OPTIMAL DESIGN OF FEMORAL HIP PROSTHESIS USING TOPOLOGY OPTIMISATION TO REDUCE STRESS SHIELDING

by

MOHAMAD IKHWAN ZAINI BIN RIDZWAN

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LIST OF ABBREVIATIONS

BMC : Bone Mineral Content.

BMD : Bone Mineral Density.

Co-Cr : Cobalt Chromium.

Co-Cr-Mo : Cobalt Chromium Molybdenum.

CT : Computed Tomography.

DEXA : Dual Energy X-ray of Absorptiometry.

ESO : Evolutionary Structural Optimisation.

FE : Finite Element.

FEA : Finite Element Analysis.

MEMS : Micro-Electro-Mechanical System.

PMMA : Polymethylmethacrylate.

PTFE : Polytetrafluoroethylene.

SIMP : Solid Isotropic Microstructure with Penalisation.

THA : Total Hip Arthroplasty.

THR : Total Hip Replacement.

Ti : Titanium.

UHMWPE : Ultra High Molecular Weight Polyethylene.

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GLOSSARY

Arthroplasty	:	Total joint replacement.
Atrophy	:	Continuous decline of a body part or tissue following a period of disuse or immobility.
Biocompatibility	:	The way of the body tissues interact with the biomaterial.
Biomaterial	:	Material of natural or manmade origin that is used to direct, supplement or replaces the function of living tissues.
Bone grafting	:	Bone is removed from a living body and attached to a damaged part.
Distal	:	Farther from any point of reference; opposed to proximal.
Femur	:	Thigh bone.
In vitro	:	Outside the body
In vivo	:	Inside the body
Lateral	:	Lying away from the median and sagittal plane of a body.
Medial	:	In or near a centre or constituting a centre; the inner area.
Osteoporosis	:	Bone becomes fragile and more likely to break.
Pneumonia	:	Difficulty in breathing.
Proximal	:	Situated nearest to point of attachment or origin.

Pulmonary embolism	:	Occurs when there is a blockage of the blood vessels in the lungs.
Resorption	:	The process of resorbing.
Rheumatoid arthritis	:	A chronic disease marked by stiffness and inflammation of the joints, weakness, loss of mobility, and deformity.

LIST OF PUBLICATIONS & SEMINARS

1.1 M. Ikhwan Zaini Ridzwan, Solehuddin Shuib, & Ahmad Yusuf Hassan, "A Review in Stress Shielding Problem", Mechanical Engineering Research Colloquium 2003, Universiti Sains Malaysia, Malaysia, 16 – 17 April 2003.

1.2 M. Ikhwan Zaini Ridzwan, Solehuddin Shuib, Ahmad Yusuf Hassan, Abdus Samad Mahmud, & Jamaluddin Abdullah, "A Review in Topology Optimisation Method and its Current Developments", Entech 2003, Universiti Malaysia Sarawak, Malaysia, 30 July – 1 August, 2003.

1.3 M. Ikhwan Zaini Ridzwan, Solehuddin Shuib, Ahmad Yusuf Hassan, Abdus Samad Mahmud, & Jamaluddin Abdullah, "Effects of Increasing the Load Transferred in Femur to the Bone/Implant Interface", International Conference On Chemical and Bioprocess Engineering, Universiti Malaysia Sabah, Malaysia, 27 – 29th August, 2003.

1.4 M. Ikhwan Zaini Ridzwan, Solehuddin Shuib, Ahmad Yusuf Hassan, A.A Shokri, & Radzuan Razali, "Topology Optimisation of Hip Implant Design", Kuala Lumpur International Conference On Biomedical Engineering, Kuala Lumpur, Malaysia, 2 - 4th Sept, 2004.

1.5 M. Ikhwan Zaini Ridzwan, Solehuddin Shuib, Ahmad Yusuf Hassan, A.A Shokri, & M.N. Mohd Ibrahim, "Design and Optimisation of Hip Prosthesis to Reduce Stress Shielding", OPTI 2005, Skiathos, Greece, 23 – 25th May 2005.

REKABENTUK OPTIMUM ALAT GANTI FEMUR MENGGUNAKAN PENGOPTIMUMAN TOPOLOGI DALAM MENGURANGKAN HADANGAN TEGASAN

ABSTRAK

Kemasukan implan ke dalam tulang paha telah mengurangkan agihan beban semulajadi kepada tulang. Kesannya, ketumpatan dan isipadu tulang menjadi kecil. Implan mula longgar dan menyukarkan pergerakan pesakit menyebabkan pembedahan ulangan perlu dilakukan. Fenomena pengurangan beban ini dipanggil hadangan tegasan.

Kajian ini bertujuan mengenalpasti faktor-faktor berlakunya hadangan tegasan dan menggunakan kaedah pengoptimuman topologi untuk mengurangkannya. Analisa teori rasuk komposit mudah telah digunakan dan membuktikan bahawa bahan dan luas permukaan implan adalah merupakan dua faktor penting yang mempengaruhi agihan beban pada tulang dan implan. Keputusan analisa menunjukkan bahawa bahan yang mempunyai modulus kekenyalan yang lebih tinggi berbanding tulang seperti Titanium (Ti) dan Cobalt-chromium (Co-Cr) akan mengurangkan agihan beban kepada tulang sebanyak 43.04% dan 58.23%. Kewujudan rongga pada implan boleh meningkatkan agihan beban kepada tulang sebanyak 15.19% (iso-elastik), 73.33% (Ti) dan 109.10% (Co-Cr).

Seterusnya, kaedah pengoptimuman topologi digunakan dalam analisis 3 dimensi model implan, simen dan tulang menggunakan perisian ANSYS 7.1. Pengoptimuman dilakukan dengan tujuan untuk meminimumkan nilai kepatuhan implan dalam julat peratus pengurangan isipadunya iaitu sebanyak 30% V_o (isipadu awal) hingga 70% V_o. Analisis dilakukan dengan menganggap bahawa semua model bertindak secara linear, isotropik serta homogen. Titanium dipilih sebagai bahan

implan. Beban serta tindak balas otot (greater trochanter) semasa berjalan telah digunakan. Model dikekang pada hujung bawah tulang pada paksi x, y dan z. Keputusan analisa menunjukkan pengurangan isipadu kepada 50% V_o dan 60% V_o menghasilkan geometri yang boleh diterima pakai (sempadan yang tertutup).

Kedua-dua implan telah dibandingkan dengan implan sebelum dioptimumkan dan tulang tanpa kehadiran implan dari segi agihan tegasannya. Nilai agihan tegasan diambil pada bahagian medial dan lateral tulang, simen dan implan. Keputusan menunjukkan bahawa, tegasan yang dihasilkan oleh kedua-dua implan optimum adalah hampir sama. Agihan beban pada implant optimum meningkat sebanyak 4% berbanding dengan implan konvensional. Walaupun nilai ini tidak terlalu besar namun implan optimum telah berjaya meningkatkan tegasan menghampiri sebagaimana yang berlaku pada tulang tanpa implan terutamanya di sepanjang implan. Oleh yang demikian, ini menunjukkan kehadiran implan optimum dapat mengurangkan hadangan tegasan berbanding dengan implan konvensional.

OPTIMAL DESIGN OF FEMORAL HIP PROSTHESIS USING TOPOLOGY OPTIMISATION TO REDUCE STRESS SHIELDING

ABSTRACT

Introducing an implant into a femur might reduce the natural stress distribution of the femur. The reduction could cause its density and volume shrinkage. The implant starts to loose and causes patients hardly to move, thus needed a revision surgery. The phenomenon of reduction in load was identified as stress shielding.

This study was conducted to find the factors that will contribute to the stress shielding and to apply topology optimisation method to minimise the problem. A simple composite beam theory was used and it proved that implant material and its cross-sectional area would mostly affect the load distribution in femur (F_b/F). The results showed that the implant materials with higher modulus of elasticity compared with femur such as Titanium (Ti) and Cobalt-chromium (Co-Cr) would reduce F_b/F to 43.04% and 58.23%. Hollow implant would increase the F_b/F to 15.19% (iso-elastic), 73.33% (Ti) and 109.10% (Co-Cr).

Topology optimisation method was employed in the analysis of model of implant, cement and femur in 3-dimension by using ANSYS 7.1. The objective of the optimisation was to minimise implant compliance subjected to percentage of reduction in its initial volume (V_o) ranges from 30% V_o up to 70% V_o. The analysis was performed with the assumption that the models responded linearly, isotropic and also homogeneous. Titanium was chosen as an implant material. The load and reaction from muscle of greater trochanter occurred during walking were used in the analysis. Model was constrained at the distal end of femur along x, y and z-axes. Results showed that implant with 50% V_o or 60% V_o would produce closed boundary and hence were acceptable in shape.

Both implants were compared in stress distribution with conventional implant and intact femur (without implant). All values were obtained from locations along medial and lateral sides of femur, cement and implant. Results showed that, stresses produce in both optimum models were very close to each other. Load transfer has increased in femur with the optimised implants almost 4% compared to before optimise in medial and lateral side. Although the differences were not too far, but, it has been proved that optimised implants have tried to bring the stress as closed as in intact femur especially along the length of implants. Hence, it showed that the new optimised implants were better than the conventional implant in order to reduce stress shielding problem.

CHAPTER ONE
INTRODUCTION

1.0 Background

Hips are very important in helping us to accomplish our daily activities such as walking to the workplace, playing games, cycling, getting up from the seat, climbing upstairs etc. Unfortunately, there is no guarantee that our hips will always be in a good condition. Thigh bone or femur can be broken in an accident or damaged by osteoporosis and disease like rheumatoid arthritis. Damaged femur needs to be replaced with an implant through the operation like total hip arthroplasty or hemiarthroplasty.

Over 800,000 artificial hip joints have been implanted worldwide annually (Li *et al.*, 2003) suggesting that it is a successful and well-accepted treatment. However, patients still have possibility of suffering long-term side effect. Many implants are loosened within the femur after 10 years, which eventually leads to implant failure (Kuiper, 1993). Mechanical loosening of the implant is one of the most frequent complications after hip replacement which resulted from implant movement or migration in the bone or cement (Tang *et al.*, 2002). Implant position may slightly change in comparison to its initial location resulting from loss of bone mass. This has been a result of stress shielding and occurs in cemented and cementless implants.

Based on the principle known as Wolff's Law, stress shielding refers to the tendency of bone to atrophy when it does not receive adequate mechanical loading. Originally, the bone carries its external load by itself. When implant is introduced into the femur, now the bone has to share the load and the carrying capacity with the implant. As a result, the bone is subjected to reduced stresses, and hence stress shielded (Huiskes *et al.*, 1992). Many studies have demonstrated that there would be a reduction in stress and relative density occurred in a proximal femur after arthroplasty. Figure 1.1 shows the distribution of bone relative density measured before and after the implantation. The cortical wall became thinner in the proximal medial part and thicker in the distal part. Areas of bone experiencing high stress will react by increasing the bone mass, while areas under lower stress will react by decreasing it. This phenomenon is actually similar as in application of topology optimisation. In this method, domain or design space is optimised based on loads and boundary conditions that we placed. During optimisation, region with high stressed will be kept and remained in a final solution whereas region that experienced low stress will be removed from initial domain.

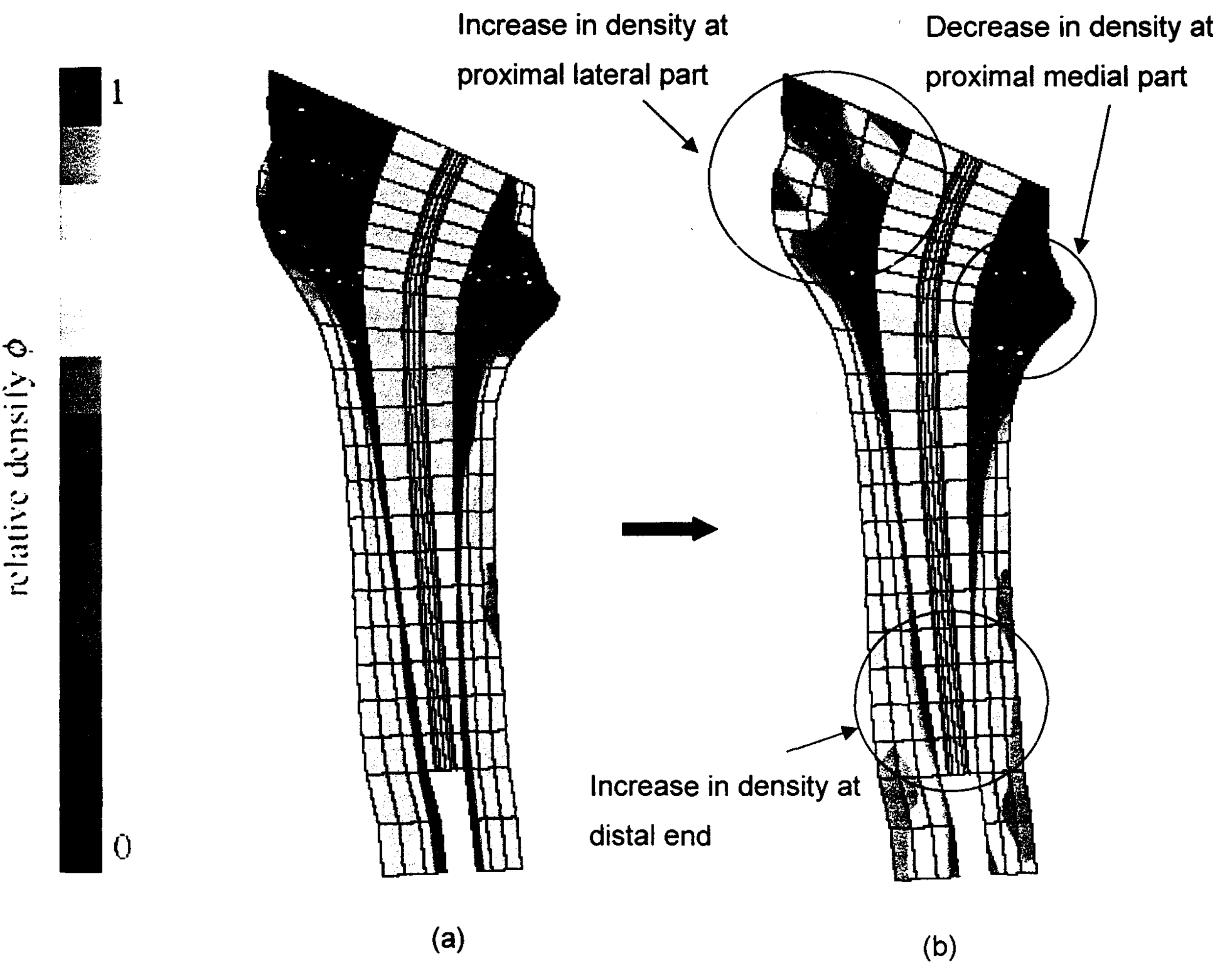


Figure 1.1: Bone remodelling in hip joint prosthesis. (a) Initial relative density distribution and, (b) final relative density distribution. After remodeling, densification occurred at the distal end of the stem and resorption at the proximal medial part of the femur (Terrier, 1999).

Stress reduction observed in implanted bone will lead to bone resorption and implant loosening. It can cause difficulties to patients, thus they might require a revision surgery.

1.1 Scope of Work

This work is focused on the design of an implant in order to reduce the problem of stress shielding. The implant will be design such that, it will take less amount of load, thus the bone will receive load as close as before implanted. For that purposes, the factors that have a major effect to the problem needs to be identified. By knowing these factors, a good implant that can reduce the problem can be proposed.

There are two methods that will be implemented in this work. The first method is a simple theory of composite beam to find the contribution factors to the increasing or decreasing of loads transfer to the bone. The second method is to obtain an optimum implant that can reduce the problem of stress shielding by using topology optimisation method. The optimum implant will be compared to the reference implant.

1.2 Objectives

The main objective of this study is to reduce the problem of stress shielding after hip replacement. In order to achieve the above objective, the following sub-objectives were identified: -

1. To determine the factors that will contribute to the problem.
2. To apply topology optimisation method to minimise the problem.
3. To demonstrate the effectiveness of the method in achieving optimised implant.

Figure 1.2 shows an overall flowchart of the methodology to achieve the main objective.

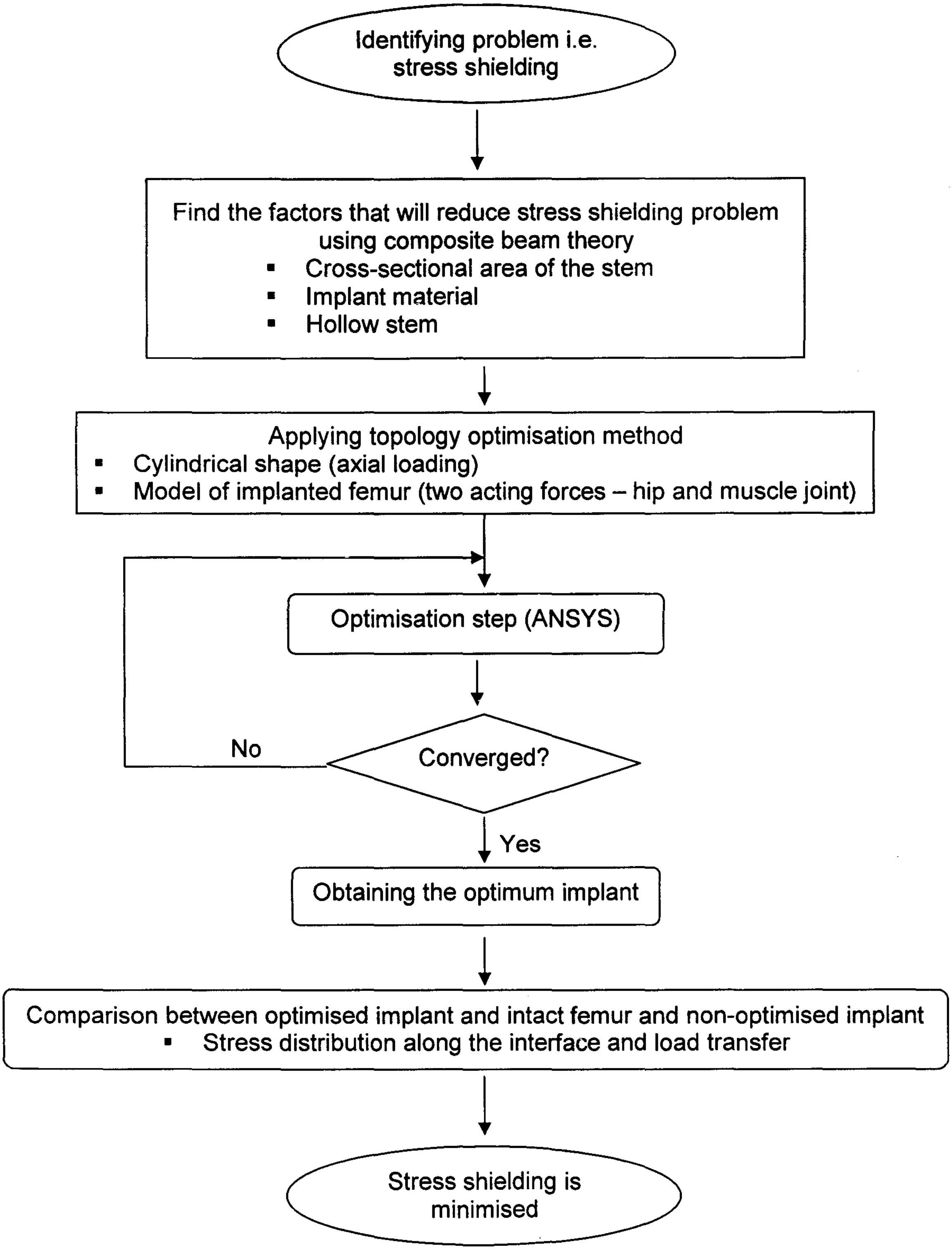


Figure 1.2: Overall flowchart of methodology

1.3 Thesis Outline

This thesis is divided into seven chapters. Chapter One introduces THR and an overview of the way implant is fixed into the femur. It also addresses a long-term effect such as stress shielding that occurs after hip replacement to some of the patients. In Chapter Two, the detailed discussion of stress shielding problem and the conditions for improvement and eradications are presented. It also reviews previous implant designs in order to reduce the problem. Chapter Three extends the problem factors from mathematical viewpoint. This is to prove that there are two important factors that will contribute to the associated phenomenon i.e., selected implant material as well as a cross sectional area of the implant. Chapter Four introduces topology optimisation method and tries to solve simple cylindrical hip stem by using finite element (FE) software, ANSYS 7.1. Chapter Five validated the method in the design of an optimum three-dimensional implant. The concept and approach is explained systematically. A stem topology is optimised to achieve a minimum compliance subjected to several sets of its volume reduction. A comparison between the stress distribution in intact and implanted femur with optimal design is being carried out. Chapter Six discusses the results obtained and the last chapter (Chapter Seven) summarises the contributions of the work and presenting future directions and extensions of the thesis.

CHAPTER TWO
LITERATURE SURVEY

2.0 Introduction

For the past few decades, various studies in hip replacement joint have been carried out in order to improve the performance of hip implant. Most of them were trying to make the artificial joint behaves like the normal joint. Design aspects like stem – bone bonding, the most suitable implant material and shapes, the stability of the implant inside the femur and bone reaction along interface, the effects to the patients' routine life etc have been given the greatest consideration. This chapter starts with a brief discussion about hip joint and focus on the anatomy of the femur. Furthermore, the causes of hip replacement, how implant is fixed inside the femur and several of implant material that are usually used are mentioned. Detailed discussion of stress shielding problem and the conditions for improvement and eradications are presented. It also reviews previous implant designs in order to reduce the problem.

2.1 Hip Joint

The hip joint as shown in Figure 2.1 is located at the upper part of thigh bone or femur at which it meets the pelvis. A ball (femoral head) at the top of femur fits into a rounded socket (acetabulum) in pelvis. Normally, all of these parts work in harmony by allowing us to move easily without pain. The femur is the longest and strongest bone in human body. Its length is necessary to accomplish the biomechanical needs of gait. It is nearly cylindrical throughout its length.

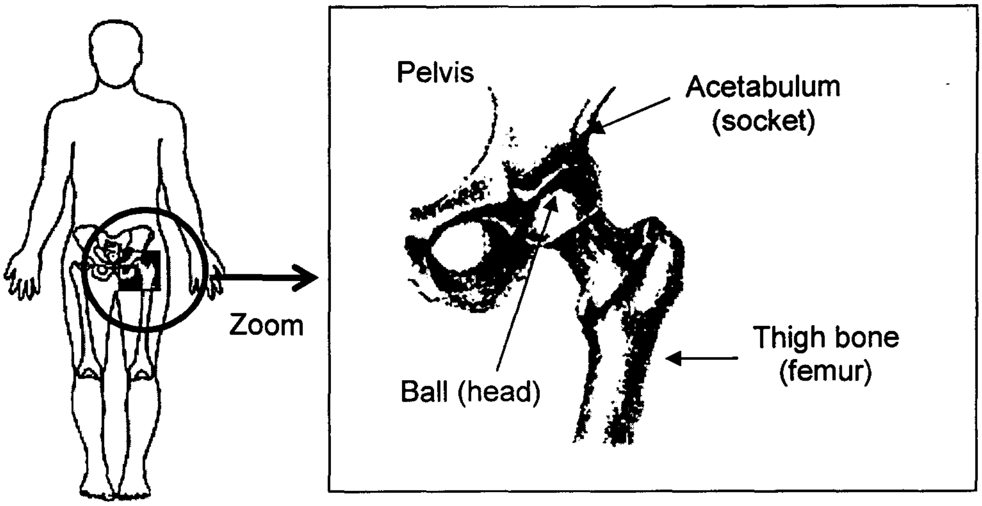


Figure 2.1: Normal hip (Callaghan *et al.*, 1997).

The femur consists of two parts that are cortical bone, which is the denser bone that makes up primarily the shaft of long bone and cancellous bone, which is also known as trabecular bone, the porous bone that makes up the end of a long bone. Figure 2.2 illustrates the anatomy of the femur showing cortical bone and cancellous bone.

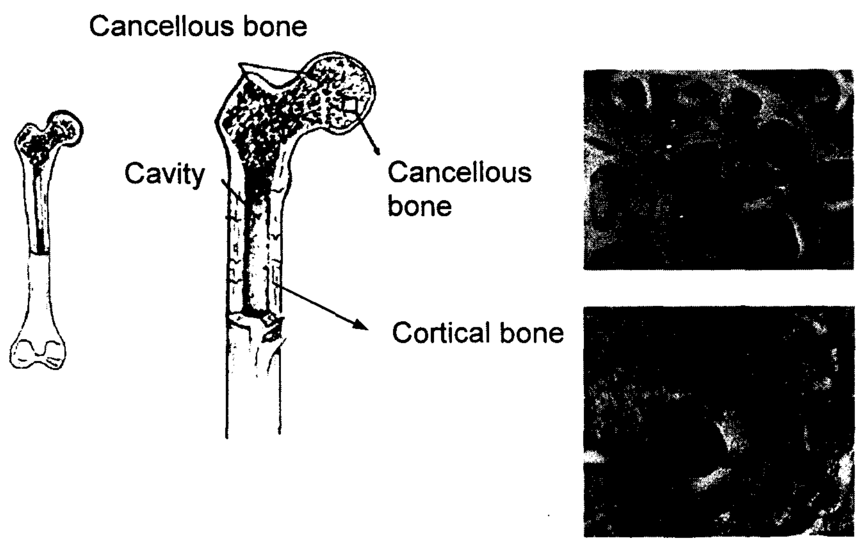


Figure 2.2: The illustration of the femur anatomy (Terrier, 1999).

Table 2.1 below summarised the mechanical properties of cortical bone and cancellous bone obtained from several authors based on different method of measurements.

Table 2.1: Mechanical properties of the femur.

Parts	Modulus of Elasticity, E (GPa)	Method of Measurement	Authors
Cortical bone	17	Computed Tomography (CT) Scan with an assumption that the cortical bone behaves in linear elastic, isotropic and homogeneous throughout the femur	Duda *et al.* 1998
	17	CT Scan with an assumption that the cortical bone behaves in linear elastic and isotropic	Kleemann *et al.* 2003
	20.3	CT Scan with an assumption that the cortical bone behaves in linear elastic, isotropic and inhomogeneous	Bitsakos *et al.* 2005
Cancellous bone	1.5	CT Scan with an assumption that the cancellous bone behaves in linear elastic, isotropic and homogeneous throughout the femur	Duda *et al.* 1998
	The value were varied 2.0,1.0,0.5 and 0.25 from proximal to distal	CT Scan with an assumption that the cancellous bone behaves in linear elastic and isotropic	Kleemann *et al.* 2003
	0.47 MPa	CT Scan with an assumption that the cancellous bone behaves in linear elastic, isotropic and inhomogeneous	Bitsakos *et al.* 2005

The femur as shown in Figure 2.3 can be divided into several zones such as proximal (upper), distal (lower), medial (inside) and lateral (outside). These zones will be repeatedly mentioned in the forthcoming chapters.

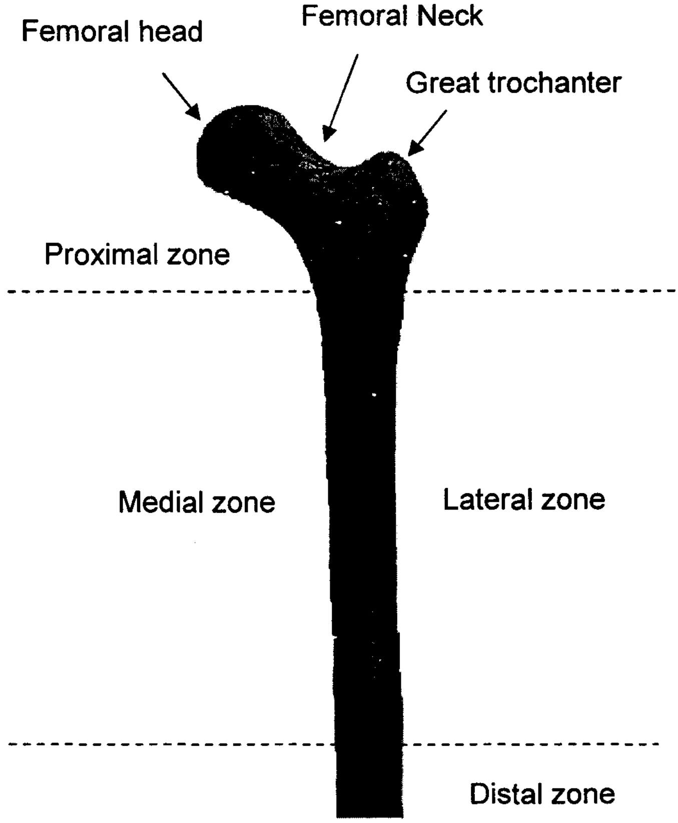


Figure 2.3: Zones in standard femur.

2.1.1 Hip Joint Replacement

The hip joint can fracture and damage due to various reasons such as involving in road accident, falling down stairs, osteoporosis, or disease that affects joint tissue like rheumatoid arthritis. The hip fracture is a serious injury that can occur to anybody. Buford and Gosawami (2004) mentioned that, in a year 2000 alone, almost 11% from 500,000 operations were performed in The United States of America for patients aged within 40 years. Hip fracture can lead to permanent disability, pneumonia, pulmonary embolism and death. Worldwide, Keyak and Falkinstein (2003) stated that, the numbers of hip fractures are expected to increase to over 6.26 million in the year 2050.

Most of the patients with fracture hip experience difficulty in doing their routine activities. Consequently, they require hip replacement or arthroplasty to overcome this difficulty (Lieberman *et al.,* 2003). A hip replacement is a procedure of replacing the diseased hip joint with a new artificial part called prosthesis. It is used to transfer load from the acetabulum to the femur through a metal stem that is inserted into the femur (Terrier, 1999). The procedure is aimed to relieve the pain and improve mobility.

The hip replacement operation can be either total hip arthroplasty (THA) or hemiarthroplasty. Normally in the total hip replacement (THR), the implant consists of three parts, which are: -

1. The stem that fits into the femur and provides stability.
2. The ball that replaces the spherical head of the femur.
3. The cup that replaces the worn-out hip socket.

Meanwhile, for hemiarthroplasty, the implant consists of only two parts: the stem and the ball. In this procedure, the normal hip socket is still being used. Each part comes in various sizes in order to fulfil various body sizes and types. In some design, the stem and the ball are one piece, other design are modular, allowing for additional customisation in fit. Figure 2.4 shows the separated components of hip implant.

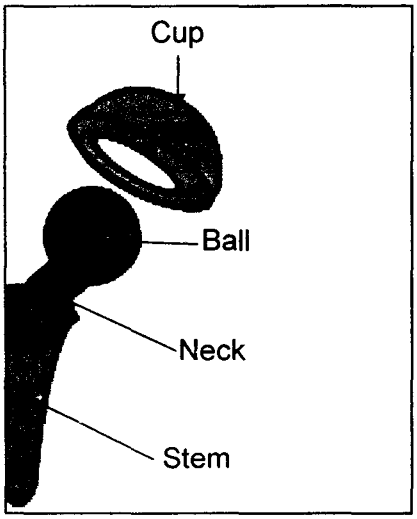


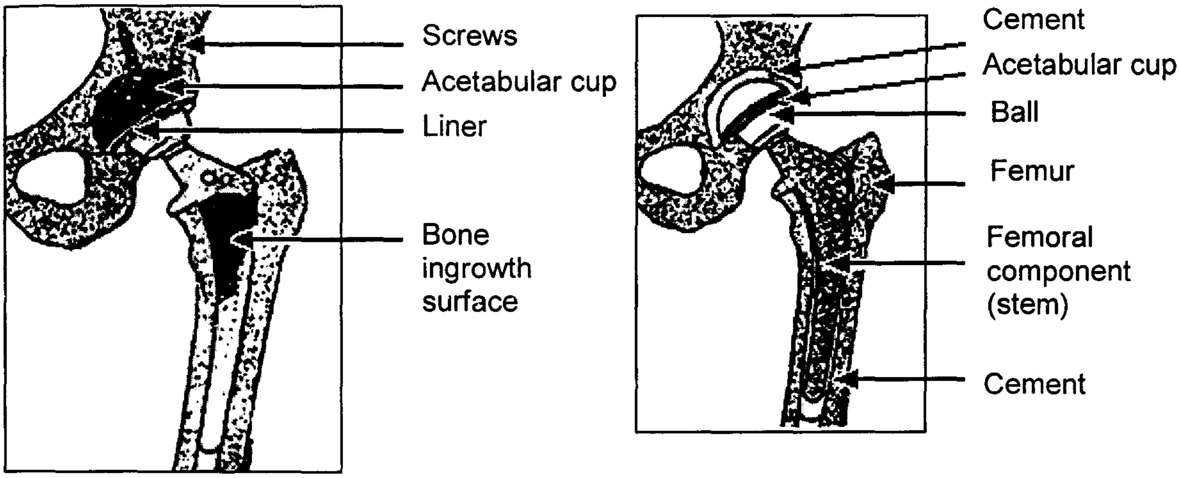
Figure 2.4: Components in hip prosthesis.

During THR, the surgeon will remove the damaged femoral head and drill a hole at the centre of the femur. The head will be replaced with a ball and a long femoral stem in which its size is equal or less than the size of the canal will be inserted into it to support the artificial joint so that it will be in place. Meanwhile, a new acetabular cup is implanted securely within the prepared hemispherical socket. Li *et al.* (2003) reported that, more than 800,000 patients all over the world have undergone the replacement operation for their broken and damaged femur suggesting that it was a well-accepted and successful treatment.

2.1.2 Stem Fixation Techniques

Hip implant can be placed permanently in the femur by using two different methods. It can be either cementless (non-cemented) design or cemented design. In cementless design, the surface of the stem is designed to be more porous in order to facilitate the growth of bones on its surface. By using this method, the prosthesis as shown in Figure 2.5(a) will be tied up with the femur. Hence, it requires a longer healing time because it depends on a new bone growth for stability. The first femoral implant to demonstrate the possibility of biological fixation was developed by Austin-Moore in the early 1950s.

Cementless prosthesis was used exclusively before 1958 (Kuiper, 1993). However since early 1960s, the use of polymethylmethacrylate (PMMA) or bone cement for stem fixation has been the gold standard in THA (Ranawat *et al.*, 2004). This method was also known as cemented total hip arthroplasty, which was first introduced by Sir John Charnley in 1961 as shown in Figure 2.5(b).



(a) (b)

Figure 2.5: (a) Cementless design and (b) cemented design (Callaghan *et al.*, 1997).

There were two reasons for introducing of bone cement. First was to prevent local stress concentrations and second was to stabilise the prosthesis inside the femur. Although it was very successful for some patients but there was an increase in femoral component failure cases for younger and the heavier patients (Kuiper, 1993). The factors that influence arthroplasty success with a cemented femoral stem were patient selection, implant geometry and its surface finish and surgical technique (Berry, 2004).

2.1.3 Material

There are two primary issues in material science about bone replacement material. They are mechanical properties and biocompatibility (Katti, 2004). The term *biocompatibility* can be briefly described as the way of the body tissues interact with the biomaterial. *Biomaterial* is defined as a material of natural or manmade origin that is used to direct, supplement or replaces the function of living tissues (Katti, 2004). As with all foreign objects in the body, a hip implant may stimulate an auto-immune response, which could be ruinous for the success of the implant. The materials selected should minimize the risk of rejection.

Hip implant has been made using variety of materials such as metals, ceramics, polymers and composites. In early 1960s, the stainless steel femoral total hip replacement (THR) component was mated with a polytetrafluoroethylene (PTFE) acetabular cup. However due to poor wearabality, the stainless steel was replaced by the Cobalt-chromium-molybdenum (Co-Cr-Mo) alloy, whereas the PTFE was replaced by ultra high molecular weight polyethylene (UHMWPE). Both materials have shown a good wear resistance. Wear might occur on surfaces which are always in contact especially when the ball is articulating within the acetabular cup in every patient's movement. As well as metals, ceramics like alumina and zirconia are also widely used as a femoral head. In fact, it has been reported that wear rates for alumina on UHMWPE are 20 times less than metal on UHMWPE (Katti, 2004).

The Co-Cr-Mo is about 10 times stiffer than femur, whereas the alumina is about 19 times stiffer than femur as shown in Table 2.2. These differences can be a significant problem associated with stress shielding, which is directly related to the difference in stiffness of the femur and the implant material. Titanium (Ti) alloy has low modulus of elasticity as compared to Co-Cr-Mo alloy and alumina. It is also shown improvement in wear properties, even it is much lower when compared to Co-Cr-Mo alloy and ceramic but it has the highest fatigue strength among all alloys reported. Hence, it can be a suitable candidate for THR components.

Table 2.2: Mechanical properties of alloys, polymers and ceramics used in total hip replacement.

Materials	Tensile strength (MPa)	Elastic modulus (GPa)
Alloy		
• Co-Cr alloys	655-1896	210-253
• Co-Cr-Mo	600-1795	200-230
• Ti-6Al-4V	960-970	110
• Stainless steel 316 L	465-950	200
Polymers		
• UHMWPE	21	1
• PTFE	28	0.4
Ceramics		
• Zirconia	820	220
• Alumina	300	380

2.2 Revision Surgery

Although patients will be able to return and enjoy their activity even not as active as before the operation, the possibility for revision surgery still exists. The term revision surgery is used when replacing a previously replaced hip joint. Almost 10% from overall operations would undergo for revision surgery (Kuiper, 1993). However this situation depends on patients' conditions and types of prosthesis that were used. For heavier patient and age 30 years old during the operation, nearly 33% of them will need to do the revision operation after 10 years.

Based on the research conducted by Malchau *et al.* (2000), there were almost 20% of 10,000 operations made in Sweden would go for revisions which 7% from it used cemented femur and the other 13% used cementless design. The risk of revision operation is extremely high especially to elderly patients and its complications include cardiac problem, pulmonary problem and mortality (Pagnano *et al.*, 2003). Hence, the possibility for it to occur should be minimized.

Havelin *et al.* (1993) also did the same survey in Norway from September 1987 to end of 1990 where the most common reasons for revisions were loosening of the stem, which contributed almost 64%. In other survey performed by Malchau *et al.* (1993) in Sweden from 1987 to 1990, 79% of all revisions were due to implant loosening. Implant loosening is a mode of failure resulting from implant movement or migration in the bone or cement. The most common cause of implant loosening is the loss of bone mass due to stress shielding (Huiskes *et al.*, 1992; Tang *et al.*, 2002).

2.2.1 Stress Shielding

Stress shielding in femur occurs when some of the loads are taken by prosthesis and shielded from going to the bone (Kuiper, 1993; Paul, 1999). Normally, femur carries its external load by itself where the load is transmitted from the femoral head through the femoral neck to the cortical bone of the proximal femur as shown in Figure 2.6 (a). When stiffer stem is introduced into the canal, it shares the load and the carrying capacity with bone. Originally, the load is carried by bone, but it is now carried by implant and bone. As a result, the bone is subjected to reduced stresses, and hence stress shielded (Huiskes *et al.*, 1992). The upper part of the femur receives fewer loads. The stress shielded area is whiter as shown in Figure 2.6 (b). The femur around the distal end of the femoral component is overloaded (darker area as shown in Figure 2.6 (b)).

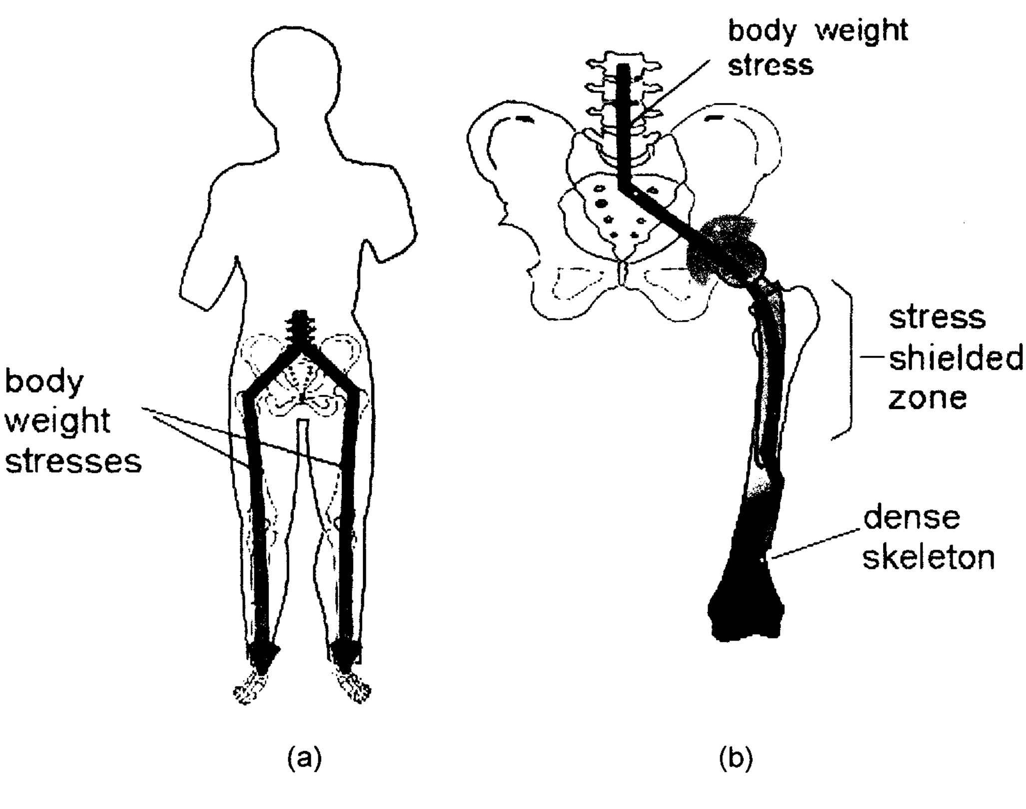


Figure 2.6: Simple scheme of stress shielding (Surin, 2005).

Based on Wolff's law, a bone develops a structure most suited to resists the force acting upon it. Areas of bone experiencing high load or stress will respond by increasing bone mass, and areas under lower load or stress will respond by decreasing bone mass (Bugbee *et al.*, 1996). Decreasing in bone mass is known as bone resorption, may lead to the loosening of failure of the implant.

Most of the previous work quantified the stress shielding in implanted femur from the stress differences with intact femur. Typically a finite element model of the femur is used to calculate the stresses in the bone. Then the change in stress, caused by the introduction of the implant, is used as a comparison. Joshi *et al.* (2000) measured the stress shielding from the difference in the stress for each element in the bone before and after THA was calculated and divided by the stress occurring in the element pre-THA. This ratio was then volume-averaged over a specific region. Weinans *et al.* (2000) defined the stress shielding as a change in strain energy (SE) in each element of the implanted bone relative to a reference value of SE in the intact bone as in eq. (2.1).

$$\text{Stress shielding} = \frac{\text{SE(treated) - SE(reference)}}{\text{SE(reference)}} \qquad (2.1)$$

Where the strain energy (SE) is calculated as the strain energy density divided by the apparent density. Other definitions related to stress or strain might be applicable as well. Gross and Abel (2001) measured the stress shielding by taking the ratio of maximum bone stress that occur in implanted femur to the reference implant.

The location where stress shielding occurs can also be determined in finite element model as shown in Figure 2.7 (Swanson *et al.*, 1977). The analysis compared the stress distribution occurred in intact (without implant) and after implanted at 16 different points along medial and lateral sides. As shown in Figure 2.7(a) and (b), the stress in each point (noted as O) was reduced after the implant had been inserted into the femur. This reduction occurred both in medial and lateral side. The most differences in stress occur at the proximal medial part similar as in Terrier (1999).

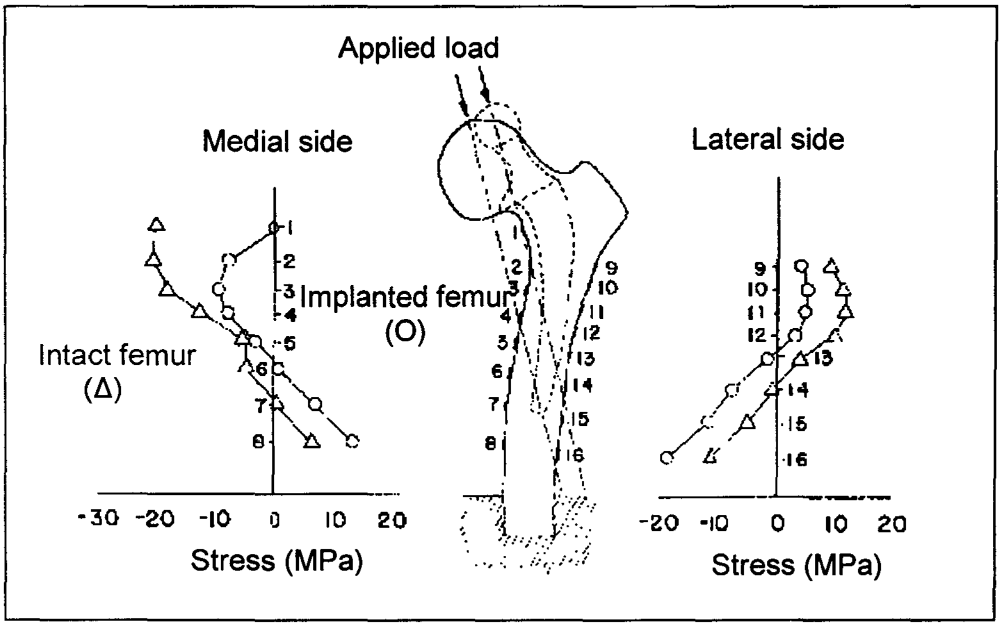


Figure 2.7: Stress distribution along medial and lateral sides when 4 000 N applied load was given onto proximal head (Swanson *et al.,* 1977).

Other example of the stress shielding phenomena is shown in Figure 2.8. This figure showed a comparison between the bone stresses that occur in a noncemented femoral stem and cemented stem at the same external loads. The stress shielding is clearly reduces from proximal to distal. Below the tip of the stem the stresses are again normal. The amount of stress shielding is more severe for noncemented stem as compared to cemented due to the difference in flexibility of the two methods of fixation. The size of noncemented stem is larger than cemented stem, hence stiffer and takes away more load from the bone, thus create more stress shielding.

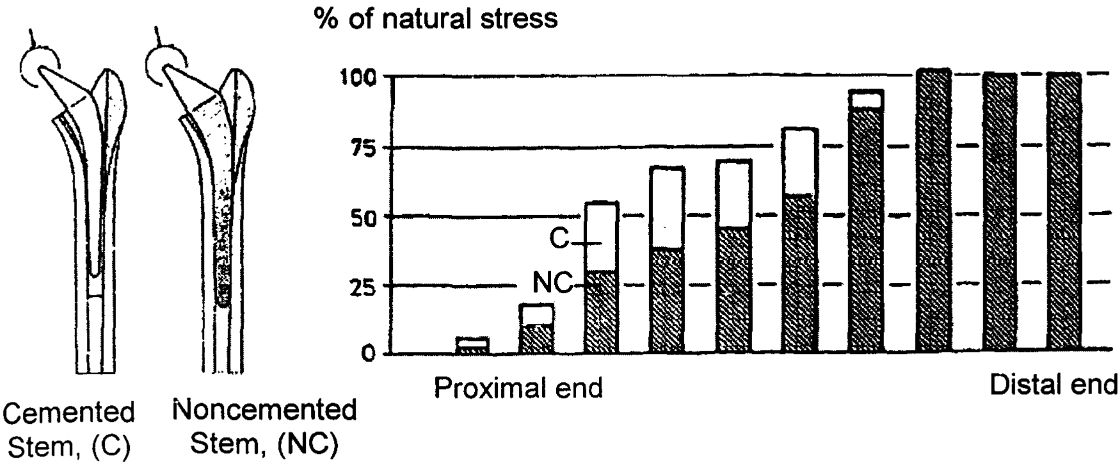


Figure 2.8: An illustration of stress shielding around a cemented (C) and a noncemented (NC) femoral stem. The cortical bone stresses are shown, in each case, as a percentage of the natural case for the same hip joint load if the stem were not present. The difference between natural and actual is the extent of stress shielding (Huiskes, 1993).

2.2.2 Bone Loss

Stress reduction observed in implanted bone will lead to bone loss. Niinimäki *et al.* (2001) defined bone loss as the difference between the operated and the non-operated sides. If is seen through x-ray film, there will be small gaps along bone/implant interface. Dual Energy X-ray of Absorptiometry (DEXA) is a widely used method for quantifying bone mass and bone mineral density (BMD) at the lumbar spine, proximal femur, distal radius, and other skeletal sites. Lozynsky *et al.* (1996) quantified the bone mineral content (BMC) and bone mineral density (BMD) of proximal femur in autopsy retrieved from cemented femoral stems. DEXA radiographic analysis was used to quantify bone content and density in 13 femurs containing cemented implants with duration of 12-191 months. The proximal region had the greatest bone loss, on average 40%. McAuley (2002) also reported that out of 426 patients that used cementless stem; on average 24% of them show loss of BMC.

All of these data proved that, there would be a reduction in volume of femur after hip replacement operation. The changes in bone's volume and mass will take a few years, as its reaction to outside environment is too slow (Bagge, 2000). However, after certain period of time, the implant will no longer stabilise in femur. Stress shielding reduces the support of the implant and therefore increases the risk of implant loosening. The effects from implant loosening and micromotion of prosthesis relative to femur can cause difficulties to patients whenever they do daily activities. If this situation continues, revision surgery will be most beneficial and likely to be carried out.

However, the bone around the removed femoral component has less bone stock. Therefore, the new implant needs to be longer and thicker so that it will be stabilised steadily in the bone. But, the same problem like stress shielding may occur. The new implant possibly works for another years until it will loose again and needs to be replaced. Normally, this process does not continuously occur. There must be some limit such as how many years as one can expect to keep a series of prostheses depends on patient's bone stock. After that, patient needs to consider bone grafting. Thus, after considering this entire problem, the phenomena like stress shielding must be eliminated.

2.3 Implant Design to Reduce Stress Shielding

Almost all of the previous works that have been carried out to reduce stress shielding problem focused on stem design. Aspects like stem stiffness, geometry and shape had been getting serious attentions by most of the authors.

2.3.1 Implant Stiffness

Decreasing stem stiffness would be expected an increase in load transfer from the stem to the proximal femur, hence decreasing the stress shielding (Diegel *et al.*, 1989). Stem stiffness was influenced by implant material and its cross sections.

The modulus of implant materials is a core factor in adequate transfer of stress to the surrounding bone. The elastic modulus of the stem (e.g. Cobalt Chromium is 200 GPa) is typically much higher than the cortical bone it replaces i.e. 20.3 GPa (Bitsakos *et al.* 2005). The more rigid the stem, the less load it transfers proximally so the greater the stress shielding of the proximal femur. By decreasing the implant modulus of elasticity enhances implant-to-bone stress loading and can minimize bone atrophy due to stress shielding.

The effects from flexibility of implant material towards stress shielding have been studied by Bobyn *et al.* (1990). Two porous-coated femoral implants of substantially different stiffness were compared, i.e. cobalt-chromium (Co-Cr) alloy and titanium alloy. Femur with the flexible stems consistently showed much less bone resorption than those with the stiff stems. This finding was also verified by Sumner and Galante (1992) who did the experiments to the canine using a low stiffness cementless porous-coated stem. The result showed that the bone loss in its proximal part was reduced. Although the flexible stem can reduce stress shielding problem and bone resorption when compared to rigid stem, however it has also increased the stress along proximal implant/bone interface and may possibly leads to implant failure (Huiskes *et al.*, 1992).

Foam metals, which are basically metal-air composites, are also one possible solution to reduce elastic modulus of implant. As porosity increases, Young's modulus will decrease. Rahman and Mahamid (2002) have tried to use cellular metallic alloy implant which was more compliant and acts nearly as a normal femur. The cellular implant has a topology like a spongy bone and it has increased the load transfer to the bone when compared to the solid implant. Hence, may slow down the potential for stress shielding to occur. However, one of the undesirable effects is that the strength of the foamed metal also decreases significantly as the porosity increases.

Modifying the stem cross-section can reduce its flexural stiffness. Thicker stem will take more loads from the bone when compare to thinner stem. From radiographics findings by Jergesen and Karlen (2002) to the patients with larger stems showed higher grades of stress shielding compared with femur implanted with medium stems and small stems. Most of the current designs are to develop a stem geometry that restores, as much as possible, the natural load-transfer mechanism through the proximal femur.

Munting and Verhelpen (1995) have designed an implant without stem that was different from the conventional concept. The implant was fits into the femoral neck and strongly supported by several trans-tochanteric screws. Form their in-vitro experiments showed minimal micromotion and from the short-term clinical studies have shown low initial failure rates. However Munting has claimed that the stemless implant was effective for short term fixation and besides there were no significant data or results proving that the problem can be reduced in real situation.

Joshi *et al.* (2000) work was an extension to Munting and Verhelpen (1995). He and his colleagues designed the prosthesis with a new geometry. According to him, the shortened stem can reduce stress shielding problem and shear stress along the interfaces. He used a rectangular plate to uniformly distribute the stress throughout the femur and the implant. A few cables as shown in Figure 2.9 have been used to support the implant. Then the design was compared with Munting's work and conventional design by various regions on femur using FEM and it showed less of stress shielding everywhere except at underneath of the greater trochanter.

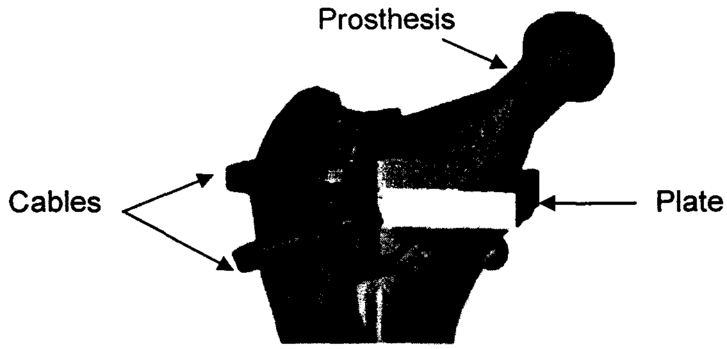


Figure 2.9. Schematic design for shortened implant as been suggested by Joshi *et al.* (2000).

Niinimäki *et al.* (2001) used DEXA to measure the BMD in 24 patients with total hip replacement using a short anatomic femoral stem. The results show that the proximally porous-coated short anatomic stem seemed to be better for bone mass preservation than cemented and longer stiff prostheses.

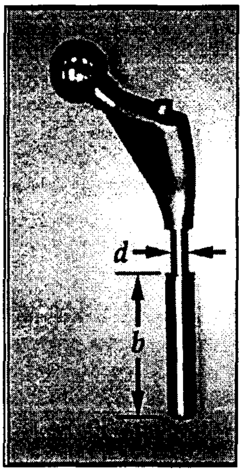
However in other work done by Rietbergen and Huiskes (2001) to investigate the effects of reducing stem length to load transfer in ABG (Anatomique Benoist Girard) hip prosthesis, it was found that by reducing the length can hardly increased interface failure probability. The short design might also have other disadvantages such as the possible of loss of initial stability and are not positioned correctly during an operation.

2.3.2 Optimising Implant

Mattheck *et al.* (1990) analysed a hollow stem prosthesis using FEM and found that the hollow geometry helps to decrease the stress peak beneath the tip of the prosthesis, while at the same time increases the stress in the proximal cortical bone about 20%. The increase in the loading of the bone causes a reduction in stress shielding in this region. Schmidt and Hackenbroch (1994) studied 40 patients that implanted with the hollow stem. From their clinical results, they found that after one year, the implantations were very satisfactory and no thigh pain has been reported, which is probably due to the effectiveness of the increased elasticity and the better fit of the stem.

Gross and Abel (2001) optimised a hollow stem to reduce stress shielding and simultaneously reduced the maximum stress occurred in cement. The implant inner diameter was chosen as a design variable and cement stress was selected as the design constraint. The stress distribution in hollow optimised stem was compared with reference solid stem. However, the study only used a cylindrical shape with a simple point load and boundary conditions.

Chang *et al.* (2001) designed a thin mid-stem diameter to maintain satisfactory stability. Two variables were selected in order to improve load transfer by reducing cross-sectional area of the stem and to increase stability of the implant within the bone. The two variables were shown in Figure 2.10.



b – The distance from distal end

d – Reduced stem diameter

Figure 2.10. Implant designed proposed by Chang *et al.* (2001).

Table 2.3 summarised the objectives done by other people in the literature in order to reduce the stress shielding problem.