with patient-specific bone densitometry data could not be established at the present stage as no clinical data was available. The validation was performed by correlating the bone remodelling results with published clinical densitometry and radiographic results. At 94 months post-operation, Lonner et al. (2001) found significant bone loss in the proximal tibia for fixation using a fully cemented stemmed tibial prosthesis. The medial tibial plateau experienced a larger amount of bone resorption as compared to the lateral compartment. The bone remodelling simulation has predicted severe proximal bone resorption for the fully cemented fixation and greater bone loss at the medial condyle. In another study, bone hypertrophy was observed distally at the tip of an uncemented tibial stem (with cemented tray) (Bertin et al. 1985). Bone densification was predicted to occur at the stem tip region of the hybrid cementing fixation in the current study. The amount of bone mineral density reduction in the implanted tibia reported by densitometry studies ranged from 10-12% at one to two years post-operatively (Karbowski et al. 1999; Li and Nilsson 2000), and up to 23-39% at five to eight years after operation (Levitz et al. 1995; Saari et al. 2007). The current predictions of 11-29% decrease in the proximal bone apparent density at 5 years post-operation were in good agreement with the densitometry data.

Three different extents of osseointegration – i) no ingrowth, ii) partial ingrowth, and iii) fully ingrowth were modelled for the cementless fixation. For the partial ingrowth case, it was predicted that bone ingrowth was likely on 33% of the prosthesis surface area (tray and stem). In retrieval studies, while extensive bone ingrowth onto 40-90% of the tray area was found in canine models (Turner et al. 1989; Sumner et al. 1994), only limited bone ingrowth of less than 30% of the tray area for TKR patients was observed (Ranawat et al. 1986; Sumner et al. 1995). In a worst case, 95% of the tibial components retrieved from patients showed less than 5% of bone ingrowth onto the tray (Cook et al. 1989). The current FE models of partial and no ingrowth thus represented the extremes of clinical circumstances. The fully ingrown case would

only represent a rare clinical situation where extensive bone ingrowth onto the tibial tray has occurred.

The variation in cementing techniques was found to influence the stress-shielding effect and load transfer capability of the prosthesis. With the bonded interfaces modelled for the fully cemented and fully ingrowth cases, a firm anchorage was formed between the prosthesis (tray/stem) and the bone. The joint load acting on the tibial tray could be transferred to the bone distally through shear stresses along the bone-stem interfaces. For the uncemented regions and where bone ingrowth did not occur, the unbonded interfaces modelled with contact surfaces and friction would result in a less firm anchorage. Shear stresses to be transferred across contact surfaces with friction would be reduced, and interfacial stress transfer would primarily be achieved by normal compressive stresses. As a result, a firm fixation of the stem would be able to transfer more joint load distally thereby relieving the proximal bone stresses, consequently leading to bone resorption. A greater amount of bone resorption from 0-20mm below the resected surface was thus observed for the fully cemented fixation than the hybrid case, where the stem was uncemented. The partial ingrowth fixation was modelled by bonding 33% of the bone-prosthesis interfaces (tray and stem), in which approximately 15% of the area was on the stem. It provided a more secured anchorage of the prosthesis to the bone. As such, the rate of proximal bone resorption was between the cementless cases of full and no ingrowth.

Since the stem was uncemented in both the hybrid cementing and cementless no ingrowth fixations, the load transfer capability of the stem was comparable, hence leading to a similar amount of proximal bone resorption predicted. The effect of interface bonding has also been investigated in computational bone remodelling studies of the knee femoral fixation. It was found that bone resorption was less extensive when the interfaces between the cement and prosthesis were debonded as compared to when the interfaces were bonded (van Lenthe et al. 1997; Barink et al. 2003). The firm anchorage of the femoral prosthesis to the bone (bonded interface) resulted in the joint forces being transferred more proximally to the anterior and posterior flanges, thereby leading to bone densification, and severe bone loss distally in the bevel regions of the femoral component (van Lenthe et al. 1997).

The amount of proximal bone resorption was marginally higher for the fully ingrown uncemented fixation than the fully cemented, even though a firm anchorage was formed between the prosthesis and bone for both cases. This suggested that direct bonding of the stem to the bone (due to bony ingrowth) would lead to more load transfer distally, whereas the cement in the stem-cement-bone bonded interface provided some buffer which reduced the shear stresses transferring load from the stem to the periprosthetic bone. This was reciprocated with a small increase in bone densification at the stem tip for the fully ingrown case over fully cemented. Nevertheless, the influence of the thin layer of cement was minimal as the difference in change of bone apparent density was less than 5%.

Bone densification near the distal end of the prosthesis stem was predicted for all the cemented and cementless fixations. As greater proximal stress-shielding was experienced by the fully cemented and fully ingrown fixations, the load being transferred distally was anticipated to induce greater bone densification near the stem tip region for both cases. However, this was not evident: greater bone densification underneath the stem tip was observed for the uncemented stem fixations instead. This is possibly due to the direct contact between the metallic stem tip and bone leading to higher bone stresses than with an intermediate layer of cement. The increase in bone density was in agreement with bone hypertrophy observed in-vivo at regions adjacent to the tip of the uncemented tibial stems (Bertin et al. 1985). With the cement providing a firm interlock between the bone and prosthesis, the load could be distributed more evenly to the entire periprosthetic bone regions rather than concentrated at specific regions underneath the stem tip. For the cementless and partial ingrowth cases, bone densification was also predicted at the lateral condyle of the tibia, which indicated that high forces were transmitted from the tibial tray to the bone underneath.

While the current bone remodelling simulations on tibial fixations have shown good correlations with in-vivo studies, some specific limitations were present:

- 1) The current FE modelling approach assumed that bone was ingrown onto the porous-coated prosthesis at time zero of bone remodelling (i.e. immediately after operation) for the partial and fully ingrown cementless fixations. In separate histological analyses, bony ingrowth was found to occur as early as 1 month (4

weeks) (Søballe et al. 1992) and 3 months (12 weeks) (Bobyne et al. 1981) after implantation. The duration of ingrowth was short compared to the simulated bone remodelling period of 60 months, thus the assumption of bonded interfaces between the bone and prosthesis at time zero of bone remodelling should not have a great influence on the end results. It should however be noted that the above histological analyses were conducted on canine models. If the metabolism rate for a dog is faster than for human, then bone fixation will be slower in clinical use. Assuming that the metabolism rate of a dog is four times faster than a human, osseointegration would only occur between 4 and 12 months after prosthesis implantation for human. With the central stem bonded to the bone at a later stage after operation (and hence its distal load transfer effect only occurred later), proximal bone resorption at 5 years for the partial and fully ingrowth cases would be lower compared to the currently predicted values. In addition, it remains unclear when the periprosthetic bone reduces its density due to proximal stress-shielding (a mechanical process), how and to what extent it would hinder the biological osseointegration process. In another words, the relationship between the level of bone density and the rate of osseointegration is not known, other than the effect of interface micromotion. A unified modelling theory or algorithm may be needed to capture this interfering behaviour.

2) In comparing computational predictions to patient-specific densitometry data in hip replacement studies, bone loss was overestimated when the bone remodelling simulation was continued to the equilibrium state (Kerner et al. 1999; Bitsakos 2005). Specifically, an almost complete bone resorption in the lesser trochanter region was predicted by Kerner et al. (1999). They hypothesized that the adaptive process was limited to a certain finite post-operative period. In the current study, complete bone resorption at the antero-medial and lateral cortices of the proximal tibia were predicted (which was rarely a clinical observation) when the equilibrium state of the remodelling simulation was reached. Thus a hypothesized cut-off time for the bone adaptive process after five years (60 months) was assumed, which concurred with clinical observations that no further decrease in BMD was found after three to five years of knee joint replacements. In this study, the simulated bone adaptive process time was considered to be equivalent to physical time, whereas a relationship between them has yet to be fully established. It would be valuable to correlate patient-specific computational predictions with the bone scan results so that a time constant could be

determined to relate the simulated time to physical time, as per the time constant obtained for an animal model (Weinans et al. 1993).

5.5. Interface Micromotion Analysis for Cementless Tibial Prosthesis Replacement

5.5.1. Introduction

The fixation strength of the prosthesis to the surrounding bone is crucial to the long-term performance of the tibial component of total knee replacement. Polymethylmethacrylate bone cement is commonly used to provide mechanical attachment of the prosthesis to the bone. However cement fatigue and bone-cement interface failures may eventually lead to aseptic loosening of the tibial component (Jasty et al. 1991; Rakotomanana et al. 1994). Cementless fixation, an alternative to the cemented technique, relies on bony ingrowth into or attachment onto the porous or roughened surfaces of the prosthesis thereby providing a biological attachment. Comparable clinical results of the cementless tibial fixation to the cemented fixation had been reported recently (Hofmann et al. 2001; Whiteside 2001). Biological attachment for reliable fixation strength depends largely on the initial stability of the fixation, where excessive bone-prosthesis relative motion would inhibit the bone ingrowth or osseointegration process. In previous in-vivo studies, bone ingrowth into the porous surfaces of the prostheses was observed for bone-prosthesis interface micromotion ranging from 20-50 μm (Pilliar et al. 1986; Burke et al. 1993; Jasty et al. 1997a). However for interface micromotion in excess of 50-150 μm , fibrocartilage and fibrous tissues were formed instead (Jasty et al. 1997b; Kienapfel et al. 1999) where the strength of fixation could be compromised and eventually lead to loosening and failure of the fixation.

To provide a favourable interfacial condition for bony ingrowth, it is desirable to minimise the interface micromotion of the designs of tibial prostheses to be used in cementless fixation. Computational finite element (FE) studies have been carried out to simulate and evaluate the micromotion. The influence of various factors such as component features like the central stem and fixation pegs (Hashemi and Shirazi-Adl 2000; Rakotomanana et al. 1992; Rakotomanana et al. 1994; Shirazi-Adl and Ahmed 1989), material and geometry changes (Barker et al. 2005; Keja et al. 1994), and fixation conditions using screws or press-fitting (Tissakht et al. 1995) on the initial stability of the tibial fixation have been investigated extensively. In these FE studies, the loading conditions considered were mainly of a single vertical load, which varied

from one to three times body weight (BW) and was equally distributed between the lateral and medial compartments of the tibial tray. Barker et al. (2005) prescribed a vertical load corresponding to one BW on the tibial fixation and predicted a maximum interface micromotion of 23 μ m for a circumferentially flanged tibial component. In two separate studies looking at a stemless component with pegs, Rakotomanana et al. (1992) predicted an interface motion of 50 μ m or less by applying a 2000N vertical load with distribution of 70%/30% in the medial/lateral compartments, whereas a high 101 μ m was found by Keja et al. (1994) when a 2500N vertical force was distributed equally between the medial/lateral compartments. With a medial vertical load corresponding to 3 times BW in simulating a varus deformity, Hashemi and Shirazi-Adl (2000) predicted that the maximum interface micromotions for a tibial tray with pegs and screws would be lower than 50 μ m.

These loading conditions, however did not account for the varying loads acting at the knee joint during daily activities. Due to the anatomical alignment of the tibia and femur, and the dominance of adduction moment in the knee over a gait cycle (Andriacchi et al. 1986), approximately 70% of the vertical load across the knee joint acts at the medial compartment of the knee (Morrison 1970; Shelburne et al. 2006). Forces acting at the knee joint during gait and other activities (like stair climbing) vary with the gait cycle (Shelburne et al. 2006; Taylor et al. 2004; Zhao et al. 2007), and the tibial-femoral contact points where the joint load acts also vary with the knee flexion angle (Andriacchi et al. 1986; Dennis et al. 2003). The shear forces acting in the antero-posterior (AP) and medial-lateral (ML) directions are generally smaller than the vertical force, with magnitude of about 0.5 times BW (Taylor SJG et al. 1998) and 0.26 times BW (Morrison 1970) respectively, and these have only been considered by Rakotomanana et al. (1994) in their study. It was anticipated that the varying joint loads during gait and other activities, coupled with the change in tibial-femoral contact points with knee flexion, would induce different bone-prosthesis interface responses. In addition, most of these studies did not correlate the micromotion predictions with in-vitro and in-vivo results. Thus it was unsure if the predictions were realistic or not.

The aims of the study were twofold: i) to study the relative interface micromotion between the bone and tibial prosthesis after cementless implantation by FEM, and

correlate the predictions to in-vitro and in-vivo results, ii) to investigate the influence of different loading conditions and varying tibial-femoral contact points during knee flexion on the prediction of the micromotion. A nominal load of three times BW with AP and ML shear forces would be compared with load conditions obtained at 15% of the gait cycle and at 25% of the stair climbing cycle. A sequential loading from heel strike (0% gait cycle) to toe-off (65% gait cycle) would also be modelled to study the possible interface micromotion progression during gait. The micromotion results were correlated with an experimental test of cadaveric tibial fixation and reported retrieval studies.

5.5.2. Materials and Methods

Three-Dimensional Finite Element Modelling

The setup of the three-dimensional FE models of the tibial fixation was similar to those described in Chapter 5.4.2. The bone-prosthesis interface condition was assumed to be immediately after operation where bone ingrowth has yet to occur. Thus the modelling conditions were similar to the cementless (no ingrowth) fixation. Fig. 5.15 shows the FE model of the tibial fixation. The PE was bonded to the tibial tray, while the bone-prosthesis interfaces were unbonded and modelled as contact surfaces with Coulomb friction. A coefficient of friction of 0.6 between the bone and prosthesis was assigned (Rancourt et al. 1990; Hashemi et al. 1996) with the consideration that the prosthesis was porous-coated with beads. The tibia was rigidly fixed at the distal end 150mm below the plateau. The entire FE model consisted of approximately 100,000 tetrahedral elements. The convergence tolerance was set at 1% and the contact tolerance was defined as 10 μ m. These settings were known to produce accurate solution for contact analysis of joint replacements (Abdul-Kadir et al. 2008).

Four different loading conditions were studied (see Table 5.4). The first load case constituted of a generic vertical joint load and AP/ML shear forces acting at the centre of the medial and lateral compartments of the tibial tray, which had been adopted in previous FE studies. For load cases 2 and 3, the peak vertical joint load at 15% of the gait cycle and 25% of the stair climbing cycle were selected with the corresponding

AP shear force. The first three load cases were each defined by a single load step, whereas load case 4 involved five sequential load steps consisting of 0% (heel strike - HS), 15% (contralateral toe-off - CTO), 30% (mid stance - MS), 50% (contralateral heel strike - CHS) and 65% (toe-off - TO) of the gait cycle of a TKR patient. For load cases 2-4, the loads were applied at the tibial-femoral contact points (see Fig. 5.12b) according to the different angles of knee flexion (Andriacchi et al. 1986). As the knee flexed, the loading point at the lateral compartment moved more posteriorly than at the medial compartment. The threshold of bone-prosthesis interface micromotion where bone ingrowth is likely was set at 50 μ m, and the percentage of the prosthesis surface area (SA) with interface micromotion less than 50 μ m would be presented.

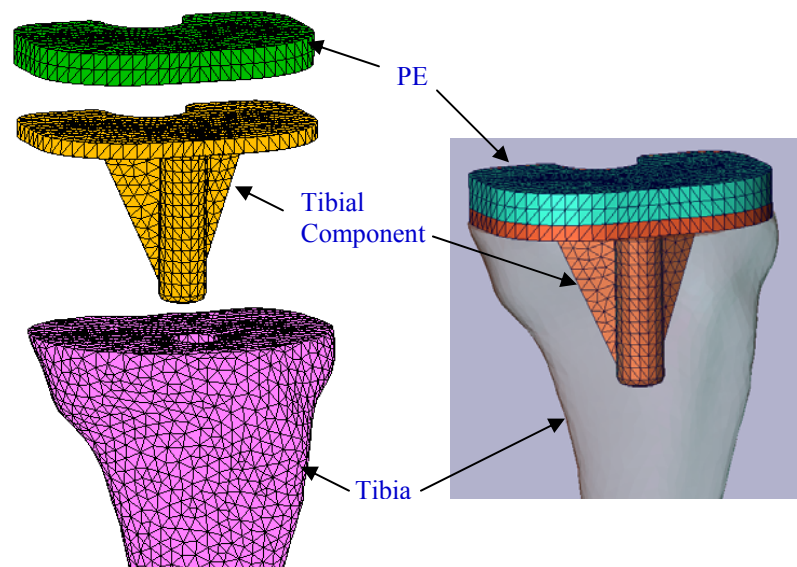


Figure 5.15: Finite element model of the tibia/prosthesis (left) and its implanted position (right).

Table 5.4

Loading conditions for the prediction of interface micromotion

No.	Load Case	Load Type	Load ($\times$ BW)				Knee Flexion Angle ($^{\circ}$)
			Medial	Lateral	AP	ML	
1	Generic	Single	2.1 ¹	0.9 ¹	0.5 ²	0.26 ¹	NA
2	15% of gait cycle ³	Single	2.3	0.46	0.08	-	15
3	25% of stair climbing cycle ⁴	Single	2	1.5	0.5	-	30
4	0, 15, 30, 50, 65% of gait cycle ⁵	Sequential	0.45	0.6	0.1	-	0
			0.83	0.83	0.08		15
			1.06	0.94	0.2		10
			1.33	0.89	0.3		20
			0.5	0.6	0.26		30

¹Morrison 1970; ²Taylor SJG et al., 1998 / ³Shelburne et al., 2006; Taylor et al., 2004

⁴Zhao et al., 2007; Taylor et al., 2004 / ⁵Zhao et al., 2007; Taylor et al., 2004

Experimental Test Set-up

The purpose of this experiment was to provide a comparison between the interface micromotion predicted by FEM and actual measurements (please refer to Chapter 8 for greater details of the in-vitro work). Eight cadaveric tibiae were implanted with the Genesis II tibial prostheses (Smith & Nephew UK Limited, London, UK) through press-fitting by an experienced orthopaedic surgeon. The proximal tibia was resected at 8mm below the lateral articulating surface of the tibial plateau, and was matched with a tray size of best fit with no overhanging of the tray edge at the cortical rim. Good cortical support of the tibial tray and sufficient bone surface coverage were found in all the cadavers. The in-plane relative micromotion between the edge of the tray and its adjacent supporting bone was measured by using linear variable differential transducers (LVDTs) (Digital Probe DP/2/S, Solartron Metrology, UK). The LVDT was mounted onto a holder which was firmly fixed to the tray edge (Fig. 5.16), whereby the in-plane bone-prosthesis relative micromotion could be measured. Three tray locations namely anteriorly, laterally and medially were measured.

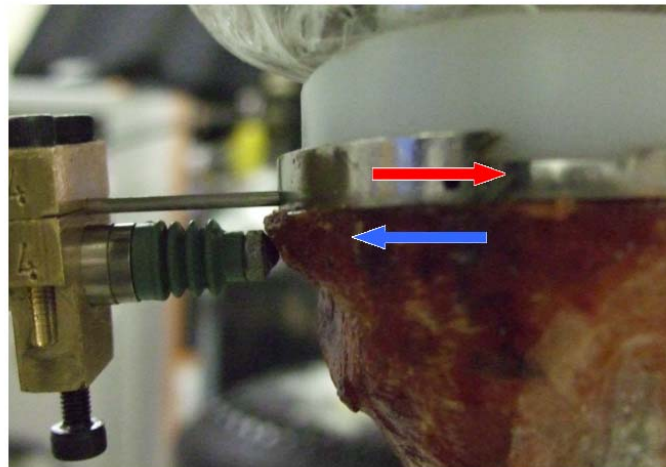


Figure 5.16: LVDT set-up for the measurement of in-plane relative motion between the edge of the tray and its adjacent supporting bone.

The implanted tibia was rigidly fixed at the distal end, and loaded by a matching size of femoral component with a vertical force of 2100N equally distributed at the medial and lateral condyles. The load was applied by an Instron 5565 materials test machine (Instron Ltd, High Wycombe, UK) at a rate of 1000N/min, and was held at 2100N for five minutes to allow for equilibrium of the bone where the micromotion reading

would then be taken. The tibia was unloaded and allowed to relax for five minutes before the loading sequence was repeated. The micromotion at each location was recorded for three load sequences and averaged. The Genesis II tibial prostheses used in the current test were not porous-coated but had rough surfaces. The same FE model was used for the comparison purpose, with the exception that the coefficient of friction was changed to 0.2 and only a single load case of the vertical force was prescribed.

5.5.3. Results

Comparison of FEM micromotion prediction with experimental measurement

Due to the difference in sizes of the tibiae and tibial prostheses used, the measured relative micromotion varied considerably. The mean micromotion (and standard deviation) for the eight tibiae were A_{meas} (anterior) = $26 \pm 29\mu\text{m}$, L_{meas} (lateral) = $63 \pm 39\mu\text{m}$, and M_{meas} (medial) = $26 \pm 15\mu\text{m}$. The FEM predicted interface micromotion were A_{FEM} (anterior) = $21\mu\text{m}$, L_{FEM} (lateral) = $41\mu\text{m}$, and M_{FEM} (medial) = $44\mu\text{m}$.

Bone-prosthesis interface micromotion prediction by finite element modelling

The contour plots of the predicted interface micromotion (MM) on the surface of the tibial prosthesis for the four load conditions are shown in Fig. 5.17. The grey regions represent the surfaces where the micromotion was lower than the threshold value of $50\mu\text{m}$, in which bone ingrowth could occur. The i) peak micromotion and ii) proportion of prosthesis surface area (SA) favourable for osseointegration are illustrated in Fig. 5.18. For the single load generic condition, bony ingrowth was likely to occur mainly at the inner portion of the tray (posterior to the flange), with regions of micromotion greater than $50\mu\text{m}$ distributed towards the periphery of the tray. This prediction coincided with a patient retrieval study where bone ingrowth had occurred at the central tray portion and fibrous tissue formation at the edge of the tray (Sumner et al. 1995). 33% of the prosthesis surface area was predicted to have a likelihood of osseointegration, with a peak micromotion of $150\mu\text{m}$ at the anterior edge of the tray.

With a prescribed single load at 15% gait cycle, a high 81% of the prosthesis surface area amenable to bony ingrowth was predicted. Unlike the single load non-gait case, high interface micromotion was not found at the tray periphery but occurred towards the stem tip region. With the increase in the vertical and AP shear loads at 25% stair climbing cycle, a peak interface micromotion of 218 μ m was predicted with 30% of the surface area where bone ingrowth could occur. The zonal areas of the prosthesis with a likelihood of bone ingrowth were similar to the single load generic condition.

Fig. 5.17b shows the progression of the interface micromotion through the gait cycle. The micromotion began to increase at the stem tip region from 0% to 50% gait cycle. At toe-off (65% of the gait cycle), the region of high micromotion migrated from the stem tip to the antero-medial edge of the tray. A peak micromotion of 133 μ m and 44% of the surface area where bony ingrowth was likely were predicted at toe-off.

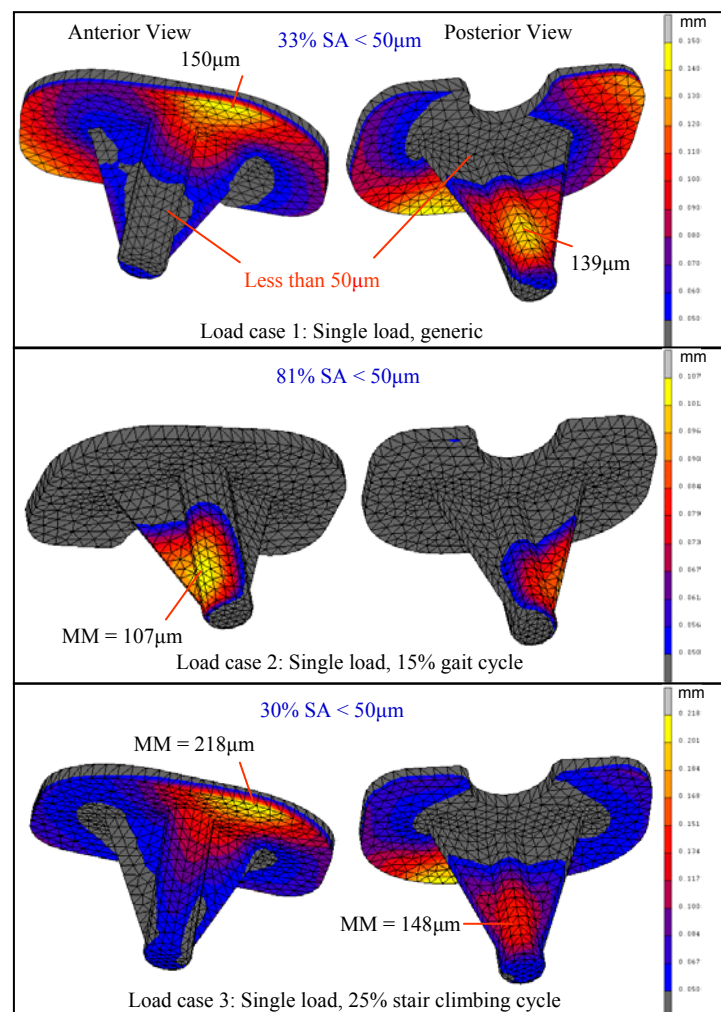


Figure 5.17a: Predicted interface micromotion at the surface of the tibial prosthesis for the various single load conditions.

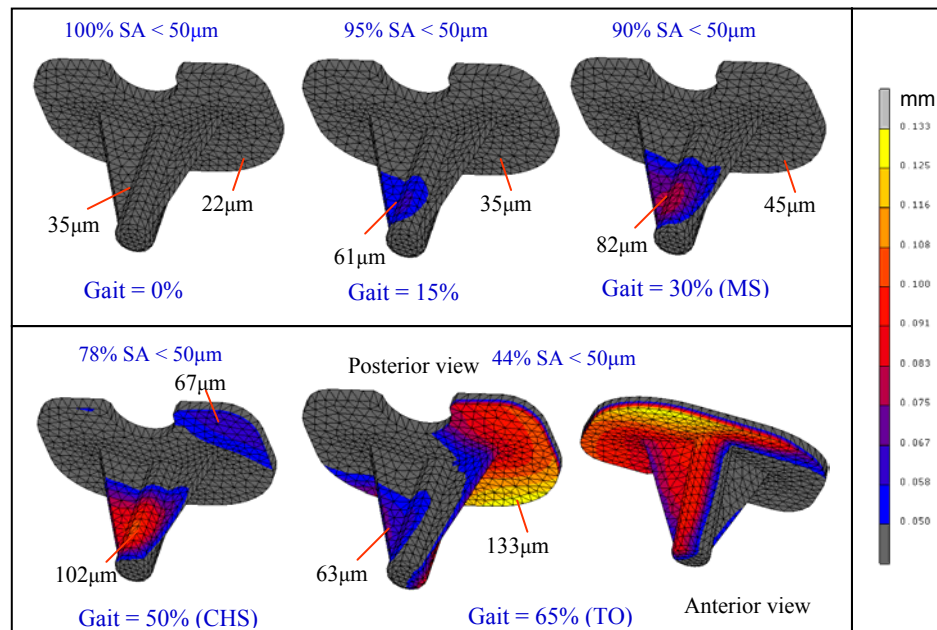


Figure 5.17b: Predicted interface micromotion at the surface of the tibial prosthesis for the sequential load condition.

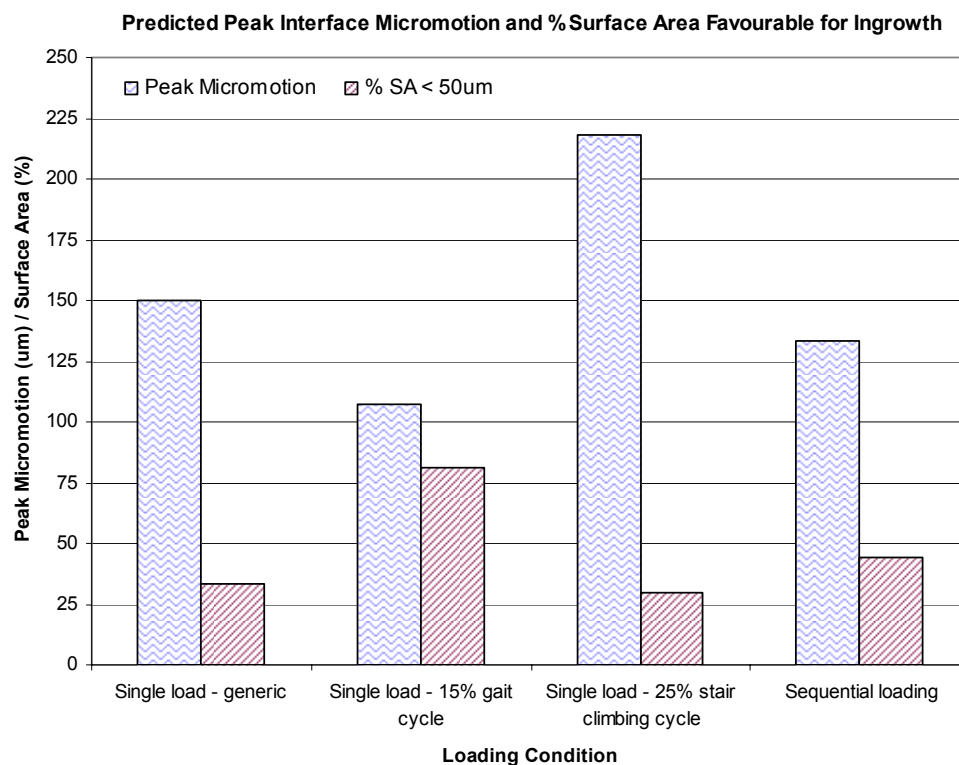


Figure 5.18: FE predictions of the i) peak interface micromotion and ii) proportion of prosthesis surface area favourable for bone ingrowth for different loading conditions.

5.5.4. Discussion

The purposes of this study were to study the bone-prosthesis relative interface micromotion after cementless tibial implantation, and to investigate how the micromotions predicted by finite element modelling would be influenced by different loading conditions and the consideration of varying tibial-femoral contact points during knee flexion. The FEM methodology used in this study had previously been correlated with an in-vitro micromotion measurement on cadaveric hip implants (Abdul-Kadir et al. 2008). In the current test, the predicted bone-prosthesis interface micromotion was compared to cadaveric tibial fixation test measurements. The measured relative micromotions ranged from 26-63 μm , and the FEM predicted interface micromotions ranged from 21-44 μm . The A_{FEM} was in good agreement with A_{meas} , whereas L_{FEM} and M_{FEM} were marginally under and over predicted with L_{meas} and M_{meas} respectively. It should be noted that the FE model was not created from the geometry of the cadavers under test. The comparison illustrated that the current FE predictions of bone-prosthesis interface micromotion were in the same order of magnitude as the measured values, and that the predictions were realistic.

In modelling a single load generic condition (load case 1), the combined loads of the vertical ($3\times\text{BW}$), AP shear ($0.5\times\text{BW}$) and ML shear ($0.26\times\text{BW}$) acting on the tibial model had induced high interface micromotion towards the periphery of the tray at anteriorly, laterally and medially, indicating that bone ingrowth would be inhibited in these regions. The peak interface micromotion occurring at the edge of the tray was in agreement with previous FE studies on cementless tibial fixations (Hashemi and Shirazi-Adl, 2000; Keja et al. 1994; Tissakht et al. 1995; Rakotomanana et al. 1992), and these sites corresponded to the high occurrence of radiolucent lines at the edge of the tray observed in clinical studies (Berger et al. 2001; Hsu et al. 1995). In using a joint load obtained from a gait measurement (load case 2), the vertical load at the knee joint was highest reaching $2.76\times\text{BW}$ at 15% of the gait cycle. However, with a small AP shear load of $0.08\times\text{BW}$ and no ML shear force applied, a much lower bone-prosthesis interface micromotion at the tray periphery was predicted. Bone ingrowth could occur in almost the entire undersurface of the tray. The stem experienced a higher interface micromotion due to the “push down” effect of the vertical joint load.

The larger AP and ML shear forces in load case 1 over load case 2 had induced larger relative movement between the undersurface of the tray and its underlying bone. In a different study of a stemless tibial tray with pegs, the addition of AP shear force had increased the interface micromotion at the tray periphery substantially (Rakotomanana et al. 1994). The vertical load acting at the knee joint during stair climbing (load case 3) was considerably higher than in gait, with the peak force reaching $3.5 \times BW$ at 25% of the stair climbing cycle. With a knee flexion angle of 30° at 25% stair climbing cycle, the large vertical loads acted at a more posterior region of the tibial tray. It caused the tray to tilt downwards posteriorly resulting in an anterior lift-off. This lift-off could have worsened the bone-prosthesis interface movement. With similar AP shear force applied in load cases 1 and 3, the zonal areas of high micromotion predicted were comparable.

The sequential load steps analysis (load case 4) showed that the interface micromotion gradually increased along the stem during the gait cycle, and progressed to a maximum at edge of the tray (antero-medial) during toe-off. The progression could be explained as follows. From 0 to 50% of the gait cycle, the stem experienced higher micromotion due to the “pushing down” effect of the vertical load and its magnitude increased with increasing joint load. At 50% of the gait cycle, a considerable amount of micromotion ($67\mu m$) was observed at the postero-medial edge of the tray. This could possibly be due the high vertical joint load acting postero-medially on the tibia tray. As the gait cycle proceeded from 50% to 65% with a reduced joint load, the tray and stem motion did not recover instantaneously. Between contralateral heel strike and ipsilateral toe-off, the medial joint load dropped by almost two thirds, this was coupled with the lateral load acting posteriorly, so a high lift-off resulted at the antero-medial edge of the tray. The zonal areas of bony ingrowth predicted by sequential loading at 0, 15, 30 and 50% of the gait cycle resembled that of a single load at 15% of the gait cycle, while the prediction at 65% of the gait cycle was closer to that of the generic single load condition.

This study showed that different load patterns have a significant influence on the prediction of bone-prosthesis interface micromotion. With a single load at 15% of the gait cycle, it was predicted that osseointegration could occur over 80% of the

prosthesis surface with a peak micromotion of 107 μ m at the stem. With a single load based on generic data and on stair climbing condition where the joint forces were higher, only 30% of the zonal area was predicted to allow ingrowth. The peak micromotions at the tray undersurface were 150 μ m for the generic load case and 218 μ m for the stair climbing condition. The sequential gait loading led to a prediction of 44% ingrowth area with a peak micromotion of 133 μ m at the edge of the tray. Although prior studies have applied the joint forces centrally, this study has shown the effect of knee flexion during the heavily-loaded stair climbing activity, when the load was applied more posteriorly, leading to a prediction of anterior lift-off of the tibial tray.

There have only been limited previous FE studies on similar prosthesis designs, and all were two-dimensional analyses. Interface micromotions of less than 23 μ m were predicted by Barker et al. (2005) and Shirazi-Adl and Ahmed (1989), with a vertical load of about 1-1.4 $\times$ BW prescribed. The load prescribed was probably too small to induce a large amount of relative motion between the prosthesis and the bone. Rakotomanana et al. (1992) used a vertical load of 3 $\times$ BW with a proportion of 70%/30% in the medial/lateral compartments and estimated an interface motion of 50 μ m or less. In the current 3D models, micromotions predicted were in excess of 50 μ m and reached peak values between 133-218 μ m underneath the tibial tray.

Differing extents of bone ingrowth onto cementless tibial prosthesis fixations have been reported in retrieval studies. Although extensive osseointegration occurred in 40-90% of the tray area in canine models (Turner et al. 1989; Sumner et al. 1994), only limited bone ingrowth of less than 30% of the tray area for TKR patients was observed (Ranawat et al. 1986; Sumner et al. 1995). The current 3D FE models with the two load conditions based on generic data and on the stair climbing load cycle predicted low interface micromotion (<50 μ m) at the inner tray region posterior to the fixation flange and approximately 30% zonal area of bony ingrowth, and were in good agreement with retrieval studies where osseointegration was found (Turner et al. 1989; Sumner et al. 1995).

5.6. Conclusions

Finite element models for the cemented and cementless tibial fixations have been set up for the purpose of studying bone remodelling due to stress-shielding and component loosening after TKR. The effect of tibial prosthesis design features on proximal stress-shielding and component loosening were characterised. Detailed bone remodelling responses and stress-shielding mechanisms of the tibial fixation with different cementing techniques were investigated. The bone-prosthesis interface micromotion predictions were correlated to in-vitro and in-vivo results and the magnitudes were found to be realistic. More specific conclusions are presented below.

The FE models were then employed for the evaluation of fixation performance of the relatively new MIS mini-keel tibial prosthesis in comparison to the standard stemmed design, and to predict its risks for bone resorption and long-term aseptic loosening (see Chapter 6).

Two-Dimensional Stress Analysis of the Tibial Fixation

Although the 2D analyses may not be as accurate as detailed 3D modelling, the relative simplicity of the method facilitates rapid parametric studies of the effects of prosthesis design changes. The trends reported are supported by numerous other publications, both stress analyses and in-vivo/in-vitro studies of tibial component fixation. The parametric study has shown clearly that the security of prosthesis fixation at time zero is enhanced by the use of longer stems on tibial components; this was reflected by lower bone-cement interfacial shear stresses and lower cancellous bone compressive stresses underneath the tray. The corollary, however, was that this also led to reduced strain energy density in the epiphyseal cancellous bone, that has been linked to loss of prosthesis support as a consequence of bone resorption caused by stress-shielding. It was also shown that, although stress-shielding could be reduced by changing the prosthesis to a material with lower stiffness, it also induced higher stresses in its supporting cancellous bone. There are, therefore, conflicting trends in the results, and it is likely that different prosthesis designs will be optimal, depending on bone quality and fixation stability. With reduced risks in both component

loosening and stress-shielding, the stemless tibial tray with fixation pegs could be an alternative option to the baseline 40mm stemmed prosthesis.

The interdependence between fixation security and the loss of bone following stress-shielding suggests that more complete design optimisation should include the simulation of bone adaptive remodelling; analyses that only examine the stresses at time zero will give an incomplete appreciation. This study also suggested that fatigue of both the cancellous bone and bone-cement interface could similarly likely be a cause for long-term aseptic loosening of the metal-backed tibial trays, and that fatigue of the supporting cancellous bone could be the dominant factor for loosening failure of the all-PE tibial prostheses.

Bone Remodelling after Tibial Prosthesis Implantation

Greater proximal bone resorption would inevitably weaken the bone supporting the tibial prosthesis, leading to potential problems such as aseptic loosening. Although the fully cemented fixation may provide initial fixation stability post-operatively, its long-term consequence on bone quality may be an issue. One main concern lies in the firm anchorage formed between the stem and the bone leading to greater load transfer distally. Thus the hybrid cementing technique or the cementless fixation with partial ingrowth being achieved may be a preferred choice for preserving bone stock while providing essential enhancement of post-operative fixation stability. The bone remodelling results suggest that a modified design for cementless tibial fixation could be recommended – porous coating of the tray undersurface with a polished stem. In this way, fixation stability could be achieved through bony ingrowth underneath the tray and proximal bone resorption caused by load transfer to the stem could be minimised.

The different cementing fixation techniques were found to influence the predictions of bone remodelling behaviour of the tibia after prosthesis implantation. A firm anchorage fixation formed by the bonded interfaces between the prosthesis and the bone for the fully cemented and fully ingrowth cases played a critical role in inducing proximal bone resorption. Bone resorption in tibial fixations with a less secure anchorage (hybrid, no ingrowth and partial ingrowth) occurred at almost half the rate

of the changes around the fixations with a firm anchorage. The fully cemented fixation resulted in the most severe proximal bone resorption, while the partial ingrowth cementless fixation led to moderate changes. The least amount of bone resorption could be achieved by hybrid cementing. Thus the hybrid cementing technique or the cementless fixation allowing for partial ingrowth (not on the stem) may be a preferred choice for preserving bone stock while providing essential enhancement of post-operative fixation stability.

The bone remodelling simulations of the tibial fixations performed in this study were in good agreement with published clinical reports of densitometry and radiographic results. The current strain-adaptive bone remodelling theory has also been applied to simulate bone density adaptation after total hip replacement (THR) and compared with clinical densitometry data (Kerner et al. 1999; Turner et al. 2005). The bone remodelling responses were found to be qualitatively similar in the regions of bone loss and densification. Hence the FE modelling techniques for bone remodelling simulations are suitable to be used for the evaluation of new prosthesis designs in minimising bone resorption after implantation (see Chapter 6).

Interface Micromotion Analysis for Cementless Tibial Prosthesis Implantation

The different load patterns altered the predictions of bone-prosthesis interface micromotion and the assessment of the risk of long-term aseptic loosening. This may raise a concern whether a prosthetic design change evaluation based on one loading condition would have a different result if a new loading pattern were to be used. Caution is also needed when comparing the fixation performance of a range of cementless tibial prosthesis designs if each design was evaluated based on a different loading condition. The current interface micromotion predictions were shown to be realistic, in which the magnitudes were correlated to in-vitro measurements.

Two of the single load conditions investigated in the current study: i) constituted of a generic vertical joint load and AP/ML shear forces acting at the centres of the medial and lateral compartments of the tibial tray, and ii) a peak vertical joint load at 25% of the stair climbing cycle with corresponding AP shear forces applied at the tibial-femoral contact points of the specific knee flexion angle, where the predicted zonal

areas of osseointegration agreed with retrieval studies, were found to be suitable for assessing bone-prosthesis interface micromotion of the cementless tibial fixation. A parallel study on the influence of load conditions on design change evaluation performed by FEM is discussed in Chapter 6.

CHAPTER 6. STUDY OF THE MIS MINI-KEEL TIBIAL PROSTHESIS FIXATION

6.1. Background

The minimally invasive surgery (MIS) approach for total joint replacement has gained popularity in recent years. Its popularity is driven by potential clinical advantages such as less post-operative pain, reduced blood loss, more rapid recovery and return of functionality, and shorter hospitalisation period. The MIS total knee replacement involves a shorter incision length of 8-12cm compared to a length of up to 25cm for the conventional approach (Chauhan et al. 2006). Although the MIS techniques has demonstrated encouraging early results in TKR patients in terms of less blood loss, rapid functional recovery and improved range of motion (Tria et al. 2003; Haas et al. 2006; Cheung et al. 2008), its long-term fixation performance is unclear compared to the conventional TKR approach. Other clinical studies also found no improvement of the MIS TKR over the conventional approach (Kim et al. 2006; Kolisek et al. 2007), and the MIS operation took longer to perform (King et al. 2007).

Finite element analyses of the fixation performance of the MIS tibial prostheses versus conventional designs have been carried out, however the outcome was diverse. One study found that the interfacial cement stresses underneath the tibial tray was higher for a short and broad stemmed MIS tibial prosthesis compared to a standard stemmed prosthesis (Coleman et al. 2006). Another study found that the bone stresses underneath the tibial tray were insensitive to the use of either conventional or MIS tibial prostheses (Bartel and Gonsallus 2007). In addition, torsional resistance of the MIS prosthesis was slightly inferior to the conventional stemmed design (Tsai et al. 2006). These differences could be due to different modelling assumptions and loading conditions used. It reflected that a better understanding of the mechanical responses of these new MIS prostheses is essential.

The objective of this study was to investigate and compare the fixation performance between the MIS mini-keel (MK) and standard stemmed tibial prostheses. The risks

of bone resorption due to stress-shielding and aseptic loosening were assessed by the FE modelling techniques established in Chapter 5. A prospective clinical study of TKR patients receiving either the conventional stemmed and mini-keel (stemmed or stemless) tibial prostheses was conducted in Singapore General Hospital, Singapore, to evaluate the prostheses early stability. The tibial component migration up to two years post-surgery was assessed by RSA. Finally, patient-specific FE modelling was performed and the results were correlated to the migration data.

This chapter will outline the following: i) bone remodelling and ii) interface micromotion analyses of the MIS mini-keel tibial prostheses, iii) RSA measurements of the standard stemmed and MIS mini-keel tibial prostheses, iv) the validation of the patient-specific finite element models with RSA data.

6.2. Bone Remodelling and Fixation Analysis of the MIS Mini-Keel Tibial Prostheses

6.2.1. Introduction

The MIS approach for total knee replacement with shorter incision length allows tibial trays with shorter and wider keels to be implanted. A typical MIS tibial prosthesis features two broad mini-keels, and a stem extension can be “dropped-down” for extra fixation stability (Fig. 1.2). Although there is growing interest in the MIS prostheses, their fixation performance compared to standard stemmed prostheses is unclear. Conflicting design trends have been noted by FE modelling of the stemmed and unstemmed MIS tibial prostheses (Coleman et al. 2006; Bartel and Gunsallus 2007). In addition, proximal tibial bone resorption due to stress-shielding around the stiff prosthesis remains a clinical concern. The objectives of this study were to investigate the comparative fixation performance in relation to bone remodelling of the MIS mini-keel prostheses (stemmed and stemless) with the standard stemmed design, and to assess the impact of the “drop-down” stem extension on the mini-keel prostheses. The relative risk of bone resorption was assessed by FE simulations.

6.2.2. Materials and Methods

The setup of the three-dimensional FE models of the tibial fixation was similar to those described in Chapter 5.4.2. Two new designs of the mini-keel tibial prostheses, i) with a stem extension of 45mm (MK-L45) and ii) stemless (MK-L0) were studied (Fig. 6.1). The standard stemmed prosthesis with a central stem of length 40mm (STD-L40) was included for relative comparison.

Five different cementing cases were modelled. The first four corresponded to the cases described in Chapter 5.4.2 namely i) fully cemented, ii) hybrid cementing, iii) cementless no ingrowth, and iv) cementless partial ingrowth. The fifth case was to simulate a fully cemented fixation on osteoporotic bone. For an osteoporotic bone or patient with osteoporosis, the cancellous bone support of the tibial prosthesis is usually weaker than a normal bone, and could render the cementless fixation by bony ingrowth inappropriate. Orthopaedic surgeons would normally adopt the fully cemented technique to achieve a stable tibial fixation for this group of patients

undergoing TKR (personal communications with surgeons in Singapore and Malaysia). In modelling the osteoporotic case, the apparent density of the bone was reduced by 15% of the original tibia.

The strain-adaptive bone remodelling algorithm described in Section 5.2 was incorporated in the FE simulation to predict the change in apparent bone density with time after joint replacement. Three different physiological knee joint load conditions corresponding to 0% and 15% of the gait cycle and 25% of the stair climbing cycle were prescribed in the FE model (see Table 5.3) to represent the daily loads of the subject. The results of bone remodelling and the change in apparent density of the bone over time are presented for three levels (in the transverse plane) at the tibial resected surface, at mid-stem and at stem tip.

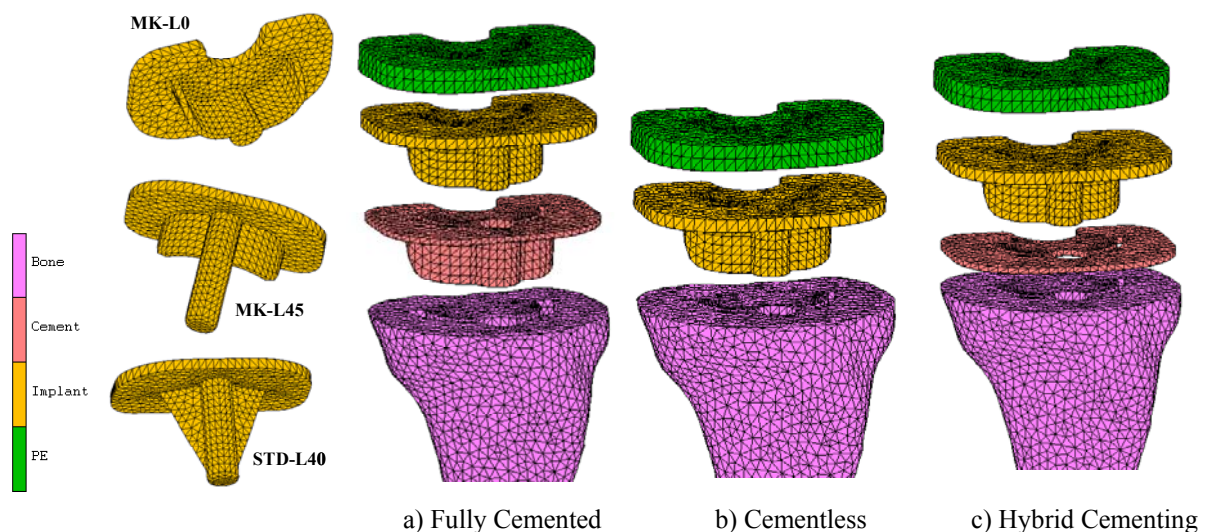


Figure 6.1: FE models of the mini-keel (stemmed/stemless) and standard tibial prostheses.

6.2.3. Results

Bone Remodelling after Prosthesis Implantation

The predicted change in apparent densities over time in the transverse plane at three levels of the tibial resected surface, mid-stem and stem tip for all the cemented and cementless cases are shown in Fig. 6.2. Proximal bone resorption was predicted for all the three different prosthesis designs and various methods of cementing techniques at sixty months. The predicted regions of bone resorption and densification in the

transverse plane (of the three levels) are illustrated in Figs. 6.3a-e. Detailed observations for each cementing technique are discussed below.

For the fully cemented fixation, MK-L45 (28%) induced a similar amount of proximal bone resorption as the STD-L40 (26%), with a slightly lower extent of bone loss observed for MK-L0 (23%) (Fig. 6.2). At the mid-stem level, cortical bone resorption was observed antero-medially for MK-L45 and STD-L40 (Fig. 6.3a). On the contrary cancellous bone densification occurred posteriorly for the stemless MK design. As a result of load transfer of the cemented stem, cortical bone densification was observed at the posterior and antero-medial regions underneath the stem tip (Fig. 6.3a).

When the stem was uncemented in hybrid cementing cases, the less firmly anchored bone-prosthesis surfaces (refer to Chapter 5.4.4) limited its load transfer capability thus resulting in a lower extent of proximal bone resorption (11-21%) than the fully cemented stem (23-28%) (Figs. 6.2 & 6.3b). Adding a stem extension to the mini-keel tray did not increase its stress-shielding effect. The extent of proximal bone resorption induced by the mini-keel designs (21%) increased by two times over the standard stemmed prosthesis (11%). With the direct contact between the stem tip and bone generating higher bone stresses than the pre-operated state, it led to a high amount of bone densification distally.

For the cementless fixation where bone ingrowth did not occur, tibiae with stemmed prostheses (MK-L45 and STD-L40) experienced comparable level of proximal bone resorption (11-17%) as the hybrid fixation (11-21%) at sixty months (Fig. 6.2). For MK-L0, bone densification at the resected surface was observed at the antero-lateral side of the keel while bone resorption occurred posteriorly to the keel (Fig. 6.3c). A considerable amount of bone densification was observed at the mid-stem region for all three designs, possibly due to the loads from the flange and stem acting directly on the adjacent bone. Again, direct contact between the stem tip and bone led to the high amount of bone densification at the stem tip region.

In cementless fixation with partial osseointegration, all the three designs induced a higher amount of proximal bone resorption (17-25%) as compared to absence of bony ingrowth (4-17%), but of lesser extent relative to the fully cemented case (23-28%).

Cortical bone resorption antero-medially for the stemmed designs (MK-L45 and STD-L40) at mid-stem was similar to the fully cemented case, however cancellous bone densification occurred at the antero-medial side for stemless MK design (Fig. 6.3d).

In the case of tibial implantation in an osteoporotic bone, a large amount of proximal bone resorption was predicted for the three designs (40-45%) at the resected surface and mid-stem level, which increased density still occurred below the stem tip (Fig. 6.3e).

6.2.4. Discussion

This study investigated the fixation performance of the MIS mini-keel prostheses in relation to bone remodelling. The amount of bone resorption relative to the standard stemmed prosthesis was assessed by FE modelling. The bone remodelling predictions had previously been validated by correlating them with published clinical densitometry and radiographic results (Chapter 5). The predicted proximal tibial bone resorption and bone hypertrophy distally, at the tip of an uncemented tibial stem, were in agreement with reported clinical studies (Bertin et al. 1985; Lonner et al. 2001; Saari et al. 2007).

In many cases, the MK-L45 design induced greater proximal bone resorption than the STD-L40, thereby increasing the relative risk of weakening the strength of the bone-prosthesis support. The stemmed MK design did not induce a greater amount of proximal bone resorption than its stemless counterpart, unlike bone density scans of conventional tibial trays where the stress-shielding effect was more significant with stemmed prostheses (Lonner et al. 2001). The broad keels, with a surface area about 10% larger than the flange of the standard stemmed prosthesis, which tapers distally, situated directly underneath the resected tibial surface could have dominated the stress-shielding effect.

As discussed in Chapter 5, the firmness of the anchorage of the stem to bone plays a critical role in its load transfer capability. In the hybrid cementing fixation, the uncemented stem of the MK tray was less firmly anchored to the bone, and the interfacial contact condition with a friction of coefficient of 0.1 had a minimal effect

in transferring load distally. It therefore induced a similar amount of proximal bone resorption as its stemless counterpart (Fig. 6.2). This was in accordance with a measurement of hybrid fixation in-vitro (Jazrawi et al. 2001), where no significant changes in the proximal tibial bone strain were found when the uncemented stem length of the tibial prosthesis was varied. However in the cementless (no ingrowth) case, the amount of bone density reduction predicted at 60 months was lowest for the MK-L0, and that did not match the MK-L45. It was observed that bone resorption and densification occurred simultaneously in different areas of the resected surface for the MK-L0 (Fig. 6.3c), thus the averaged bone apparent density computed was higher and led to a lower density change relative to time zero. This suggested that the joint load may be distributed unevenly or differently to normal across the stemless mini-keel tray when implanted without any cement. Due to a firm anchorage of the stem to the bone in the fully cemented fixation and where bone ingrowth (in cementless fixation) occurred, the stem extension transferred additional load distally and led to greater proximal bone resorption than the stemless MK design.

The partial ingrowth cases were modelled based on the amount of prosthesis surface area where bone ingrowth could occur. Chong et al. (2009) showed that the area favourable for ingrowth was 60% for the mini-keel design with a stem extension, which was almost twice the area of the standard stemmed prosthesis (33%). The increase in the area of the firmly anchored bone-prosthesis interface has led to greater load transfer capability of the prosthesis. If the standard stemmed prosthesis design could be improved to generate a larger surface area where ingrowth was likely, its extent of proximal bone resorption would be worsened. It is known that increased osseointegration in cementless fixation increases its fixation strength and reduces its risk of long-term loosening. This revealed the conflict in design requirement for addressing the problem of stress-shielding and aseptic loosening concurrently.

The osteoporotic (fully cemented) case was modelled by reducing the apparent density of the tibia of a healthy subject by 15%. In this case, the amount of proximal bone resorption predicted was almost 60% higher than that of a non-osteoporotic bone. This showed that degraded bone quality in patients receiving knee implants may result in a greater compromise in fixation strength and long-term loosening failure. The inverse relationship between the amount of bone resorption and the initial level of

bone density was also observed in patients receiving hip (Kerner et al. 1999) and knee (Li and Nilsson 2000) implants.

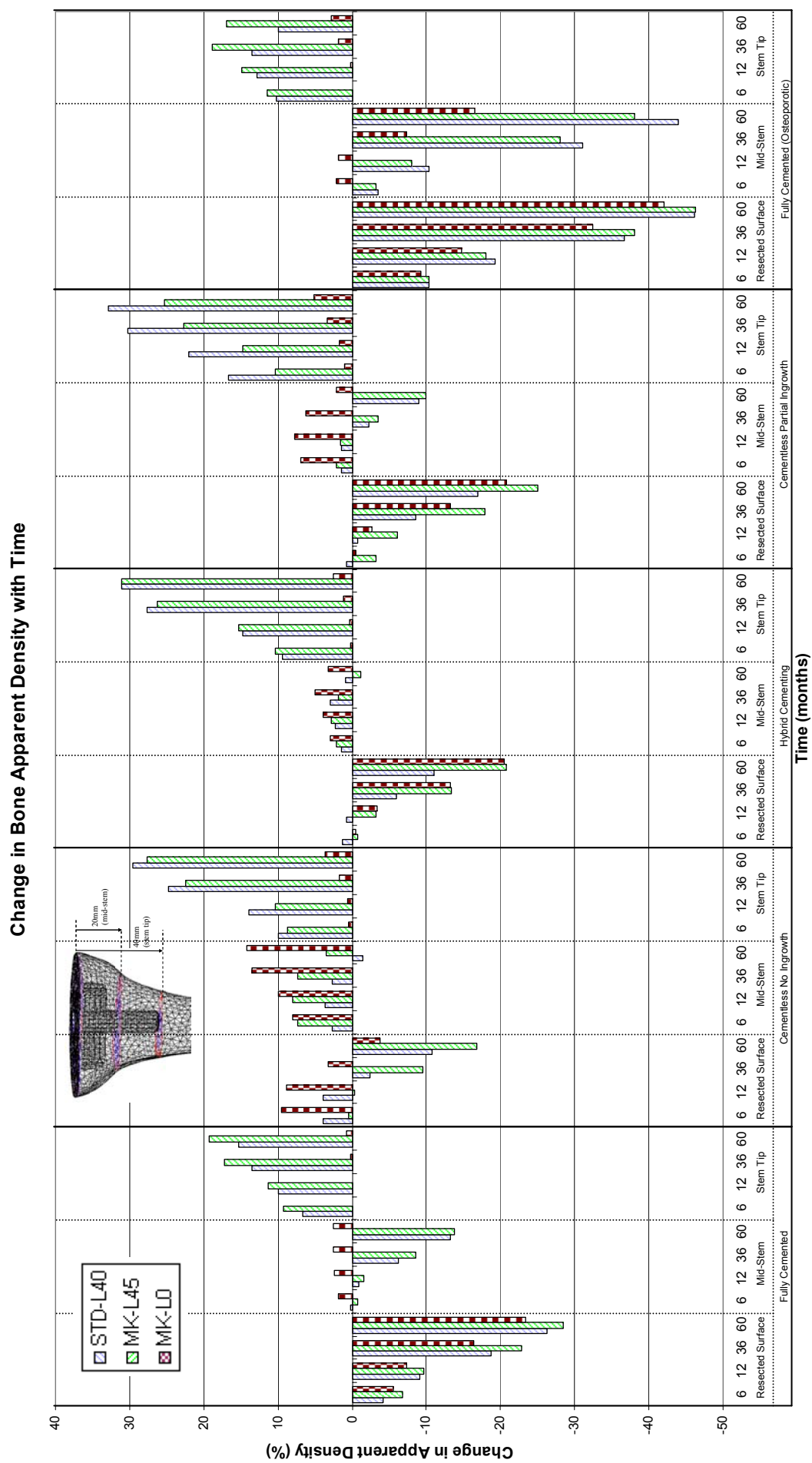


Figure 6.2: Predicted change in apparent densities over time in the transverse plane at levels of the tibial resected surface, mid-stem and stem tip.

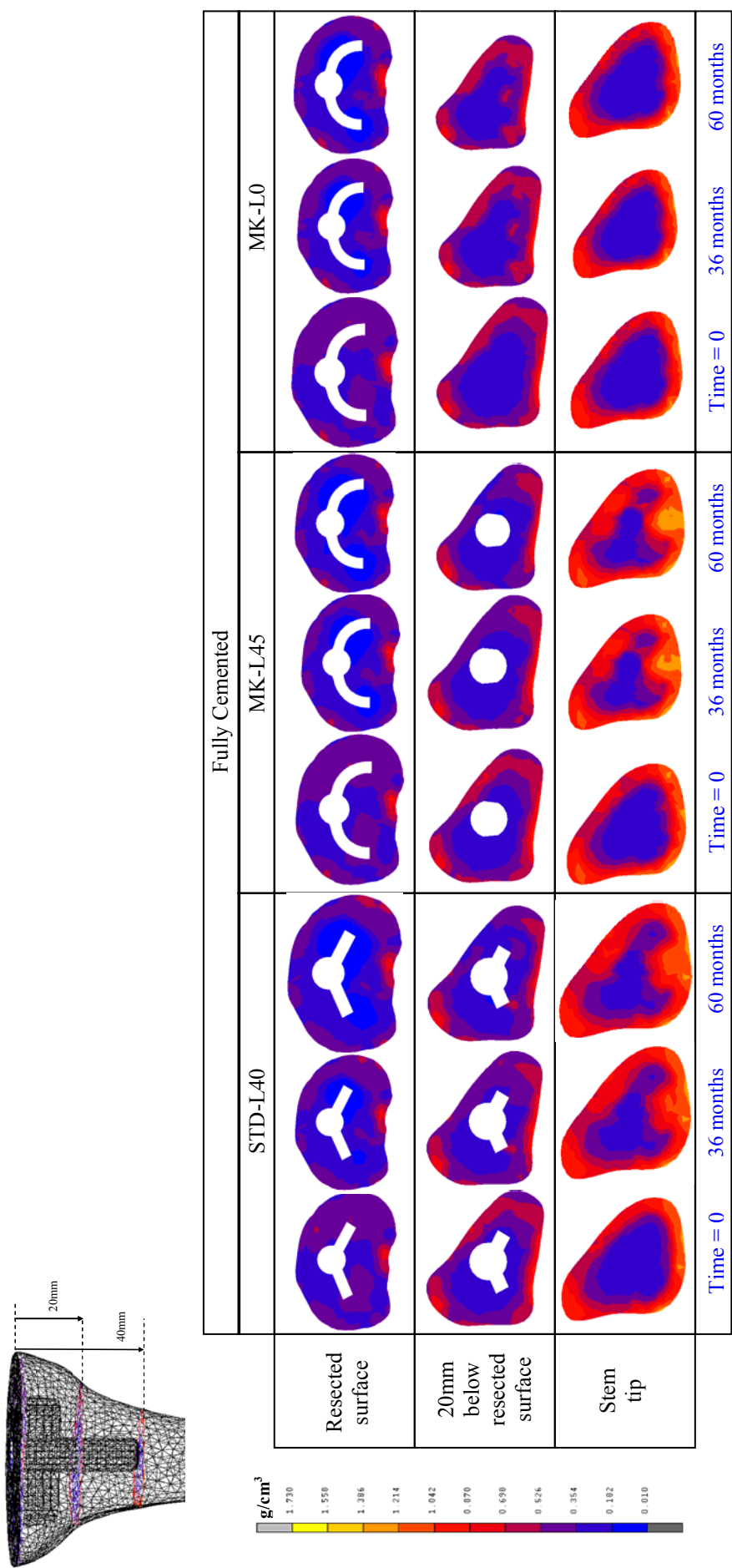


Figure 6.3a: Bone apparent density plots showing the regions of predicted bone resorption and densification in the transverse plane at levels of the tibial resected surface, mid-stem and stem tip for the fully cemented case.

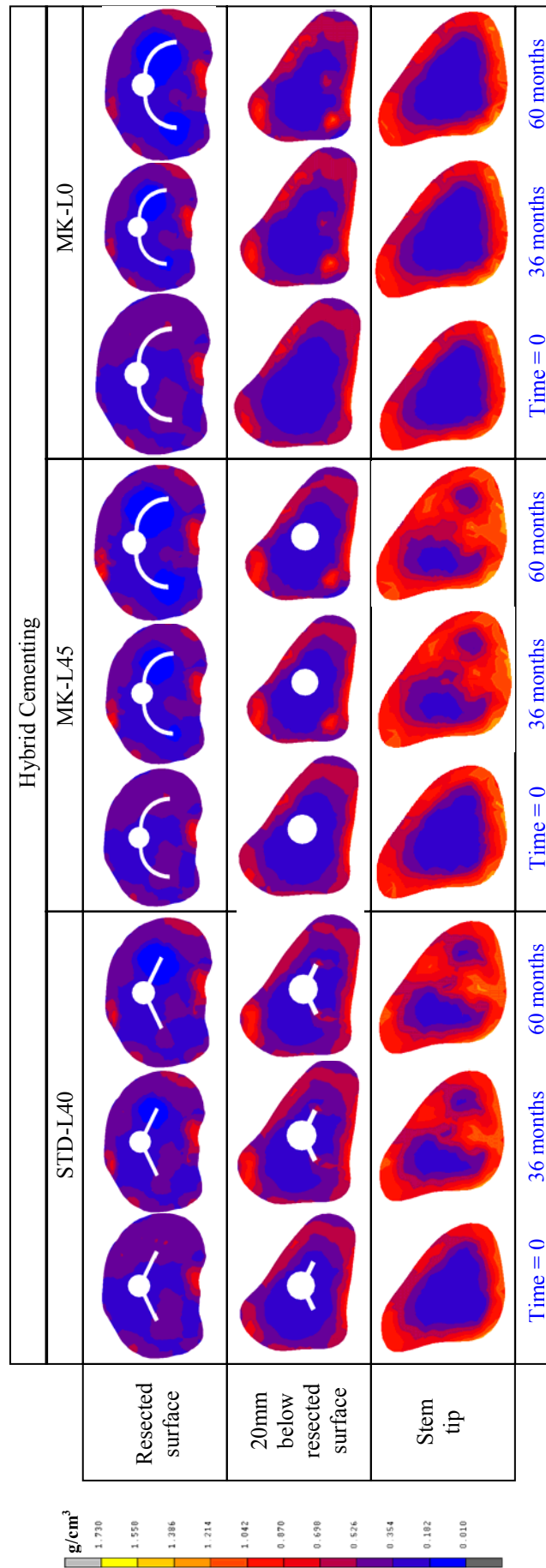
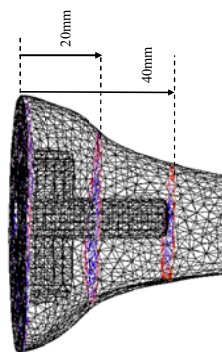


Figure 6.3b: Bone apparent density plots showing the regions of predicted bone resorption and densification in the transverse plane at levels of the tibial resected surface, mid-stem and stem tip for the hybrid cementing case.

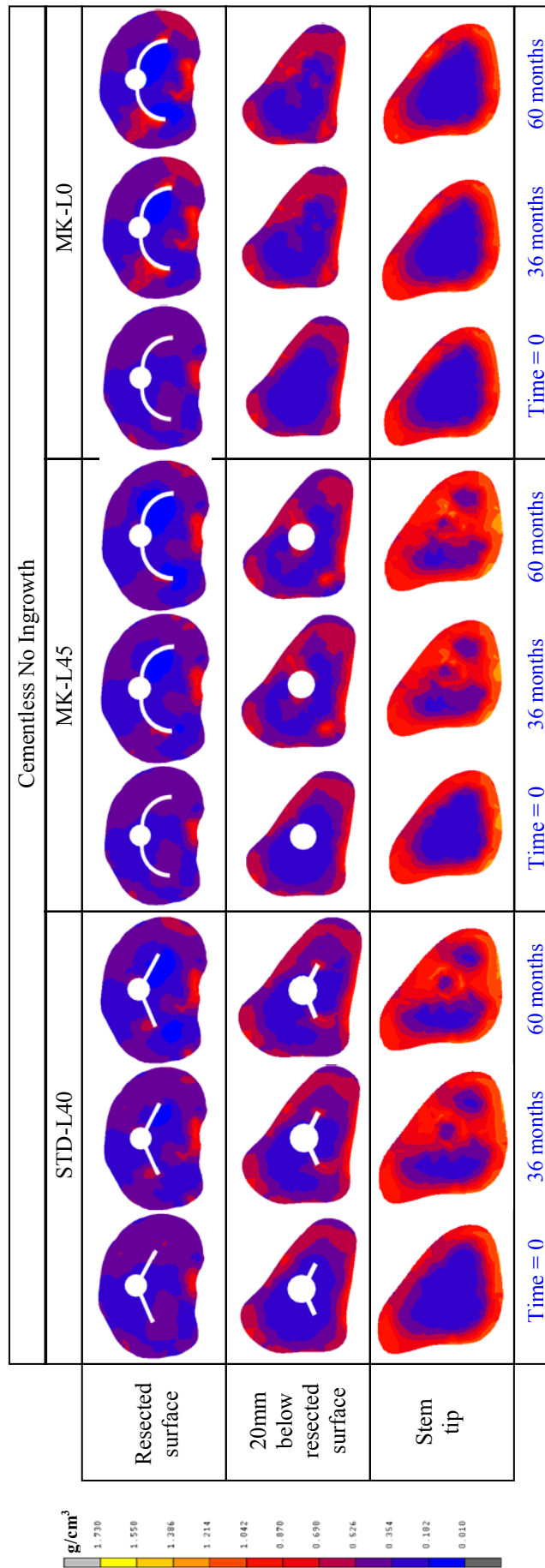
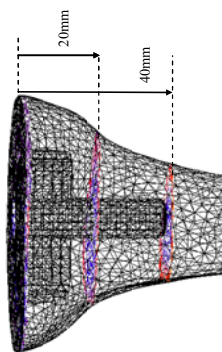


Figure 6.3c: Bone apparent density plots showing the regions of predicted bone resorption and densification in the transverse plane at levels of the tibial resected surface, mid-stem and stem tip for the cementless no ingrowth case.

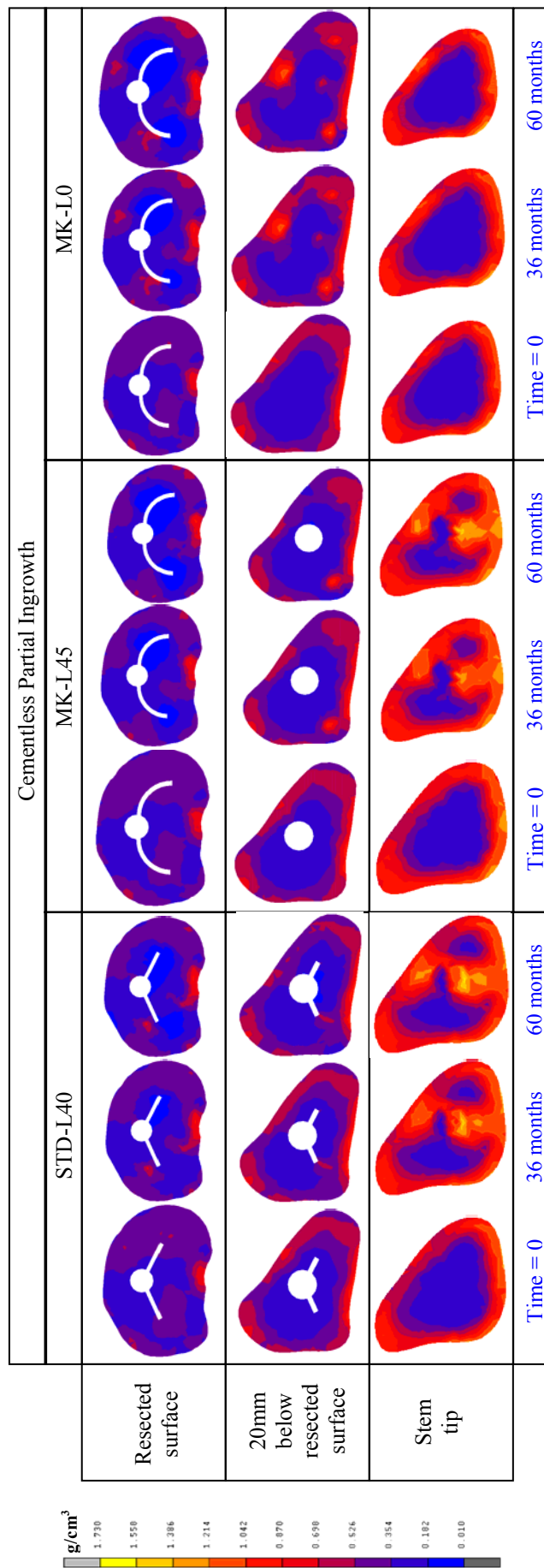
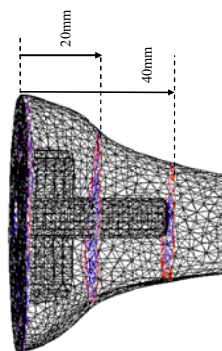


Figure 6.3d: Bone apparent density plots showing the regions of predicted bone resorption and densification in the transverse plane at levels of the tibial resected surface, mid-stem and stem tip for the cementless partial ingrowth case.

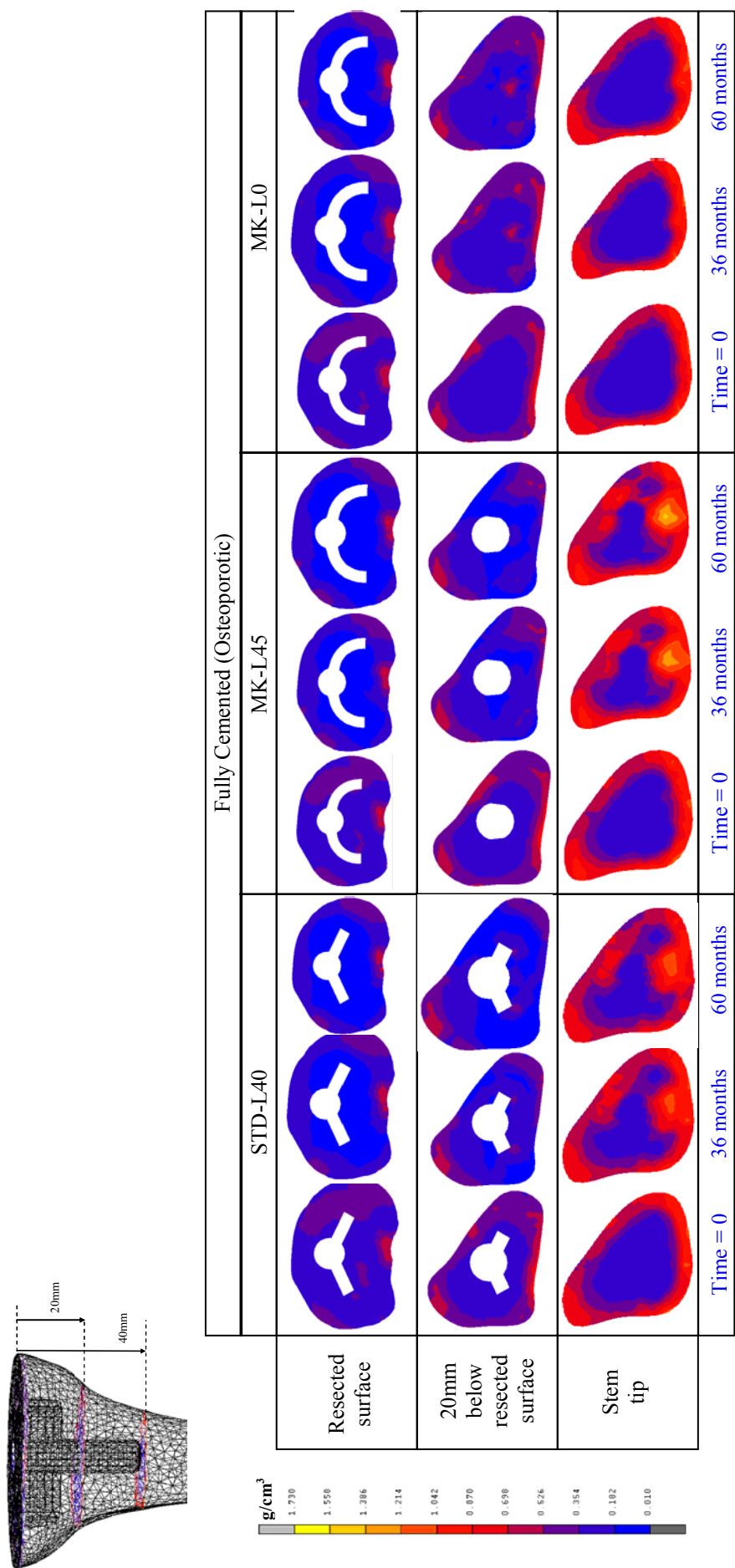


Figure 6.3e: Bone apparent density plots showing the regions of predicted bone resorption and densification in the transverse plane at levels of the tibial resected surface, mid-stem and stem tip for the fully cemented osteoporotic case.

6.3. Interface Micromotion Analysis of the MIS Mini-Keel Tibial Prostheses

6.3.1. Introduction

The MIS total knee replacement utilising the cemented fixation technique was discussed in the preceding section on bone remodelling. Due to long-term cement fatigue and bone-cement interface failures, the tibial fixation may eventually become loosened and lead to revision surgery. The cementless fixation, relying on biological attachment of the prosthesis to the bone, requires minimal bone-prosthesis relative motion. Computational FE studies have therefore been carried out to simulate and evaluate the interface micromotion between the bone and prosthesis. It was noted in Chapter 5.5 that different load patterns altered the predictions of bone-prosthesis micromotion and were anticipated to have an impact on the risk assessment of aseptic loosening in design change evaluation. The objectives of this study were to assess the comparative fixation performance of the MIS mini-keel tibial prostheses with the standard stemmed design in relation to bone-prosthesis micromotion and long-term aseptic loosening, and to investigate the influence of different load conditions on the outcome of design changes.

6.3.2. Materials and Methods

The 3D finite element models of the tibial fixations were similar to those described in Chapter 5.5.2. The two mini-keel tibial prostheses studied were i) with a stem extension of 45mm (MK-L45) and ii) stemless (MK-L0). The standard prosthesis with a stem of 40mm (STD-L40) was included for relative comparison (Fig. 6.4). Similarly to Chapter 5.5, the bone-prosthesis interface condition was assumed to be immediately after operation where bone ingrowth has yet to occur. Thus the case of cementless fixation with no ingrowth was modelled.

The four different loading conditions analysed were as listed in Table 5.4, corresponding to i) generic non-gait, ii) 15% of the gait cycle, iii) 25% of the stair climbing cycle, and iv) gait sequential. For load cases ii-iv, the loads were applied at the tibial-femoral contact points according to the different angles of knee flexion. The upper limit of bone-prosthesis interface micromotion with a likelihood of bone

ingrowth was set at $50\mu\text{m}$. The percentage of the prosthesis surface area (SA) with interface micromotion less than $50\mu\text{m}$ would be presented.

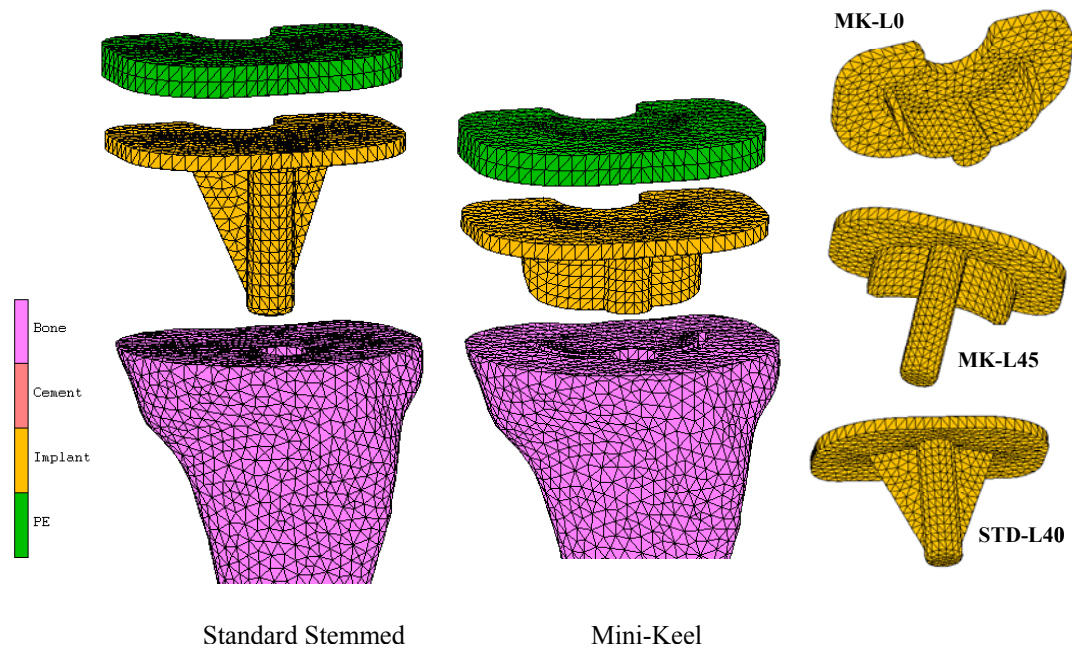


Figure 6.4: FE models of the mini-keel (stemmed/stemless) and standard tibial fixations.

6.3.3. Results

The i) peak interface micromotion (MM) and ii) proportion of prosthesis surface area (SA) favourable for bony ingrowth for the four loading conditions are illustrated in Fig. 6.5. The contour plots of the predicted micromotion on the surface of the tibial prosthesis are shown in Fig. 6.6. The grey regions represent the surfaces where the micromotion was lower than the threshold value of $50\mu\text{m}$, in which bone ingrowth could occur.

Under the generic single load condition, the zonal area amenable for bone ingrowth for the mini-keel prostheses (stemmed and unstemmed) was predicted to be almost twice the size of the area of the standard stemmed implant (Fig. 6.5b). The surfaces where osseointegration would be possible were similar for the MK-L0 and MK-L45 designs, mainly located at the antero-medial and posterior regions of the tray and mini-keel (Fig. 6.6a). Similar regions of high micromotion were observed at the antero-lateral edge of the tray for all three designs. The peak micromotion predicted for the MK-L0 was the highest, 20% greater than for the STD-L40 (Fig. 6.5a),

probably due to the lack of the stem in resisting tray tilting. As a result, a higher lift-off was experienced at the anterior edge. The peak micromotion predicted for the MK-L45 was the lowest.

By prescribing a single load of 15% of the gait cycle, more than 80% of the surface area of MK-L45 and STD-L40 was predicted to be favourable for bone ingrowth (Fig. 6.6b). Unlike the single load non-gait case, high micromotion was not found at the edge of the tray but occurred towards the stem tip region for the stemmed designs. For the stemless MK prosthesis, bony ingrowth was predicted to occur over the entire bone interface of the prosthesis.

At 25% of the stair climbing cycle (increased vertical and AP shear load), only half of the surface of the MK-L45 was predicted to have favourable ingrowth conditions, especially at the posterior and postero-medial regions of the tray (Fig. 6.6c). The STD-L40 design resulted in 30% of the area where ingrowth was possible, a decrease of 40% over the MK-L45 prosthesis. Micromotion at the edge of the tray was higher for the MK-L45 than that of STD-L40, while micromotion at the stem was lower. Much higher peak micromotion was predicted for the MK-L0 design (Fig. 6.5a), with an increase of 56% and 46% over the STD-L40 and MK-L45 designs respectively.

Fig. 6.6d shows the progression of interface micromotion around the prosthesis surface at different points through the gait cycle. The progression was similar for both the stemmed prostheses. The micromotion at the stem tip region increased during 0% to 50% of the gait cycle. At toe-off (65% gait cycle), the region of high micromotion migrated from the stem tip to the antero-medial edge of the tray. A peak micromotion of 118 μ m and 67% surface area allowable for ingrowth was predicted for the MK-L45, however a higher peak micromotion of 133 μ m and a lower 44% prosthesis surface for osseointegration was estimated for STD-L40. For the stemless MK-L0, micromotion underneath the tray increased with the gait cycle and similar lift-off was observed at the anterior-medial edge of the tray as the gait cycle proceeded from 50% to 65%. Without the central stem support, the tilting of the tray due to uneven medial/lateral loading would be more severe hence leading to a high micromotion of 217 μ m during toe-off. Approximately 18% reduction in the ingrowth surface

compared to MK-L45 was predicted, but with an improvement of 25% over STD-L40.

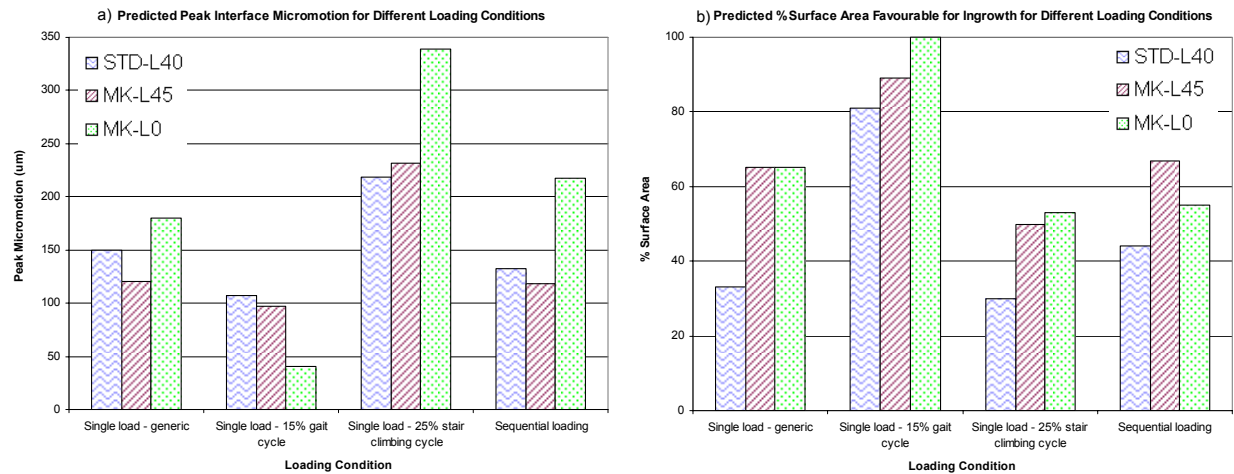


Figure 6.5: FE predictions of the a) peak interface micromotion and b) proportion of prosthesis surface area favourable for bone ingrowth for different loading conditions.

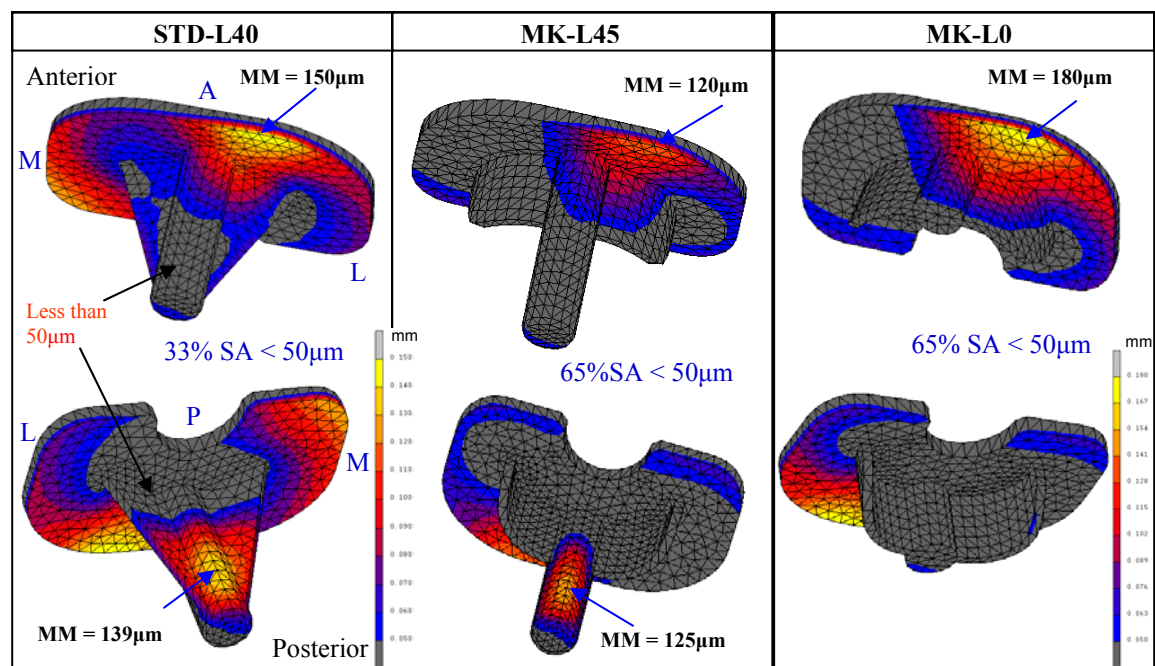


Figure 6.6a: Predicted interface micromotion at the surface of the tibial prosthesis – single load condition, non-gait.

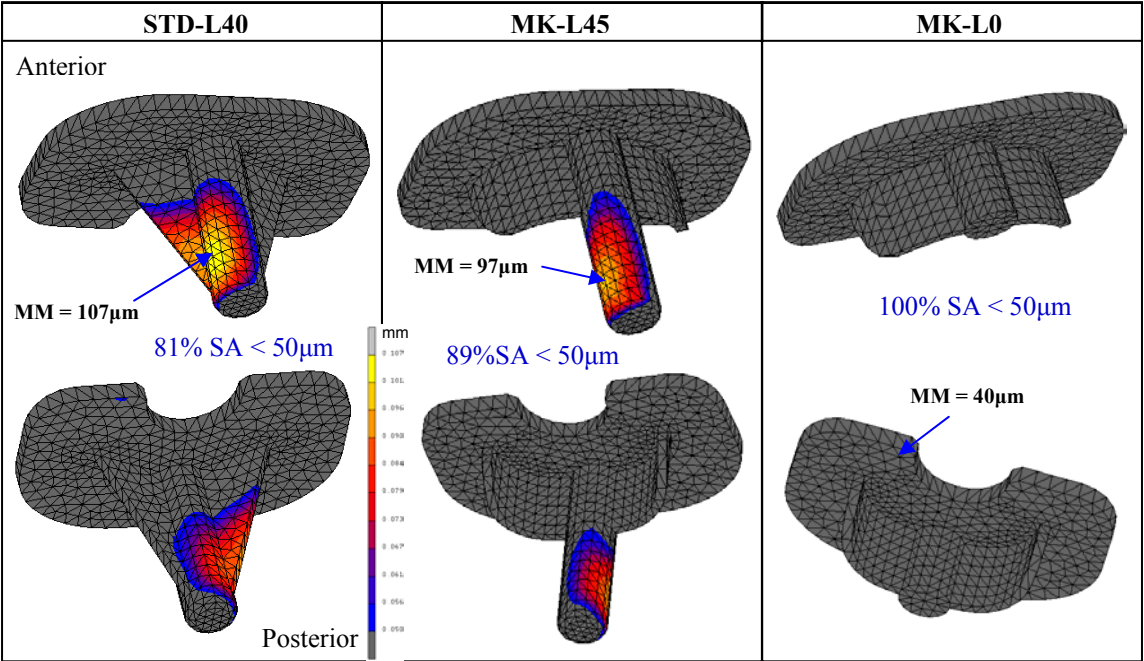


Figure 6.6b: Predicted interface micromotion at the surface of the tibial prosthesis – single load condition at 15% of the gait cycle.

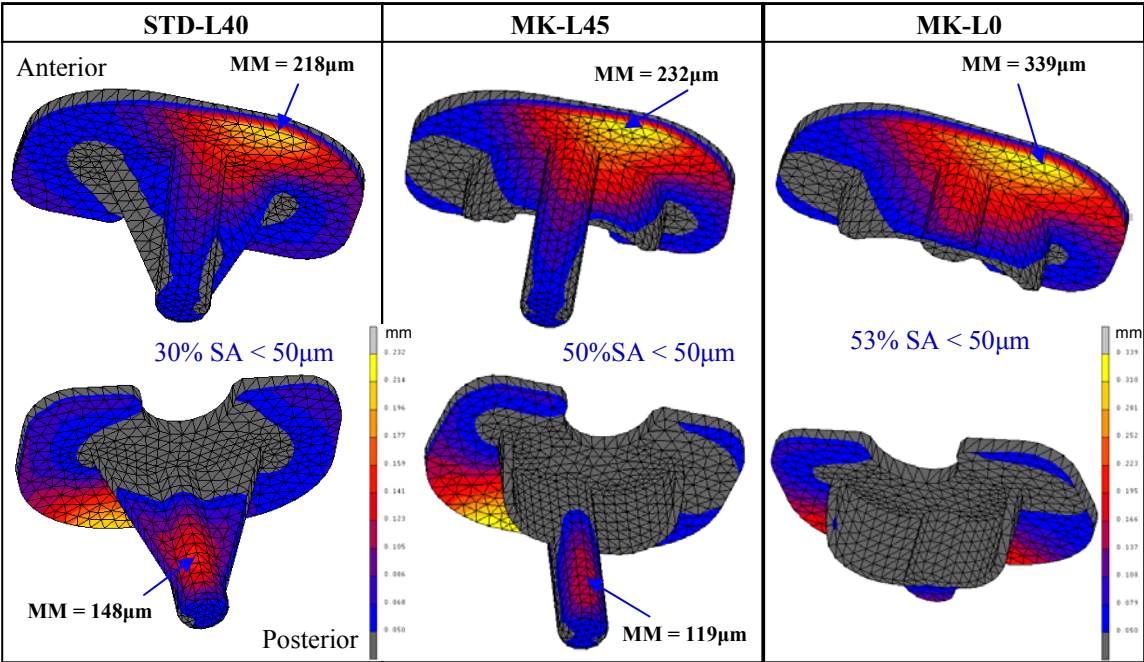


Figure 6.6c: Predicted interface micromotion at the surface of the tibial prosthesis – single load condition at 25% of the stair climbing cycle.

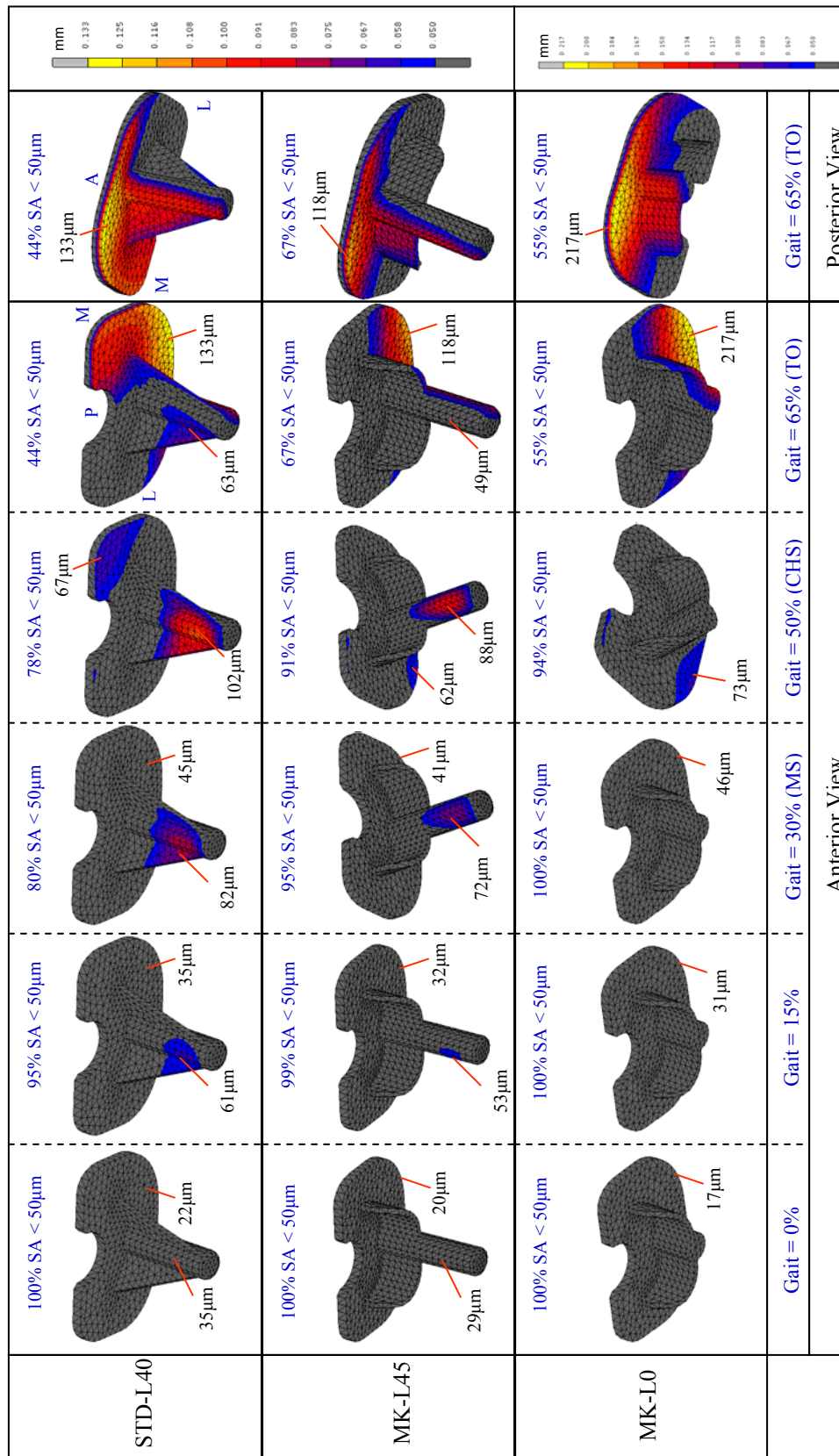


Figure 6.6d: Predicted interface micromotion at the surface of the tibial prosthesis – gait data with sequential loading.

6.3.4. Discussion

The bone-prosthesis interface micromotion of the MIS mini-keel tibial prostheses was investigated and its relative risk of long-term aseptic loosening was compared with the standard stemmed design. The influence of load conditions on the outcome of design change evaluation was also evaluated. It was observed that the three single load conditions (non-gait, 15% of the gait cycle, 25% of the stair climbing cycle) and gait sequential loading generated different responses of micromotion around the prosthesis surfaces.

For the single non-gait load case, the shear loads subjected the tibial tray to higher micromotion at the antero-lateral region for the three prosthesis designs, while the “push down” effect of the vertical load induced higher relative movement between the stem and periprosthetic bone. As for the single load at 15% of the gait cycle, the relative movement between the tray and supporting bone was greatly reduced due to a low AP shear force of $0.08 \times BW$. High micromotion was only observed at the stem region of the MK-L45 and STD-L40 designs when the stems were pushed down by the vertical load. For the stemless mini-keel prosthesis, bone ingrowth was predicted to occur at the entire surface of the tray and keel.

Results obtained from the single load at 25% of the stair climbing cycle were considerably different from the above two load cases. Firstly, higher peak micromotion and smaller extent of bone ingrowth onto the prosthesis were predicted for all three designs. This was primarily due to the higher vertical joint force prescribed, so the prosthesis moved more within the periprosthetic bone. The other difference was that the peak micromotion at the edge of the tray of the MK-L45 design was higher than for the STD-L40, which was the opposite trend to that seen with the single non-gait load case. With a knee flexion angle of 30° , the lateral compartment vertical load acted more posteriorly on the tray, thus imposing a posterior tilt of the tray. As the mini-keels did not extend to the distal stem tip (unlike the flange of the standard stemmed prosthesis), a lower resistance to posterior tilting of the tibial tray was experienced. Higher lift-off at the anterior edge of the tray occurred as a result.

The tibial-femoral contact points after TKR vary significantly between prosthesis designs and manufacturers, and even with individual patients (Dennis et al. 2003; Cates et al. 2008). It is difficult to select specific loading points for different prosthesis designs. For ease and reliable analysis of assessing the relative risk of aseptic loosening between cementless tibial fixations, a *single non-gait load condition* where joint loads are prescribed at the centres of the medial/lateral condyles of the tibial tray could be recommended. When using this load condition, the high micromotion predicted at the edge of the tray correlated well with clinical occurrence of the radiolucent lines (Hsu et al. 1995; Berger et al. 2001). The predicted regions of bony ingrowth were also in agreement with retrieval studies (Turner et al. 1989; Sumner et al. 1995).

6.4. RSA measurements of Standard Stemmed and MIS Mini-Keel Tibial Prostheses

6.4.1. Introduction

Roentgen Stereophotogrammetric Analysis (RSA) is a quantitative method for evaluating prosthesis motion in total knee replacement. The RSA technique primarily measures the relative movement (in six degrees of freedom - translation and rotation), or migration, between the prosthesis and bone. Clinical evidence has shown that early migration of knee prostheses could be related to long-term aseptic loosening (Grewal et al. 1992; Ryd et al. 1995). RSA measurements have been conducted for evaluating the fixation performance between different tibial prosthesis designs (Hyldahl et al. 2005a; Saari et al. 2006b), fixation techniques (Önsten et al. 1998; Hyldahl et al. 2005b; Uvehammer et al. 2007), and arthritis conditions (Fukuoka et al. 2000).

The NexGen MIS mini-keel tibial prosthesis is a relatively new design for TKR introduced by Zimmer (Zimmer Inc., Warsaw, Indiana, USA). It was specifically designed to address the challenges and demands of MIS TKR. The new design incorporates broad proximal keels that engage the tibia in the area of highest bone density for secure fixation, while its low profile makes it easier to insert into the minimally invasive arthrotomy. However its long-term fixation performance and how it compares to the standard stemmed prosthesis remain unclear. Through early RSA measurements, it is hoped that an indicative trend of its fixation performance in relation to aseptic loosening could be determined. The objective of this study was to assess the comparative fixation performance of the MIS mini-keel tibial prosthesis to the standard stemmed design by RSA. This study was conducted in collaboration with the Department of Orthopaedic Surgery, Singapore General Hospital (SGH), Singapore. It was to note that the clinical study was not conducted by the present author. The RSA data was made available for the validation of the FE models developed in this project for component loosening analysis.

6.4.2. Materials and Methods

Ethical approval was obtained from the Institutional Review Board for the clinical study to be carried out in SGH. A total of forty patients were recruited (8 males, 32 females, mainly above the age of sixty). The reason for knee replacement was Osteoarthritis for all patients. The TKR operation was performed by a single orthopaedic surgeon, Dr YEO Seng Jin, Senior Consultant Orthopaedic Surgeon, SGH. The implantation of the MIS prostheses was carried out as per the surgical procedures recommended by Zimmer Inc. Bone cement was applied underneath the tray, leaving the stem and keels uncemented (hybrid cementing). The patients were randomly assigned to receive either a i) standard stemmed - 40mm length (Zimmer NexGen Legacy LPS), ii) mini-keel with stem extension (45mm), or iii) mini-keel with no stem extension tibial prosthesis. The breakdown of the prostheses implanted was seventeen (17) STD-L40, sixteen (16) MK-L45, and seven (7) MK-L0. Typical radiographic images of the implanted prostheses are shown in Fig. 6.7.

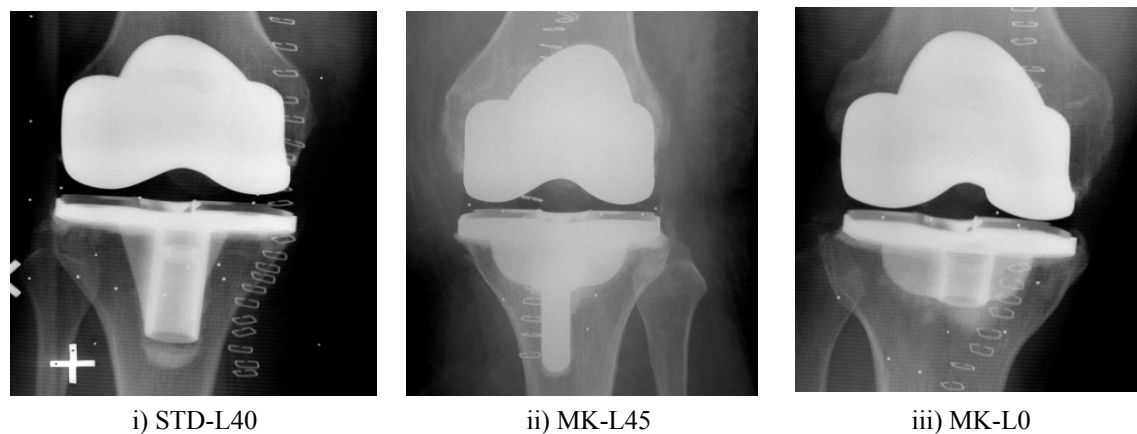


Figure 6.7: Radiographic images of the implanted prostheses.

RSA measurements were made at intervals of 6, 12, 18 and 24 months post-operatively. The movement of the prosthesis relative to the bone was measured in translation (Tx, Ty, Tz / mm) and rotation (Rx, Ry, Rz / degrees). The resultant of the translation and rotation were then computed as $\text{Resultant} = (X^2 + Y^2 + Z^2)^{1/2}$. Statistical analyses of the results were performed using ANOVA. A p value of less than 0.05 was considered to be statistically significant.

6.4.3. Results

Up to February 2009, a total of twenty-two (22) patients had undergone the RSA scan at six months post-operatively. The breakdown of the prostheses was nine (9) STD-L40, eight (8) MK-L45, and five (5) MK-L0. The x, y and z components of the translation and rotation measured for each patient are recorded in Fig. 6.8. The averaged values of the translation and rotation for the three groups of patients/prostheses are shown in Fig. 6.9. Although statistically not significant, the STD-L40 prosthesis registered the lowest component translation and rotation at 6 months post-operatively, followed by the MK-L45 and MK-L0 prostheses.

	Implant	Translation (mm)				Rotation (degrees)			
		Tx	Ty	Tz	Resultant	Rx	Ry	Rz	Resultant
N = 9	STD-L40	0.020	-0.669	0.071	0.673	-0.710	0.270	-0.060	0.762
	STD-L40	-0.228	-0.149	0.110	0.294	-0.570	-0.400	0.040	0.697
	STD-L40	-0.010	-0.097	-0.156	0.184	0.220	-0.120	-0.170	0.303
	STD-L40	0.083	-0.035	-0.041	0.099	0.300	0.450	-0.060	0.544
	STD-L40	-0.341	0.161	-0.286	0.473	-0.740	-1.480	0.070	1.656
	STD-L40	0.118	-0.014	-0.461	0.476	0.710	-0.060	-0.430	0.832
	STD-L40	0.256	-0.150	-0.597	0.667	0.440	0.150	-0.120	0.480
	STD-L40	-0.257	0.108	-0.007	0.279	-0.700	-0.830	-0.270	1.119
	STD-L40	0.088	-0.108	-0.212	0.254	0.320	-0.050	-0.130	0.349
N = 8	MK-L45	0.021	0.133	0.409	0.431	-0.430	0.010	-0.150	0.456
	MK-L45	0.137	-0.053	-0.145	0.206	-0.530	-0.420	-0.430	0.801
	MK-L45	0.090	-0.229	-0.418	0.485	0.720	-0.070	0.150	0.739
	MK-L45	0.131	-0.538	-0.171	0.580	1.440	-0.110	-1.580	2.141
	MK-L45	0.027	0.069	-0.056	0.093	0.570	-0.120	-0.130	0.597
	MK-L45	-0.324	-0.218	-0.574	0.694	-1.280	0.870	0.810	1.747
	MK-L45	0.429	0.002	0.502	0.660	0.110	1.260	-0.380	1.321
	MK-L45	0.121	0.061	0.348	0.373	-0.200	0.190	-0.180	0.329
N = 5	MK-L0	-0.083	0.019	-0.502	0.509	-0.970	1.240	0.020	1.574
	MK-L0	-0.536	-0.113	0.288	0.619	1.510	-1.150	1.760	2.588
	MK-L0	-0.379	-0.373	0.136	0.549	0.150	-0.640	0.200	0.687
	MK-L0	-0.094	0.027	-0.377	0.389	0.800	-0.010	0.120	0.809
	MK-L0	-0.021	0.060	0.553	0.557	-0.350	-0.380	-0.070	0.521

Figure 6.8: X, y and z components of the translation and rotation of the prostheses measured by RSA at 6 months post-operatively.

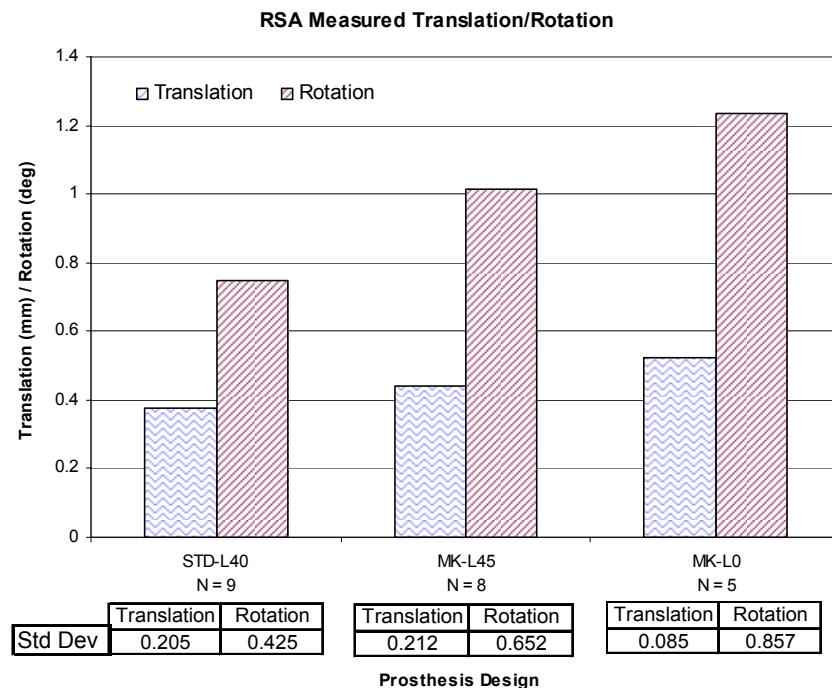


Figure 6.9: Prosthesis movements (translation/rotation) measured by RSA at 6 months post-operatively.

6.4.4. Discussion

Twenty-two out of the forty patients recruited had undergone the RSA scan and measurement up to the present stage. The sample sizes for the STD-L40 (N = 9) and MK-L45 (N = 8) groups were reasonably sufficient for a reliable statistical analysis, however the number of patients for MK-L0 (N = 5) were still too low. Although the component migration at 6 months did not differ statistically between the three prosthesis designs, it was found that the stemless mini-keel prosthesis resulted in highest component migration, followed by the stemmed mini-keel and the standard stemmed was the lowest. The mean translation (resultant) of 0.38mm for STD-L40 in the current study was in the range of 0.3-0.4mm for a similar stemmed tibial prosthesis measured previously (Fukuoka et al. 2000; Saari et al. 2006b). The mean translation for the MK-L45 was 0.44mm and the MK-L0 of 0.52mm, which were 16% and 37% higher than for the STD-L40 respectively. The mean rotation (resultant) for the MK-L45 and MK-L0 were 36% and 65% higher than the STD-L40 respectively.

The trend in component migration could possibly be related to proximal tibial bone resorption due to stress-shielding. In Chapter 6.2, the mini-keel prostheses (stemmed

and stemless) were found to induce greater bone resorption than the standard stemmed design. The strength of the bone-prosthesis support would be weakened, and the mini-keel prostheses thus migrated more. Without the stem extension, resistance to tilting of the mini-keel tray would be reduced, leading to greater migration.

Migration of tibial components has been observed to be faster in the early post-operative period of three to six months, and slower down after one to two years (Ryd et al. 1990; Önsten et al. 1998; Fukuoka et al. 2000; Saari et al. 2006b). The faster rate of migration in the early period could be due to localised bone trauma and component instability after surgery. Migration data at one to two years after implantation where the fixation became more stable were used for correlation with late component loosening (Grewal et al. 1992; Freeman and Plante-Bordeneuve 1994; Ryd et al. 1995; Walker et al. 1995) (see Chapter 3.4.2 for greater details).

The RSA results for the current study at 12-24 months were yet to be collected, thus the longer-term fixation performance comparison between the mini-keel and standard stemmed prostheses could not be carried out. A preliminary assessment based on the RSA measurements at six months could suggest that fixation performance of the MIS mini-keel prostheses would be worse than the standard stemmed design in relation to long-term aseptic loosening (although the results were not statistically significant). A firmer conclusion could be drawn from RSA results of more patients and at 12 and 24 months post-operatively. The author intends to continue to work with SGH on analysing the RSA results from the subsequent scans.

6.5. Validation of Patient-Specific Finite Element Models

6.5.1. Introduction

The finite element method is used extensively for the analysis of orthopaedic and implant biomechanics (Huiskes and Chao 1983; Bernakiewicz and Viceconti 2002). The FEM is able to simulate and provide possible explanations for the biomechanical responses in the bone and the prosthesis after a joint replacement. It is important for the FE models and predictions to be validated with actual results and data, so that the users are confident that the predicted outcome will be realistic and accurate. Kerner et al. (1999) and Bitsakos et al. (2005) both correlated their bone remodelling predictions of hip implantation to bone densitometry results. Although the bone remodelling trends were qualitatively in agreement, the amount of bone loss was overestimated. In using equivalent strain as a mechanical stimulus for bone remodelling (Turner et al. 2005), the predicted and clinical bone density changes after 2 years were in good agreement. Taylor et al. (1998) compared the stresses of the cancellous bone underneath the tibial tray for different prosthesis designs with implant migration data at 1 year and their respective survivorship against loosening at 5 years, a qualitative correlation was achieved but the magnitude of the bone stresses were not accurate.

As explained in Chapter 5.4.4, a direct validation of the current bone remodelling predictions with patient-specific bone densitometry data was not possible due to unavailability of clinical data. However the bone remodelling results did correlate well with published clinical densitometry and radiographic results. The bone-prosthesis interface micromotion predictions were correlated with in-vitro measurements of cadaveric tibial fixation, which showed that the magnitudes of the micromotion predicted were realistic (Chapter 5.5). To the author's knowledge, there has not been a direct and patient-specific correlation of the FE predictions to tibial component loosening. In the preceding section, early component migration at six months was measured by RSA for the standard stemmed and mini-keel prostheses, and previous studies have shown that early migration of knee prostheses could predict long-term aseptic loosening. Retrieval studies have also revealed that bone cement failure is a detrimental factor for late aseptic loosening, and that the maximum tensile

stresses of the cement underneath the tibial tray predicted by FEM could be used to evaluate the relative risk of loosening between different prosthesis designs (Chapter 5.2).

The purpose of this study was to investigate if a correlation could be established between bone cement stresses predicted by FEM and component migration (translation and rotation) measured by RSA. If there is, the current FE modelling methodology would be validated and proven to be effective for the assessment of loosening of tibial components.

6.5.2. Materials and Methods

The three-dimensional patient-specific FE tibial models were built from the CT images of three TKR patients who each received a STD-L40, MK-L45 and MK-L0 tibial prosthesis. The details of the patients are listed in Table 6.1. The setup of the FE models was similar to those described in Chapter 5.4.2 (see Figs. 5.12a-(c) and 6.1c). The proximal tibia was virtually resected at 8mm below the lateral articulating surface of the tibial plateau, and the prosthesis was placed in the tibia. The position of the prosthesis was verified by the senior orthopaedic surgeon (Dr YEO Seng Jin) who performed the operation. Cement was applied underneath the tray leaving the stem/keel uncemented (hybrid cementing). Interfaces where cement was applied were modelled as bonded. The unbonded bone-stem/keel interfaces were modelled by defining contact between the surfaces, and the friction between the surfaces in contact was modelled with Coulomb's coefficient of friction of 0.1. The entire FE model consisted of approximately 35,000 tetrahedral elements, and the convergence tolerance was set at 1%. The tibia was fixed rigidly at the distal end 150mm below the tibial plateau.

A strain-adaptive bone remodelling algorithm (Huiskes et al. 1987) was incorporated into the FE simulation to predict the changes in apparent bone density with time after prosthesis implantation. Three different physiological knee joint load conditions were prescribed in the FE model, corresponding to 0% and 15% of the gait cycle and 25% of the stair climbing cycle (see Table 5.3). The maximum principal (tensile) stresses averaged in the cement layer underneath the tibial tray were extracted for correlating

with the component translation and rotation measured by RSA. For analytical purposes, the mean of the cement stresses generated by the two peak loads at gait (15%) and stair climbing (25%) cycles was taken.

The correlation was performed by two approaches. For the first approach, the FE models for each tibial component type were created from CT images of the respective individual patients. The loading conditions were applied according to each patient's body weight. This was termed as "*individual-tibia*" FE modelling approach. In the second approach, the FE tibial model was created only from one patient (P3 – TAT), and the three different prostheses were virtually implanted on the same tibia. In this case, all the three prostheses were of size 5 and the load was applied according to the patient's body weight of 81kg. This second approach was termed as "*shared-tibia*" FE modelling. The relationships between the component migration (translation and rotation) measured by RSA at six months and the cement stresses were studied.

Table 6.1
Details of the patients for FE modelling

Patient Number	Prosthesis Type	Prosthesis Size	Gender	Weight (kg)	Knee
P1 (NAB)	STD-L40	3	Female	60	Left
P2 (FAL)	MK-L45	3	Female	69	Right
P3 (TAT)	MK-L0	5	Male	81	Right

6.5.3. Results

The relationships (linear regression) between the component translation and rotation at six months and the cement stresses are illustrated in Fig. 6.10 for the "*individual-tibia*" approach and Fig. 6.11 for the "*shared-tibia*" approach. The maximum tensile cement stresses before bone remodelling, and after the bone has remodelled for six months were examined.

"Individual-Tibia" FE modelling – Before bone remodelling ($T = 0$), no correlations were found between component migration and the cement stresses (Translation: $R^2 = 0.007$, $P = 0.946$ / Rotation: $R^2 = 0.003$, $P = 0.964$). However when bone adaptation was simulated at six months, good correlations were achieved between component

migration and the cement stresses (Translation: $R^2 = 0.85$, $P = 0.254$ / Rotation: $R^2 = 0.935$, $P = 0.164$).

“Shared-Tibia” FE modelling – For cement stresses extracted before remodelling and after bone adaptation at six months, inverse relationships were noted with the component translation and rotation. A good correlation with the component migration was only found when the cement stresses were extracted at thirty-six months after surgery (Translation: $R^2 = 0.98$, $P = 0.089$ / Rotation: $R^2 = 1.0$, $P = 0.0$).

The trends of the predicted cement stresses versus component migration of different prostheses are showed in Fig. 6.12. The MK-L0 prosthesis experienced the highest component translation and rotation at six months, followed by the MK-L45 and the STD-L40 was the lowest. A good relationship was obtained by the “individual-tibia” FE approach at six months after surgery. However, a significant relationship was only achieved by the “shared-tibia” FE approach at thirty-six months after remodelling.

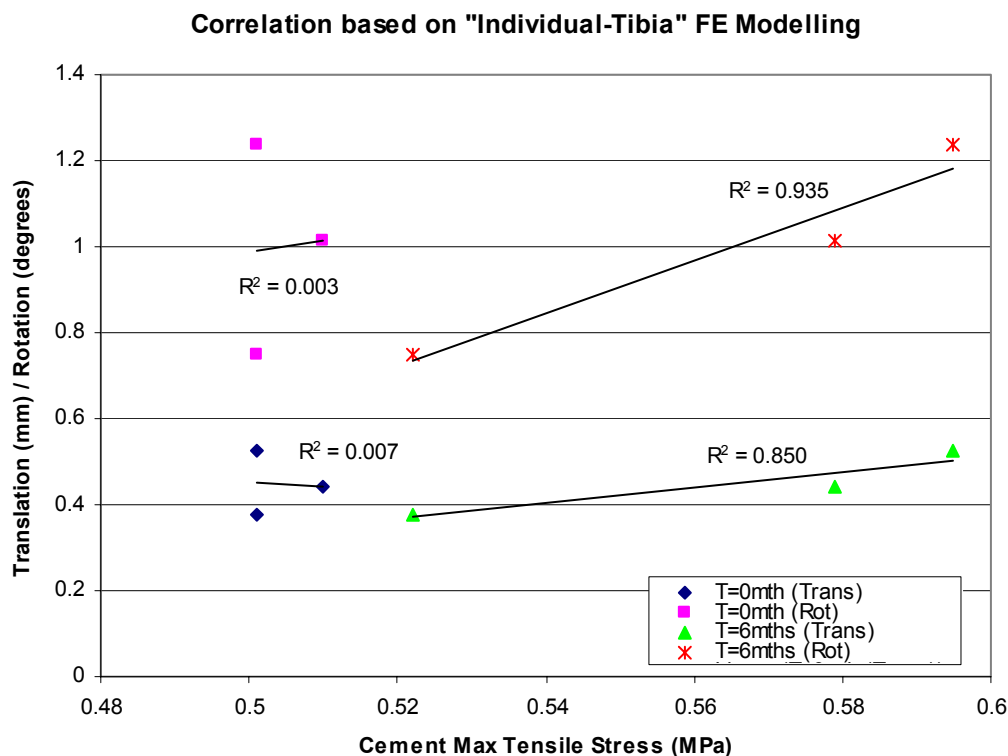


Figure 6.10: Graph of relationship between component translation/rotation and cement stresses – “individual-tibia” FE modelling approach.

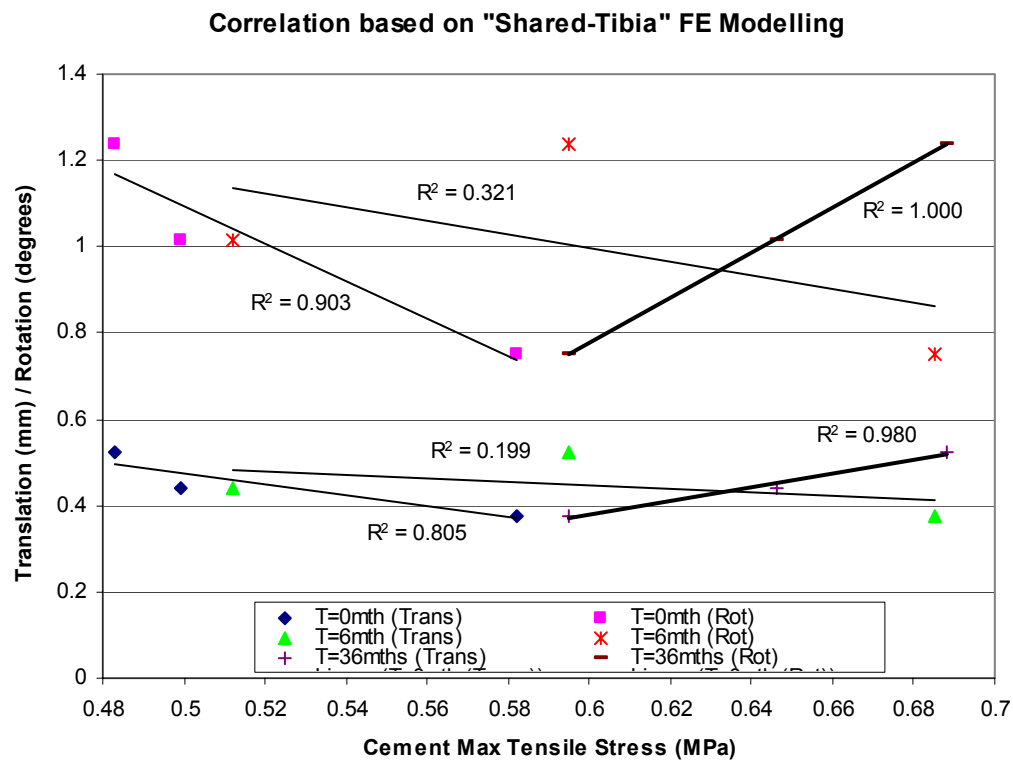


Figure 6.11: Graph of relationship between component translation/rotation and cement stresses – “shared-tibia” FE modelling approach.

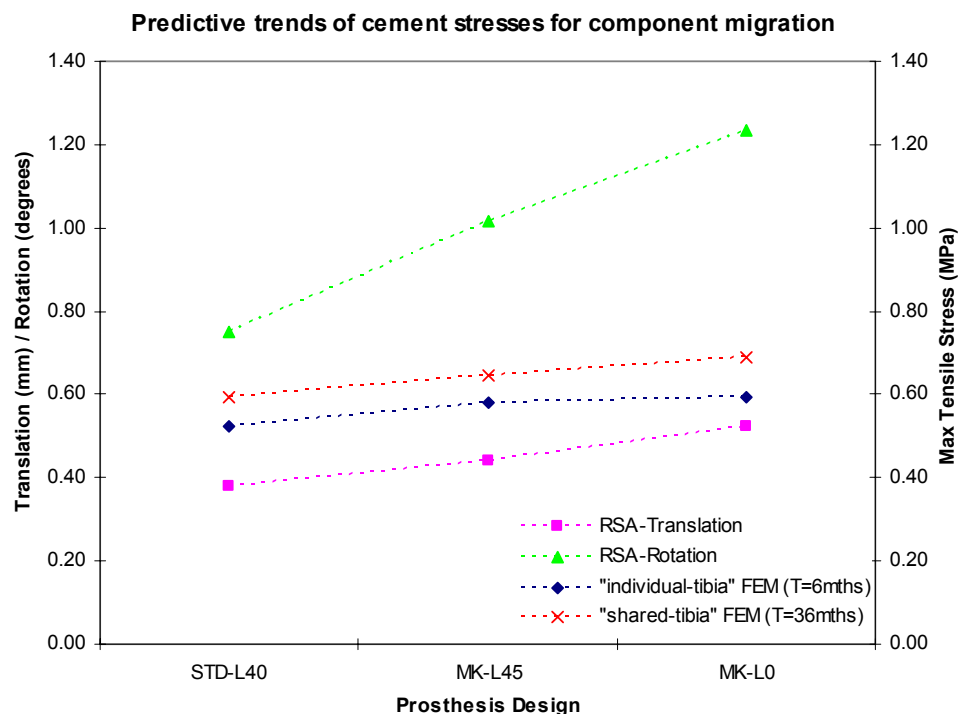


Figure 6.12: Predictive trends of the bone cement stresses for component translation/rotation of different prostheses measured by RSA.

6.5.4. Discussion

The FEM results should be compared to actual results so that their validity could be assessed. In this study, the cement stresses (maximum tensile) underneath the tibial tray predicted by patient-specific FE modelling were compared with measured RSA data. The relationship between cement stresses and component migration (translation and rotation) was investigated. For both the modelling approaches (“individual-tibia” versus “shared-tibia”), it was found that the implementation of bone remodelling was essential to achieve a good correlation between the FEM predictions and the RSA results. Without the consideration of bone remodelling, the greater stress-shielding effect of the mini-keel prostheses leading to a weaker bone-prosthesis support (see Chapter 6.2) could not be simulated. The predicted migration of the mini-keel prostheses was thus lesser leading to smaller cement deformation and cement stresses. As a result, the predicted cement stresses at time zero did not agree well with the component migration data.

By creating individual FE models of the tibiae of patients with the specific prosthesis implanted, the FE predictions after simulating six months of bone adaptation correlated well with the RSA measurements at a similar period. When a single tibial FE model had different prostheses implanted and analysed, bone remodelling of a longer period (thirty-six months) was needed for the FE results to correlate with the RSA measurements at six months. In this case, a scaling factor was needed to relate the simulated remodelling time to the actual time, and could be determined with subsequent RSA data at 12, 18 and 24 months. Despite this, both the single-tibia and individual patient approaches led to surprisingly good correlations to the RSA migration data.

Some specific limitations in this correlation should be noted. The above findings depended on the selection of patients whose CT images were used to create the FE tibial models. If a fourth patient was to replace a patient in the current “individual-tibia” approach, or if patient P3-TAT in the “shared-tibia” approach was to be replaced by patient P1-NAB or P2-FAL, the changes brought about by this replacement on the FE models such as tibia and implant geometries, bone strength and loading conditions etc, would result in some variation of the predicted cement

stresses, which may affect the correlation results. However this study demonstrated that the level of cement stresses predicted was very much prosthesis-dependent (Fig. 6.12), rather than tibia-dependent, as both of the approaches predicted similar trend of cement stresses variation with prosthesis designs.

The use of maximum tensile stresses of the cement underneath the tibial tray predicted by patient-specific FE modelling for the evaluation of relative risk of loosening between different prosthesis designs was validated with RSA measurements. Good correlations were achieved with the component translation and rotation. The current FE modelling methodology has therefore been shown to be effective for the assessment of the relative risk of tibial component loosening, and may be extended to the assessment of other joint replacements like hip and shoulder. With the subsequent RSA measurements due at 12, 18 and 24 months, it is recommended that further correlations of the FE predictions with the component migration data should be calculated, in order to strengthen these findings.

6.6. Conclusions

The mechanical responses of the MIS mini-keel prostheses and their comparative fixation performance compared with standard stemmed tibial prostheses were investigated in relation to bone resorption and aseptic loosening. A clinical study to evaluate early migration of the conventional stemmed and mini-keel tibial prostheses is currently in progress, where the RSA results will be followed up for two years. The FE modelling methodology developed in this project for the assessment of the relative risk of component loosening of the tibial prostheses was validated with the early RSA migration data. More specific conclusions are presented below.

Bone Remodelling and Fixation Analysis of the MIS Mini-keel Tibial Prostheses

Implantation of the mini-keel prostheses by applying cement underneath the tibial tray and leaving the keels and stem uncemented has led to a reduced amount of proximal bone resorption compared to a fully cemented fixation, hence is preferable. It was also observed that adding an uncemented stem extension to the cemented mini-keel tray did not increase the prosthesis stress-shielding effect. The stem extension would only cause more proximal stress-shielding if the stem was firmly anchored to the bone, as in the fully cemented and partial ingrowth cases. A central stem can help to limit the tilting of the tibia tray thereby enhancing its initial stability and bone ingrowth fixation strength. Tray tilting could lead to higher cement stresses which may result in cement fatigue failure and eventual component loosening. Therefore a cemented mini-keel tray with uncemented stem extension could be recommended.

Extensive bony ingrowth is essential for enhancing fixation stability and minimising the risk of long-term aseptic loosening for cementless fixation. The mini-keel stemmed prosthesis has almost twice the surface area favourable for bony ingrowth than the standard stemmed design. For enhanced fixation stability, a mini-keel stemmed prosthesis would also be recommended for implantation without cement.

For patients with osteoporosis where fully cemented fixation is the preferred option, and presumably having a less active lifestyle after TKR, a stemless mini-keel prosthesis may be recommended because it reduces bone resorption at the mid-stem

level relative to the stemmed designs (an effective 60% reduction in the amount of bone to be resorbed).

Greater proximal bone resorption was observed for the mini-keel prostheses (either stemmed or unstemmed) compared to the standard stemmed design. It is still uncertain if the early promises of the MIS approach in TKR will be maintained in relation to long-term fixation failure. Long-term clinical follow-up of patients with the mini-keel prostheses would be necessary to provide a clear conclusion on functionality versus fixation stability. The difference in design features suggested that bone quality and fixation stability have to be considered mutually for the optimisation of different prosthesis designs.

Interface Micromotion Analysis of the MIS Mini-keel Tibial Prostheses

The mini-keel prostheses, either with or without a stem extension, were predicted to have a greater extent of osseointegration than the standard stemmed design under all load conditions. This showed that the mini-keel feature is able to restrain tray movement relative to the resected bone surface better than the standard stem/flange. The risk of long-term aseptic loosening could also potentially be reduced by this factor.

This study showed that although different load patterns have a significant influence on the prediction of the magnitude of the bone-prosthesis interface micromotion and the extent of osseointegration onto the prosthesis, the outcome of design change evaluation in cementless tibial fixation remains unchanged. Therefore, a straightforward *single non-gait load condition* of prescribing joint loads at the centre of medial/lateral condyles of the tibial tray is recommended for ease and comparative analysis of risk of aseptic loosening for cementless tibial fixation.

RSA measurements of Standard Stemmed and MIS Mini-Keel Tibial Prostheses and the Validation of Patient-Specific Finite Element Models

Based on the RSA measurements at six months, although the component migration at 6 months did not differ statistically between the three prosthesis designs, the trend

suggested that fixation performance of the MIS mini-keel prostheses could be worse than the standard stemmed design in relation to long-term aseptic loosening. A more definite conclusion may be drawn with RSA results at 12 and 24 months post-operatively.

When the strain-adaptive bone remodelling algorithm was incorporated in the FE analysis, the predicted maximum tensile stresses of the cement underneath the tibial tray correlated well with the clinical component migration data and reflected the qualitative trend in fixation performance between prosthesis designs. This patient-specific FE modelling technique has shown to be effective in the assessment of the relative risk of component loosening of the tibial prostheses. This is probably the first attempt to correlate patient-specific FE modelling predictions to clinical measurements related to the loosening of tibial components.

The author intends to continue to work with SGH on analysing the RSA results from the subsequent scans at 12, 18 and 24 months, and to perform further correlation of the FE predictions with the component migration.

CHAPTER 7. FACTORS AND PARAMETERS INFLUENCING FINITE ELEMENT MODELLING PREDICTIONS

7.1. Background

The bone remodelling and micromotion results generated by finite element analyses are sensitive to the factors and parameters defined in the FE models. These factors and parameters can be physical in nature, as well as non-physical, i.e. purely numerical. The level of accuracy in results generated by the FEM depends on proper definition of many numerical parameters, where the *convergence tolerance* was found to be critical in establishing accurate predictions in contact analysis (Bernakiewicz and Viceconti, 2002). In the current study, the predicted micromotions did not vary much (less than 3%) with convergence tolerance settings of 0.1%, 0.5% and 1%. However for higher settings of 2% and 5%, the peak micromotion was decreased by 25% and the prosthesis ingrowth area was reduced by 50%, both relative to the 0.1% setting. For low convergence tolerance settings of 0.05% and 0.01%, bony ingrowth was predicted to occur over the entire prosthesis surface. A second numerical parameter, the *contact tolerance*, was also analysed. This setting defines the distance below which a node is considered touching a surface. With a range of 5 μ m to 100 μ m, the predicted micromotions varied by less than 5%. The FE model could not be solved with a contact tolerance of 1 μ m. A convergence tolerance of 1% and contact tolerance of 25 μ m was found to produce accurate interface micromotions prediction and a good correlation to in-vitro measurements for femoral hip implants (Abdul-Kadir et al. 2008). Using a similar FE modelling methodology as Abdul-Kadir et al., a convergence tolerance of 1% and contact tolerance of 10 μ m were used for all the modelling cases in this project.

In addition to the numerical parameters, three physical factors, namely bone remodelling, coefficient of friction and torque acting on the tibial prosthesis were addressed. This chapter will outline the influence of the bone remodelling algorithm on the evaluation of component loosening for both cemented and cementless tibial fixations. New codes were written in the bone remodelling algorithm to extract the

bone-prosthesis interface micromotion as the bone remodelled with its altered load conditions. The effect of varying the coefficient of friction between the bone and a cementless prosthesis, and the influence of inclusion of internal-external (IE) torque acting at the tibial tray on the prediction of micromotion would also be discussed.

7.2. Influence of Bone Remodelling Algorithm on FE Predictions of Cement Stresses and Bone-Prosthesis Interface Micromotion

7.2.1. Introduction

In the preceding chapters, aseptic loosening of tibial prostheses was associated with bone cement fatigue failure for the cemented fixation and excessive bone-prosthesis interface micromotion for the cementless fixation. The immediate state of the tibial prosthesis after operation was usually modelled in finite element studies (Shrivastava et al. 1982; Keja et al. 1994; Hashemi and Shirazi-Adl 2000; Barker et al. 2005; Au et al. 2005), and the initial cement mantle stresses and interface micromotions were extracted as indicators for risk assessment against component loosening. However, the strength of the bone-prosthesis support changes as the periprosthetic bone adapts and remodels with its new loading conditions after implantation. Consequently, an adverse effect on the cement stresses and bone-prosthesis relative movement might evolve in the long-term. It was hypothesised that the predictions of cement stresses and micromotions would vary with bone remodelling, and that the outcome of relative risk assessment of aseptic loosening between prosthesis designs would be influenced by the implementation of a bone remodelling algorithm in the FE simulations. The two stemmed designs, the standard and the MIS mini-keel tibial prostheses, were used for this comparative study.

7.2.2. Materials and Methods

The setup of the three-dimensional FE models of the tibial fixation was similar to those described in Chapter 5.4.2. Two cemented cases of i) fully cemented and ii) hybrid cementing, and one cementless case with no ingrowth were studied (see Fig. 5.12). The two prosthesis designs studied were i) standard stemmed with 40mm stem – STD-L40, and ii) mini-keel with 45mm stem extension – MK-L45.

The strain-adaptive bone remodelling algorithm described in Section 5.2 was incorporated in the FE simulation to predict the change in apparent bone density with time after joint replacement. In Chapters 5.5 and 6.3, the bone-prosthesis interface micromotions were studied with the assumption of the immediate post-operative state and without considering the effect of bone remodelling. In order to investigate the influence of bone remodelling on the prediction of the micromotion, new codes were developed and written in the bone remodelling algorithm to extract the micromotion as the bone adapted to its altered load conditions with time. At the end of each remodelling increment (simulation), besides the densities of each finite element being adapted to a new value (see Chapter 5.2), new bone-prosthesis interface micromotions would be computed. In this way, interface micromotions could be predicted at different periods after operation.

Three different physiological knee joint load conditions corresponding to 0% and 15% of the gait cycle and 25% of the stair climbing cycle were prescribed in the FE model (see Table 5.3). For the purpose of analysing the results, two specific load cases of i) 15% of the gait cycle, and ii) 25% of the stair climbing cycle were discussed.

The maximum principal (tensile) stresses in the cement underneath the tibial tray were extracted for evaluating the relative risk of aseptic loosening between different prosthesis designs for the cemented fixation. In cementless fixation, bony ingrowth onto the pores of the prosthesis could occur as early as four weeks post-operatively in mechanically stable fixations (Søballe et al. 1992), and generally between three to six months after implantation (Bobyne et al. 1981; Turner et al. 1989). In this study, the worst scenario was considered in that osseointegration occurred only at a late six months. Interface micromotion before and after six months bone remodelling were analysed.

7.2.3. Results

Cemented fixation – Influence on Cement Stresses

Cement failure usually initiates at a localised site where the tensile stress is highest and propagates to other regions. The localised peak cement stress was found to occur

mainly at the anterior edge of the tray in this study. The global stress state of the cement was determined by averaging the nodal stress values of the cement layer underneath the tibial tray. The maximum tensile cement stresses before bone remodelling, and after the bone remodelled at twelve and thirty-six months are presented in Figs. 7.1 and 7.2. The stresses under the stair climbing load case were higher as the forces acting on the prosthesis were greater.

Before bone remodelling was implemented ($T = 0$), the initial localised and global cement stresses were comparable between the STD-L40 and MK-L45 prostheses for the fully cemented fixation (Figs. 7.1a/b). However the stresses for the MK-L45 were predicted to be lower than for the STD-L40 in hybrid cementing, and the difference was greater with the stair climbing load (Figs. 7.2a/b). After twelve and thirty-six months post-operation with bone adaptation simulated, the peak cement stresses for the MK-L45 began to increase and surpassed the level of the STD-L40, in both the fully and hybrid cemented cases (Figs. 7.1a & 7.2a). The average cement stresses induced by the MK-L45 prosthesis in both cementing cases remained lower than those of the STD-L40 during gait, but increased with bone remodelling during stair climbing (Figs. 7.1b & 7.2b).

The localised peak cement stress, which is an indicator for the site of cement failure initiation, was compared to a threshold tensile stress of 3.5MPa for a 90% probability of cement survival over 10 million cycles (Murphy and Prendergast 2000). Without consideration of the bone remodelling algorithm, the peak stresses induced by the STD-L40 and MK-L45 prostheses using either of the cementing techniques during normal gait were below the threshold level (Figs. 7.1a & 7.2a). During stair climbing, the peak stresses for the fully cemented fixation were only marginally above the threshold (Fig. 7.1a). For hybrid cementing, the cement stresses around the STD-L40 were above the threshold while the stresses around the MK-L45 remained low (Fig. 7.2a). After bone adaptation, the peak cement stresses of the fully cemented cases exceeded the threshold limit during stair climbing, but not during gait loading (Fig. 7.1a). As for hybrid cementing, the cement stresses exceeded the threshold after the bone had remodelled for both the gait and stair climbing loads (Fig. 7.2a).

Cementless fixation – Influence on Interface Micromotion

Contour plots of the predicted relative micromotion (MM) on the surface of the tibial prostheses before and after six months of bone remodelling are shown in Fig. 7.3. The regions of the prosthesis surface area (SA) favourable for bone ingrowth (defined as having MM less than 50µm) are shown in grey.

With the gait loading, regions of high micromotion were predicted along the stem for the STD and MK prostheses before bone adaptation (Fig. 7.3a). The MK-L45 prosthesis had a 9% lower peak micromotion and a 10% larger surface area of bony ingrowth than the STD-L40 design. However after six months when the bone had remodelled, the region of high micromotion migrated from the distal stem to the edge of the tray antero-laterally for both prosthesis designs. The high micromotion was a resultant of both in-plane shear motion and tray lift-off. In addition, the surface area with a likelihood of osseointegration was larger than that prior to bone remodelling. Osseointegration was predicted across almost the entire surface of the MK-L45, and the peak micromotion was 17% lower than the STD-L40 design.

The interface micromotions were rather different for the stair climbing load case where higher joint forces (especially AP shear) acted on the tibial tray. The peak interface micromotion was observed at the anterior edge of the tray for the 2 designs prior to and after bone adaptation, with the magnitude increased slightly after bone remodelling (Fig. 7.3b). Relatively high micromotion also occurred around the stem distally. The magnitude however decreased after the bone had remodelled, which was the opposite response to the micromotion at the edge of the tray. The peak micromotion for the MK-L45 was marginally higher than for the STD-L40, but despite that its surface area where ingrowth could occur was 50-56% as compared to only 30-36% for the STD-L40 design.

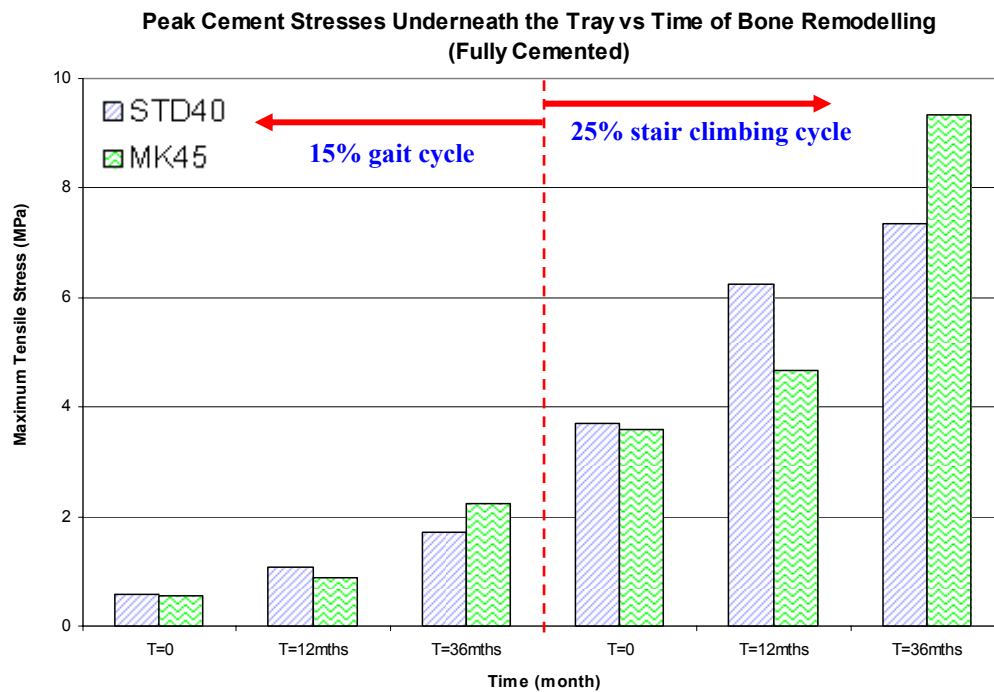


Figure 7.1a: Predicted peak cement stresses for the fully cemented fixation.

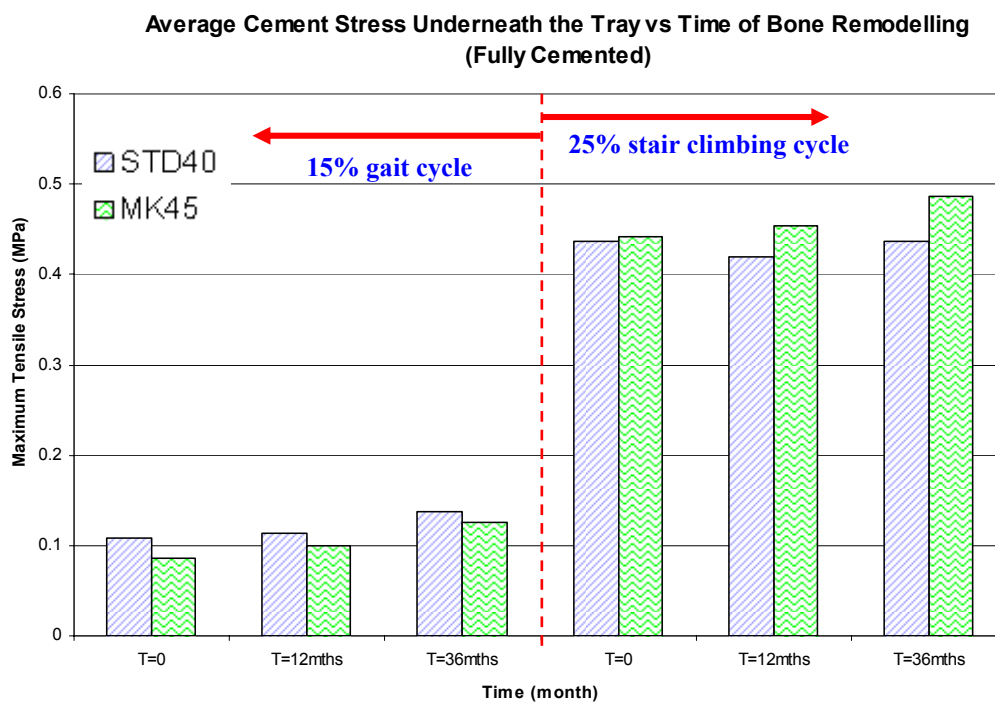


Figure 7.1b: Predicted average cement stresses for the fully cemented fixation.

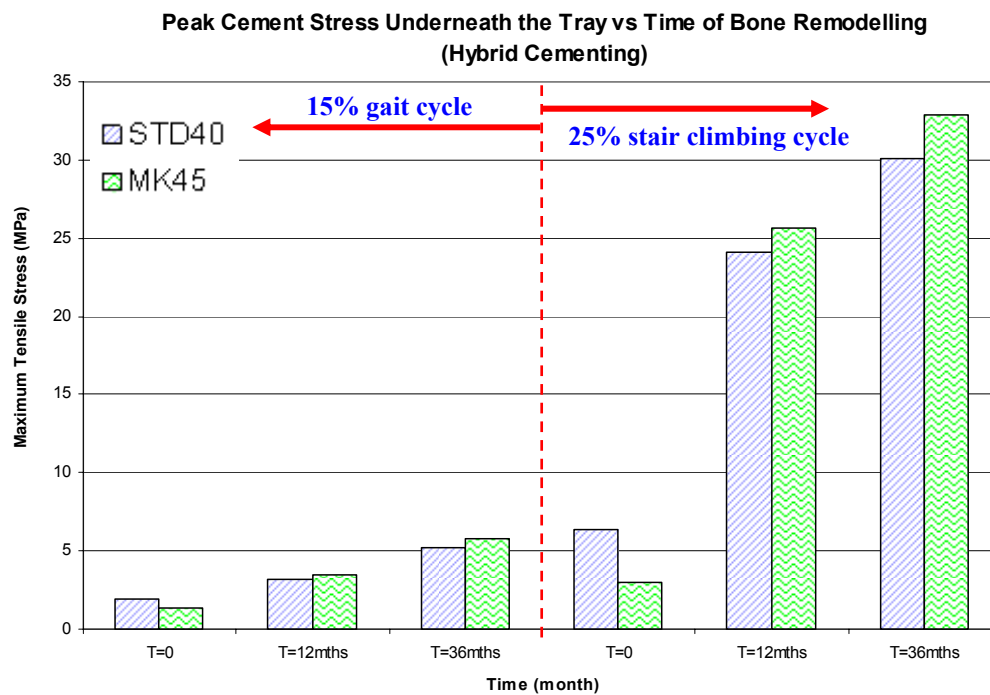


Figure 7.2a: Predicted peak cement stresses for the hybrid cementing fixation.

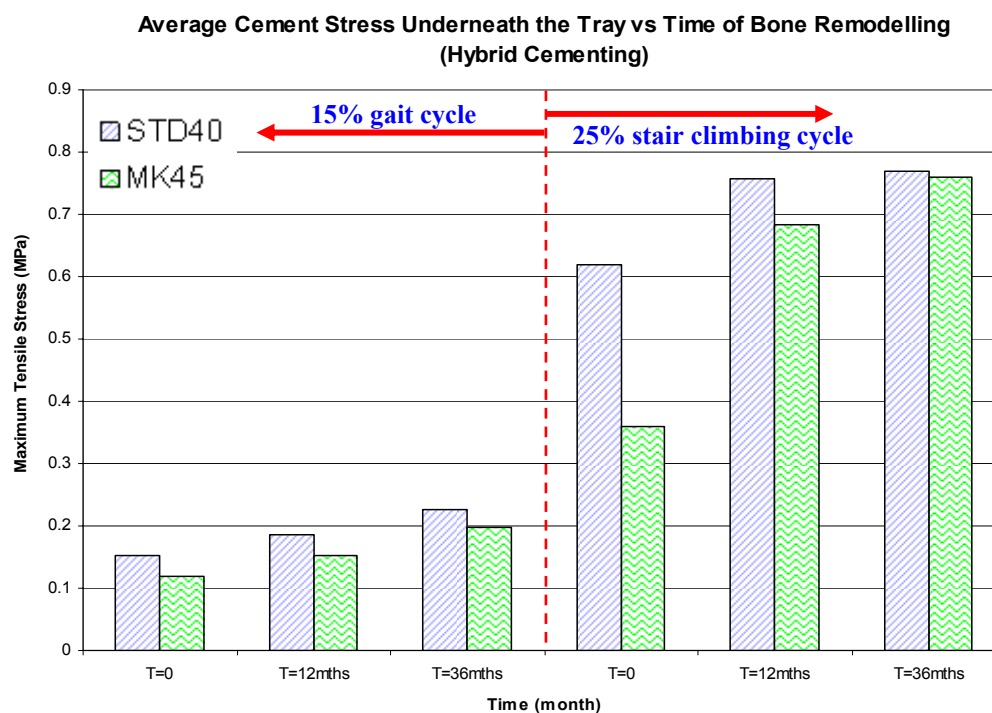


Figure 7.2b: Predicted average cement stresses for the hybrid cementing fixation.

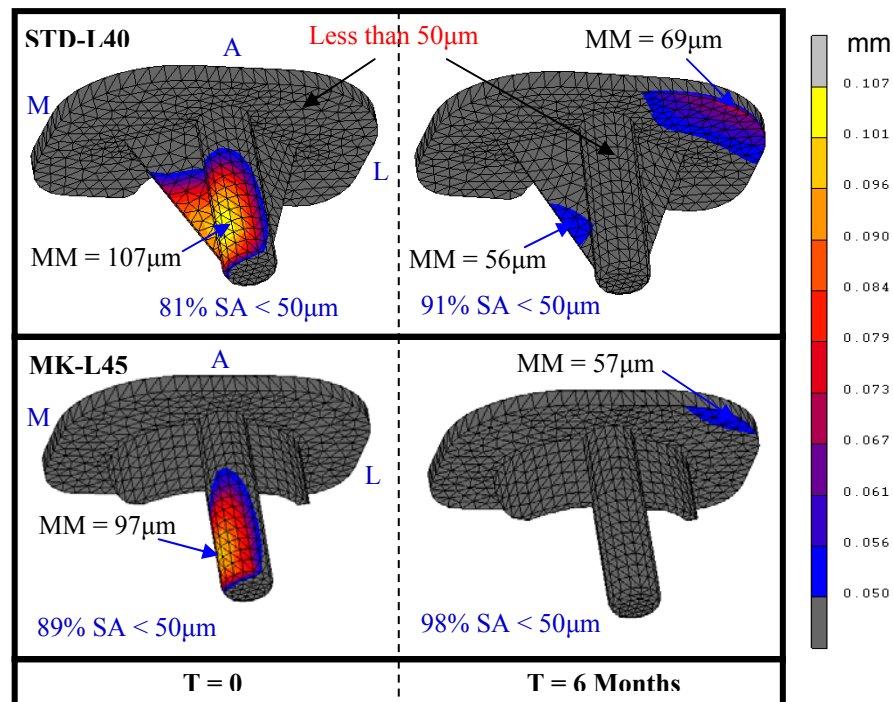


Figure 7.3a: Predicted interface micromotion before and after bone remodelling at the surface of the tibial prosthesis at 15% of the gait cycle loading.

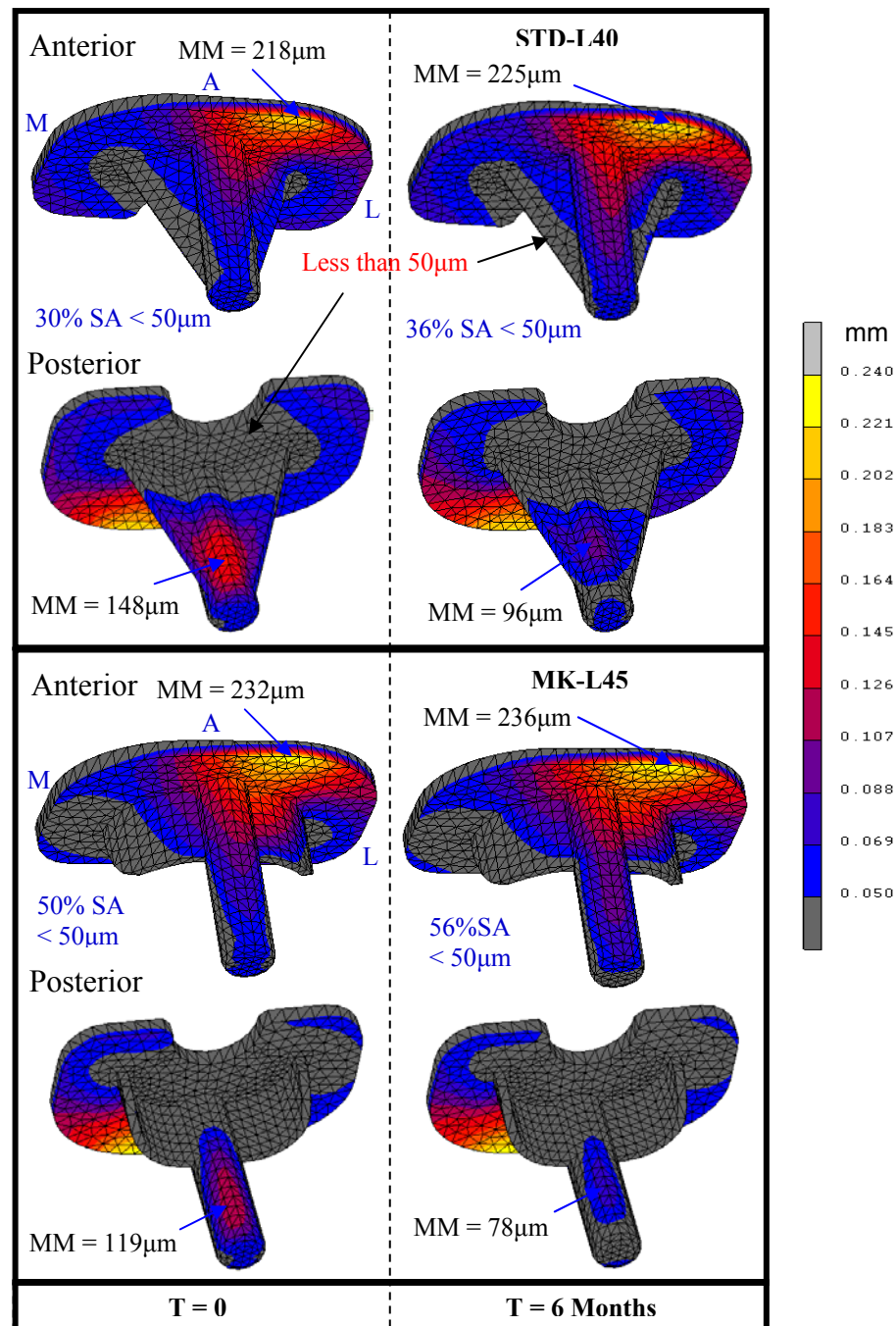


Figure 7.3b: Predicted interface micromotion before and after bone remodelling at the surface of the tibial prosthesis at 25% of the stair climbing cycle loading.

7.2.4. Discussion

The purpose of this study was to test the hypotheses that bone cement stresses and interface micromotions predicted by FE modelling would vary with bone remodelling, and that the implementation of the bone remodelling algorithm would influence the outcome of an assessment of the relative risk of aseptic loosening between prosthesis designs. The results supported the above hypotheses.

Cemented fixation – Influence on Cement Stresses

Before bone remodelling was simulated, a lower risk of aseptic loosening due to cement failure was predicted for the mini-keel prosthesis relative to the standard stemmed design using both the peak and average stresses criteria. A 90% probability of cement survival over 10 million cycles could be achieved by both the STD-L40 and MK-L45 designs using either the fully or hybrid cementing technique. However after bone remodelling, the risk assessment outcome was different. For a possible localised cement failure, the mini-keel prosthesis was then worse off than the standard stemmed implant. With the peak cement stresses (predicted after bone adaptation) exceeding the threshold tensile stress of 3.5MPa, the probability of cement survival over 10 million cycles would be lower than 90% for both the mini-keel and standard stemmed prostheses. The global stress state of the cement around the MK-L45 prosthesis during stair climbing exceeded that around the STD-L40 for the fully cemented fixation, and rose to a similar level with the STD-L40 in the hybrid cementing case.

The changes in the cement stresses and the reversal in the outcome of risk assessment after bone remodelling could be explained by stress-shielding of the stiffer prosthesis, whereby the bone adapted to the new functional condition and began to remodel. Bone resorption occurred at the proximal tibia, which led to weakening of the supporting cancellous bone. In the current study, the MK-L45 prosthesis was predicted to induce greater proximal bone resorption than the STD-L40. Due to the weaker supporting bone structure, the tibial component would migrate more under load thus leading to greater deformation of the cement layer. As a result, the cement stresses in MK-L45 prosthesis began to build up and eventually surpassed the level of the STD-L40 after 3 years of post-operation.

Cementless fixation – Influence on Interface Micromotion

Fixation strength would be enhanced by having a larger proportion of the prosthesis surface biologically attached to the periprosthetic bone, where the risk of long-term aseptic loosening could be reduced. With cementless fixation, a lower relative risk of aseptic loosening was predicted for the mini-keel prosthesis compared to the standard stemmed, regardless of the loading conditions and bone remodelling effect. The mini-keel feature provides a larger surface area of contact with the proximal bone of greater strength and density, thereby anchoring the prosthesis better to the resected tibial surface than the standard flange.

When bone remodelling was not considered, the peak micromotion occurred at the stem due to the “push down” effect of the vertical load at 15% of the gait cycle. The AP shear force was fairly small and did not induce any large movement of the tibial tray relative to the resected tibial surface. With the stair climbing load, the peak micromotion was observed at the anterior edge of the tray for the two designs prior to bone remodelling instead. With a larger shear force component, the tibial tray moved more relative to the resected tibial surface. Thus the interface micromotion at the periphery of the tray when climbing stairs was three to four times that induced by gait loading.

Osseointegration was assumed to occur only after six months of implantation, where the fixation stability could be affected by the change in bone density due to bone adaptation. This assumption of delayed bone-prosthesis osseointegration was chosen in order to evaluate the performance of the different fixation designs under adverse conditions. After six months of bone remodelling, the region of high micromotion migrated from the distal stem to the periphery of the tray for the gait loading, while micromotion at the periphery of the tray was increased and along the stem was reduced for the stair climbing loading. The surface area favourable for osseointegration increased for both the load cases. This could be a consequence of weakened supporting cancellous bone after bone resorption at the proximal tibia. Gradually, the interfacial holding strength underneath the tray was reduced thus leading to increased micromotion at the bone-prosthesis interface. On the other hand, bone densification at the distal end of the stem (due to load transfer) led to an increase

of the local bone strength and better prosthesis support in that area. This resulted in a much lower interface micromotion at the stem region and the increase of the overall surface area where bony ingrowth could occur after bone adaptation.

A previous TKR retrieval study found that bone ingrowth was limited to 30% or less of the area of the tray, and that osseointegration occurred mainly at the central area of tray with fibrous tissue formation at the edge (Sumner et al. 1995). The predicted surface area with a likelihood of ingrowth for the standard stemmed prosthesis was a close match to the retrieval results with the stair climbing load, but not the gait loading. This suggested that higher load bearing activities on knee joints would create a limit on the osseointegration process.

7.3. Influence of Interface Coefficient of Friction and Internal-External Rotation Torque on Prediction of the Interface Micromotion

7.3.1. Introduction

The initial stability of the cementless fixation is critical in order to minimise the relative motion between the prosthesis and bone interfaces to allow osseointegration, thereby providing a strong prosthesis-to-bone biological attachment. Finite element modelling was used to investigate the bone-prosthesis interface micromotion and the relative risk of aseptic loosening. The unbonded interfaces between the bone and prosthesis were modelled by defining contact between them, and the friction between the surfaces in contact defined by Coulomb's friction. The friction properties at the interface depend on the type of surface coating on the prosthesis, where the coefficient of friction could vary between 0.2 for a smooth surface (Rancourt et al. 1990), 0.46 for fiber mesh coating (Rancourt et al. 1990), 0.6 for beads porous-coating (Rancourt et al. 1990; Hashemi et al. 1996), and 0.9 for cast mesh coating (Dammak et al. 1997 N1). In the earlier studies performed in Chapters 5 and 6, the tibial prosthesis was considered to be porous-coated with beads.

The internal-external rotation torque acting on the knee joint could be small and may not play a substantial role in loading the knee (Andriacchi et al. 1986) as compared to the joint and muscle forces. This additional rotation moment may however induce an

adverse effect on the initial stability of cementless tibial prostheses and aggravate the bone-prosthesis relative motion. The IE torque at the knee joint measured in-vivo ranged from -1Nm (external rotation of the tibia) to +8Nm (internally rotated) (Taylor SJG et al. 1998). The ISO standard for pre-clinical wear testing of the PE insert defines a tibial rotational torque of -1 to +6 Nm (BS ISO 14243-1 2002). In the preceding studies, the IE torque was not considered in the FE modelling.

A sensitivity study was performed to investigate the influence of the coefficient of friction between the bone and cementless prosthesis, and the inclusion of IE torque acting at the tibial tray, on the prediction of interface micromotions.

7.3.2. Materials and Methods

The three-dimensional FE models of the cementless tibial fixation were identical to those described in Chapter 6.3.2 (interface micromotion analysis of the MIS mini-keel prosthesis versus standard stemmed design). The load case used consisted of a generic vertical joint load of $3 \times BW$ (70%/30% medial/lateral) and shear forces in the AP ($0.5 \times BW$ towards posteriorly) and ML ($0.26 \times BW$ towards laterally) direction acting at the centres of the medial and lateral compartments of the tibial tray. The baseline reference for the sensitivity study was i) coefficient of friction of 0.6, and ii) no IE torque prescribed.

7.3.3. Results

Coefficient of Friction

The sensitivity study was performed for a coefficient of friction ranging from 0.1 to 0.8 (Fig. 7.4). There was minimal change in the peak micromotion for the three prosthesis designs. The variation in zonal area for ingrowth was less than 10% for the standard stemmed prosthesis, and was 2% or lower for the mini-keel designs.

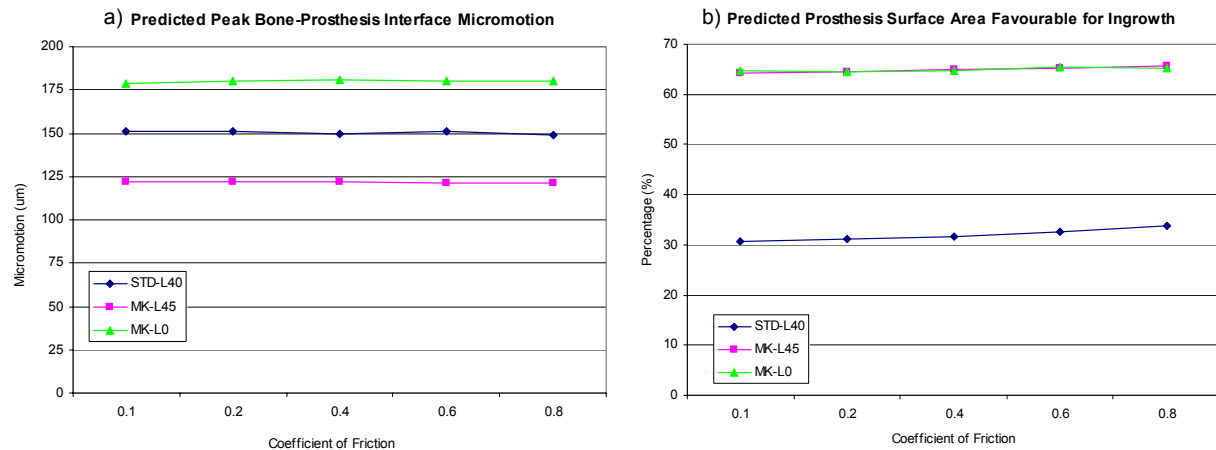


Figure 7.4: Influence of coefficient of friction on a) peak bone-prosthesis interface micromotion, b) surface area favourable for bone ingrowth.

Internal-External Torque

The IE torque acting on the tibial tray was varied from -1Nm to +8Nm. The inclusion of IE torque resulted in an increase of the peak micromotions (Fig. 7.5a) for the stemmed prostheses (STD-L40 and MK-L45). The peak micromotion was increased by 83% when a maximum torque of +8Nm was applied to the STD-L40 prosthesis, with a smaller increase of 38% for the MK-L45 design. The impact on the stemless MK prosthesis was however minimal when the tibia was internally rotated (+ve torque), with a 9% decrease in peak micromotion under the external rotation of the tibia (-1Nm). Fig. 7.6 shows the contour plots of the predicted micromotion on the surface of the STD-L40 tibial prosthesis at different IE torque loadings. When the IE torque was added, the region of peak micromotion migrated from the antero-lateral edge of the tray to the postero-medial edge. The change was mainly due to the increased in-plane shear movement of the tibial tray (not lift-off) as a result of the IE torque. As for the mini-keel prostheses (stemmed and unstemmed), the peak micromotion remained at the antero-lateral edge of the tray, regardless of the IE torque.

Fig. 7.5b shows the effect of IE torque on the proportion of the prosthesis surface area where osseointegration was likely. The zonal area for ingrowth increased slightly with a positive torque of up to +6Nm for the standard stemmed prosthesis. With a maximum torque of +8Nm or when the tibia was externally rotated (-1Nm), the zonal

area for ingrowth decreased slightly. For the mini-keel designs (MK-L45 and MK-0), the predicted zonal area for ingrowth changed only marginally when the IE torque was included.

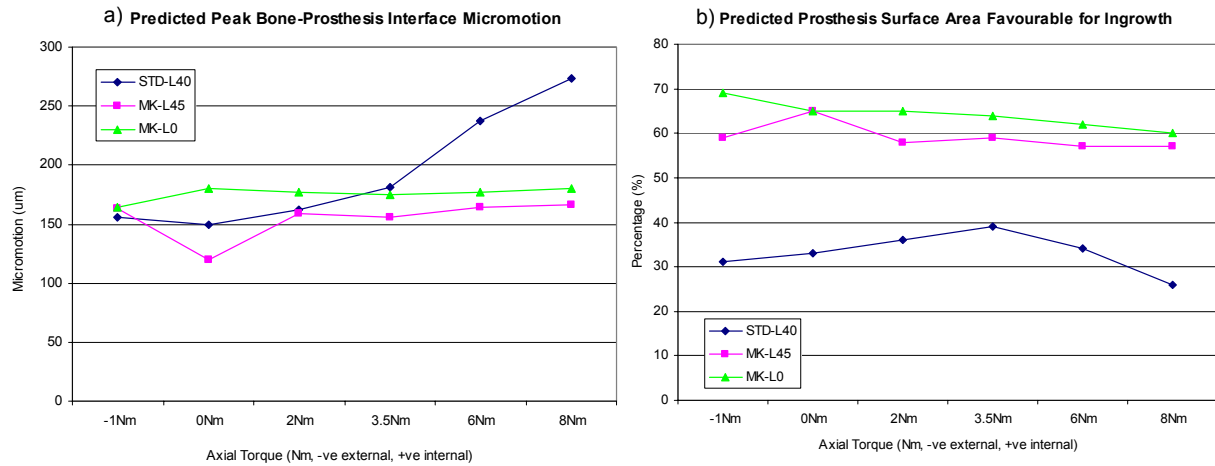


Figure 7.5: Influence of internal-external torque on a) peak bone-prosthesis interface micromotion, b) surface area favourable for bone ingrowth.

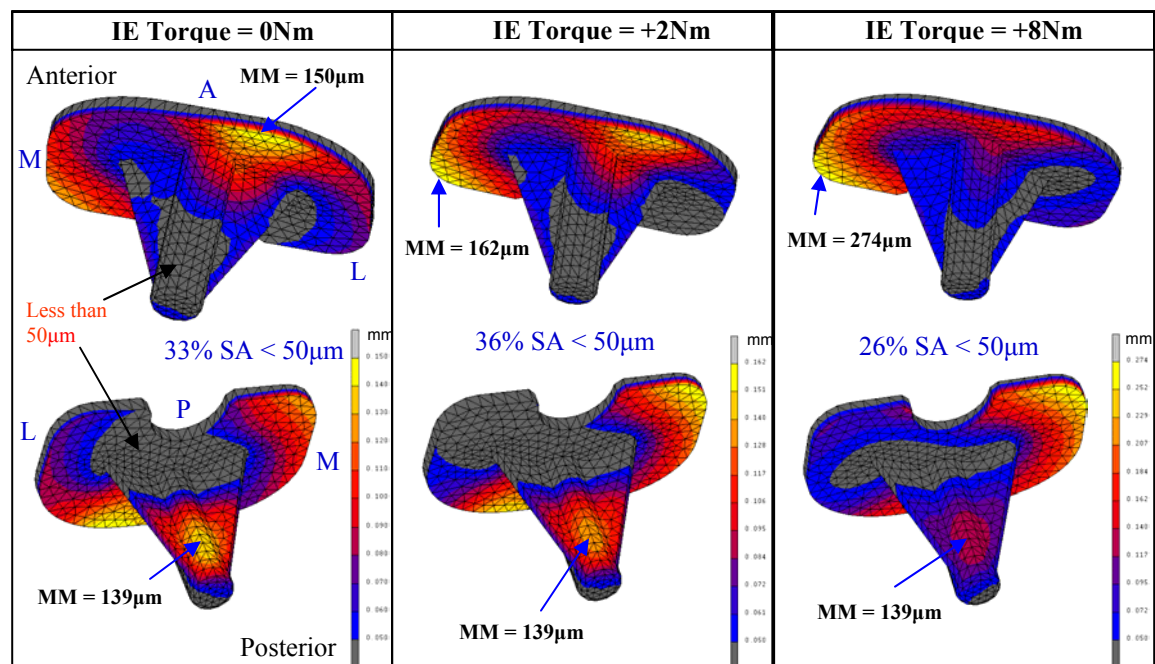


Figure 7.6: Predicted interface micromotion at the surface of the STD-L40 tibial prosthesis – with and without IE torque.

7.3.4. Discussion

Coefficient of Friction

It was found that by varying the coefficient of friction from 0.1 to 0.8 in simulating different types of surface coating such as fiber mesh, beads or cast mesh, the influence on the prediction of bone-prosthesis interface micromotion was small. This observation could be explained as follows. Shear movement and tilting of the tibial tray relative to the resected surface was restrained by the stem, flange and mini-keels that were embedded securely in the cancellous bone. The downward movement of the prosthesis caused by the vertical forces acting on the knee joint was also constrained by the tibial tray as it was well supported at the resected surface of the bone. This shows that the physical construct of the stemmed tibial fixation could resist excessive movement of the prosthesis after implantation, and the interfacial frictional forces play a less significant role in constraining prosthesis movement. For a circumferentially flanged and stemmed tibial fixation, Barker et al. (2005) also found that a variation of friction coefficient from 0.2 to 0.7 had a small effect on the micromotions predicted by FE modelling. However in a computational study of a stemless tibial fixation (Tissakht et al. 1995), the relative movement of the prosthesis predicted increased with the decrease in coefficient of friction. The lack of sensitivity to the coefficient of friction means that the micromotion predictions should be accurate even if the exact value of the coefficient of friction is not known for a specific coating.

Internal-External Torque

Although the additional rotation moment acted on the knee joint resulted in a considerable increase in the peak micromotion of the stemmed prosthesis, the influence on the zonal area for osseointegration was marginal. Regardless of the IE torque, the proportion of surface area with a likelihood of osseointegration predicted for the mini-keel prostheses remained greater than the standard stemmed design. To the author's knowledge, the effect of IE torque on the FE modelling of relative movement between tibial prosthesis and its periprosthetic bone has not been reported

in literature. This work could serve as a reference for future FE studies of the cementless tibial fixation.

7.4. Conclusions

Influence of Bone Remodelling Algorithm on FE Predictions

The study showed that the predictions of cement stresses and micromotions were different before and after bone remodelling, and the risk assessment of aseptic loosening between prosthesis designs was influenced by the implementation of the bone remodelling algorithm. The impact of bone remodelling on the risk of aseptic loosening was greater on the cemented fixation than the cementless case—the cemented mini-keel prosthesis poses a greater risk of aseptic loosening compared to the standard stemmed after the bone has remodelled, whereas the cementless mini-keel tibial fixation presents a lower risk of loosening relative to the standard design regardless of bone remodelling.

The peak (localised) cement stresses in the fully cemented fixation were predicted to exceed the threshold level for 90% probability of cement survival over 10 million cycles of stair climbing after bone remodelling, but not in gait. These cement stresses (after the bone remodelled) were also much lower than in the hybrid cementing fixation. These observations may suggest that fatigue failure of the cement in the fully cemented tibial fixation will only be triggered by higher load bearing activities on the knee joints such as stair climbing, jogging etc coupled with proximal bone resorption. In addition, the fully cemented fixation is able to relieve proximal cement stresses better than hybrid cementing.

Influence of Coefficient of Friction and Internal-External Torque on Interface Micromotion Predictions

Long-term performance of the cementless fixation relies on sufficient biological attachment of the periprosthetic bone onto the prosthesis. The variation of coefficient of friction between the bone and prosthesis did not have any influence on the risk

assessment of aseptic loosening for tibial prosthesis designs. The inclusion of IE torque in FE modelling of the cementless fixation only had a small quantitative effect on the micromotion predictions. But it did not affect the results qualitatively—the risk assessment showed that the fixation performance of the cementless mini-keel prostheses in relation to aseptic loosening remained superior to the standard stemmed design.

CHAPTER 8. IN-VITRO CADAVERIC STUDY OF TIBIAL PROSTHESIS FIXATION

8.1. Introduction

Aseptic loosening caused by mechanical factors is a recognised failure mode for the tibial components of knee prostheses. A higher revision rate due to loosening was reported for cementless fixations than if bone cement was applied (Fehring et al. 2003). In radiographic analyses, there were more radiolucent lines (RLLs) observed around the cementless tibial components than for cemented fixations (Duffy et al. 1998; Schai et al. 1998), where most of the RLLs were located underneath the periphery of the tibial tray. Stress-shielding in the proximal tibia leading to bone resorption is also a clinical concern, and this may complicate revision surgery. Bone resorption was evident in many cemented tibial fixations (Lonner et al. 2001; Goldberg and Kraay 2004; Mulhall et al. 2006). While the difference in the change of BMD between cemented and cementless tibial fixations were not statistically significant (Li and Nilsson 2000; Abu-Rajab et al. 2006), Seki et al. (1999) reported more bone loss for the femoral knee prostheses fitted with cement than prostheses relying on bony ingrowth.

Pre-clinically, in-vitro cadaveric tibial strain and prosthesis micromotion measurements have been conducted extensively to assess the performance of different TKR prosthesis designs and fixation techniques. Strains measured in the proximal tibial cortex in-vitro were reduced by tibial prostheses with a longer stem and larger diameter (Bourne and Finlay 1986; Jazrawi et al. 2001), which was in agreement with an in-vivo study that found a greater extent of bone resorption in the proximal tibia for a tray with a central stem than without a stem (Lonner et al. 2001). Hence longer prosthesis stems were discouraged. In assessing fixation stability experimentally, *linear variable differential transducers* (LVDTs) have been mounted on the prosthesis to measure its absolute displacement or movement relative to the bone. A cemented fixation was found to give better initial stability (less component motion and migration) than the cementless fixation (Stern et al. 1997), while increasing the stem

length in cementless fixation could reduce tibial tray subsidence and lift-off (Yoshii et al. 1992).

It was noted that implantation of tibial prostheses with cemented stems resulted in strain shielding in the proximal tibia when compared to the intact tibia (Bourne and Finlay 1986), and the proximal strains were also reduced when the stems of cementless tibial prostheses were cemented (Jazrawi et al. 2001). It was thus apparent that a cemented stem had transferred the proximal load distally. However, a direct comparison of the proximal tibial strain after cementless fixation with the intact tibia has not been reported. There have been limited bone densitometry measurements around cementless tibial stemmed fixation (Abu-Rajab et al. 2006). Hence it remains unclear how much proximal strain shielding in the tibia would be induced by a tibial prosthesis implanted without cement (or by press-fitting), what would be the extent of the strain shielding, and its severity as compared to cemented prostheses.

Clinical evidence has shown that early migration of knee prostheses could lead to long-term aseptic loosening (Grewal et al. 1992; Ryd et al. 1995). If the initial stability of tibial fixations measured in-vitro could be correlated to the early migration trend, the in-vitro test method could then potentially be used to provide a pre-clinical indication of long-term fixation performance in relation to aseptic loosening for tibial prosthesis implantation. Various studies have been conducted to assess the initial stability of tibial fixation by measuring the bone-prosthesis relative motion using different techniques such as LVDTs (Volz et al. 1988; Yoshii et al. 1992; Seki et al. 1997; Stern et al. 1997; Jazrawi et al. 2001), laser displacement sensors (Pérez-Blanca et al. 2008) and liquid metal strain gauges (Branson et al. 1989). In some of these studies, the setup was complex and mechanical holders were fixed onto the proximal tibia (Yoshii et al. 1992; Jazrawi et al. 2001; Pérez-Blanca et al. 2008). It was not clear whether the additional weight of the holders or the localised destruction of the cortical bone would influence the results. The current study explored a modified technique by mounting the LVDT holder onto the edge of the tibial tray (instead of on the tibia) so that the tibia would be subject to minimal disturbance. The measured bone-prosthesis relative motion for cemented and cementless tibial fixations would be compared to clinically reported RSA migration data and trends.

Approximately 60-70% of the joint load acts at the medial compartment of the knee. After TKR, it may be desirable for the surgeon to redistribute the joint load evenly between the medial and lateral compartments of the tibial tray (Insall 1993). However there has been very limited work to measure the load distribution in the knee joint after TKR: Zhao et al. (2007) reported a 55%/45% M/L distribution based on a single patient. It was decided that for this experimental study, two load configurations of i) 70%/30% M/L and ii) 50%/50% M/L would be investigated in order to cover the likely range of load distribution across the knee joint after TKR. Some degree of valgus deformation in the knee joint could increase the joint load at the lateral condyle of the tibia, for example. The ML5050 load case could represent one such conditions of a valgus intact knee joint.

There were two main objectives for this in-vitro cadaveric study. Firstly, it was to investigate the strain-shielding effect in the proximal tibia after implantation of a metallic stemmed prosthesis without cementing (by press-fitting), and to compare the effect to its cemented counterpart. Secondly, a modified technique of measuring bone-prosthesis relative micromotion would be explored, and used to examine the difference in initial stability between the cemented and cementless (press-fit) tibial prostheses fixations. The measured relative motions from both fixation techniques would be correlated to clinically reported RSA migration data and trends.

Based on the test protocol, four days were needed to complete a set of cadaveric tibia-implant tests – day one setup and preparation, day two to four testing on intact tibia, cementless and cemented fixation respectively. This involved thawing of the frozen tibia the night prior to the setup (strain gauge mounting) and repeated refrigeration of the tibia over a number of the test days. Therefore the influence of repeated freezing and thawing and the effect of long-term frozen storage on the mechanical properties of bone were studied. The compressive properties of the cancellous bone were not altered after five cycles of freezing and thawing in the study by Linde and Sørensen (1993), and the ultimate indentation load and stiffness of cancellous bone were not significantly affected by five freezing-thawing cycles (Kang et al. 1997). Storing bone specimens at -20°C for a period of less than 9 months had little effect on their mechanical properties (Panjabi et al. 1985; Kang et al. 1997). As the cadaveric bone was exposed to drying in air with long hours of test in a day, the bone was sprinkled

with water every hour to keep it moist. The effect of drying and re-wetting on the mechanical properties of bone was found to be minimal (Currey 1988). However, the effect of repeated refrigeration on the mechanical properties of the bone and the strains measured was not known. A mechanical test was designed to study this effect.

This chapter outlines the in-vitro test methods and results of using cadaveric tibiae to investigate the effect of strain-shielding in the proximal tibia after implantation of a metallic stemmed prosthesis, and the use of a modified technique to measure bone-prosthesis relative micromotion between the cementless and cemented tibial fixations.

Ethical permit for this study was obtained from the Riverside Research Ethical Committee.

8.2. Materials and Methods

The overall measurement test procedure is shown in Fig. 8.1. Cortical bone strains of the intact tibia upon loading were to be measured first. After that, the bone strains and bone-prosthesis relative motion were collectively measured after press-fitting of the tibial tray. Bone cement was lastly applied to the entire tibial tray and the bone strains and bone-prosthesis relative motion were measured again.

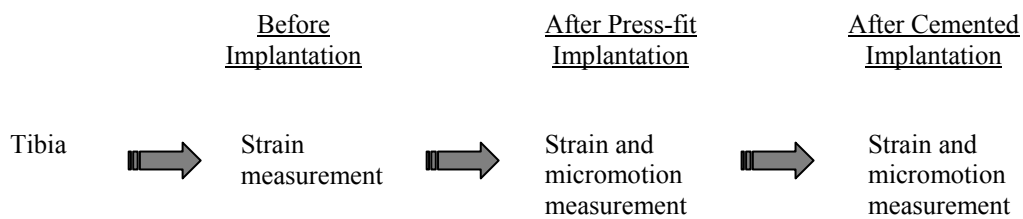


Figure 8.1: Overall strain and bone-prosthesis relative motion measurements test procedure.

Eight frozen cadaveric tibiae with no prior history of knee surgery or disease were used for the experimental work (mean age 72 years; range 54-79). The cadavers were obtained from the International Institute for the Advancement of Medicine (Jessup, PA, USA), where screening and consent for the use of the knees for research were undertaken by the institute. The tibiae were stored at a temperature of -20°C and thawed only one day prior to the mechanical testing.

Strain Gauge Mounting and Strain Measurement

Uniaxial strain gauges (EA-06-125AD-120, Vishay Micro-Measurements Group, Basingstoke, UK) were used for the strain measurement. The strain gauges were mounted along the longitudinal axis of the tibia at three levels under the resected surface (Fig. 8.2). A total of ten locations were measured; four strain gauges located at anterior, posterior, lateral and medial of the tibia at the proximal 10mm and metaphyseal 40mm levels, and two gauges located laterally and medially at the distal 60mm level. The cadaveric tibia was first cleared of all soft tissues (including the periosteum) prior to gauge mounting. The specific gauge locations were dried thoroughly with acetone (or alcohol) and abraded with fine abrasive paper. The bone cortical surfaces were then carefully cleaned and the gauges were attached to the

surface with M-Bond 200 adhesive (Vishay Micro-Measurements Group, Basingstoke, UK). The detailed procedure of strain gauge mounting onto cadaveric bone is described in Appendix A. After all the gauges were attached, the tibia was placed vertically in a holder with the distal end rigidly fixed using bone cement (see Fig. 8.2). When the cement had polymerised, leadwires were soldered onto the solder tabs of the gauges. The strain gauges were then coated with a layer of silicone rubber (Everflex Silicone) to water-proof the gauges. Throughout the experiment, the tibia was constantly sprinkled with water every hour to keep it moist.

The strain gauges were connected to a strain amplifier (Schlumberger Sangamo, Sussex, UK) using the leadwires. The amplifier used the half-bridge configuration, where a “dummy” gauge was needed for each active gauge to complete the Wheatstone bridge circuit. The active gauges were mounted on the tibia specimen where it would be strained during loading. The dummy gauges were mounted on a separate bone (not the specimen under test) where it would not be strained. The advantage of the half-bridge configuration is to eliminate the increase or decrease in strain value due to a temperature change of the test specimen (or the test environment).

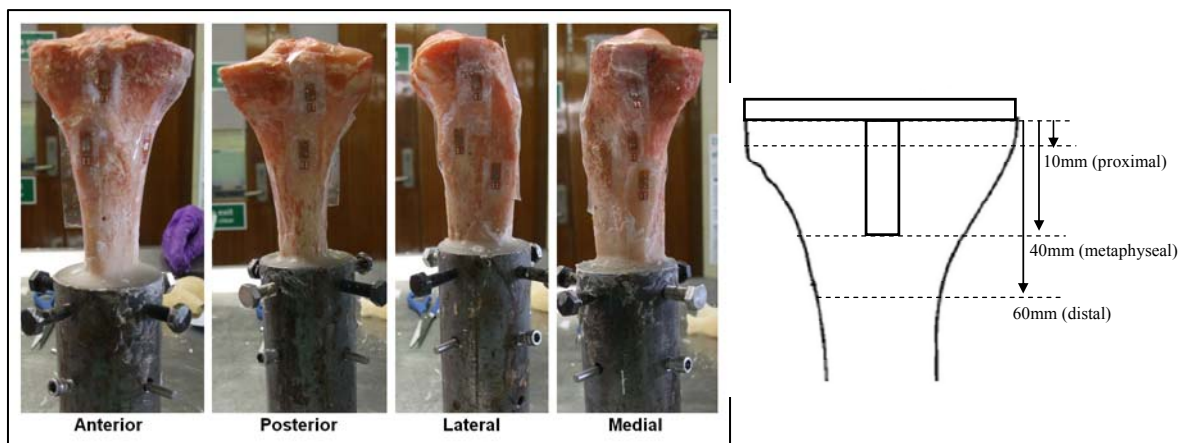


Figure 8.2: Levels and positions of the strain gauges mounted on the cadaveric tibia.

Tibial Prosthesis Implantation onto the Cadaveric Tibia

The cadaveric tibiae were implanted with the Genesis II tibial prostheses (Smith & Nephew UK Limited, London, UK) by an experienced orthopaedic surgeon, Dr Azhar

M. Merican (Consultant Orthopaedic Surgeon, University of Malaya Medical Centre, Malaysia). The tibial prosthesis has a central stem length of 40mm and a diameter of 12mm. The tray is shaped anatomically: the medial compartment is larger than the lateral compartment, in accordance to the tibial plateau where the medial condyle is larger in size. The proximal tibia was resected 8mm below the lateral articulating surface of the tibial plateau, and matched with a tray size of best fit with no overhanging of the tray edge at the cortical rim. The resected surface was first reamed with a hole about 2mm smaller than the stem diameter to cater for a press-fit implantation. After the strain and micromotion measurements were completed, the prosthesis was carefully removed for minimal destruction of the periprosthetic bone. The original reamed hole was then widened by 4mm to provide a 2mm cement layer around the stem. The cement layer underneath the tray was also controlled at a thickness of 2mm. Good cortical support of the tibial tray and sufficient bone surface coverage were found in most of the cadavers. The respective sizes of the tibial prostheses for each cadaver are listed in Table 7.1.

Table 7.1
Tibial prosthesis sizes for each cadaver

Set	Side	Tibial Tray Size
S1	R	5
S2	L	8
S3	R	7
S4	L	3
S5	R	4
S6	L	8
S7	L	6
S8	L	8

Bone-Prosthesis Relative Micromotion Measurements Setup

The in-plane relative micromotion between the edge of the tray and its adjacent supporting bone for both the press-fit and cemented fixations was measured by using linear variable differential transducers (LVDTs) (Digital Probe DP/2/S, Solartron Metrology, UK). The measurement of relative motion between the inner tray surfaces and the underlying bone was comparatively difficult due to the constraint of placing the LVDT at the inner undersurfaces of the tray. In the current test setup, instead of mounting the mechanical holders of the LVDTs onto the proximal tibia (Yoshii et al.

1992; Pérez-Blanca et al. 2008), the LVDT was mounted onto a holder which was firmly fixed to the periphery of the tray by an extended rod which had been secured in a hole drilled in the rim of the tray (Fig. 8.3a). In this manner, the in-plane bone-prosthesis relative micromotion at the edge of the tray could be measured precisely with minimal disturbance on the tibia. When the LVDT probe was compressed (Fig. 8.3b), it corresponded to either the bone moving outwards with reference to the tray, or the tray moving inwards relative to the bone. When the probe was extended, it corresponded to either the bone moving inwards or the tray moving outwards. As bone cement was not applied to the press-fit fixation, interfaces between the tibial tray and the underlying bone were not bonded. The measured micromotion thus accounted for the relative shear movement between the interfaces of the undersurface of the tray and the bone. When cement was applied and formed a layer in between the tray and bone, the micromotion registered would be dependent on a number of factors such as shearing of the cement layer and bone movement due to hoop stresses. Four tray locations namely anteriorly, posteriorly, laterally and medially were measured. In the case when any of these locations were not accessible, alternative locations of antero-lateral (AL), antero-medial (AM), postero-lateral (PL) and postero-medial (PM) were measured. Fig. 8.3a shows the LVDTs attached on the anterior and lateral sides of the tibial tray. As there were only two LVDTs available, the test was repeated for measurements at the posterior and medial sides to be taken.

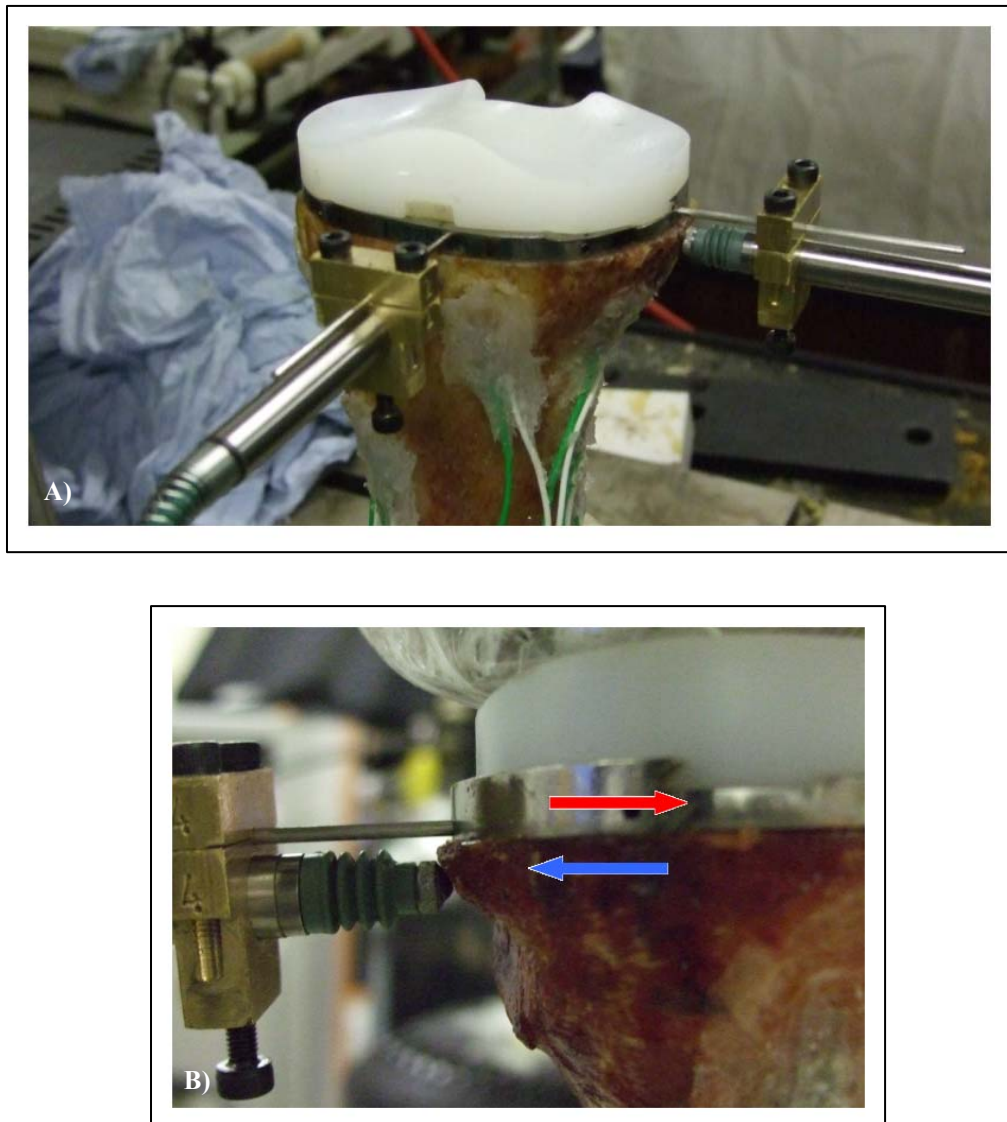


Figure 8.3: LVDT setup on the edge of the tibial tray and its underlying cortex.

Loading Setup and Load Conditions

The tibia under testing was rigidly fixed at the distal end, and loaded by a matching size of the femoral component with a vertical force of 2100N. The load was applied by an Instron 5565 materials test machine (Instron Limited, High Wycombe, UK) at the rate of 1000N/min, and was held at 2100N for five minutes to allow for equilibrium of the bone where the strain and micromotion readings would be taken. The tibia was then unloaded and allowed to relax for another five minutes before the loading sequence was repeated. The strain and micromotion at each location were

recorded for three load sequences and averaged. Statistical analyses of the results were performed using ANOVA and t-test. A p value of less than 0.05 was considered to be statistically significant.

Two loading conditions were used:

- i) ML5050 - 2100N with distribution of 50%/50% in the medial and lateral condyles.
- ii) ML7030 - 2100N with distribution of 70%/30% in the medial and lateral condyles.

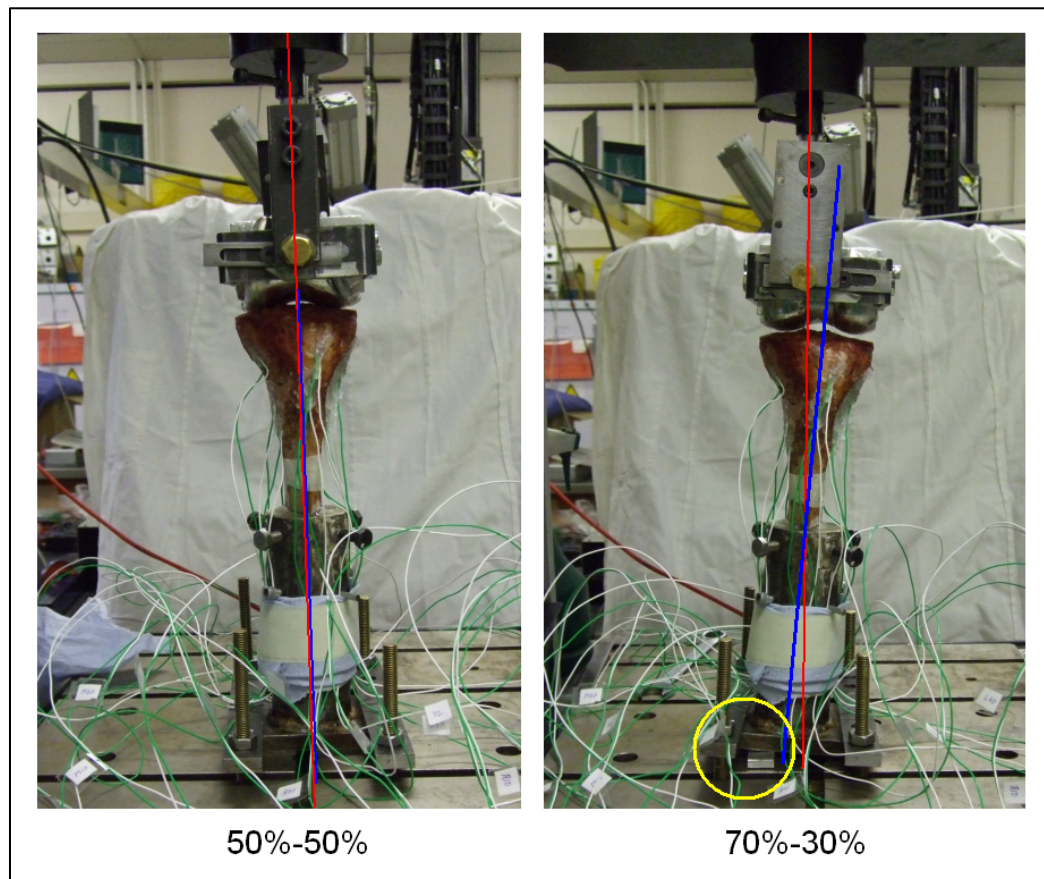


Figure 8.4: Experimental setup for the ML5050 and ML7030 loading conditions.

Fig. 8.4 shows the experimental setup for both the loading conditions. For ML5050, with the mechanical axis of the tibia (blue line) in line with the loading axis of the femoral component (red line), no bending occurred in the tibia upon loading. In the ML7030 load case, the load plunger was offset medially (thus the loading axis) to increase the load proportion at the medial condyle of the femoral component to 70%. As a result, the off-centred load would induce a bending of the tibia medially (about the distal fixed end) when the load was applied. It is difficult to ascertain if the tibia would bend in-vivo during daily activities. Therefore the tibia was tilted to an angle

where the loading axis intersected with the tibia mechanical axis at the fixed distal end, thereby eliminating the bending of the tibia. In both experimental setups, the load distribution of ML5050 and ML7030 were verified by using pressure sensors (K-Scan 4000, Tekscan Inc., South Boston, MA, USA) placed underneath the femoral component.

Effect of Repeated Refrigeration on Cortical Bone Strain Measurements

Eight bone specimens obtained from the shaft of two femurs (S1 and S2) were cut into the size of approximately 10mm × 3mm × 120mm. Strain gauges were mounted on the periosteal side of the specimens. The specimens were tested by three-point bending with a span of 100mm. The location of the strain gauge and span supports on the specimens were clearly marked for repeated testing. The specimen was subjected to a bending load at the rate of 100N/min until a strain of above 1000 $\mu\epsilon$ was reached. The bending force was then recorded and the same force was used for repeated measurements over subsequent days. The vertical displacement at the centre of the bone specimen was also recorded. The bending load was held constant for 5 minutes to allow equilibrium, with strain reading taken at the end of the holding period. After which, the specimen was unloaded and allowed to relax for 5 minutes before the loading sequence was repeated. The test was repeated twice and the strain values were averaged.

The test protocol of the bone specimens was similar to the tibia testing. The specimens were cut and strain gauges were mounted on Day 1, and were wrapped with moist towels and stored in the refrigerator. On the subsequent days, the specimens were removed from the refrigerator at 9am and the bending test was conducted at 10am and 5pm. The specimens were kept at room temperature during the day, and were sprinkled with water every hour to keep them moist. After the test, the specimens were stored in the refrigerator at 6pm. The test sequence was repeated for three consecutive days for the specimens from femur S2 and extended to five consecutive days for femur S1.

8.3. Results

8.3.1. Strain-Shielding Effect in the Proximal Tibia after Prosthesis Implantation

Figs. 8.5a-c illustrate the strain distribution around the tibia at various locations and at levels of 10mm, 40mm and 60mm below the resected surface. The mean values of the eight cadavers measured are shown. The strains were predominantly compressive, with the exception at the 40mm level anteriorly. Strains at different locations around the tibia (A, P, L, M) at the same level were averaged to represent the mean compressive strain at that particular level, and the values before and after prosthesis implantation are shown in Fig. 8.6. The plots in Fig. 8.7 illustrated the differences in strain distribution in the medial and lateral aspects of the tibia before and after prosthesis implantation, and the changes in strain (compressive) between ML7030 and ML5050 loading conditions after surgery.

Statistical analyses were performed based on, i) repeated-measures ANOVA for comparing the strains between intact tibia (I), cementless fixation (C-) and cemented fixation (C), ii) paired t-test for comparing the difference in strain between medial and lateral when the load condition was changed from ML5050 to ML7030. P value of less than 0.05 was considered to be statistically significant.

Intact Tibia

The bone strains around the intact tibia generally increased from the proximal periphery down to the metaphyseal cortex and distal level for both the ML5050 and ML7030 load conditions. An exception was observed on the anterior side, where the metaphyseal cortex strain was lower than proximally. With the normal ML7030 load condition, high compressive strains were observed medially at all levels (700 $\mu\epsilon$ proximally, 1000 $\mu\epsilon$ at metaphysis, 1010 $\mu\epsilon$ distally). Comparatively, strains at the lateral locations were very much lower (80 $\mu\epsilon$ proximally, 260 $\mu\epsilon$ at metaphysis, 320 $\mu\epsilon$ distally). Intermediate strain values were observed at the anterior and posterior locations. Some distinct changes in the strain distribution around the tibia were observed when the load was changed to ML5050. At the proximal level, the medial

and lateral strains were more even (500-600 $\mu\epsilon$), with moderate strains anteriorly and posteriorly (300-400 $\mu\epsilon$). At the metaphyseal level, strain was highest laterally (730 $\mu\epsilon$) with slightly lower strains at the posterior and medial sides (520-600 $\mu\epsilon$). The strain at the anterior tuberosity was extremely small (30 $\mu\epsilon$). At the distal level, the medial strain (800 $\mu\epsilon$) was higher than lateral (650 $\mu\epsilon$). When the medial load was reduced from ML7030 to ML5050 in the intact tibia, the reduction in the medial strains and the increase in lateral strains were both statistically significant (paired t-test).

Tibia with cementless and cemented fixations

From Figs. 8.5a-c and 8.6, it was observed that implantation of the prosthesis resulted in different strain patterns around the tibia due to altered loading conditions. Although there were no statistically significant differences ($p>0.05$) in the strain values between the intact tibia, cementless fixation and cemented fixation at all levels, various distinctive trends in strain change were observed. Firstly, there was a clear trend of an increase in the compressive strains (localised or mean) at the proximal level when the prosthesis was implanted by press-fitting and subjected to either ML7030 or ML5050 loading. The anterior strains were increased by 3.2-3.6 times, though not statistically significant. When cement was applied to the tibial fixation, proximal strains in the tibia were reduced as compared to the intact tibia, indicating proximal stress-shielding and distal load transfer by the cemented prosthesis. Secondly, the mean tibial strains at the metaphyseal level (40mm) increased after press-fitting of the prosthesis, and after the cemented fixation with the ML5050 load (Fig. 8.6). The cemented case under ML7030 loading was an exception where the mean strain was reduced. The localised lateral strains increased after the stemmed implant was placed, but the medial strains were reduced (Fig. 8.7). These changes were larger for the ML5050 load case compared to ML7030, although the differences were not statistically significant, presumably reflecting an overall bending effect as the load distribution changed. In addition, strains for the cementless fixation were higher than the cemented fixation in both load cases.

Thirdly, the distal lateral strains in the tibia were increased while the medial strains were reduced after cemented and cementless fixations (Fig. 8.7). The observation was

similar to the metaphyseal level, but with a smaller amount of strain change. The amount of strain reduction medially was higher than that of strain elevation laterally, thus resulted in a net reduction of the mean strains distally (Fig. 8.6). Fourthly, regions of high and low strains around the tibia had migrated after fixation. For both the cementless and cemented fixations with ML7030 load distribution after surgery, high compressive strains were located medially in all three levels under the resected surface, similar to the intact tibia (see Fig. 8.7a). This was mainly due the larger proportion of joint load acting on the medial compartment of the tibial tray. The highly uneven medial/lateral strain proportions observed in the intact tibia with M/L strain ratios of 3.2 to 8.8 were reduced to 1.8-2.5 for the cementless fixation and 2.0-4.3 for the cemented fixation. In the case where an equal M/L load distribution was assumed after surgery (both cementless and cemented), the lateral strains in the tibia were higher than medially at the 10 and 40mm levels, but remained lower than medially at 60mm (Fig. 8.7b). The M/L strain ratios were also lower compared to the intact tibia, ranging from 0.53-1.24 for the cementless fixation and 0.39-1.8 for the cemented fixation. When the medial load was reduced from ML7030 to ML5050 for the cementless and cemented fixations, the decrease in the medial strains and the increase in the lateral strains were both statistically significant ($p < 0.05$). The anterior strains at the tuberosity of the tibia (40mm) turned from compressive to tensile after cementless and cemented fixations, regardless of ML7030 and ML5050 load cases.

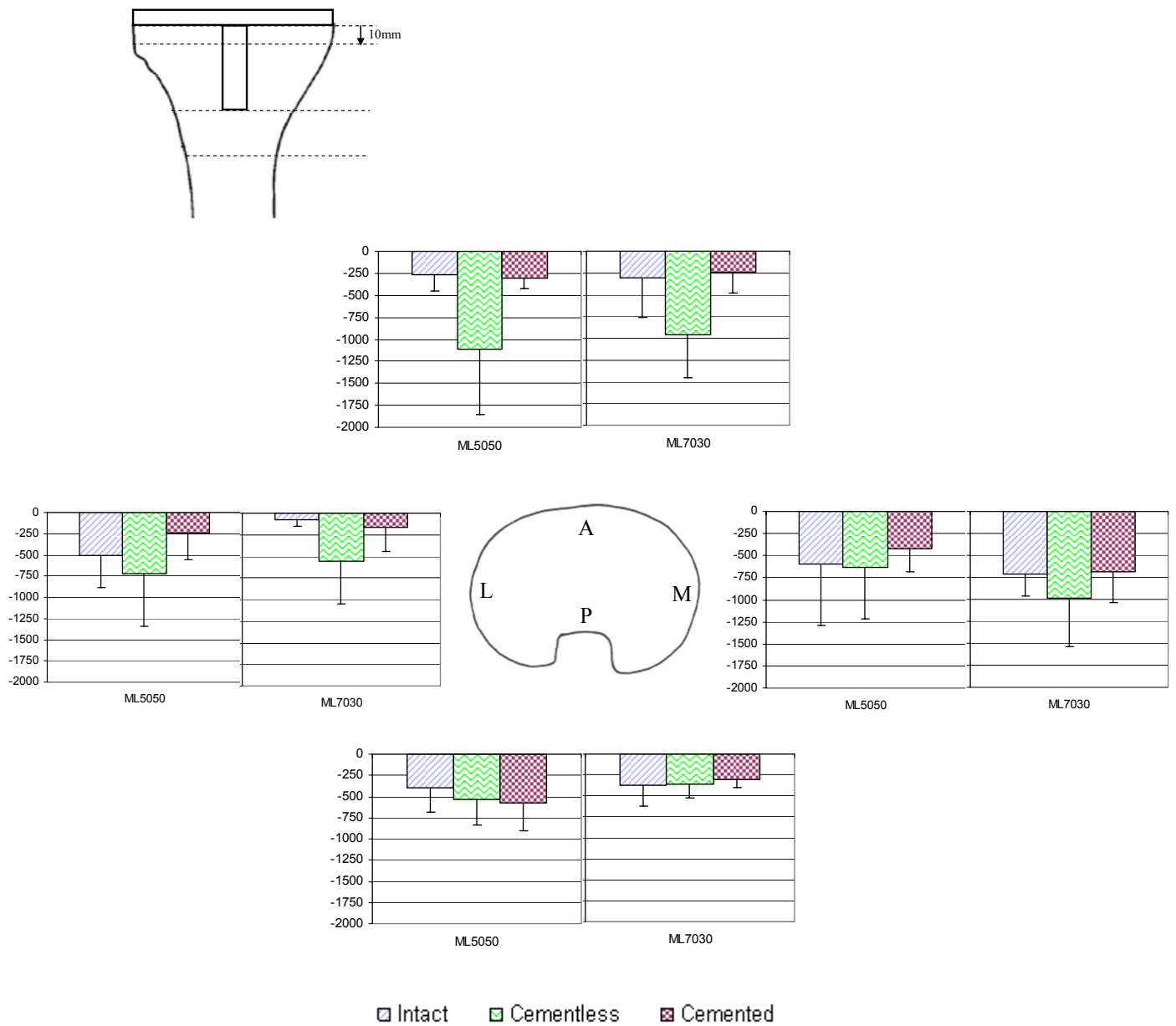


Figure 8.5a: Strains (microstrain) measured around the proximal tibia at 10mm under the resected surface.

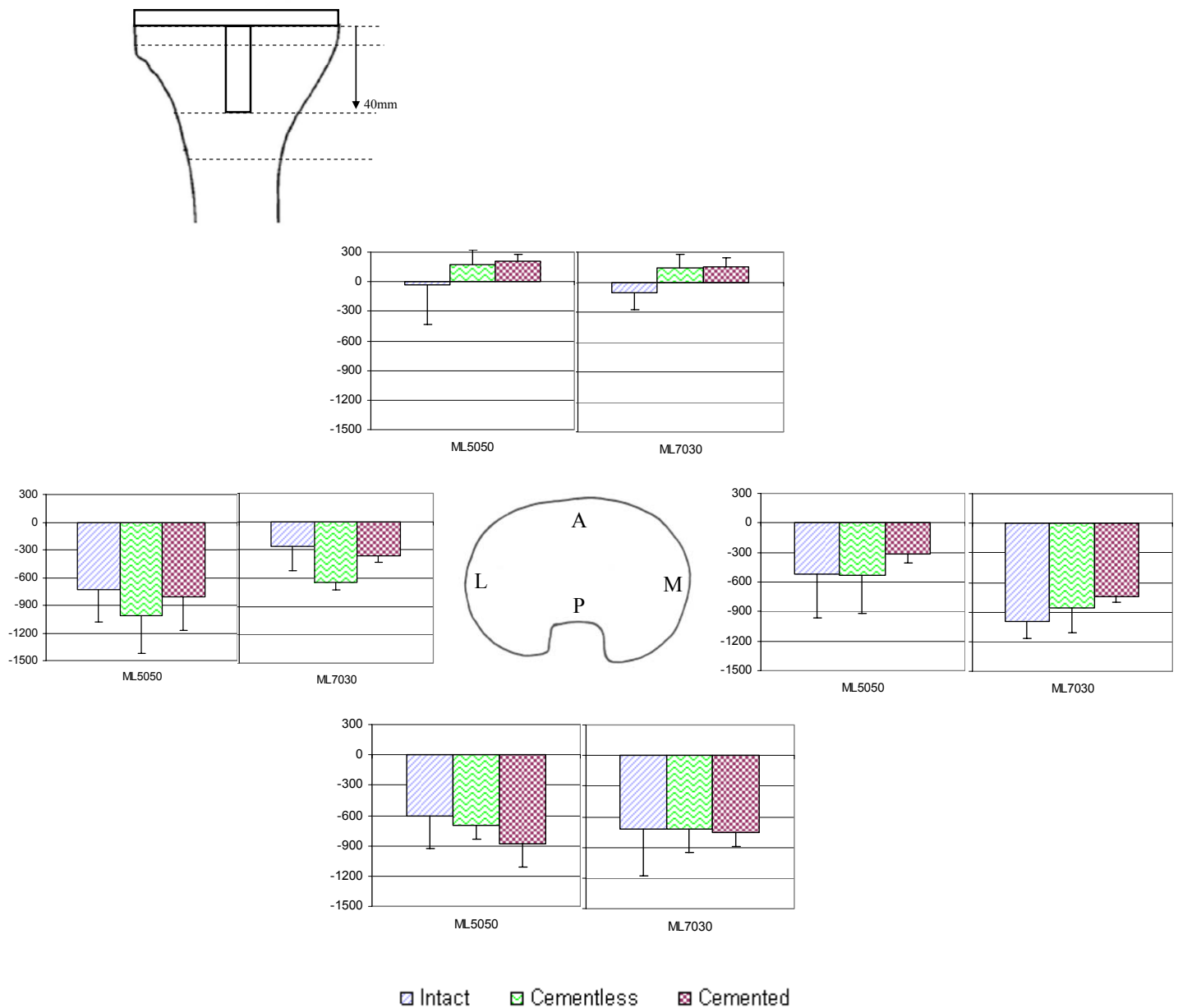


Figure 8.5b: Strains (microstrain) measured around the tibia at 40mm under the resected surface.

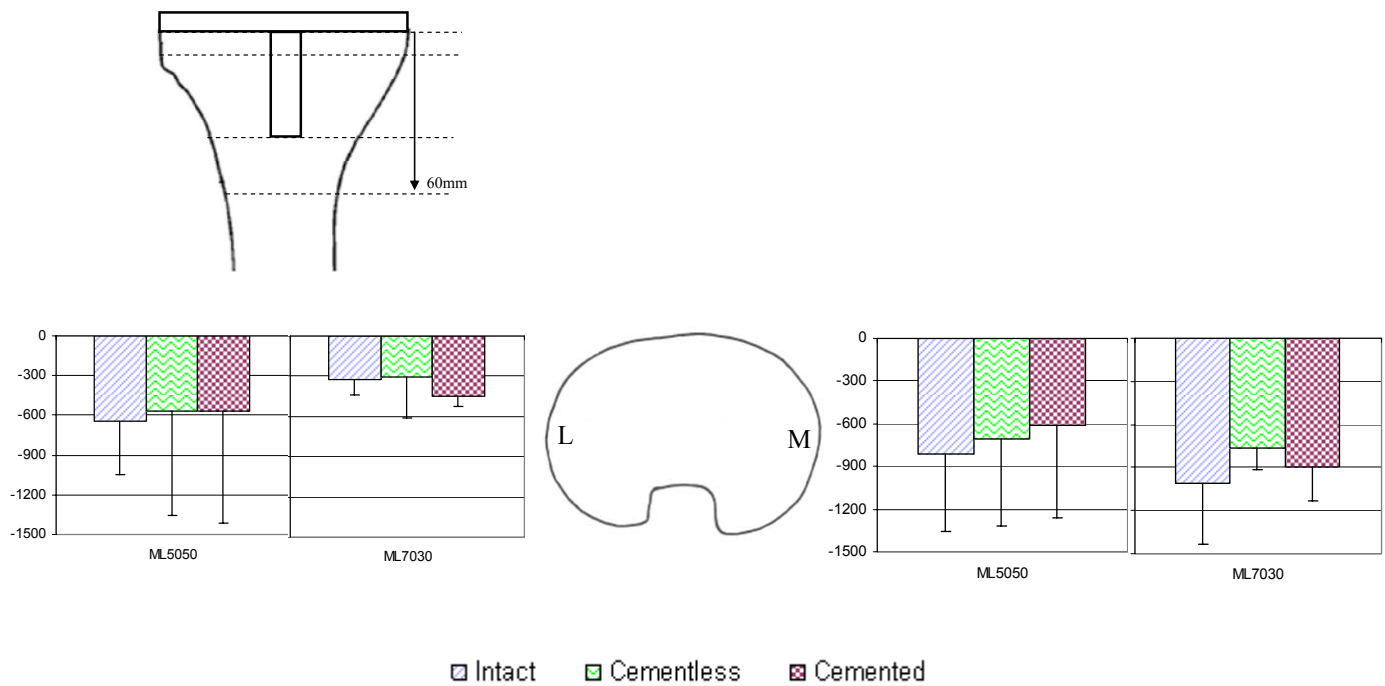


Figure 8.5c: Strains (microstrain) measured at the lateral and medial sides of the tibia at 60mm under the resected surface.

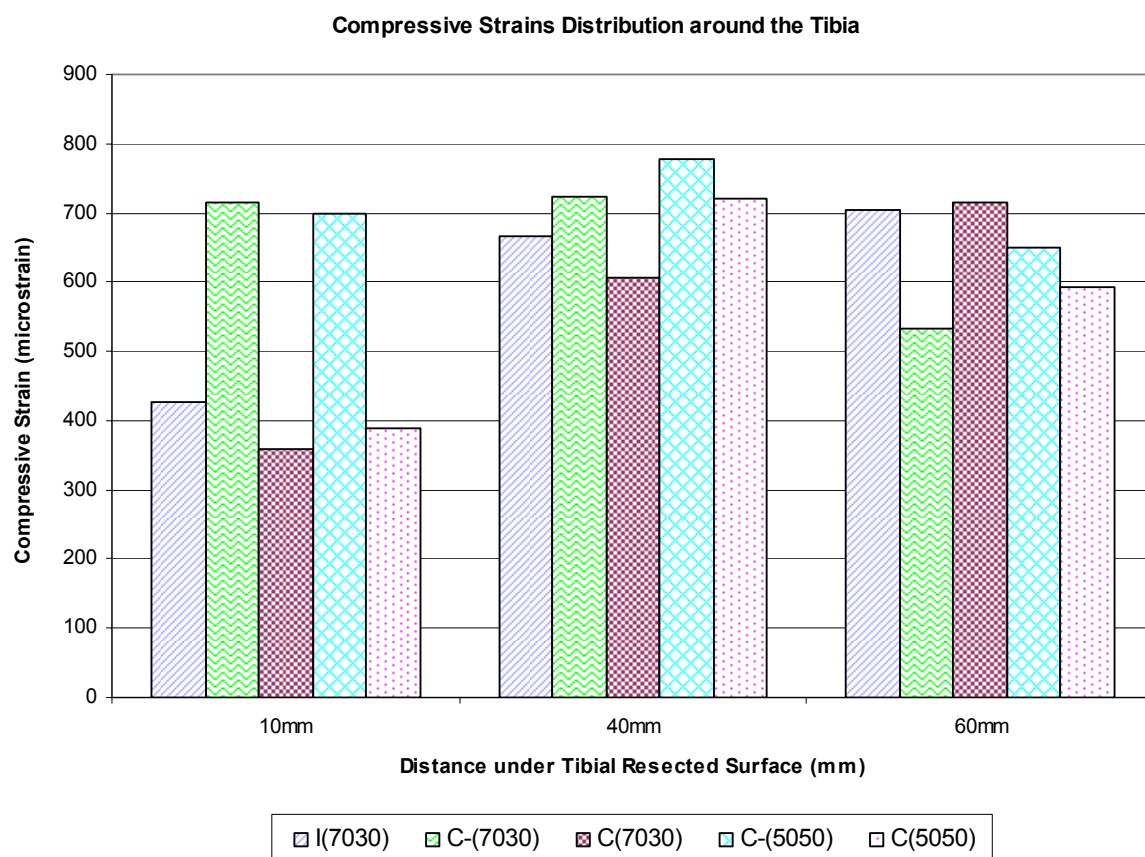


Figure 8.6: The mean compressive strains around the tibia at different levels under the tibial resected surface before and after prosthesis implantation (cementless:C- / cemented:C).

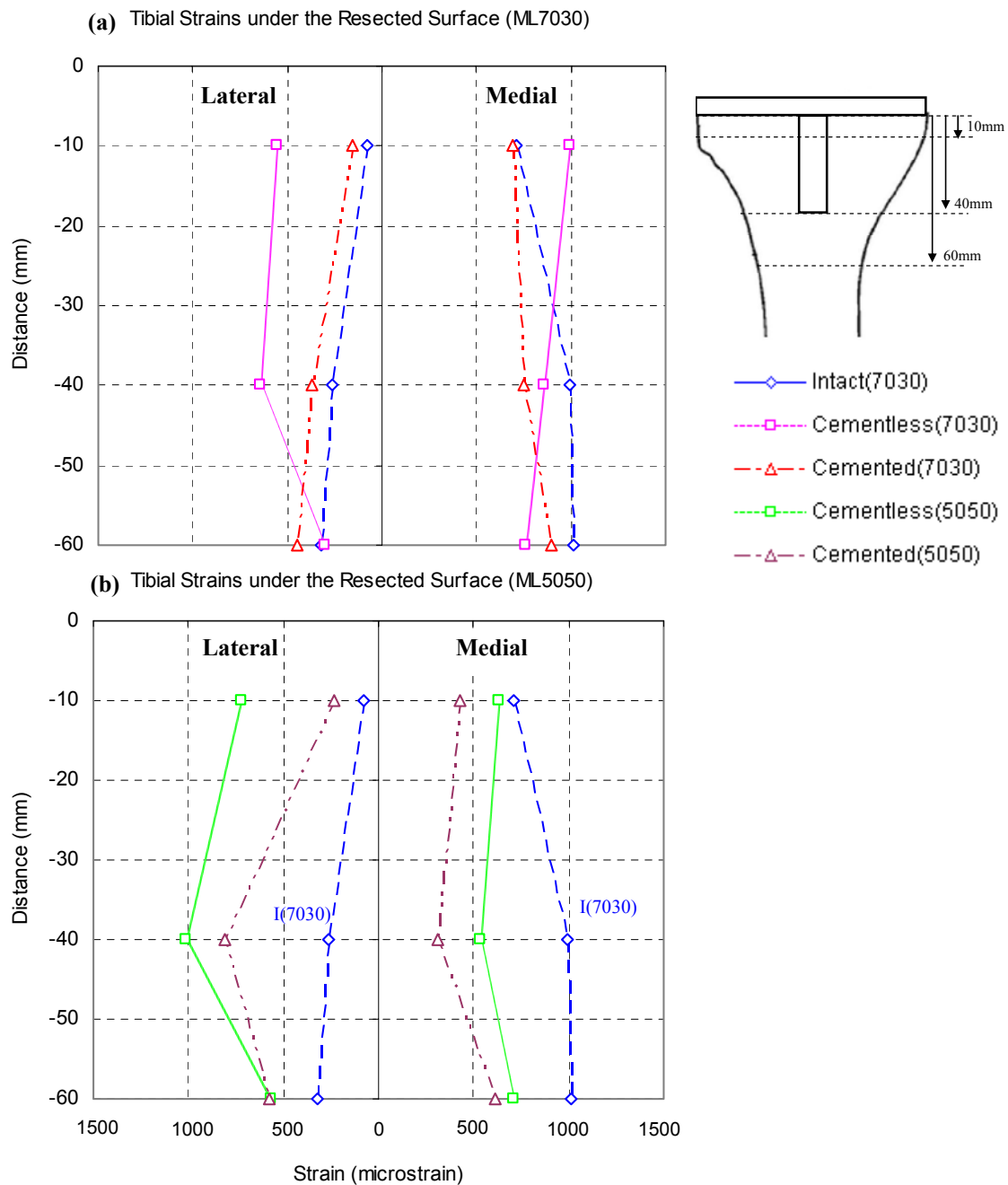


Figure 8.7: Compressive strains in the medial and lateral aspects of the intact tibia, cementless and cemented fixations for a) ML7030 and b) ML 5050 loading conditions.

8.3.2. Effect of Repeated Refrigeration on Cortical Bone Strain Measurements

Fig. 8.8 shows the variation in strains of the bone specimens over consecutive days (and time) under the three-point bending test. The average value is the mean of the strain readings for each specimen taken over three (femur S2) or five days (femur S1). The cortical bone strains measured were relatively consistent over the period of 3-5 days with repeated refrigeration. The standard deviation (Std Dev) and the standard error of mean (SEM) of the strain readings for each specimen was small. The Std Dev and SEM of specimens from S2 were slightly higher than S1.

Statistical analysis performed using paired t-test found no significant difference ($P > 0.05$) in strains between Day 1 (am) and Day 3 (pm) for all the eight specimens, and in strains between Day 1 (am) and Day 5 (pm) for the four specimens of S11, S12, S13 and S14.

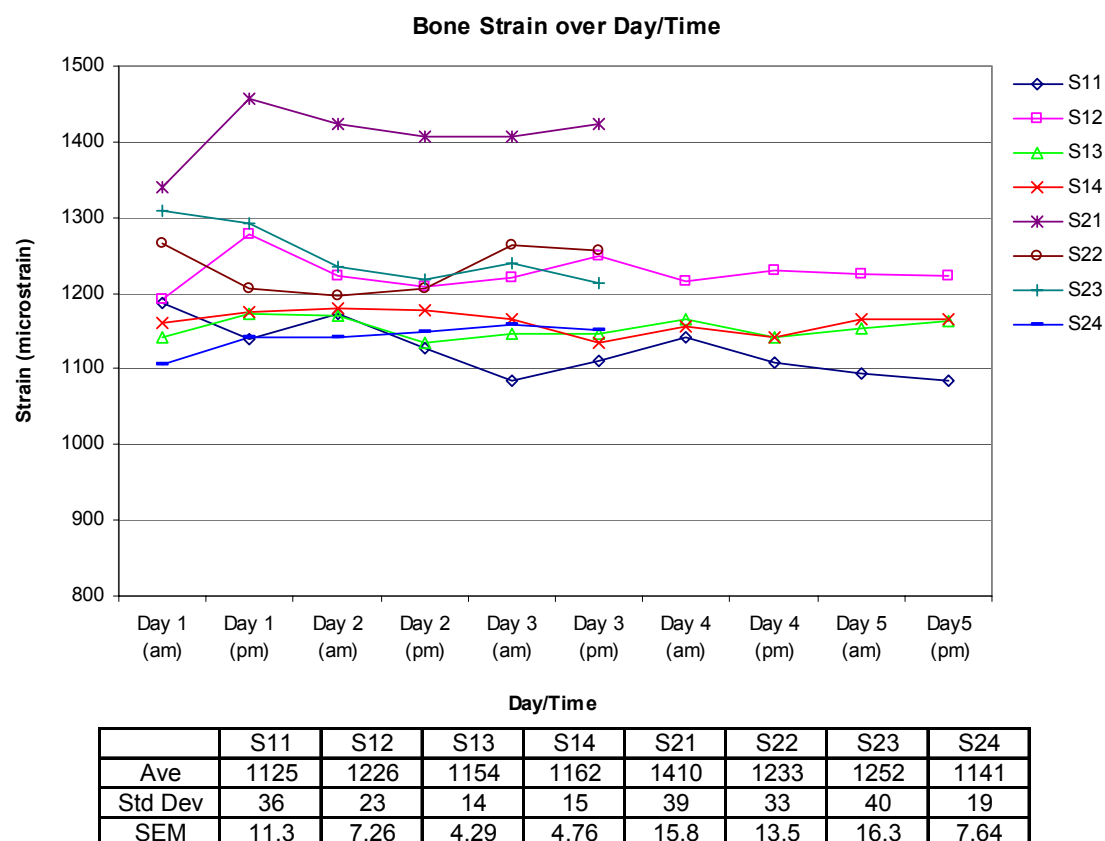


Figure 8.8: The variation in cortical bone strains over consecutive days and time under the three-point bending test.

8.3.3. Bone-Prosthesis Relative Micromotion Measurements

The bone-prosthesis relative movements registered by the LVDT probe are shown in Figs. 8.9a-h, and are represented by the blue and red lines for the cementless and cemented fixations respectively. In the present measurement setup, the bone surface and LVDT probe moved (compressed or extended) in relation to the position of the edge of the tray where the extended rod was fixed. It was unclear whether the probe movement was caused by the tray or bone movement as only the relative motion was captured. When the probe readings for cadaver S1 were checked, compression (corresponded to either bone moving outwards or the tray moving inwards) was registered at all four edges of the tray. Since the tibial tray is made with Titanium alloy of high stiffness (110GPa), deformation or shrinkage of the tray would be negligible. Therefore, the likely cause of probe compression was the bone moving outwards due to hoop stresses induced by the tibial tray and its central stem when loaded. When extension of the probe was measured in cadaver S6 (anterior of tray), the tray moving outwards was anticipated as the bone would be unlikely to move inwards due to the hoop stresses experienced. And compression was registered by the probe at the opposite side (posterior of S6) indicating that the tray had moved inwards. With these observations, the following conventions were used for the interpretation of results – the bone had moved outwards when a compression was registered, and extension of the probe indicated an outward shift of the tibial tray. Referring to Figs. 8.9a-h, lines drawn out of the tibial tray indicated that the bone moved outwards relative to the tray. For lines drawn inside of the tray, it implied the tray shifted outwards in the particular direction relative to the bone.

Movement of the bone outwards was observed in most cases for both the cementless and cemented fixations, and under both ML5050 and ML7030 load conditions. There was more occurrence of the tray shifting in the cementless than the cemented fixation. Tray shifting was observed in the cementless fixations of i) S4 - L5050 postero-medially, ii) S5 - ML5050 antero-medially, iii) S6 - ML5050/7030 antero-medially, iv) S7 - ML5050 anteriorly, while only one case was noted for cemented fixation of S7 - ML7030 medially. A specific direction of tray shifting could not be determined as it appeared that tray shifting could be random depending on individual fixation strength and loading conditions.

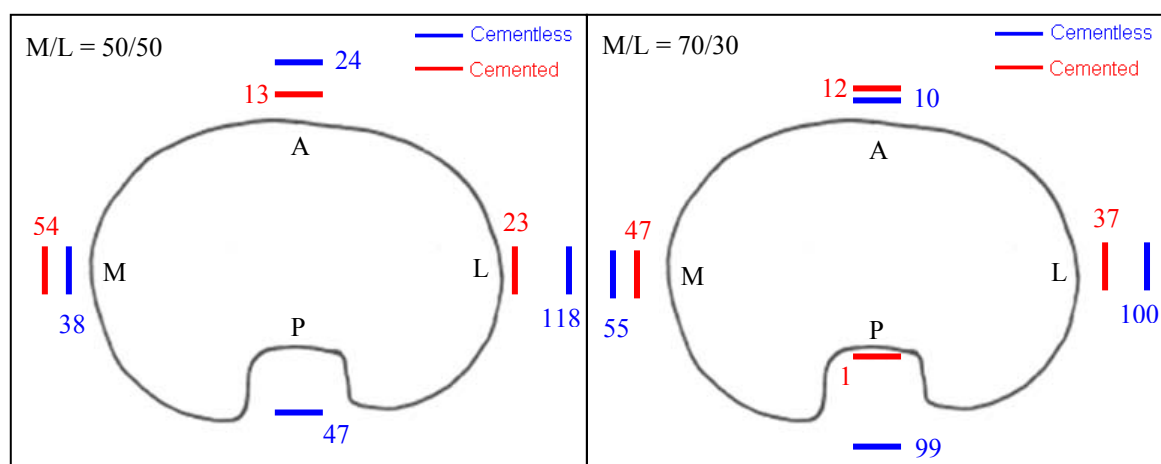


Figure 8.9a: S1- Right tibia with tray size 5R.

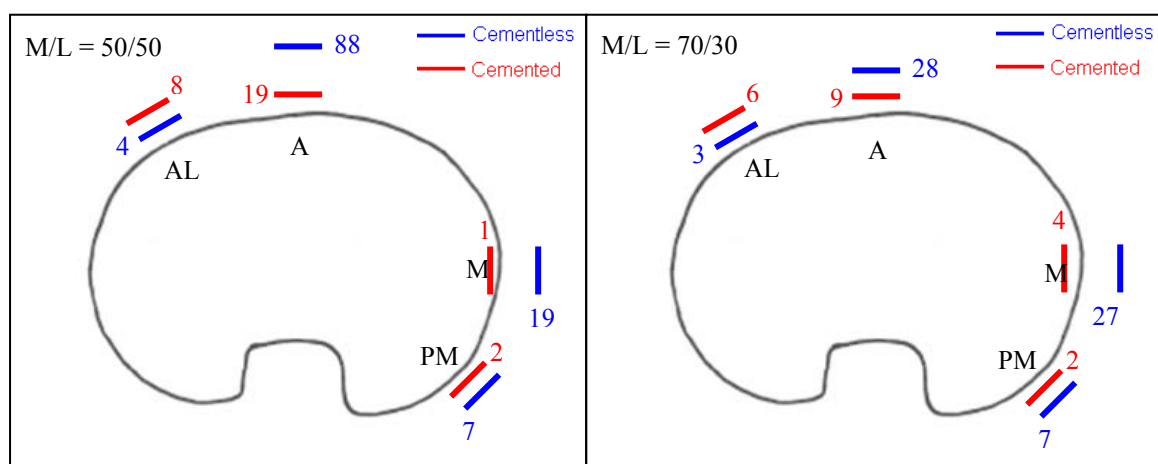


Figure 8.9b: S2 - Left tibia with tray size 8L.

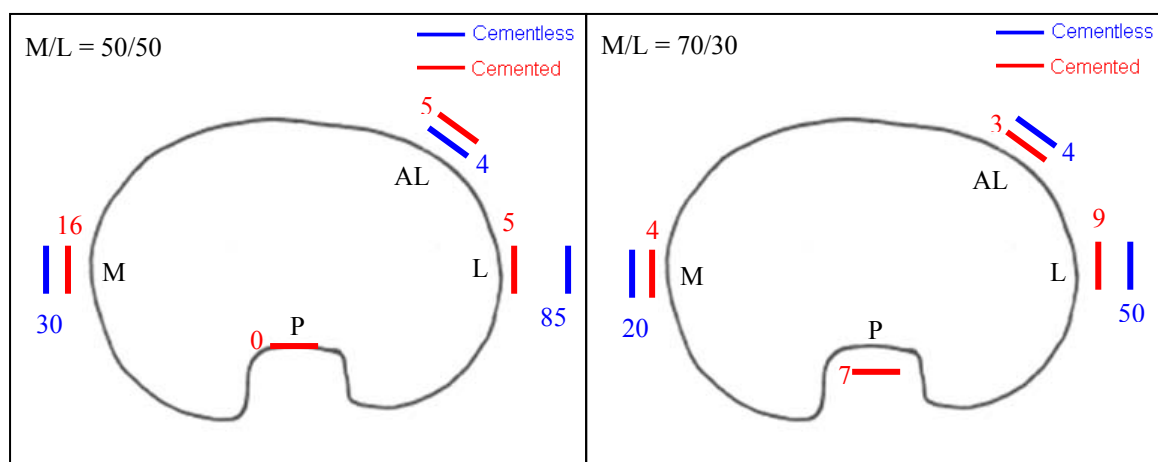


Figure 8.9c: S3 - Right tibia with tray size 7R.

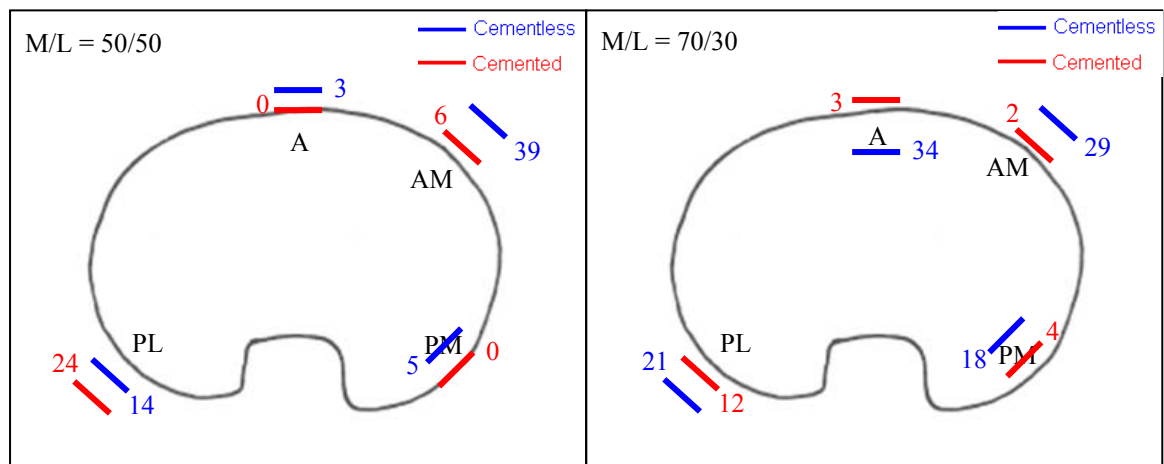


Figure 8.9d: S4 - Left tibia with tray size 3L.

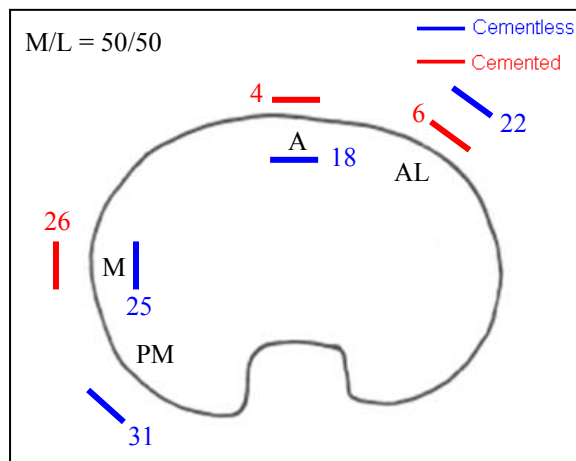


Figure 8.9e: S5 - Right tibia with tray size 4R.

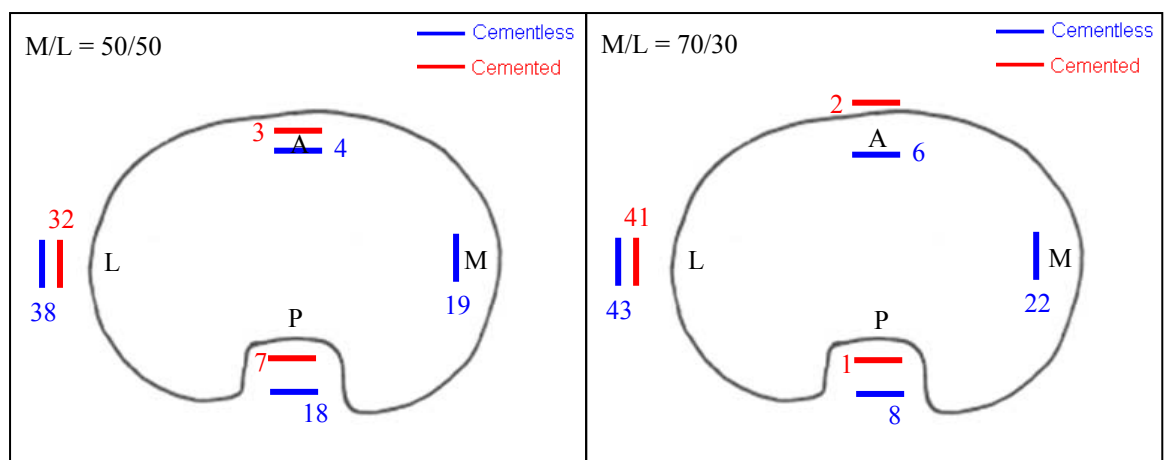


Figure 8.9f: S6 - Left tibia with tray size 8L.

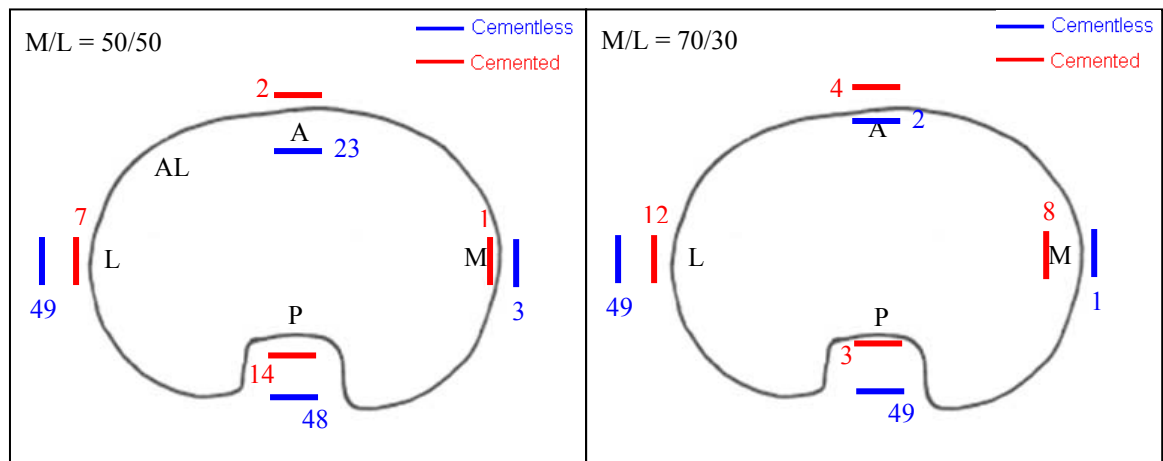


Figure 8.9g: S7 - Left tibia with tray size 6L.

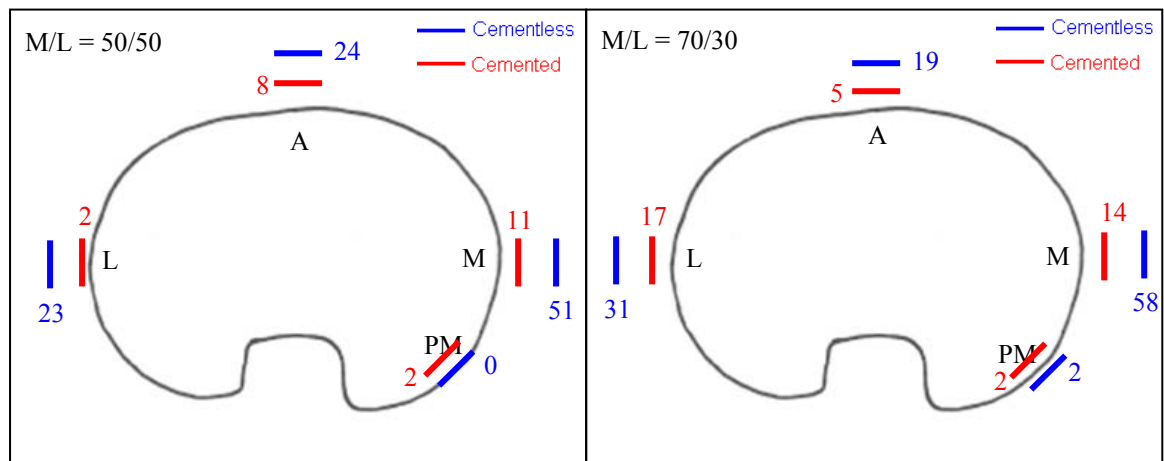


Figure 8.9h: S8 – Left tibia with tray size 8L.

Fig. 8.10 shows the averaged bone-prosthesis relative micromotion measured at different locations of the tray under ML5050 and ML7030 load conditions for both the cementless and cemented fixations. Although the differences in micromotion between the four edges of the tray for all load cases and fixation techniques were not statistically significant (ANOVA), the magnitudes varied by a large range.

For the cementless fixation, the highest micromotion was observed at the lateral edge of the tray, followed by posterior and medial, with anterior being the lowest. Under the ML5050 load, a statistically significant difference (t-test) in the micromotion was observed between lateral (63µm) and medial (26µm). When the lateral load was

decreased in the ML7030 configuration, the micromotion at the lateral edge decreased (to 55 μ m) with an increase at the medial edge (31 μ m). For the cemented fixation, high micromotion was observed laterally and medially, with lower micromotion at the anterior and posterior edges. The differences in magnitude between the lateral and medial edges were less drastic.

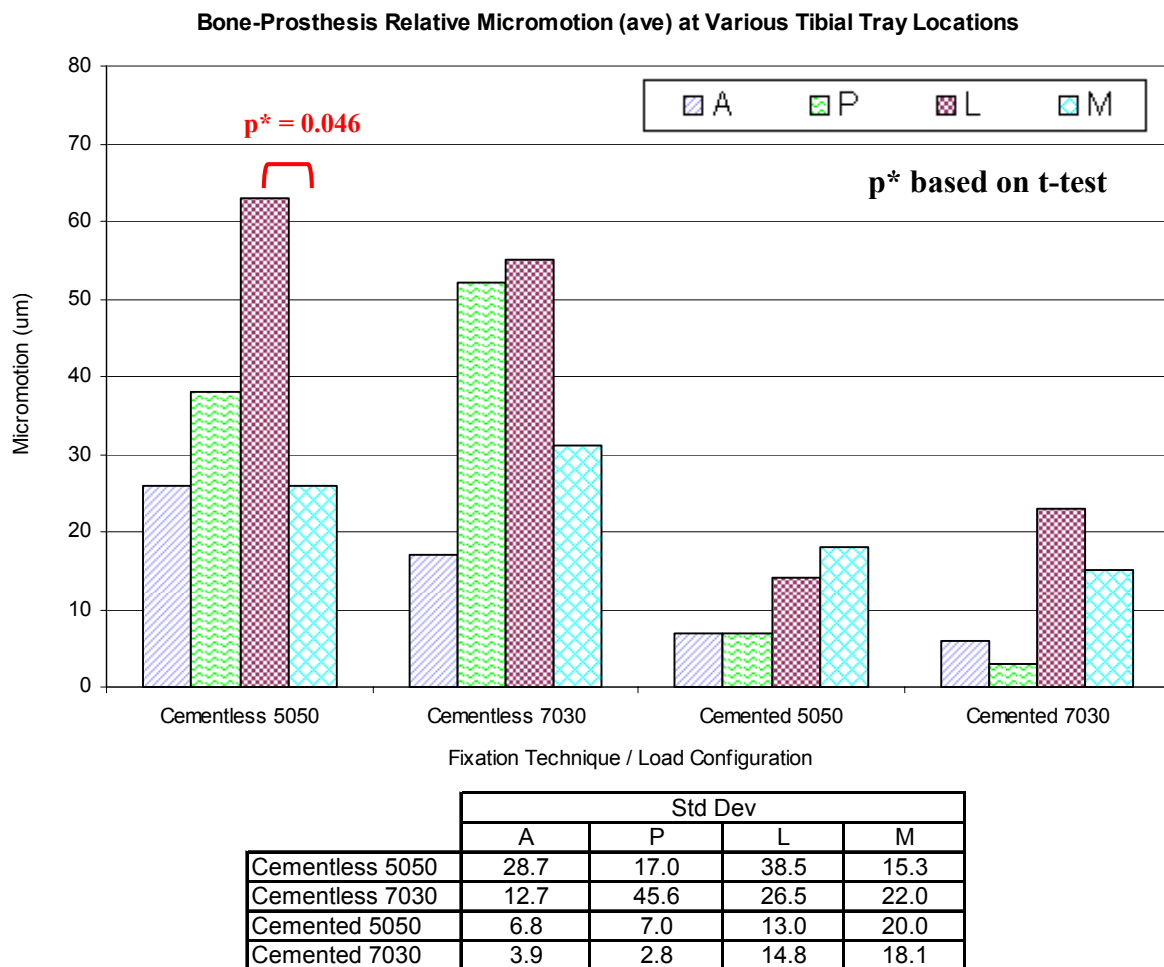
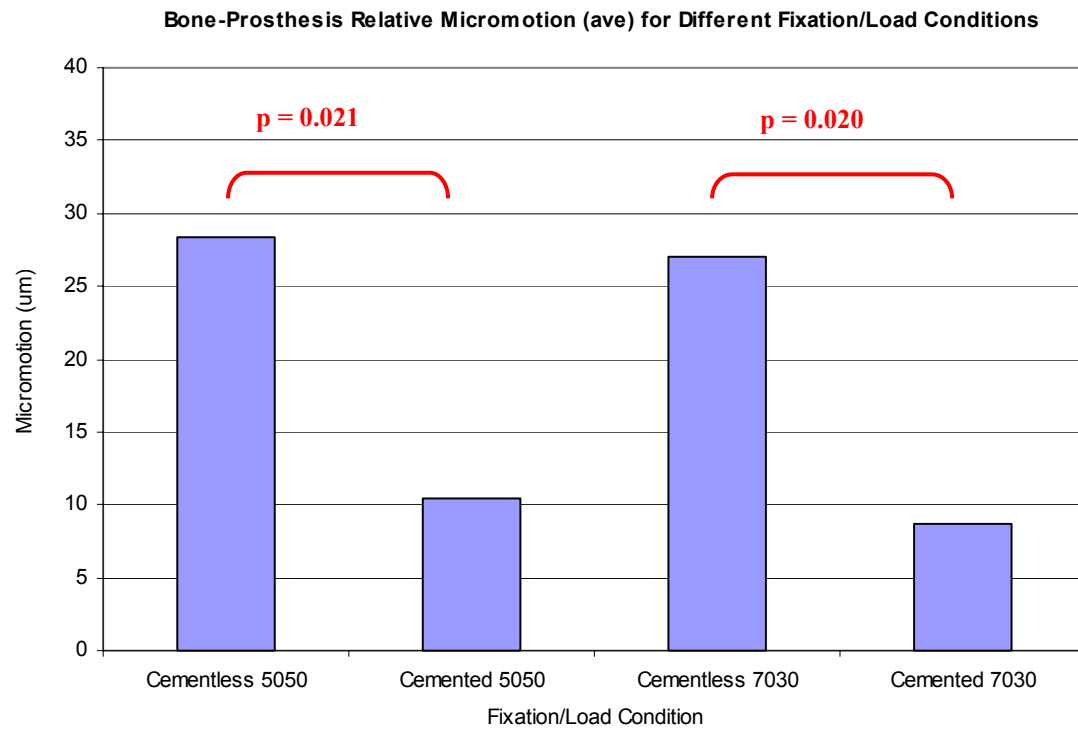


Figure 8.10: Bone-prosthesis relative micromotion at various tibial tray locations.

Micromotions at all the locations of the edges of the tray were averaged for each fixation and loading configuration and presented in Fig. 8.11. Statistically significant differences were found in the micromotion between the cemented and cementless fixations (t-test). The bone-prosthesis relative micromotions measured for the cementless fixations were 2.7-3.1 times higher than the cemented fixation. No significant difference was found in the bone-prosthesis micromotion between ML5050 and ML 7030 for both the cemented and cementless fixations (t-test).



	Cementless 5050	Cemented 5050	Cementless 7030	Cemented 7030
Std Dev	18.0	7.6	18.6	7.4

Figure 8.11: Overall bone-prosthesis relative micromotion for different fixation and loading configurations.

8.4. Discussion

In this study, the strain-shielding effect in the proximal tibia after cementless (press-fit) and cemented tibial fixations was investigated by mechanical testing. The bone-prosthesis relative micromotions for cemented and cementless fixations were quantified experimentally in-vitro, and initial stability of the fixations was correlated to clinical RSA migration data and trends.

Strain-Shielding Effect in the Proximal Tibia after Prosthesis Implantation

In the intact tibia, the ML7030 load configuration resulted in large medial strains which were highly unbalanced around the tibia. With the ML5050 load case mimicking a valgus intact knee joint, a more balanced distribution between the medial and lateral strains was found in this study. A similar observation was made with a ML6040 load condition (Reilly et al. 1982). A small valgus loading had also reduced compressive strains in the medial tibia but increased the strains laterally (Bourne et al. 1984).

The strains in the proximal tibia were found to increase predominantly in the anterior and lateral sides after a press-fit implantation, while the posterior strains under ML7030 loading and medial strains under ML5050 loading were nominally reduced. It could be deduced that bone densification and resorption could occur locally at the antero-lateral and postero-medial regions respectively. When bone cement was used, the proximal strains at the anterior, posterior and medial regions were lower than the intact tibia under the ML 7030 load condition. With ML5050 loading, proximal strain was reduced mainly at the medial tibia. These observations after cemented implantation were in accordance with the studies by Reilly et al. (1982) and Bourne and Finlay (1986). The proximal stress-shielding observed could result in bone resorption where strength of the supporting bone underneath the tray would be weakened and eventually lead to prosthesis migration or collapse. In other separate in-vitro studies where strains of the intact tibiae were not measured, the proximal strains were found to be higher in tibiae with a press-fit central stem compared to a cemented stem (Seki et al. 1997; Jazrawi et al. 2001). A finite element study found that the load transfer capability of the stem was reduced by 75% when cement was not used

(Completo et al. 2008b). It showed that in cementless fixation, less joint load was being transferred distally by the central stem and more of it was transmitted through the tibial tray as compressive stresses to the underlying bone.

At the metaphyseal level, the mean tibial strains increased after the prosthesis was placed. This was primarily due to the proximal load being transferred distally by the stem to its tip at this level, and that it has caused a stress/strain concentration hence increasing the bone strain. A greater increase in the strain was also observed for the cementless than the cemented fixation. This may probably caused by the direct contact between the stem tip and bone leading to higher bone strains than the pre-operated state, and could be correlated to bone hypertrophy in regions adjacent to the tip of the uncemented tibial stems clinically (Bertin et al. 1985). With the cement providing a firm anchorage between the bone and prosthesis, the load borne by the tray and stem could be distributed more evenly to the entire periprosthetic bone regions rather than accumulated at specific regions underneath the stem tip. For the localised strains at the metaphyseal level, the lateral strains were increased after the prosthesis was implanted but the medial strains were reduced (Fig. 8.7). A similar behaviour was found in a test conducted on synthetic tibiae (Completo et al. 2008a). The authors related it to the pivoting effect of the prosthesis about the stem tip, in which the stem tip was pressed against the adjacent bone due to the bending moment generated in the tray hence inducing more bone straining. Under the current ML7030 load setup, the off-centred resultant force on the tray generated a local valgus moment about the stem pivot that pressed the tip against the lateral bone, leading to higher strains and at the same time relieving the strains medially.

The ML5050 load condition has not induced any local valgus moment on the tray as the resultant force was aligned with the stem tip and the mechanical axis of the tibia. With an equal load distribution, two observations were made (from Fig. 8.7). The first was the amount of change in tibial strains after implantation was greater than the ML7030 load distribution. And the lateral strains were higher than medially at the proximal and metaphyseal levels. These could partly be due to the current tray design where the lateral compartment is smaller than the medial compartment. With a similar force acting on both compartments, the bone underneath the lateral compartment of a smaller surface area would be subjected to larger stresses. Coupled with the increase

in lateral load from ML7030 to ML5050, greater deformation and straining in the lateral tibia would be induced. In addition, the denser cancellous bone at the medial condyle could provide a stronger mechanical support than the lateral condyle. Thus with medial load lowered (from ML7030 to ML5050) to a level similar to that of laterally, it would lead to smaller deformation and strains in the medial tibia.

The change in the distal localised strains was smaller than at the metaphyseal region. This change observed was not due to stress-shielding after the prosthesis was implanted, but the alteration in load pattern of the tibia. Under the ML7030 load, tray pivoting at the stem tip induced a moderate effect on bone deformation at some small distance distal to the tip, which resulted in a marginal lateral strain elevation and medial strain relief. With the ML5050 loading, the increase in lateral load and the decrease in the medial load after implantation would lead to a corresponding increase in the lateral strains increase and decrease of the medial strains distally, but of slightly greater extent.

The in-vitro tibial strain changes in the current test have shown some correlations to clinical bone remodelling. The decrease in bone mineral density at the proximal tibia of patients after cemented implantation (Lonner et al. 2001; Saari et al. 2007) corresponded to the in-vitro strain reduction in the proximal tibia. The reduction in the proximal medial strain (Fig. 8.7b) and the increase in the metaphyseal lateral strains (Figs. 8.7a & 8.7b) after cementless implantation could be related to roentgenographic observations of peripheral bone atrophy and cancellous bone hypertrophy at the metaphysis region respectively (Whiteside and Pafford 1989).

Bone-Prosthesis Relative Micromotion Measurements

When the tibial prosthesis was implanted by press-fitting, bone-prosthesis relative movement was found to be sensitive to the loading condition and tray design. Under the ML5050 loading, there was more occurrence of tray shifting and a highest micromotion registered at the lateral edge (63µm in average). This could be attributed to a number of reasons. Firstly while the load was equally distributed at the lateral and medial compartments, bone underneath the lateral compartment of a smaller surface

area would be subjected to greater stresses (reflected by higher lateral strains than medially). As a result the bone moved more thus leading to the high relative micromotion measured at the lateral edge. Secondly, with a larger force-to-surface-area ratio at the lateral compartment (than medially), the unbalanced force-area ratio loading could push the tray to shift medially. Thirdly, the less dense cancellous bone at the lateral condyle could have a weaker holding strength than the medial condyle, and would result in greater relative movement between the tray and the underlying bone.

When the loading was changed to ML7030, bone-prosthesis relative motion at the lateral edge and the occurrence of tray shifting were reduced. With a larger medial force acting on a larger medial compartment of the tray, the force-to-surface-area ratios medially and laterally were more balanced. This has seemingly been able to improve the stability of the tibial prosthesis. Some implications could be drawn. In the first instance, if the joint load distribution is 50%/50% M/L for a patient fitted with the current tibial prosthesis design, bone-prosthesis micromotion would increase and hinder bony ingrowth. Secondly, for a tibial tray design with equal size of lateral and medial compartments, osseointegration process could be enhanced for patients with a more balanced M/L load after TKR. However, the present M/L areas reflected the M/L loads, ensuring uniform contact stresses across the tibial plateau.

The observations on the cementless fixation were not replicated in the cemented fixation. The bonding between the bone and prosthesis provided by the bone cement resulted in a firm fixation whereby the bone-tray relative movement was minimised. Transfer of the joint load to the distal region by the cemented central stem also helped to alleviate stresses in the proximal underlying bone below the tibial tray.

The bone-prosthesis relative micromotion measured in the current test provided a measure of the initial stability of the tibial fixation. The micromotions measured for the cementless fixation were 2.7-3.1 times higher than for the cemented fixation. The differences were statistically significant, and results are in accordance with other in-vitro tests conducted earlier (Branson et al. 1989; Stern et al. 1997; Jazrawi et al. 2001). The trend is also in good correlation with clinical RSA results showing that early migration of cementless tibial components was 2-2.5 times higher than

cemented tibial prostheses (Ryd et al. 1990/1995). Knee prostheses that registered higher migration were found to relate to a shorter survivorship against aseptic loosening (Grewal et al. 1992; Ryd et al. 1995). In another study, Fukuoka et al. (2000) measured the initial stability of tibial components in-vivo after cementless implantation for groups of OA and RA patients and found that tray subsidence and lift-off were both significantly worse for the RA group. A significant correlation was then found between the initial stability and component migration determined at 2 years by RSA, and the migration was significantly higher for the RA group than the OA.

The migration of prostheses could be due to numerous reasons such as weakened periprosthetic bone strength (common to both cementless and cemented fixations), cement or cement-bone/cement-prosthesis interface damage, or insufficient bone ingrowth in cementless fixation. Although the mechanism leading to component migration may differ between cementless and cemented fixations, migration measured by a standardized RSA method was found to relate to survivorship against aseptic loosening. It illustrated that measurement of the initial stability of the tibial fixation could be correlated to early component migration and eventually be associated with late aseptic loosening. This shows that the in-vitro test method used in the current study has the potential of providing an indication of long-term fixation performance in relation to aseptic loosening for tibial prosthesis implantation. Further study could involve initial stability measurements of new prosthesis designs and early RSA migration measurement, and follow-up of the long-term performance and clinical outcome.

8.5. Conclusions

Strain-Shielding Effect in the Proximal Tibia after Prosthesis Implantation

The strains in the proximal intact tibia were predominantly increased after implantation of a cementless prosthesis, instead of strain reduction which may lead to bone resorption. More of the joint load was transmitted across the tibial tray as compressive stresses to the underlying bone than was transferred distally, the opposite trend to the cemented fixation. There have been only limited densitometry studies comparing cemented and cementless fixations in the knee joint. In Seki et al.'s study (1999), a cemented femoral component resulted in significantly greater distal femur bone resorption than when a cementless porous-coated component (of identical design) was used. On the contrary with a slightly different femoral component implanted by press-fitting, bone mineral density near the posterior flange of the component was increased significantly. This could likely be due to load transmission across the component to its adjacent bone thus leading to bone hypertrophy. In another study by Abu-Rajab et al. (2006), while not statistically significant, marginal bone densification and resorption were observed in the proximal tibia for the cementless and cemented fixations respectively. Hence implanting a tibial prosthesis by press-fit potentially reduces the chance of proximal bone resorption as compared to the cemented fixation. However, the increase in the bone strains (and stresses) proximally and at the region of the stem tip may elevate the risk of bone fracture and fatigue failure.

The strain distribution medially and laterally of the intact tibia was not uniform after implantation even if an equal joint load distribution in the medial and lateral compartments was imposed. It may result in a greater bone resorption in the proximal tibia and the metaphyseal region than the case where the uneven load distribution was not corrected. This study suggests that a modified tibial tray with a smaller medial compartment (or similar size with lateral) may help to reduce the strain-shielding phenomenon.

Effect of Repeated Refrigeration on Cortical Bone Strain Measurements

It was found that repeated refrigeration (up to 3-5 days) and concurrent drying and re-wetting of the bone specimens did not have a significant effect on the strain measurement of the human cortical bone. Therefore the experimental protocol for strain analysis of whole bones, which took several days to complete, would not affect the elastic behaviour of the bone.

Bone-Prosthesis Relative Micromotion Measurements

The bone-prosthesis relative micromotion for tibial prosthesis fixation was measured in-vitro using a modified method in which the LVDT was mounted onto the tibial tray (with a holder and extended rod) instead of attaching to the bone. The higher micromotions measured for the cementless fixations (than cemented) were in good agreement with the clinical RSA results showing that early migration of the cementless tibial components was higher than for cemented tibial prostheses. This study showed that initial stability of a tibial fixation measured in-vitro could be used to provide an indication for long-term fixation performance in relation to aseptic loosening for tibial prosthesis implantation.

CHAPTER 9. CONCLUSIONS AND PROPOSED FUTURE WORK

9.1. Conclusions

As surgical techniques progress and new and improved prosthesis designs are introduced, bone resorption after prosthesis implantation (Whittaker et al. 2008) and component failure due to loosening (Attar et al. 2008; Loughhead et al. 2008) remain a clinical concern. The push for longevity in primary TKR for younger patients can be supported by a comprehensive understanding of the failure mechanisms of these prostheses. Finite element methods for investigating the fixation performance of TKR in relation to bone resorption and aseptic loosening were developed with the implementation of a strain-adaptive bone remodelling algorithm. New codes were developed for the bone remodelling algorithm to capture the bone-prosthesis interface micromotion as the bone adapted to its altered load conditions with time. These FE models were validated with in-vitro and in-vivo test data. The FE models were subsequently used for the evaluation of the fixation performance of the new MIS mini-keel tibial prostheses, and to predict its risks for bone resorption and long-term aseptic loosening when compared to the conventional stemmed prosthesis. A modified in-vitro technique of measuring bone-prosthesis relative micromotion was also developed for relating initial stability of the cemented and cementless (press-fit) tibial prostheses fixations to late aseptic loosening. The specific conclusions of the project are summarised below.

Bone Remodelling after Tibial Prosthesis Implantation

The choice of tibial fixation techniques was found to influence the bone remodelling behaviour after prosthesis implantation. A firm anchorage formed between the prosthesis stem and the bone for the fully cemented fixation resulted in a severe proximal bone resorption. Bone loss with cementless fixation with partial osseointegration (less firm anchorage between prosthesis and bone) occurred at almost half the speed as compared to the fully cemented fixation. The hybrid cementing tibial fixation induced the least amount of bone resorption. Hence the

hybrid cementing technique or the cementless fixation allowing for partial ingrowth are preferred choices for preserving bone stock while providing the essential post-operative fixation stability.

Aseptic Loosening Analysis of the Cemented Tibial Prosthesis Fixation

The stress responses at the interfaces of bone-cement-prosthesis were examined for the purpose of investigating the cause of aseptic loosening in cemented fixations (see Chapter 5.2). The minimum principal stresses in the cancellous bone at the resected surface, and the shear stresses along the bone-cement interface underneath the tibial tray, were used in the parametric study of tibial prosthesis designs (Chapter 5.3). The findings suggested that fatigue of both the cancellous bone and the bone-cement interface could similarly likely be a cause for long-term aseptic loosening of the metal-backed tibial trays, and that fatigue of the supporting cancellous bone could be the dominant factor for loosening failure of all-PE tibial prostheses. The maximum principal stresses in the cement layer underneath the tibial tray were also found to correlate well with the component translation and rotation measured by RSA (Chapter 6.5). The above proposed failure parameters of cancellous bone stress, cement tensile stress and bone-cement interfacial shear stress were shown to be effective for the assessment of component loosening of the tibial prostheses.

Interface Micromotion Analysis for Cementless Tibial Prosthesis Implantation

The two single load conditions constituted of i) a generic vertical joint load and AP/ML shear forces acting at the centres of the medial and lateral compartments of the tibial tray, and ii) a peak vertical joint load at 25% of the stair climbing cycle with corresponding AP shear forces applied at the tibial-femoral contact points of the specific knee flexion angle, were found to be suitable for assessing bone-prosthesis interface micromotion of the cementless tibial fixation.

Fixation Performance of the MIS Mini-Keel Tibial Prostheses

In minimising the effect of stress-shielding leading to bone resorption, a mini-keel tray with stem extension implanted by either i) hybrid cementing for a cemented tibial

fixation, or ii) cementless implantation allowing partial bony ingrowth could be recommended.

The mini-keel prostheses (with or without stem) implanted by the cementless method were predicted to have a greater extent of osseointegration than the standard stemmed design. This showed that the mini-keel feature is able to restrain tray movement relative to the resected bone surface better than the standard stem/flange. The risk of long-term aseptic loosening could potentially be reduced by 50% as compared to the standard stemmed fixation.

Early RSA measurements at six months revealed that component migration of the MIS mini-keel prostheses was greater than for the standard stemmed design (but not statistically significant), indicating a higher relative risk of long-term aseptic loosening. Thus it is uncertain if the early promises of the MIS approach in TKR could prevail over the increased risk in long-term fixation failure. Long-term clinical follow-up on patients implanted with the mini-keel prostheses is necessary to provide a clearer implication on functionality versus fixation stability.

Proximal Tibial Bone Resorption of Healthy and Osteoporotic Patients

The osteoporotic case was modelled by reducing the apparent density of the tibia of a healthy subject by 15%. The amount of proximal bone resorption then predicted was almost 60% higher than that of a non-osteoporotic bone. It revealed that degradation in the initial bone quality of TKR patients may result in a greater risk of reduced fixation strength and long-term loosening. For the group of patients with osteoporosis and presumably having a less active lifestyle after TKR, implantation of a stemless mini-keel prosthesis with fully cementing could be recommended for minimal bone resorption impact, especially where some bone at the mid-stem level could be preserved relative to the stemmed designs.

Prosthesis Design Characteristics

The parametric study on tibial prosthesis designs showed that the analysis of both stress-shielding and fixation security in one combined study has led to novel insights

in tibial component fixation design. It appears that the best overall approach would be to choose a prosthesis design which has relatively small fixation features. In addition, it was predicted that a tibial prosthesis with elastic modulus similar to the surrounding cancellous bone would lead to an increase in the risk of loosening. The use of a stiffer prosthesis (CoCr) in place of the Titanium alloy has negligible impact on long-term tibial fixation performance.

The stemmed MK design did not induce a greater amount of proximal bone resorption than its stemless counterpart, unlike bone density scans on conventional tibial trays where stress-shielding effect was more significant with stemmed prostheses (Lonner et al. 2001). The broad keels, with a surface area of about 10% larger than the flange of the standard stemmed prosthesis which tapers distally, situated directly underneath the resected tibial surface, could have dominated the stress-shielding effect.

In-vitro Measurements of the Tibial Strains

Repeated refrigeration of up to 3-5 days and concurrent drying and re-wetting of the bone specimens did not have a significant effect on the strain values measured of the human cortical bone. It showed that a test period of up to five days would not affect the elastic behaviour of the cadaveric bone. This study complimented the previous observations of minimal influence of repeated freezing and thawing and long-term frozen storage on the mechanical properties of bone.

In-vitro Measurements of the Bone-Prosthesis Relative Micromotion

Higher micromotions measured for the cementless than the cemented fixations agreed well with RSA results showing that early migration of the cementless tibial components were higher than cemented tibial prostheses. With clinical evidence showing that early migration of the knee prostheses would lead to late aseptic loosening, measurement of the initial stability of the tibial fixations in-vitro could provide an indication of long-term aseptic loosening for tibial prosthesis implantation.

This research project has various novel contributions in the field of implant biomechanics research:

- 1) This study demonstrated that the mechanical concerns of bone resorption due to stress-shielding and aseptic loosening have to be considered mutually for the optimisation of different prosthesis designs (Chapter 5.3).
- 2) The consideration of bone remodelling in FE simulations for fixation analyses is paramount as it influences the risk prediction of aseptic loosening between prosthesis designs (Chapter 7.2). The cement stresses and bone-prosthesis interface micromotions predicted were different prior to and after bone adaptation. The impact of this effect was greater for the cemented than the cementless fixation.
- 3) This is probably the first attempt for patient-specific FE modelling predictions to be correlated to component migration of the tibial prostheses measured by RSA (Chapter 6.5). By implementing the strain-adaptive bone remodelling algorithm in FE modelling of the mini-keel and standard stemmed prosthesis fixations, the predicted maximum tensile stresses of the cement underneath the tibial tray correlated well with the component translation and rotation.
- 4) Different load patterns altered the predictions of the magnitude of the bone-prosthesis interface micromotion and the extent of osseointegration onto the prosthesis (Chapter 5.5). Nevertheless, the outcome of design change evaluation in cementless tibial fixation remains unchanged (Chapter 6.3). A straightforward *single non-gait loading condition*, which prescribes joint loads at the centres of the medial/lateral condyles of the tibial tray, is recommended for ease and comparative analysis of risk of aseptic loosening for cementless tibial fixation.
- 5) The initial stability of the tibial component fixation was measured in-vitro using a modified method in which the LVDT was mounted onto the tibial tray instead of attaching to the bone. The resulting measurement of the bone-prosthesis micromotion could be used to provide an indication of the risk of long-term aseptic loosening for different tibial prostheses and implantation methods (Chapter 8).

Although some of the FE models used in the current study were validated with in-vitro and in-vivo test results, the aim of obtaining precise predictions remains a challenge. These are bounded by the accuracy of the materials properties and constitutive models used in the FE codes and the assignment of realistic physiological loading conditions in the FE models. As mentioned by Kuhl (2008), in contrast to

traditional engineering materials, living organisms show the remarkable ability to adapt not only their function, but also their material properties, their internal architecture and their entire external structure to environmental changes. Continuous improvement of the computational models would enable realistic representation of a true clinical case to be achieved.

9.2. Proposed Future Work

The FE models used in this study are capable of simulating the biomechanical and bone remodelling responses in the bone after implantation of a stiff prosthesis. The models also provided possible explanations for the mechanisms of proximal stress-shielding and aseptic loosening after tibial prosthesis implantation. Further improvements to the FE models are recommended as follow:

1) Creep behaviour of bone cement – The cement stresses predicted by FE modelling were found to vary with bone remodelling. However the variation was mainly due to the change in cement deformation as a result of a reduction in the strength of the bone-prosthesis support, but not due to its time-dependent creep behaviour which may have allowed stress-relaxation to occur. Cement degradation due to creep and fatigue could be simulated simultaneously with the bone remodelling process, where a more accurate prediction of the cement fatigue failure leading to aseptic loosening could be achieved.

2) The inclusion of muscle loading – Forces contributed by muscles attached to the knee joint are not considered in the current FE models. Bitsakos et al. (2005) showed considerable differences in the amount of bone loss predicted after total hip replacement for FE models with and without muscle loading. Muscles in the knee contribute greatly to the forces acting on the knee joints during daily activities like walking, stair climbing and standing up from a seated position (Andriacchi et al. 1986). The inclusion of muscle loading in the FE models could generate a better representation of the bone remodelling responses in the tibia after prosthesis implantation.

3) Micro FE modelling of the cementless bone-prosthesis interface micromotion – A mechanically stable bone-prosthesis interface is essential for osseointegration to occur. The interfaces between the bone and prosthesis were modelled at the macro-scale when the relative bone-prosthesis micromotion was predicted. Little is known about the micro-mechanical behaviour at the interface. The intimate interaction between the trabeculae and the pores on the prosthesis surface may provide further insights to the mechanical factors which may help or hinder the osseointegration process.

Last but not least, the author intends to continue to follow-up the in-vivo study in SGH when the RSA results from the subsequent scans at 12, 18 and 24 months become available. It is also of interest for further correlation of the FE predictions with the longer-term component migration to be performed.

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APPENDIX A

Procedure of Mounting Strain Gauge onto Cadaver Bone Surfaces

1. Clean bone off all soft tissues and remove periosteum.
2. Dry the bone thoroughly with tissue paper.
3. Clean SG (strain gauge) site with acetone (or alcohol) and abrade with silicone-carbide paper No. 320/400.
4. Mark SG location.
5. Clean site with CSM-1A (chlorinated degreasing solvent) and wipe with a swab.
6. Follow by M-Prep Neutraliser 5A (ammonia-based neutralising material) and wipe with a swab.

(Steps 7 to 9 for cadaver bone surfaces where fluid is flowing out)
7. *Ensure an air-dried surface, apply a thin layer of adhesive catalyst (M-bond 200 catalyst) and dry for 1 minute.*
8. *Apply 2 drops of adhesive (M-bond 200) to the area and press into a thin layer using finger pressure and a piece of polythene sheet (or spread thinly over the bone surface). Remove the pressure after 1 minute and allow it to harden for another 5 minutes.*
9. *Smooth the area down with No. 400 silicone-carbide paper.*
(this will stop the flow of fluid in the bone surface and allows effective SG attachment)

10. Use adhesive tape to align SG and terminal pad assembly in position on the bone mounting site (alignment by eye with the vertical axis of the bone).
11. Apply a thin layer of M-bond 200 catalyst on both the SG and terminal pad assembly (and bone).
12. After 1 min of drying, apply 2 drops of M-bond 200 to the bone.
13. Press the SG/terminal assembly into position and hold under finger pressure for 1 minute.
14. Solder lead cable to terminal pad, and lead wire from terminal pad to SG.
15. Water-proof the SG and solder leads with polyurethane M-coat A (or nitrile rubber).
16. Check carefully to ensure all edges of the SG and terminal pad are securely adhered to bone.

