

DETERMINATION AND EVALUATION OF S/N CURVES FOR TiN AND ZrN COATED 316 L HIP STEMS

A Thesis Submitted to the
Graduate School of Natural and Applied Sciences of
Dokuz Eylül University
In Partial Fulfillment of the Requirements for
the Degree of Master of Science in Metallurgical and Materials Engineering,
Material Sciences Program

**T.C. YÖKSEKÖĞRETİM KURULU
DOKÜMANTASYON MERKEZİ**

by
N. Funda AK

July, 2002
İZMİR

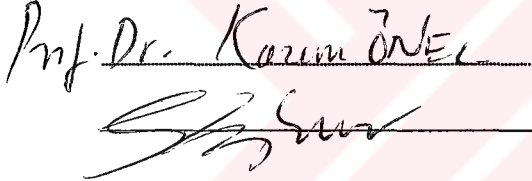
Ms. Sc. THESIS EXAMINATION RESULT FORM

We certify that we have read the thesis, entitled “Determination and Evaluation of S/N Curves for TiN and ZrN coated 316 L Hip stems” completed by N.Funda AK under supervision of Prof. Dr. Ahmet ÇAKIR and that in our opinion it is fully adequate, in scope and in quality, as a thesis for the degree of Master of Science.

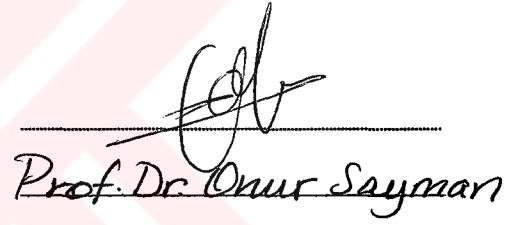


Prof. Dr. Ahmet ÇAKIR

Supervisor



Committee Member



Committee Member

Approved by the
Graduate School of Natural and Applied Sciences



Prof. Dr. Cahit Helvacı

Director

ACKNOWLEDGEMENTS

There are many people who have made a difference to my master program, and I would like to specifically name a few. First, I would like to acknowledge Prof. Dr. Ahmet akır, my supervisor, for training me in effective research and experimentation. Whenever I had a problem or question regarding my research, he was available and eager to help in any possible. I wish to thank him for entrusting me with the set up and management of this experimental study. This has given me a unique and valuable opportunity for training.

A crucial part of this study consisted of computer modeling of prosthesis, and would not have been possible without the support of Zeki Kırıl, who was generous with his time and expertise.

I'd like to extend my appreciation to my friends and colleagues, Bahadır Uyulgan, aęrı Tekmen and İsmail Özdemiş, for their big help and friendship.

Finally, I would like to thank all my family members whose support and persistence have made it possible for me to accomplish this task.

N. Funda AK

ABSTRACT

Objective of this study is to perform fatigue testing of the total joint replacements made of 316L stainless steel to validate the safety of the component before clinical use. Thompson hip prosthesis was tested by using double cantilever beams bending machine designed and manufactured at Department of Metallurgical and Materials Science Engineering. The physiological environment, namely the body fluid, can be very corrosive for implant materials. In order to ensure the safety of a hip prosthesis against corrosion fatigue failure, fatigue tests must be performed in a corrosive medium with low frequency load application. Component fatigue tests were therefore performed in Ringer's solution (0.9% NaCl) at a frequency of 10 Hz in accordance with ISO 7206/4 standard. At this rate, a single hip stem fatigue test requires 11,5 days of continuous testing without any failure for a numbers of 10^7 cycles.

Like mechanical testing, FEA has been applied to orthopaedic implants. 3-D model of prosthesis was constructed and loaded in a static manner by means of IDEAS to investigate stress distribution occurred the stem of hip prosthesis. As a result of static analyses of hip stem, stress concentration area corresponding to tensile stress presented on latero-anterior stem portion, was found to be located approximately 10 millimeters above the cement surface. It was determined that the maximum stress values computed under different loads were proportional to the applied loads.

ÖZET

Bu çalışmanın amacı, klinik kullanımdan önceki yorulma hasarına karşı güvenilirliğini geçerli kılmak üzere, 316L paslanmaz çelikten imal edilmiş kalça protezlerinin yorulma deneylerinin yapılmasıdır. Metalurji ve Malzeme Mühendisliği bölümünde dizayn edilip imal edilen çift ankastre eğmeli yorulma makinası kullanılarak, Thompson kalça protezi test edilmiştir. Fiziksel çevre yani vücut sıvısı implant için korozyon olabilmektedir. Korozyon yorulmasına karşı kalça protezinin güvenilirliği açısından, yorulma deneyleri bir korozyon ortamı içerisinde, düşük frekanslı yükleme uygulaması ile gerçekleştirilmelidir. Protezin yorulma deneyleri bu yüzden, %0.9 NaCl Ringer solüsyonunda, 10 Hz yükleme frekansında, ISO 7206/4 standardına uygun olarak yapılmıştır. Bu frekansta, tek bir protezin yorulma testi için 10^7 çevrim sayısında herhangi bir hasar oluşmadan 11,5 gün gerekmektedir.

Mekanik test gibi, sonlu elemanlar yöntemi de ortopedik implantlara uygulanmıştır. Protezin üç boyutlu modeli IDEAS programı ile oluşturulup statik olarak yüklenerek, protezin sap kısmında oluşan gerilme dağılımı tespit edilmiştir. Bu statik yükleme sonucunda çekme gerilmesine karşılık gelen gerilme yoğunlaşma bölgesi, sap boyunca dış-ön yüzde, çimento yüzeyinden yaklaşık 10 mm kadar yukarıda oluşmaktadır. Farklı yükler altında hesaplanan maksimum gerilme değerlerinin uygulanan yük ile orantılı olduğu tespit edilmiştir.

CONTENTS

	Page
Acknowledgements.....	I
Abstract.....	II
Özet.....	III
Contents.....	IV
List of Tables.....	IX
List of Figures.....	X

Chapter One

INTRODUCTION

Introduction.....	1
-------------------	---

Chapter Two

GENERAL OVERVIEW OF HIP JOINT

2.1. Biologic Properties of Hip Joint	3
2.1.1. Acetabulum and Femur.....	3
2.1.2. Forces Acting on Hip.....	4

Chapter Three

JOINT REPLACEMENT IN USE

3.1. History of THR	7
3.2. Parts of Hip Prosthesis	8
3.2.1. Femoral Head.....	9
3.2.2. Acetabular Cup.....	10
3.2.3. Femoral Stem.....	10
3.2.3.1. Cross-section of Stem.....	12
3.2.3.2. Length of Stem.....	13
3.2.3.3. Stiffness of Stem.....	13
3.2.3.4. Surface Properties of Stem.....	15
3.3. Materials Used in Total Joint Replacements.....	16
3.3.1. Stainless Steel.....	17
3.3.2. Cobalt-Based Alloys.....	19
3.3.3. Ti Alloys.....	20
3.3.4. Ceramics.....	22
3.3.5. Polymers.....	24
3.4. Fixation Methods.....	26
3.4.1. Cemented Fixation.....	27
3.4.2. Uncemented Fixation.....	28

Chapter Four

COMPLICATIONS OF THR

4.1. Wear.....	30
4.2. Loosening.....	34
4.2.1. Effect of wear particles.....	34
4.2.2. Micromotion.....	35
4.2.3. Effect of mechanical factors.....	35

4.2.4. Stress shielding.....	36
4.2.5. Factor of PMMA Loosening.....	37
4.3. Corrosion.....	40
4.3.1. General Aspects Of Corrosion.....	40
4.3.2. Types of Corrosion.....	42
4.3.2.1. Galvanic Corrosion.....	42
4.3.2.2. Pitting Corrosion.....	43
4.3.2.3. Crevice Corrosion.....	44
4.3.2.4. Grain Boundary Attack (Intergranular Corrosion).....	45
4.3.3. Role of Corrosion on Mechanical Failure.....	46
4.3.3.1. Stress Corrosion Cracking.....	47
4.3.3.2. Fretting Corrosion.....	49
4.3.3.3. Corrosion Fatigue.....	51
4.3.4. Contribution Factors on the Corrosion Process.....	52
4.3.4.1. Effect of Metallurgical Variables.....	52
4.3.4.2. Incorrect Metallurgical Condition.....	53
4.3.4.3. Poor Design and Use of Implants.....	53
4.3.4.4. Effects of Surface Finish.....	54
4.4. Fatigue.....	56
4.4.1. Initiation of Fatigue Cracks.....	58
4.4.2. Growth of Fatigue Cracks.....	61
4.4.3. Fatigue Failure of Stem.....	65
4.4.3.1. Failure Modes Of Hip Stem.....	67
4.4.3.1.1. Mode I: Pistoning Behaviour.....	67
4.4.3.1.2. Mode II: Medial Midstem Pivot.....	68
4.4.3.1.3. Mode III: Calcar Pivot.....	68
4.4.3.1.4. Mode IV: Bending Cantilever Fatigue.....	68
4.4.3.2. Contributing Factors on Fatigue Failure of the Stem.....	68
4.4.3.2.1. Loss of Fixation.....	69
4.4.3.2.2. Varus Position.....	70
4.4.3.2.3. Metallurgical Causes.....	71
4.4.3.2.4. Excessive Load.....	73

4.4.3.2.5. Failure of Support by Bone.....	73
4.4.4. Corrosion Fatigue of 316L Stainless Steel.....	74
4.5.Coating Applications Against Failures of Metallic Materials.....	78

Chapter Five

EXPERIMENTAL STUDY

5.1.Purpose.....	82
5.2.Material and Method.....	83
5.2.1. The Component.....	83
5.2.2. The Apparatus and Set-up for Fatigue Test.....	85
5.3.Experimental Procedure of ISO 7206/4.....	88
5.4.Orthopaedic Applications of FEA.....	92
5.4.1.FEA of Femoral Stem According to ISO 7206/4 Standard.....	93

Chapter Six

RESULTS AND DISCUSSION

6.1.Mechanical Properties.....	96
6.1.1. Tensile Tests.....	96
6.1.2. Hardness Tests.....	96
6.1.3. Microstructural Examination.....	97
6.2.Stress Distribution of the Femoral Stem.....	99

Chapter Seven

CONCLUSION

Conclusion.....104

References.....105



LIST OF TABLES

	<u>Page</u>
Table 2.1. Load history assumed for implanted hip prosthesis.....	6
Table 3.1. Compositions of 316L stainless steel.....	19
Table 3.2. Chemical compositions of Co-Cr alloys.....	21
Table 3.3. Chemical Compositions of titanium and its alloy.....	22
Table 3.4. Some characteristics of orthopaedic metallic implant materials.....	23
Table 3.5. Physical and mechanical properties of implant metals and alloys used in orthopedic surgery applications.....	24
Table 4.1. Young modulus of cancellous bone and cortical bone compared to the metallic biomaterials.....	38
Table 5.1. Chemical properties of 316L stainless steel.....	83
Table 5.2. Mechanical properties of 316L stainless steel.....	84
Table 6.1. Mechanical properties of 316L stainless steel.....	96
Table 6.2. Average micro-hardness values of 316L stainless steel specimens.....	97

LIST OF FIGURES

	<u>Page</u>
Figure 2.1. Acetabulum and upper femoral shaft	4
Figure 3.1. A schematic diagram of a hip replacement showing the metal protheses inserted into the femur, and the cement layer surrounding the protheses. The medial and lateral, and the distal and proximal sides are indicated.....	9
Figure 3.2. Stresses on the femur.....	11
Figure 4.1. Schematic representation of the load transfer before and after THA.....	38
Figure 4.2. Carbide particles at grain boundaries leading to the setting up of electrochemical cell and grain boundary dissolution.....	46
Figure 4.3. Notch-Peak geometry of slip bands at a free surface.....	59
Figure 4.4. Stage I and II fatigue crack growth	63
Figure 4.5. Beach marks on fatigue surface.....	64
Figure 4.6. Fatigue crack growth by the plastic blunting mechanism.....	65
Figure 4.7. Schematic diagram of the 4 modes of failure characterizing the various mechanisms of hip stem.....	69
Figure 4.8. Schematic diagram showing; (a) a stem in varus, (b) a stem in valgus...	71
Figure 4.9. Schematic illustration of a cross-section of a deformed metallic biomaterial surface showing the complex interactions between the material's surface and the physiologic environment.....	76
Figure 5.1. Dimensions of Thompson hip prosthesis.....	84
Figure 5.2. Dimensions of tensile test specimens.....	85
Figure 5.3. Front and back view of the double cantilever beams bending machine..	87

Figure 5.4. The load-deflection curve of the test rig together with the fixed prosthesis.....	90
Figure 5.5. As indicated in the ISO 7206 standard position of the stem for the fatigue test. The flexion angle β is 0° for the set without torque and $9\pm 1^\circ$ for the test with torque.....	91
Figure 5.6. Specimen mounted on the test rig.....	91
Figure 5.7. (a) The stem mesh, (b) The stem mesh with the cement layer.....	94
Figure 6.1. Stress- strain behaviour of the specimen.....	97
Figure 6.2. Microstructure of the specimen; (a) specimen 1, (b) specimen 2, (c) specimen.....	98
Figure 6.3. Graph of grain size distribution.....	99
Figure 6.4. The stem with cement mesh stress distribution for 4800 N.....	100
Figure 6.5. (a) Stress distribution at various load levels along the stem edge for all loads applied, (b) The σ_{33} (stress parallel to the stem axis) on the stem edge adjacent to the cement upper surface plotted for all stem distal constraints.....	101
Figure 6.6 Correlation between Von Mises stress and load.....	102
Figure 6.7. (a) and (b) stress distribution on cement surface for 4800 N.....	103

CHAPTER ONE

INTRODUCTION

The human hip joint is subjected to high mechanical stress and undergoes considerable abuse. As a result of some osteological diseases such as osteitis, osteolysis, osteopenia and breakage of hip joint in consequence of a severe accident that forms unpredictable loads, total hip replacement (THR) may be required. THR has proven to be a successful procedure for the relief of pain and restoration of normal daily activities in elderly patients with hips disabled by disease or injury. Consequently, the general use of the total hip prosthesis has been extended to younger and more active patients (Gruen et al., 1979). This is the process of completely removing the existing hip and replacing it with an artificial one. Today, THR is performed more than 250,000 times a year in the United States, a sixty-four percent increase since 1982. The main goal of total hip replacement is to improve the quality of life of the patient by reducing the amount of pain in the hip and restoring its function. The major causes of failure in total hip arthroplasty are infection, dislocation of the joint, loosening of the stem and failure of the stem (Edmonson & Crensham, 1989). In every failure of an orthopaedic implant the patient is made to experience the trauma of repeated surgery besides severe pain experienced during the process of rejection of the device. The removal of the implant may cause great expense and hardship to patient. Therefore, it is highly desirable to keep the number of failures to a minimum. Hence, the determination of the mechanism that caused failure of an implant is important, but it is also necessary to explore the event or sequence of events, which caused that particular mechanism to become operative. Furthermore, failure investigation will help to improve the total performance of implant devices, besides revealing the details of the mode and origin of the failure mechanism.

The mechanism of failure appears to be caused by the resorption of the bone for uncertain reasons around the section where the head and neck are detached from the femur resulting in the reduction of strength. For whatever reason the resorption occurs, the result is that the implant is effectively not supported at its proximal end and the condition may arise where the implant is firmly fixed in a plug of cement at its distal end and loaded by the joint force. This gives a stress system, such as cantilever under bending, leading to fatigue failure at a section situated at between 1/3 and 2/3 of the stem length from its tip. The majority of these fatigue failures involve a fracture surface that is not perpendicular to the axis of the stem. This corresponds in fact to a combination of longitudinal bending and torsional loading and for this reason the test procedure proposed currently by ISO 7206/4 standard involves the proximal femoral component being held in fixing medium, in such a way that load applied to the head of the femur causes such a combination stresses varying down the length of the stem (Azem, 1999).

In spite of the recent innovative metallurgical and technological advances and remarkable progress in the design of implants, failures of implants do occur. Although failures of implants have been reported to be due to fatigue, corrosion and/or other general mechanisms, the underlying causes for the initiation of these failure mechanisms are seldom determined. The causes of failures may also due to biomechanical reasons rather than to faults in the basic design and/or metallurgy of the implant (Sivakumar et al., 1995).

In this study, corrosion fatigue properties of 316 L Stainless Steel Thompson hip prosthesis is investigated. The fatigue test is usually performed according to the ISO 7206/4 standard which describes the test apparatus and procedure to assess the fatigue resistance of femoral stems with torque. Tests were carried out in 0.9 % NaCl solution at 37 ± 1 °C simulating body fluid at 10 Hz by Double Beams Bending Machine. The 3-D model of the prosthesis was performed by using a commercial CAD software I-DEAS® and then finite element model was formed. The theoretical results of stress distribution were verified with the experimental results.

CHAPTER TWO

GENERAL OVERWIEV OF HIP JOINT

2.1. Biologic Properties of Hip Joint

Hip is composed of the head of the femur and the acetabulum of the pelvis. The hip joint is one of the most stable joints in body. The stability is provided by the rigid ball-and socket configuration. In contrast to the knee, the hip joint has intrinsic stability, provided by its relatively rigid ball-and-socket configuration. It also has a great deal of mobility, which allows normal locomotion in the performance of daily activities such as sitting, walking, and squatting (Bronzino, 1995).

2.1.1. Acetabulum and Femur

The acetabulum is the concave component of the ball-and-socket configuration of the hip joint. The acetabular surface is covered with articular cartilage that thickens peripherally and predominantly laterally. The cavity of the acetabulum obliquely forward, outward, and downward.

The femur is the longest bone of skeleton and articulates with the hip bone above and the tibia below; it carries the patella in front of it. The femoral head is the convex component of the ball-and-socket configuration of the hip joint and forms two thirds of sphere. The articular cartilage covering the femoral head is thickest on the medial-central surface and thinnest toward the periphery. The variations in the cartilage thickness result in a different strength and stiffness in various regions of the femoral head. These differences in the mechanical properties from point to point on the femoral head cartilage may influence the transmission of stresses from the

acetabulum through the femoral head to the femoral neck. Although it is known just how stresses on the femoral head are distributed, the joint reaction force usually acts on the superior quadrant.

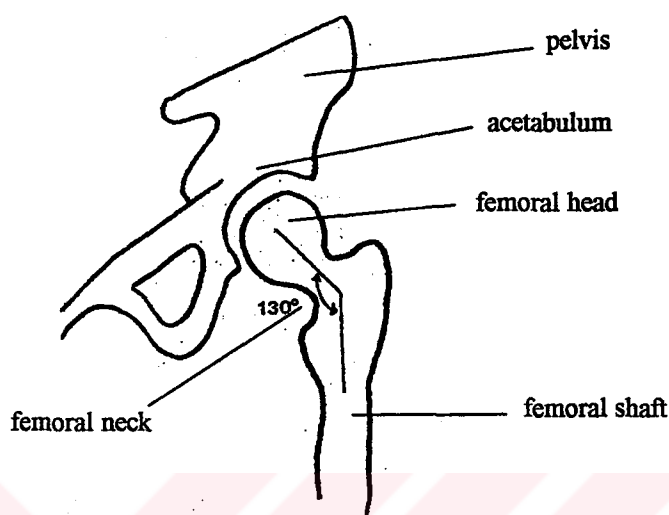


Figure 2.1. Acetabulum and upper femoral shaft (Bronzino, 1995).

2.1.2. Forces Acting on Hip

For the purpose of determining the forces acting on the hip joint, the body weight (BW) may be depicted as a load applied to a lever arm extended from the center of gravity of the body to the center of the femoral head.

The external and internal bony architecture of the proximal femur is exquisitely designed to withstand the enormous forces that act across the hip joint. These forces are generated by contraction of powerful muscles that move and stabilize the hip, by superincumbent body weight, and by inertial effects. The abductor musculature, acting on a lever arm extending from the lateral aspect of the greater trochanter to the center of the femoral head, must exert an equal moment to hold the pelvis level while one stands on one leg and a greater moment to tilt the pelvis to the same side while walking or running. Since the ratio of length of the lever arm of the body weight to that of the abductor musculature is about 2.5:1, the force of the abductor muscles must approximate 2.5 times the body weight to maintain the pelvis level while

standing on one leg. These forces can be resolved into a resultant compression load acting across the hip joint, which has been estimated to range from about the same as body weight during performance of a straight leg raise in a recumbent position, to three or four times body weight during normal level walking, to more than six times body weight during running. But one is jumping, the load may be equivalent to 10 times the body weight. More importantly, these loads are repetitive and fluctuating depending on the activities such as standing, sitting, jogging, stretching, and climbing. The femoral neck is loaded in bending in cantilever mode, which creates large tensile forces in the superior portion of the neck and compression forces in the inferior neck. Internal linear thickenings of the trabecular bony architecture serve to resist these stresses. Tensile forces produced by contraction of the hip abductor muscles tend to reduce this bending load. Therefore excess body weight and increased physical activity add significantly to the forces that act to loosen, bend or break the stem of the femoral component which is used in place of hip joint that not work properly no longer. Knowledge about femoral components will be explained with details in Chapter 3.

The forces on the joint act not only in the coronal plane, but because the center of gravity of the body (in the midline anterior to the second sacral body) is posterior to the axis of the joint, they also act to rotate and bend the hip posteriorly; these latter forces increase when the joint is flexed, as in getting up from a chair, ascending and descending stairs or incline, or lifting. It is this cycling loading with such forces acting in different planes and occurring more than a million times a year that tends to bend, rotate and loosen the stem of the femoral component and, to a lesser extent, loosen the acetabular cup. The durability of total hip components may well exceed that expected of some industrial machine parts.

The load which may occur during daily activities within 1 year according to body weight for active patients is given in Table 2.1. The annual occurrence is roughly separated into specific activities. The last column reports the maximum hip joint load corresponding to each activity.

Table 2.1. Load history assumed for implanted hip prosthesis (Baleani et al., 1999).

Activity	Cycles year ⁻¹	Specific activity/speed	Supposed occurrence (%)	Max load (% BW)
Walking	2.5 x 10 ⁶	Level walking / 1 km h ⁻¹	20	282
		Level walking / 3 km h ⁻¹	60	324
		Level walking / 5 km h ⁻¹	20	429
Jogging	6.4x10 ⁵	Level jogging / 5 km h ⁻¹	50	484
		Level jogging / 7 km h ⁻¹	30	496
		Jogging upstairs	10	515
		Jogging downstairs	10	384
Ascending Stairs	4.2x10 ⁴	Walking upstairs / slow	20	333
		Walking upstairs / normal	70	356
		Walking upstairs / fast	10	386
Descending stairs	3.5x10 ⁴	Walking upstairs / slow	20	374
		Walking upstairs / normal	70	387
		Walking upstairs / fast	10	432
Sitting/rising	7.2x10 ⁴	Rising from a chair	100	123
Jolting	1.8x10 ³	Stumbling	100	720

CHAPTER THREE

JOINT REPLACEMENT IN USE

Total hip replacement (THR) is the process of completely removing the existing joint and replacing it with an artificial hip. When the hip joint is out of use because of disease or breakage, prosthesis is implanted in place of injured joint part to carry out function of hip joint.

Total joint replacements have improved the quality of life for thousands of people over the last quarter century. Clinical objective of joint replacement is pain relief and increased joint motion, the engineering objective is to provide a stress as physiological as possible to the remaining bone so that the integrity and functionality of the bone and prosthetic materials are maintained over a lengthy service-life.

3.1. History of THR

Two English surgeons made outstanding contributions to the development of total hip replacements in the 1950s and 1960s. In 1951, G.K. McKee introduced metal-on-metal prostheses in which both the femoral and acetabular components were made of stainless steel. The acetabular cup was initially fixed into the pelvis by means of screws, but because these came loose within a year, no doubt due to the excessive friction associated with a stainless steel ball seated within a close-fitting acetabular cup, the material of construction was changed to Vitallium, a cobalt-chromium-molybdenum alloy. McKee then adopted a modified form of Thompson femoral component developed in the United States and a cloverleaf form of acetabular cup that was again fixed by a screw. A success rate about 50% was reported in the period of 1956 to 1960. In 1960, when McKee and his colleague Watson-Farrar introduced

methyl methacrylate as a cement to hold the components in place, the success rate rose to an encouraging 90%. It was further recognized that the use of identical metals in the tribological pair, though necessary to avoid galvanic corrosion, was not an optimized tribology design. A high rate of loosening was encountered with early metal-on-metal artificial joints due to non-optimum fit between the articulating surfaces which produced high frictional moments and excessive wear of bearing surfaces. These early concerns limited to the application of metal-on-metal articulating devices, although follow-up examinations of metal-on-metal hip prostheses have shown very low wear rates for prostheses implanted for up to 20 years.

In the 1960s Sir John Charnley recognized that it was necessary to combat loosening of the components by reducing the frictional torque generated by the articulating surfaces. The outcome was his concept of a “low-friction arthroplasty” based upon a small-diameter metallic femoral head engaged in a polymeric acetabular cup. The philosophy prompted Charnley to introduce polytetrafluoroethylene (PTFE, or Teflon) acetabular cups and stainless steel femoral stems in 1959. Attempts were made to improve the wear resistance of the polymer by introducing fillers into the PTFE, but the improvements noted in laboratory test were not reproduced in the body. In 1961, Charnley turned to ultrahigh molecular weight polyethylene (UHMWPE) as the cup material. This material exhibits a higher coefficient of friction than PTFE, but vastly enhanced resistance to wear. Its introduction was astonishingly successful, and today, some 30 years later, it is still the dominant polymeric material in total replacement joints (Dowson, 1992).

3.2. Parts of Hip Prosthesis

Artificial hips are composed of three main components. These components include the femoral head, the acetabular insert or component and a femoral stem. During the surgery, the insert replaces the deteriorated acetabulum or socket. The femoral stem and femoral head replace the original femoral neck and head,

respectively which are excised early in the procedure. Once these components are fixated or secured into place, the surgery is completed and the patient has a new hip.

3.2.1. Femoral Head

Femoral head is an articulating joint which transfers load from the femur to pelvis. Any articulating joint will involve the friction and wear of the two opposing members. Apart from the surface finish of the articulating portion of the prosthetic femoral head, the most mechanical feature is the head diameter. Charnley described the effect of head size: he proposed a small head because it would create a lower frictional torque than a larger head and thus reduced the potential loosening. However, smaller heads imply greater contact stresses on the polyethylene cup. The

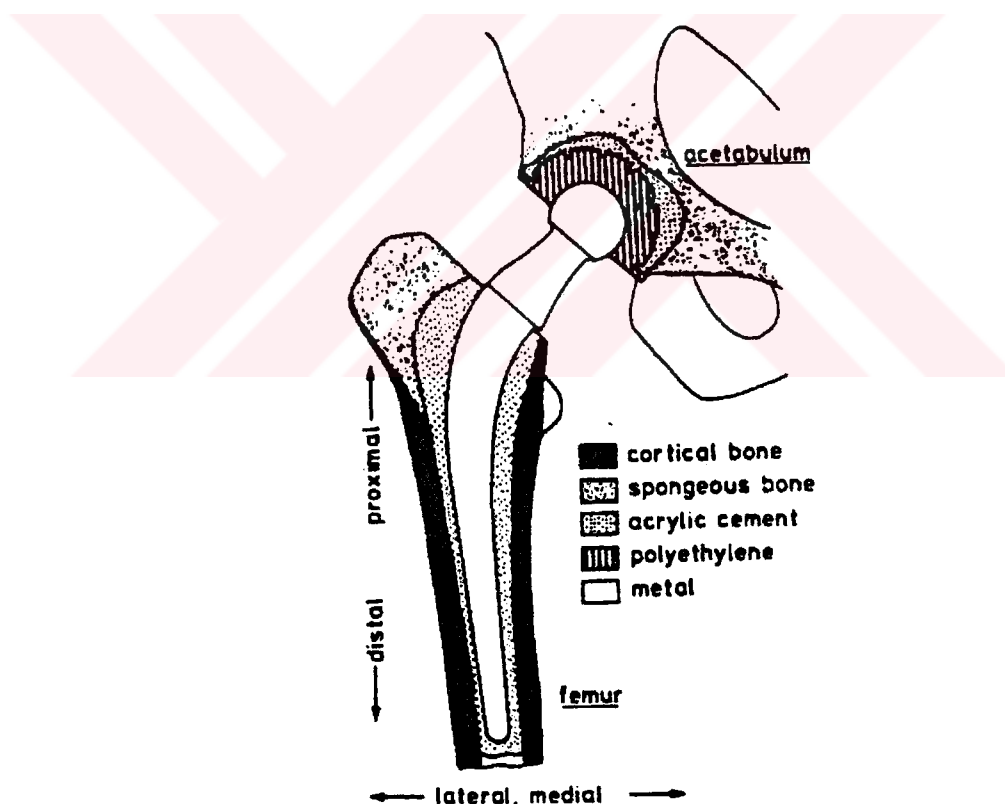


Figure 3.1. A schematic diagram of a hip replacement showing the metal prostheses inserted into the femur, and the cement layer surrounding the prostheses. The medial and lateral, and the distal and proximal sides are indicated.

size of the head and the geometry of the neck determine the range of the motion of the reconstruction. For a given neck geometry, a larger head size will permit a

greater range of motion of the artificial joint. As wear progress, the head penetrates the acetabular cup, decreasing the range of the motion. For these reasons, head diameter is a crucial design variable for which a compromise is required (Cowin, 2001). For this reason the choice of femoral head size seems to have settled on 26 or 28 millimeters. The 32 millimeters head produces too much wear or creep. Less acetabular strain and lower revision rates are associated with used of a 26 or 28 millimeters head. Note also that the head may be removable from the tapered neck (modular prostheses) (Friedman et al., 1993).

3.2.2. Acetabular Cup

Acetabular cup is a counterpart articulating against femoral stem head. Orientation is critical for stability. In total hip arthroplasties the acetabular cups are made of UHMWPE, a viscoelastic material of limited flexibility under loading conditions. It also has the characteristic of creep or deformation under constant loads; this creep is minimized by containing the cup within rigid boundaries, such as the bone of the acetabulum (Edmonson & Crensham, 1989).

3.2.3. Femoral Stem

Femoral stem transfers loads from head of the prostheses to femur by means of a medium such as polymethylmethacrylate (PMMA) or directly, that means cemented or uncemented fixation, respectively. The material properties, shape, and methods used for fixation of the implant to the patient determine the load transfer characteristics. Stresses on the femur can be defined in terms of three unique loads:

Axial Loads: The loads transmitted straight down the canal.

Bending Loads: The “tipping” loads seen in the A-P (Anterior-Posterior) and M-L (Medial-Lateral) planes.

Torsional Loads: The loads twisting around the long axis of the bone.

Prior to reconstruction, all three of these loads are transmitted directly to the host bone. Once a femoral component is introduced into the canal, it now shares the responsibility of taking up these loads while allowing less of the load to be transmitted to the bone. If the three loads are looked at independently, axial and torsional loads can essentially be addressed with tapered or cylindrical stems distally.

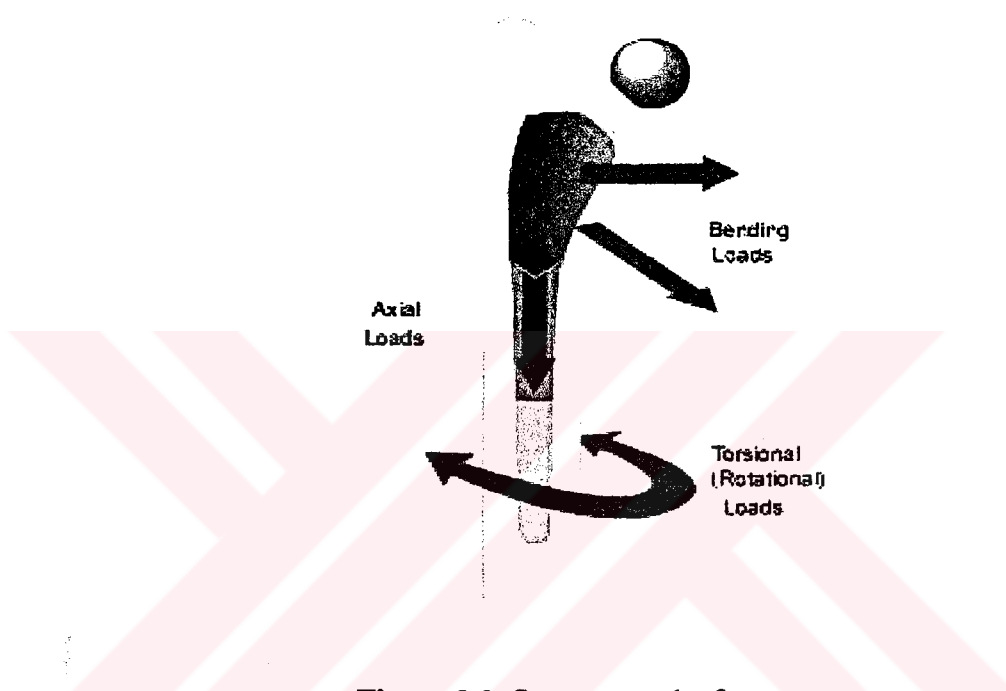


Figure 3.2. Stresses on the femur.

An implant design that transmits axial load distally seems to be the most damaging. It has been reported that a cylindrical, distal-fit prosthesis has shown as much as 64 to 78% bone demineralization and stress shielding at five year follow-up. Torsional load transfer is also vitally important to prevent loosening. Designs, which depend heavily on distal fit within the femur to achieve torsional stability, run the risk of stress shielding and bone resorption. Such a trade-off may create future clinical problems. A well designed prosthesis will transmit the majority of these loads.

Some prostheses have collar placed between neck and stem, which was observed to assure a permanent contact with the calcar bone in the analysis of the hip stem. This is a paramount importance to achieve physiological loading of the proximal

femur. The neck part assures a proper load transfer to the proximal femur, whilst the stem has to assure the stability of the stem in the bone (Sloten et al., 1998). There are three potential functions of the collar. First is the transfer of load directly to the cut surface of the femoral neck by collar-calcus contact. This requires a large collar. Second is the transfer of load to the proximal end of the cement column, rather than directly to the cut surface of the femoral neck. Such collars are often small and may be flanged. Finally, for many surgeons, the primary function of the collar is as form of “stop” to indicate when they should cease pushing the stem distally into the cement column during insertion (Ling et al., 1992). Several experimental and computer studies have indicated a higher (more nearly normal) transmission of compressive stress from the prosthesis into the medial calcus femoral bone with a collar. This effect is beneficial in that it may reduce adaptive bone resorption in the proximal femur (stress shielding), reduce the bending stress in the component stem, and reduce the stress in the distal cement.

The most important design properties of stem are cross section, length, stiffness and surface properties of stem, each of which is handled in the following sections.

3.2.3.1. Cross-section of Stem

Cross-sectional geometry of a femoral component is conception of the volume and distribution of material of the stem. Certain sectional shapes produce a more favourable mechanical environment than others. Sharp corners in the stem should be avoided as they produce marked stress concentrations and may cause cement or bone failure. The area moment of inertia is a term that describes the distribution of mass of an object in regard to its neutral axis. The larger the area moment of inertia, the greater the resistance of the object to bending. The cross-sectional shape of a diamond and I-beam represent the extremes of a small and large area moment of inertia for a given mass. Those stems with a large volume of material along the lateral border are more resistant to bending and produce less tensile stress in the cement mantle. Those stems that have a relatively thick medial side also produce less compressive stress in the cement. Since bone cement is about three times stronger in

compression than in tension, compression loading may be the only safe mode (i.e., the less tensile stress, the less likely that cement will fracture, resulting in component loosening).

Changes in cross-section geometry had only a limited effect on the magnitude of the proximal cement stresses. In general, the use of a smaller medial radius of the stem resulted in increased proximal cement stresses. Clinically, stem geometries with a small medial radius have performed poorly when compared to stems with broad medial radius. The choice of A-P width of the stem cross-section had a minimal effect on the proximal cement mantle stresses. Although cement stresses may not be affected by use of a stem with a large A-P dimension, there may be other mechanical effects at the cement-bone interface (Mann et al., 1995).

Crowninshield et al. found that increasing the cross section of the stem decreased the stress in both the stem and the cement. Viceconti et al. lessened the stiffness of the stem by using transverse holes (Gross & Abel, 2001).

3.2.3.2. Length of Stem

Mathematical modelling studies have shown that either very short or very long stems have stress concentrations at some point in the component for example; very long stems produce increased stress on the stem and distal stress transfer with shielding proximal bone. Very short stems produce very high stress proximally that may exceed the ultimate strength of cement or bone. A stem length of between 100-130 millimeters seems optimum.

3.2.3.3. Stiffness of Stem

The physical properties of a prosthetic femoral device are defined by its response to loading and determined by its size and shape and also by the properties of the material from which it is manufactured. Obviously, the higher the yield stress and ultimate stress of a device the greater the safety margin and the less likely is the

device to fail (i.e., to bend or break). Repeated or cyclic loading of the device below the point of yield stress will eventually result in fatigue fracture. The number of loading cycles possible before fracture occurs is termed the fatigue strength. This property is of critical importance in the performance of a prosthetic femoral device.

The lower the elastic modulus, the more stress the device will transfer to cement and bone. Stainless steel was used to manufacture many of the early prosthetic femoral devices. However, stainless steels are relatively stiff (i.e. high elastic modulus) material but have low fatigue and yield strength characteristics. Cobalt-chromium alloys have better fatigue and yield stress but have slightly greater elastic modulus than stainless steels. Titanium alloys have been increasingly used recent years because of their favorable strength characteristic and lesser stiffness .

The elastic modulus of the materials, however, does not fully describe the properties of the prosthetic component. The stiffness of a given device depends on its cross-sectional geometry as well. If one designs a stem of a rather elastic material but makes it large and massive to resist fracture and to improve fit into the proximal femur, the overall stiffness would likely be greater than that of a smaller stem made of a stiffer material. Smaller, more flexible stems carry less internal stress but transmit more compression stress to the proximal bone and cement. Large, stiff stems reduce the thickness of the cement mantle and produce high tensile stress in the cement distally. Either situation may produce cement failure and component loosening. Titanium alloys thus have physical properties that appear advantageous for femoral components used without cement. However, with cemented devices, the vulnerability of the bone cement appears to override the theoretically advantageous material properties of titanium alloy.

Femoral components with a stiffer (higher elastic modulus) stem have been shown to decrease the stress in the proximal bone and cement for cases where there is a perfect bond between the materials (Mann et al., 1995).

3.2.3.4. Surface Properties of Stem

Surface finish is another design feature that has generated considerable discussion and controversy. Some recent prostheses, intended for use with cement fixation, have been manufactured with stem surfaces that are sandblasted, hobnailed, porous, or precoated with methyl methacrylate. The rationale is that these rough surfaces provide increased adhesion of cement to the stem and thus resist distal migration and micromotion of the stem within the cement. This may reduce the radial compressive forces (hoop stress) acting at the interface between stem and bond cement that may be an important cause of cracking or failure of the cement mantle. However, again there are compromises to be considered. It is no longer obvious that surfaces of total hip arthroplasty stems, to provide better grip on cement and prevent debonding, should be roughened. Roughness reduces slip, but it enhances abrasion if slip occurs. Clinically it was shown that particular designs have better endurance with smooth (or polished) surfaces, as opposed to rough (or matte) surfaces. The idea that a polished stem reduces the amount of abrasion particles when rubbing against cement, thus preventing bone osteolysis to develop, was suggested as an explanation for this improvement. Surface texture or roughness, or prosthetic collars, would hamper such a requirement. Finally, it was hypothesized that a polished stem, able to subside within the cement mantle, would reduce stress transfer at the cement-bone interface, thus protecting the bond against mechanical failure. (Huiskes et al., 1998)

The rough surfaces may introduce stress concentrations that weaken the stem and reduce the fracture toughness of the cement. They also may increase the technical difficulty in removing the prosthesis, should revision become necessary.

Axial load applied to the stem forces the wedge into the cement. The smooth surface of the stem and its tapered design minimize friction, such that the axial forces are converted into radial compressive forces, which favorably load the bone through the cement mantle.

3.3. Materials Used in Total Joint Replacements

A definition of biomaterials is any substance or combination of substance synthetic or natural in origin, which can be used for any period of time, as whole or as a part of a system, which treats, arguments, or replaces any tissue, organ, or function of the body (Bronzino, 1995).

Implant materials may corrode and/or wear, leading to the generation of particulate debris, which may, in turn, elicit both local and systemic biological responses. Although metals exhibit high strength and toughness, properties needed in joint replacement, they are more susceptible to electrochemical degradation, than ceramics or polymers. Therefore, a fundamental criterion for choosing a metallic implant material is that the biological response it elicits is minimal. Because of the combined mechanical and environmental demands, the metals used in bone and joint reconstruction have been limited to three classes: stainless steel (iron based), cobalt-based alloys and titanium-based materials. Each of these materials is well tolerated by the body because of its passive oxide layer. The body in trace amounts can usually tolerate the main elemental constituents, as well as the minor alloying constituents of these metals, since most materials have specific biological roles and are therefore essential. However, larger amounts of metals usually cannot be tolerated. Minimizing mechanical and chemical breakdown of implant materials is therefore a primary object.

The “ideal” material or material combination for TJR (Total Joint Replacement) prostheses should therefore exhibit the following properties: a “biocompatible” chemical composition to avoid adverse tissue reactions, an excellent resistance to degradation (corrosion) in the human body environment, acceptable strength to sustain the cycling loading endured by the joint, a low modulus to minimize bone resorption, and a higher-wear resistance to minimize debris generation (Long & Rack, 1998).

Over the 30 years considerable progress has been made in understanding the interactions between the tissues and the materials. Researchers have coined the words “biomaterial” and “biocompatibility” to indicate the biological performance of materials. Materials that are called biomaterials, and biocompatibility are a descriptive term, which indicates the ability of a material to perform with an appropriate host response, in a specific application. In simple terms it implies compatibility or harmony of the biomaterial with the living system. Wintermantel and Mayer extended this definition and distinguished between surface and structural compatibility of an implant. Surface compatibility meanings the chemical, biological and physical (including surface morphology) suitability of implant surface host tissues. Structural compatibility is optimal adaptation to the mechanical behavior of the host tissues. Therefore, structural biocompatibility refers to the mechanical properties of the implant material, such as elastic modulus and strength; implant design (stiffness, which is product of elastic modulus, E and second moment of area, I) and optimal load transmission (minimum interfacial strain mismatch) at the implant tissue interface. Optimal interaction between biomaterial and host is reached when both the surface and the structural compatibility are met. Further more it should be noted that the success of a biomaterial in the body also depends on many factors such as surgical technique (degree of trauma imposed during implantation, sterilization methods, etc), health condition and activities of the patient (Ramakrishna et al., 2001).

3.3.1 Stainless Steel

The first stainless steel utilized for implant fabrication was the 18-8 (type 302 in modern classification), which is stronger and more resistant to corrosion than the vanadium steel. Vanadium steel is no longer used in implants since its corrosion resistance is inadequate in vivo. Later 18-8s Mo stainless steel was introduced that contains a small percentage of molybdenum to improve the corrosion resistance in chloride solution (salt water). This alloy became known as type 316 stainless steel. In the 1950s the carbon content of 316 stainless steel was reduced from 0.08 to a maximum amount of 0.03% for better corrosion resistance to chloride solution and to

minimize the sensitization and hence, became known as type 316L stainless steel (Bronzino, 2000). Today, stainless steel is one of the most frequently used biomaterials for internal fixation devices because of a favorable combination of mechanical properties, corrosion resistance and cost effectiveness when compared to other metallic implants (Disegi & Eschbach, 2000). The most important alloying constituent in stainless steel is chromium, which should have a concentration of at least 12% for the steel to develop a passive chromium oxide layer necessary for corrosion resistance. Elemental compositions outside of the specified bounds can lead to less than optimal microstructures and compromise the physical and mechanical properties. For example, chromium content above approximately 28% leads to the precipitation of grain boundary chromium carbide ($\text{Cr}_{23}\text{C}_{26}$) and a localized zone of depleted chromium to the carbides. This depleted zone is anodic relative to the remainder of the alloy and, as a result, localized intergranular corrosion occurs, in a process known as sensitization. Since carbide formation occurs at 450-900 °C, stainless steels are heat treated above 950 °C to avoid carbon diffusion and formation of carbides.

The austenitic stainless steels, especially type 316 and 316L, are most widely used for implant fabrication. These cannot be hardened by heat treatment but can be hardened by cold-working. The inclusion of molybdenum enhances resistance to pitting corrosion in salt water. The American Society of Testing and Materials (ASTM) recommends type 316L rather than 316 for implant fabrication. The specifications for 316L stainless steel are given in Table 3.1. The only difference in composition between the 316L and 316 stainless steel is the maximum content of carbon, i.e., 0.03% and 0.08%, respectively, as noted earlier.

The nickel stabilizes the austenitic phase [γ , face centered cubic crystal (fcc) structure], at room temperature and enhances corrosion resistance.

The 316L stainless steels may corrode inside the body under certain circumstances in a highly stressed and oxygen-depleted region, such as the contacts under the screws of the bone fracture plate. Thus, these stainless steels are suitable to

use only in temporary implant devices such as fracture plates, screws, and hip nails. Surface modification methods such as anodization, passivation, and glow-discharge nitrogen-implantation, are widely used in order to improve corrosion resistance, wear resistance, and fatigue strength of 316L stainless steel (Bronzino, 2000), (Disegi & Eschbach, 2000).

Table 3.1. Compositions of 316L Stainless Steel (American Society for testing and Materials, F139-86, 1992)

Element	Composition (weight %)
Carbon	0.03 max
Manganese	2.00 max
Phosphorus	0.03 max
Sulfur	0.03 max
Silicon	0.75 max
Chromium	17.00-20.00
Nickel	12.00-14.00
Molybdenum	2.00-4.00

3.3.2. Cobalt-Based Alloys

By the early 1930s, a cobalt-chromium alloy called Vitallium was introduced to dentistry as an alternative to gold alloys. Cobalt-chromium alloy soon found application in orthopaedic surgery for fabrication of hip prostheses and internal fixation plates and has become one of the three major biomedical metallic materials (Greco, 1994). There are basically two types of cobalt-chromium alloys: (1) the castable CoCrMo alloy and (2) the CoNiCrMo alloy which is usually wrought by (hot) forging. The castable CoCrMo alloy has been used for many decades in dentistry and, relatively recently, in making artificial joints. The wrought CoNiCrMo alloy is relatively new, now used for making the stems of prostheses for heavily loaded joints such as the knee and hip.

The ASTM lists four types of CoCr alloys, which are recommended for surgical implant applications: (1) cast CoCrMo alloy (F 75), (2) wrought CoCrWNi alloy (F90), (3) wrought CoNiCrMo alloy (F562), and (4) wrought CoNiCrMoWFe alloy (F563). The chemical compositions of each are summarized in Table 3.2. At the present only two of four alloys are used extensively in implant applications, the castable CoCrMo and the wrought CoNiCrMo alloy. As can be noticed from Table 3.2, the compositions are quite different from each other.

The two basic elements of the CoCr alloys form a solid solution of up to 65% Co. The molybdenum is added to produce finer grains, which results in higher strengths after casting or forging. The chromium enhances corrosion resistance as well as solid solution strengthening of the alloy.

The CoNiCrMo alloy originally called MP35N (Standard Pressed Steel Co.) contains approximately 35% Co and Ni each. The alloy is highly corrosion resistant to seawater (under chloride ions) under stress. Cold working can increase the strength of the alloy considerably but there is a considerable difficulty of cold working on this alloy, especially when making large devices such as hip joint stems. Only hot forging can be used to fabricate a large implant with the alloy.

The superior fatigue and ultimate tensile strength of the wrought CoNiCrMo alloy make it suitable for the applications, which require long service life without fracture or stress fatigue. Such is the case for the stems of the hip joint prostheses. This advantage is better appreciated when the implant has to be replaced, since it is quite difficult to remove the failed piece of implant embedded deep in the femoral medullary canal.

3.3.3. Ti Alloys

Experiments on the surgical use of this metal began more than 50 years ago and it has been used in orthopaedic since the mid-1960s (Williams, 1994). Titanium and some Titanium-based alloys seem to have been well established for heavy load-

Table 3.3. Chemical Compositions of Titanium and its Alloy (American Society for Testing and Materials, F67-89, F136-84, 1992).

Element	Grade 1	Grade 2	Grade 3	Grade 4	Ti6Al4V
Nitrogen	0.03	0.03	0.05	0.05	0.05
Carbon	0.10	0.10	0.10	0.10	0.08
Hydrogen	0.015	0.015	0.015	0.015	0.0125
Iron	0.20	0.30	0.30	0.50	0.25
Oxygen	0.18	0.25	0.35	0.40	0.13
Titanium	Balance				

One titanium alloy (Ti6Al4V) is widely used to manufacture implants and its chemical requirements. The main alloying elements of the alloy are aluminum (5.5~6.5%) and vanadium (3.5~4.5%). The Ti6Al4V alloy has approximately the same fatigue strength (550 MPa) of CoCr alloy after rotary bending fatigue tests.

Table 3.4 summarizes some characteristics of orthopaedic metallic implant materials.

3.3.4. Ceramics

There are three categories of ceramics used to replace bone. The first is structural ceramics (alumina, Al_2O_3 , and zirconia, ZrO_2). These have higher stiffness and hardness than the metals and much better wear resistance. Pure zirconia can undergo phase transitions on cooling and, to avoid this, it is alloyed with CaO, MgO, or Y_2O_3 , forming partially stabilized zirconia or tetragonal zirconia. Both alumina and zirconia are used for heads of hip prostheses.

The second category of ceramic used to replace bone is calcium phosphate. Hydroxyapatite (HA), is a calcium phosphate that is found naturally in bone. Another calcium phosphate is tricalcium phosphate (TCP). TCP biodegrades more quickly than HA, indicating that the amount of TCP should be minimized to slow the dissolution rate of an HA/TCP mix. Calcium phosphates have useful osteoconductive properties and are used to coat metallic implants that aim to bond to the bone by osteointegration. They are also used for synthetic bone graft materials.

Table 3.4. Some characteristics of orthopaedic metallic implant materials (Long, 1998).

	Stainless Steels	Cobalt-base alloys	Ti&Ti-base alloys
Designation	ASTM F-138	ASTM F-75 ASTM F-799 ASTM F-1537 (Cast and wrought)	ASTM F-67 (ISO 5832/II) ASTMF-136(ISO 5832/II) ASTM F-1295 (Cast and wrought)
Principal Alloying Elements (wt%)	Fe(bal.) Cr (17-20) Ni(12-14) Mo(2-4)	Co (bal.) Cr (19-30) Mo(0-10) Ni(0-37)	Ti (bal.) Al(6) V(4) Nb(7)
Advantages	•cost, availability •processing	•wear resistance •corrosion resistance •fatigue strength	•biocompatibility •corrosion •minimum modulus •fatigue strength
Disadvantages	•long term behavior •high modulus	•high modulus •biocompatibility	•power wear resistance •low shear strength
Primary Utilizations	Temporary devices (fracture plates, screws, hip nails) Used for THR stems in UK (high Nitrogen)	Dentistry castings Prostheses stems Load-bearing components in TJR (wrought alloys)	Used in THRs with modular (CoCrMo or ceramic) femoral heads Long-term, permanent devices (nails, pacemakers)

The third category of ceramic is bioactive glass. Ceramics in this category have excellent biocompatibility. Glasses are amorphous materials have no long-range atomic order. This results when the cooling from the liquid phase is sufficiently rapid to prevent crystallization. Glass bioceramics have large amounts of SiO₂, with amounts of the following compounds: P₂O₅, CaO, Ca(PO₃)₂, CaF₂, MgO, MgF₂, Na₂O, K₂O, Al₂O₃, B₂O₃, and Ta₂O₅/TiO₂. Glass-ceramics used for implantation undergo surface dissolution in physiological environment, resulting in the formation

of a chemical bond with bone. This results in high interfacial strength. However, the toughness of the underlying glass can be low, leading to failure within the bulk material.

Table 3.5. Physical and mechanical properties of implant metals and alloys used in orthopedic surgery applications (Doewson, 1992).

	Materials		316 SS (wrought)	Co-Cr-Mo alloy (cast)	Titanium (wrought)	Ti-Al-V alloy (wrought)
Physical properties	Density (g/cm ³)		7.90	7.80	4.50	4.40
Mechanical properties	Young's modulus (GPa)		200	200	127	111
	Tensile strength (MPa)		465	665	575	900
	0.2% proof stress (MPa)		170	455	465	830
	Fracture strain, %		40	10	15	8
	Fatigue stress (MPa), 10 ⁸ cycles	Air	241	290	250	380
		Saline	103	140	120	140

3.3.5. Polymers

A wide range of polymers is used for implantable devices. The first category is polymers with no crosslinking of polymers chains-called thermoplastics. Well-known examples are polyethylene (PE) and polymethylmethacrylate (PMMA). Ultra-high-molecular-weight polyethylene (UHMWPE), so-called because it has a very long molecular chain, is very wear resistant and is used as a bearing material for the articulating surfaces of many artificial joints.

PMMA is used as an orthopaedic component to the bone. The material serves to interlock the prosthetic component to the bone. Polymerization takes place during the mixing of powder and liquid components, which is carried out in the operating

theater. Mixing is critical to the removal of pores and increasing the strength. As the polymerization reaction progresses, the material solidifies and the prosthesis is fixated into its final position. Cement must endure considerable stresses in vivo applications, thus strength characteristics are more important for its clinical success. The main function of the bone cement is to transfer load from the prostheses to the bone or increase the load carrying capacity of the surgical construction.

PMMA cement has many advantages, there are negative attributes such as thermal necrosis of bone due to the exothermic reaction associated with polymerization process, another issue is the deterioration of cement/implant or cement/bone interface with time, leading to problems of mechanical failure and instability. PMMA undergoes damage accumulation as the cyclic load is applied over the lifetime of the patient (Cowin, 2001).

PMMA is currently the only material used for anchoring cemented arthroplasties to the contiguous bones. In this application the main functions of the cement are to transfer body weight and service loads from the prosthesis to the bone and/or increase the load carrying capacity of the prostheses-bone cement-bone system. The cement performs these functions admirably because of the array of properties it possesses. It is well recognized, however, that bone cement is beset with a number of drawbacks, of which there are six main ones. First, it is postulated to have a role in the thermal necrosis of the bone, impaired local blood circulation, and predisposition to membrane formation at the cement-bone interface. All of these phenomena have been attributed to the high exothermic temperature of the cement, amounting to between 67 and 124 °C at the center of the cement mantle in vivo (depending on the cement formulation). The second drawback is the part that the cement is said to play in the chemical necrosis of the bone, this being postulated to be due to the release or leakage of unreacted monomer (MMA) liquid before polymerization of the cement in the bone bed. The third problem is the shrinkage of the cement during polymerization. The large stiffness mismatch between the cement and the contiguous bone is the fourth drawback. The fifth disadvantage is the identification of the cement mantle, the implant-cement interface, and the cement-bone interface to be the

three “weak-link zones” in the construct. The sixth drawback is that the cement particles, however produced, can interact with the surrounding tissues, evoking inflammatory periprosthetic tissue responses and increasing bone destruction.

In spite of the many drawbacks of the bone cement, the survival probabilities of recently implanted cemented arthroplasties, especially those of the hip and knee in patients aged over 50 years, are very high, averaging at least 90% after 15 years (Lewis, 1997).

The PMMA does not chemically bond to either the prosthesis or the bone; instead fixation depends on the formation of a secure mechanical interlock. Cyclic loads of several times body weight are commonly experienced leaving the PMMA cement susceptible to fatigue failure (McCormack et al., 1998).

3.4. Fixation Methods

The hip prostheses have been the most active of joint replacement research. A dramatic improvement in the efficacy of the hip implant occurred with the introduction by orthopedic surgeon John Charnley (later knighted for this innovation) of his total hip arthroplasty consisting of a metal femoral prostheses that was held in place by PMMA, with the acetabulum component made of UHMWPE, also cemented in place with PMMA. This system has seen many variations over the years, but is still a significant factor in modern joint replacement surgery (Ratner, 1996). In addition to the prostheses design and material, the fixation method is also important for the success of THRs. It is purpose of implant fixation to produce a composite structure of the implant and skeleton that minimizes relative motion at the prostheses-tissue interface and provides a long-lasting, useful joint reconstruction.

Effective long-term implant fixation requires a durable interface between the prostheses and the surrounding tissue. Interface durability can be characterized as having both mechanical and chemical components.

Mechanical interface durability is required to transfer high hip loads across the implant interface to the surrounding skeletal structure. Implant size, shape, surface area, and flexural characteristics all affect stress development at the interface. The fixation method needs to account for the magnitude of stress developed at the interface. A mechanically durable interface will occur when the stresses developed at the interface are consistent with the interface's ability to withstand those stresses. Mechanical interface strength in tension, compression, and shear are relevant measures of interface strength.

Chemical interface durability is also a relevant consideration in the overall durability of the implant. Chemical and electrochemical processes at the interface of both metallic and polymeric implants can change the character of the interface and may affect the longevity of implant fixation. It is well established that all metal implants are subjected to corrosion at some level. Contemporary hip implant metals have extremely low levels of corrosion. However, early attempts to use porous stainless steel for bone ingrowth applications failed due to excessive metal corrosion (Crowninshield, 1988).

The fixation of the stem is largely divided into two categories, i.e., cemented and uncemented. The uncemented can be classified into interface fit and porous-coated for tissue ingrowth fixation. The porous-coated type can be further coated with a hydroxyapatite layer to aid tissue ingrowth.

3.4.1. Cemented Fixation

The first total hip replacement was performed in 1938 by Wiles. These early prostheses were press fit into the medullary canal, or fixed to the bone with screws or nails. The lack of interfacial rigidity, along with stress concentration in bone caused by mechanical fixation, ultimately led to loosening. Some twenty years later, Charnley (1960) used PMMA as a grouting agent to fix prostheses to bone. The introduction of PMMA, or bone cement, enabled joint replacement surgery to advance. When the bone cement sets or hardens, it mechanically interlocks with the roughened bone surface and the prostheses. The main function of the bone cement is to transfer load from the prostheses to the bone or increase the load carrying capacity of the surgical construct.

PMMA was chosen for being relatively inert, rapidly setting, and biocompatible (Greco, 1994). Bone cement fixation creates two interfaces: cement-bone and cement-implant. The incidences of loosening for the femoral prostheses were evenly divided at about 10 and 11% for cement-bone and cement-implant interfaces, respectively.

Loosening led to biomechanical failure at the bone-cement and/or cement-implant interface, component fracture, and excessive wear of prostheses. Failure can also occur due to the brittleness and low fatigue strength of the bone cement. Pre-coating with bone cement or polymethylmethacrylate polymer can minimize the cement-implant interface loosening. Pre-coating can achieve a good bonding between the cement and prostheses (Park, 2000).

The deterioration of cement-implant or cement-bone interface with time remains to be still an important issue, leading to problems of mechanical failure and instability. Fatigue failure has been found to be a predominant in vivo failure mode of bone cement. Researchers have tried to improve bone cement mechanical properties by reinforcing with stainless steel and Ti alloy wires, and polymer fibers such as UHMWPE. Use of such fiber reinforcement also reduces the peak temperature during polymerization of the cement, and thus reducing the tissue necrosis.

In cemented THR, the cement layer cannot integrate micromechanically or chemically with bone. Impact loading forces of up to eight times the body weight on the bone-cement-implant interfaces results in cracks. This disruption of proper stress transfer from the prostheses to bone results in bone resorption, preventing bone integration and increasing chances for long-term loosening, recurrence of pain, and functional disability. The many disadvantages associated with PMMA fixation led in investigators to pursue noncemented fixation of femoral stems.

3.4.2. Cementless Fixation

Cemented fixation is achieved by establishing an interface fit between the implant and the surrounding tissue. The inherent difference between cemented and cementless implant

systems lies in the time necessary to achieve stability of the prostheses. With a cemented implant system, fixation is achieved almost immediately post-operatively, whereas with a cementless implant system, tissue integration must occur before the prostheses may be loaded. Thus cementless implant systems are conceived in such a way that the time necessary for tissue integration is minimized and interfacial stability maximized.

The introduction of noncemented arthroplasty offered three types of fixation: press fit, macrointerlock and micro interlock. Press fitting of smooth-surfaced metals has been abandoned because of excessive postoperative pain, due to a lack of mechanical fixation, resulting in increased revision rates. The macrointerlock type of fixation has shown disappointing results with osteolysis at the implant-bone interface and is not recommended in osteoporotic patients undergoing THA revision. In microinterlock devices, the implant surfaces are rough or porous so bone can ingrow and provide rigid “bioinert” fixation. Surface porosities, grooves, threads, or beads theoretically provide long-term stability by direct bone integration. Surface texture, corrosion resistance, mechanical properties, and biocompatibility influence bone ingrowth.

CHAPTER FOUR

COMPLICATIONS OF THR

Orthopaedic implants regarded as artificial mechanical devices fixed in human body are considered to have failed when they are prematurely removed from the body as the implant does not accomplish its intended function and hence has to be removed due to the implant failure. The mechanical and chemical stability of implanted materials in body fluids are of fundamental importance in the successful treatment of bone fractures and replacement.

The common failures encountered in metallic implants are wear, loosening, pitting corrosion, crevice corrosion, fretting corrosion, corrosion fatigue and fatigue (Sivakumar et al., 1995).

4.1. Wear

As the fixation of total joint implants has become more reliable and durable and as the technology of total joint replacement has been applied to younger and more active patients, the current limitations of total joint arthroplasty are related to the wear of the components. Wear is the removal of material, with the generation of wear particles that occurs as a result of the relative motion between the articulating surfaces under load. In complex mechanical-biological systems such as total hip and knee replacements, there can be many types of wear. Although the mechanical consequences of wear, such as progressive thinning of polyethylene components, can limit the functional life of a joint replacement, the clinical problems from wear more frequently are due to the release of an excessive number of wear particles into a biological environment (Schmalzried & Callaghan, 1999). Wear particulate is

produced primarily through three mechanisms: abrasion, adhesion, and fatigue. Wear debris can also act as a stress concentrator, producing secondary three-body wear (Friedman et al., 1993). Adhesive wear mode involves bonding of the surfaces when they are pressed together under load. Sufficient relative motion results in material being pulled away from one or more surfaces, usually from the weaker material. Another aspect of adhesive wear is the adhesion of passivated layer of oxide on the opposing implant surface to the ultra-high molecular weight polyethylene, resulting in transfer of the passivated layer to polymer. Thus, three-body wear develops, with oxide or cobalt-chromium oxide instead of cement as the third body. Implant-derived wear particles may potentially arise from all interfaces created in an artificial joint where there is movement between two surfaces. The main source is the articulating joint surfaces, and the presence of foreign material, such as cement particles and metal beads or hydroxyapatite particles derived from coatings on uncemented implants, exacerbate this production of wear particles by the process of three-body wear. The prostheses-bone, or the prosthesis-cement and cement-bone interfaces will all produce wear particles, as there is inevitably some movement between the surfaces, mostly due to the mismatch of the rigidity of the materials involved. Furthermore, increased surface roughness of implant surfaces have been shown to increase loosening rates (McGee et al., 2000).

Abrasion is a mechanical process wherein asperities on the harder surface cut and plow through the softer surface, resulting in removal of material. When stresses generated exceed the fatigue strength of material, that material fails after a certain number of loading cycles, releasing material from the surface. High contact stress in ultra-high molecular weight polyethylene, resulting from low conformation of the articulating surfaces, high loads, or both, can cause subsurface stress that exceeds the fatigue strength of the polyethylene. One or more of the classic mechanisms of wear may be operating on the prostheses in a particular wear mode, and a prostheses may function in several wear modes over its in vivo service life.

Friction is the resistance to movement between two surfaces in contact. The degree of resistance is proportional to the load. The ratio between frictional force and

load vertically applied on the articulating surfaces is the coefficient of friction. Frictional torque is the force created as a result of the friction of bearing. Charnley et al. initially selected a stainless steel-on-PTFE bearing couple because of a low coefficient of friction. The small, 22.2 millimeters diameter head was selected to minimize the moment arm of the frictional forces and, thus, to minimize the frictional torque. Unfortunately, Charnley hip components with the polytetrafluoroethylene bearing uniformly failed because of rapid wear with the release of polytetrafluoroethylene wear particles, formation of granulomas, and loosening of the component (Schmalzried & Callaghan, 1999).

Saikko has also studied 14 metallic head and UHMWPE cup combinations. It was concluded that the 22-mm joints produced the lowest frictional torques as well as the lowest friction factor. The frictional torque was dependent not just on the head diameter but on the surface finish, material combination, clearance ratio, thickness of the cup and stiffness of the backing (Hall & Unsworth, 1997).

UHWPE has been commonly used as a counterpart material in artificial joints because of its superior properties such as ductility and impact load damping. Polyethylene wear particles generated at the articular surface, however, have been recognized as a long-term cause of loosening and failure of the artificial hip joint due to osteolysis. It is thought that the majority of polyethylene wear debris travels distally into the fibrous tissue surrounding the implant via the peri-prosthetic fluid and body fluid. These particles are then phagocytosed mainly by macrophages (type of white blood cell that functions as a patrol cell and engulfs and kills foreign infectious invaders), osteocytes (bone cell) and giant cells in the surrounding bone. The release of different cytokines (a small protein released by cells that has specific effect on the interactions between cells, on communications between cells or on the behaviour of cells) and enzymes from macrophages and giant cells has been shown in many cases to induce the formation of osteoclasts (a cell that nibble at and breaks down bone and is responsible for bone resorption), thus resulting in local bone loss (osteolysis) and aseptic loosening of artificial femoral stem. The occurrence of Osteolysis in association with both well-fixed and loose cemented total hip

prostheses has given rise to the term cement disease. Histologically, cement disease is characterized by the presence of variable amounts of cement, ultra-high molecular weight polyethylene, and metal debris in tissue infiltrated with macrophages, giant cells, and vascular granulation tissue.

Therefore, it is essential to quantitatively minimize the polyethylene wear particles in hip joints. For the acetabular cup, metal or ceramic bearing surfaces, improvement UHWPE and various carbon-fibre reinforced synthetic materials are under investigation (Raimondi & Pietrabissa, 2000). It is generally accepted that ion implantation treatment can modify the mechanical wear properties of metals. In particular, nitrogen ion implantation is an excellent candidate to enhance the wear resistance of a wide range of ferrous materials and titanium based alloys.

Titanium alloys have many interesting properties for orthopaedic implants. The most important is their high corrosion-fatigue resistance. However, they have very poor friction and wear behavior, even when rubbing against a soft material such as polyethylene and cannot be used without a surface treatment for orthopaedic implant. On the other hand, 316L stainless steel has been applied for many years for permanent or temporary implants. Its mechanical properties are lower than those of the titanium alloy, but its friction and wear characteristics are far better. In some cases, crevice corrosion has been observed. It is often associated with wear (Rieu et al., 1991).

Several researchers have utilized the ion beam applications in the medical area, such as for orthopaedic prostheses that require high wear properties, excellent corrosion resistance and biocompatibility. In a 3-year follow-up with the nitrogen -ion implanted cobalt-chromium (Co-Cr) femoral head using ion beam process, Maruyama et. al. reported a significant reduction in polyethylene wear (Ikeda et al., 2002).

4.2. Loosening

The number of total hip replacement operations being performed is growing, with over 800,000 being carried out each year. The increase is particularly noticeable in younger people, who are on average more active and therefore impose larger and more frequent loads on the joint than do the more traditional elderly population. Prostheses are therefore more prone to failure, leading to an increased incidence of early revision operations (Gross & Abel, 2001).

Failure is generally due to aseptic loosening of the implant. Four main causes have been identified. The presence of wear particles triggers cell processes that cause osteolysis. Relative movement of the prostheses leads to the development of a soft tissue interface. Mechanical failure of the implant or cement and stress shielding of bone surrounding the prostheses due to mismatch in structural behavior can lead to bone resorption (Sloten et al., 1998).

4.2.1. Effect of Wear Particles

Implants usually fail by a combination of mechanisms, but different basic designs tend to show different dominant mechanisms of failure. There are several different mechanisms and modes of implant wear, and perhaps the most important cause of aseptic loosening is an inflammatory reaction to particles of wear debris. Abrasive, adhesive, and fatigue wear of polyethylene; metal and bone cement produces debris particles that induce bone resorption and implant loosening. Charnley found that reaction to excessive wear particles might result in bone resorption while a further biological response is the development of a soft tissue layer at the cement-bone interface, which may compromise fixation. A number of factors can stimulate bone resorption, including the inflammatory reaction associated with infection, the inflammatory reaction stimulated by particles of wear debris, insufficient mechanical load, implant motion, and, probably, high fluid pressures (Bauer & Schils, 1999).

4.2.2. Micromotion

Micromotion of implants that did not achieve adequate initial fixation is another important mechanism of loosening. Fatigue failure at the bone/cement and bone/implant interface may cause aseptic loosening, and may be especially important for implants with relatively smooth surfaces. Based on clinical, radiological, and histological observations, it is believed that micromotion between cement and bone is the cause of failure of cement fixation. The amplitude of such motion need not exceed 30 μm of displacement since this is the smallest acrylic “spherule” displaced from its bed and incorporated into the shape of modified bone. These spherules are the small particles recognisable from a mass of acrylic. In this theory the structure of the acetabulum is the cause of initiation of micromotion. The weight-bearing portion of the bone of the acetabulum after exposure of bony trabeculae by removal of the subchondral plates is responsible for the deformation of bone and micromotion at the interface. If the stiffness of the acetabulum is reduced by removal of the subchondral bone, plastic deformation of the bone may occur. Stress may then be concentrated at the exposed trabeculae which, in turn, results in bone necrosis. Necrotic bone, in time, is replaced by a fibrous membrane that may or may not turn into a strong fibrocartilaginous metaplastic weight-bearing structure. If this fibrous interface results in significantly decreased stiffness, further motion will break down the acrylic and causes more looseness (micromotion) (Azem, 1999).

4.2.3. Effect of Mechanical Factors

Loosening may be attributed to a combination of mechanical and biological factors as well. Moreland et. al. reported an increase in loosening detected radiologically in young, heavy males. Increased body weight requires the implant system to sustain increased loads. Since the patients were young their activity levels were also high, which may hasten loosening of femoral component. Willert et.al. found that varus positioning of the stem, which is the inclination of the femoral component stem in the coronal plane, may cause the implant fixation to experience higher stresses. It has been shown by experiment that considerable reductions in

tensile and shear strengths of the bone cement are caused by the infiltration of blood prior to curing. Failure of the mantle is believed to start at the cement-stem interface, which is significantly weaker than the bulk of the cement under static and fatigue loading. A number of studies have indicated that once the cement-stem interface has become loose the stresses become significantly higher in the cement mantle (Bishop et al., 1996). Other mechanical factors, which have been stated to cause loosening of the femoral component, include poor cement technique and inferior hip replacement design. The high strains or stresses on the cement at the tip of the prostheses are strong indications that this location is a likely site for the initial event of failure. High strains at the proximal and distal tip of the prostheses are appeared to cause debonding between the stem and cement and were associated with radial crack initiation at the debonded surface of the pores in the cement surrounding the areas of debonding (Humpreys et al., 1991).

4.2.4. Stress Shielding

The natural femur carries its external load by itself. When a femoral component is introduced into the canal, it shares the load and the carrying capacity with the bone. Where one structure, the bone, originally carried the load, the two stem and the bone now carry it. As a result, the bone is subjected to reduced stresses, and hence stress shielded. Wolff's Law suggests that the coupling of an implant with a previously load bearing natural structure may result in tissue loss. Indeed, it has been shown that when the tension/compression load or bending moment to which living bone is exposed is reduced, decreased bone thickness, bone mass loss, and increased osteoporosis ensue. This phenomenon, termed "stress shielding", has been related to the difference in flexibility or stiffness, dependent, in part on elastic moduli, between natural bone and the implant material.

The bone resorption resulting from stress shielding can lead to excessive stresses in the bone cement and the interfaces with the bone and the prostheses stem. This effect is a consequence of the mechanism of load transfer from the prostheses to the femur. Whereas the physiological mechanism of the proximal to distal load transfer is by direct long axis loading, in the prostheses shear forces transfer the load across

the material interfaces at the proximal and distal ends of the stem. The more rigid stem, the less load it transfers proximally so the greater stress shielding of the proximal femur. A stem of a lower stiffness material will transfer more of the load to the femur proximally, is expected to enhance stress redistribution to the adjacent bone tissues, therefore reducing stress shielding, however, this is achieved at the expense of higher load transfer stresses at the cement interfaces with the bone and implant and the risk of cement failure. At the same time, there is no means of reaching a totally satisfactory compromise between low stress shielding and low interface shear stresses in this type of implant (Gross & Abel, 2001).

Although THRs are used widely; one of the major unsolved problems in this important application has been the mismatch of the stiffness of the femur bone and the prostheses. Commercial hip joint stems are made from metal alloys, which are isotropic and at least five to six times stiffer than the bone. It has been acknowledged that the metallic stems due to stiffness mismatch induce unphysiological stresses in the bone, thereby affecting its remodeling process. It is discussed that this leads to bone resorption and eventual aseptic loosening of the prostheses. Gese et al. demonstrated that Ti alloy stems result in a 50% reduction in the femur peak stress compared to the Co-Cr alloy stem. It has been acknowledged that the implant loosening and eventual failure could be reduced through improvements in the prostheses design and using a less stiff material with mechanical properties close to the properties of bone (i.e. isoelastic materials). However, because of the high strength requirement for hip prostheses design, materials suitable for these implants are very limited.

4.2.5. Factor of PMMA Loosening

The causes of loosening itself are multifactorial, with both biological and mechanical processes operating simultaneously. In the case of the femoral side, fatigue fracture of the metal stem is sometimes reported, but fatigue damage accumulation in the polymethylmethacrylate (PMMA) cement is the most common cause of loosening. Damage accumulation can be accelerated by stress increases

caused by biological adaptations, e.g. bone resorption or fibrous tissue formation at the cement/bone interface.

Table 4.1. Young modulus of cancellous bone and cortical bone compared to the metallic biomaterials.

Material	E (GPa)
316L Stainless Steel	196
Co-Cr alloy	210
Ti alloy	116
Cancellous Bone	0.4
Cortical Bone	15-25
PMMA	2.5
UHMWPE	1

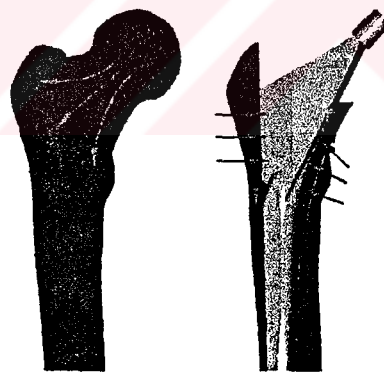


Figure 4.1. Schematic representation of the load transfer before and after THA (Gross & Abel, 2001).

Several structural analyses of hip replacements have been carried out to establish the relationship between prostheses design and joint lifetime. Despite its widespread use, PMMA is not an ideal fixation material because it cannot sustain cyclic loading over an extended period; mechanical failure of the cement can occur leading to implant loosening and need for a revision operation. For this reason, cementless or

“cement-free” fixation is sometimes preferred for younger patients who will need the implant to survive for longer and who are also likely to subject the fixation to higher loads. To improve the performance of PMMA under cyclic loading, a clear understanding of the mechanism of PMMA failure in vivo is required.

One framework for understanding the biomechanics of failure of orthopaedic implants was proposed by Huiskes. In particular the bone cement can undergo failure by microcrack growth in the bulk cement and on the cement-prostheses and cement-bone interfaces. This can lead to loosening by itself, or it can lead to the generation of particles as the crack surfaces abrade each other causing the particulate reaction failure scenario. The result is mechanical loosening of the implant fixation and pain for the patient (Prendergast, 2001).

Experimental investigation has proved to be very difficult, mainly for the following reasons: (i) the weakest structural component (the PMMA) is encased between the prostheses and the bone, and hence quantification of fatigue crack propagation is difficult; (ii) the fatigue failure is multifactorial, possibly involving crack propagation along and out from both the PMMA-metal and PMMA-bone interfaces accompanied by crack kinking into the bulk cement, and the crack propagation from defects (pores, cold shuts, etc.) within the bulk cement; and (iii) the loading conditions are complex and vary considerably during daily activities.

In an attempt to overcome the complexity of the loading, the authors have investigated the bending and torsional aspects of the load separately. McCormack et. al. described an experimental model used to investigate damage accumulation due to bending, and showed that damage accumulation under bending is by crack growth from pores with very little interface crack propagation. This result is not in agreement with autopsy-retrieved implants, where crack propagation from interfaces is observed as dominant cracking pattern. This suggests that bending is not the critical loading mode for implants in vivo, but rather that torsion may be the loading mode generating critical interface damage under cyclic loading. Torsional loading plays a significant role in creating damage in cemented hip replacements by causing

crack propagation from pores and the PMMA cement-implant interface, and should not be neglected in theoretical or experimental analyses. Because of this designers of joint hip replacements should attempt: minimize the torsional component of the load; and design cross sectional geometries, which are optimized to reduce damage accumulation due to torsion (McCormack et al., 1999).

4.3. Corrosion

4.3.1. General Aspects of Corrosion

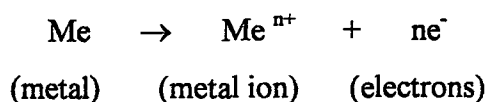
Corrosion may be regarded as the usually unwanted interaction of a metallic component with the environment in which it exists. During the process, metal ions may be lost from the metal surface to form either a solid corrosion product or one that is soluble in its environment. The corrosion environment may in general be liquid or gaseous. Corrosion of metallic materials in implants may affect the body tissue by cell reaction to electrical current, change of pH and release of metallic ions from the implant. For stainless steel the biological environment reacts by formation of connective tissue between metal surface and body tissue; besides that, allergic reactions to nickel and chromium are also reported. Surface modifications of stainless steel implants by application of ceramic coatings, such as TiN or diamond-like carbon films, have been investigated as a means to reduce friction and increase corrosion resistance. However, ceramic thin films are very brittle and cannot normally withstand plastic deformation of the substrate without cracking and/or delamination (Macionczyk et al., 2001). In dealing with the corrosion of orthopedic implants, emphasis will be given to aqueous corrosion. Tissue fluid in the human body contains water, dissolved oxygen, proteins, and various ions such as chloride and hydroxide. As a result, the human body presents a very aggressive environment for metals used for implantation. Corrosion resistance of a metallic implant material is consequently an important aspect of its biocompatibility. For this reason the biocompatibility of a metallic implant is usually equated with its corrosion resistance. Thus, the biocompatibility of metallic materials is controlled by the chemical, or more precisely the electrochemical interaction that results in the release

of metallic ions into the tissue, and the toxicology of these released substances (Zitter & Plenk, 1987).

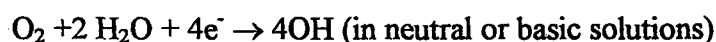
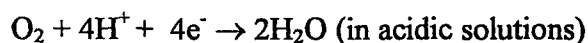
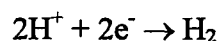
Corrosion reactions are chemical process that take place at the surface of the metal and obey well-established laws. It has been established that corrosion in aqueous media is an electrochemical process.

Corrosion can be viewed as the tendency of a metal to revert back to its natural and more stable state as an ore. Certain environments offer opportunities for these metals to combine chemically with elements to form compounds and return to their lower energy levels. The lowest free energy state of many metals in an oxygenated and hydrated environment is that of the oxide. Corrosion occurs when metal atoms become ionized and go into solution, or combine with oxygen or other species in solution to form a compound, which flakes off or dissolves. The body environment is very aggressive in terms of corrosion it is not only aqueous but also contains chloride ions and proteins. A variety of chemical reactions occur when a metal is exposed to an aqueous environment. Electrolyte, which contains ions in solutions, serves to complete the electric circuit. In human body, the required ions are plentiful in body fluids.

Anions are negative ions, which migrate toward the anode, and cations are positive ions, which migrate toward the cathode. At the anode, or positive electrode, the metal atoms are oxidized by losing valence electrons as in following. Two kinds of chemical reactions usually occur on a metal surface exposed to an aqueous solution. There is an oxidation or anodic reaction, which procedures a supply of electrons of the type:



And a reduction or cathodic reaction, which consumes the electrons, produced by the anodic reaction. The reduction of dissolved oxygen and the production of hydrogen ions are the two principles cathodic reactions, represented as:



As with any electrochemical cell, both the anodic and cathodic reactions must occur simultaneously, to preserve electrical neutrality and, must proceed at the same rate. The sites of these reactions, i.e., the anode and the cathode, need not be adjacent, but can be widely separated, providing that they remain in electrical contact.

4.3.2. Types of Corrosion

Under conditions where the anodic and cathodic sites are mobile or randomly distributed, the resulting attack may be general over the whole surface. In many instances, however, the attack is concentrated at specific sites, resulting in many different forms of localized corrosive attack, the most common of which are described below.

4.3.2.1. Galvanic Corrosion

If two dissimilar metals placed in contact with each other are subsequently exposed to a conductive solution, an electrical potential will exist between them. This will serve as the driving force for the flow of current, with subsequent corrosion, referred to as galvanic corrosion, of one of the metals in the couple. The larger the potential difference between the two, the greater is the probability of corrosion of the less noble metal (galvanic attack). Galvanic corrosion only causes accelerated deterioration of the less noble material, which would have undergone attack even if placed in the solution in isolation.

Reference may be made to the electrochemical series to determine which component of a galvanic couple will be protected and which will be attacked. The phenomenon is clearly of importance in multicomponent devices, for example, bone plates and screws, where use of items of dissimilar materials may induce galvanic attack.

Whenever stainless steel is coupled with another alloy, it will suffer from galvanic corrosion. If both alloys remain within their passive region when coupled in this way, the additional corrosion may be minimal. Some modular orthopedic systems are made of titanium alloys and cobalt-based alloys on the basis that both should remain passive.

4.3.2.2. Pitting Corrosion

Stainless steels, as is the case with many other metals, depend on the presence of a closely adherent oxide surface layer for their resistance to corrosion. The austenitic chromium-nickel-molybdenum steel achieves its “stainless” characteristics through the formation of a 1-5 nm thin and adherent chromium rich oxide film. Molybdenum is typically added to stainless steels to increase corrosion resistance—particularly in chloride containing environments. The chromium oxide that forms on the surface passivates the stainless steels (Ratner, 1996). When continuous, this thin layer of oxide protects the metal from any further oxidation. Due to the mechanism of this type of protection the corrosion resistance of the metal and the ability to maintain the integrity of the oxide film depend on the continuous presence of oxygen in the environment. Thus, the stainless steels are passive in corrosive salt solutions such as the body fluids as long as the oxygen tension remains relatively high and is uniform over the entire surface (Bement, 1971).

In surface defects like fissures or pits the local corrosion rate may be drastically increased, due to incomplete repassivation of the surface caused by the lack of oxygen. For implants made of stainless steel in vivo pitting corrosion has been observed. When differential oxygenation is present over the surface of stainless steel several means are available for corrosion to occur. Where the surface is in contact

with a low oxygen environmental the equilibrium of the reaction on metal with environmental oxygen is shifted in favor of the breakdown of the protective oxide film and producing small areas in which the protective surface is removed. The localized spots will actively corrode and pits will form in the surface of the material. The resulting exposed metal acts as an anode to the surrounding protected areas, which are cathodic. The shape of the pits varies from hemispherical to a wide variety of irregular shapes caused by undercutting with the result that the surface diameter may be less than the diameter below the surface (Ducheyne & Hastings, 1984).

Work on pitting propensity in simulated physiological saline solutions has shown that for titanium and chromium cobalt alloys, the probability of pit formation is very small. With the stainless steel, however, there is a significant probability of pit formation. This is borne out in practice where the observation of pitting is confined to stainless steel components.

Both the major elements of austenitic stainless steels, chromium and nickel, increase resistance to pitting. Other important alloying elements that increase resistance to pitting are molybdenum and nitrogen (Sedriks, 1996). Pitting attack on the prostheses would probably have been initiated owing to the low molybdenum content and excess of sulphide inclusion, which is known to play an important role in initiating pitting attack in stainless steel. The presence of pits in the implant at such a critical site had resulted in a decrease of pH in the vicinity of implant at the fractures site. The pits could have acted as stress raisers, and hence the cracks would have been initiated from these pits. Therefore, the failure of the prostheses was due to the microcracks formed on the prostheses. The cracks were aggravated by the high inclusion content and large grain size of the implant material (Sivakumar, 1992).

4.3.2.3. Crevice Corrosion

As the principal cathode reaction in aqueous solutions is the reduction of oxygen to hydroxyl ions, it follows therefore that regions of highest oxygen concentration and easy oxygen access will be principally cathodic, whereas those regions with restricted oxygen access will become anodic. A circuit will flow between a well-

aerated electrode and a less-aerated one with the latter suffering preferential attack. This phenomenon is known as differential aeration and is important in many corrosion phenomena, noticeably crevice attack.

Because the electrolyte in a crevice has only limited access to the surrounding saline fluid, corrosion leads to a build-up of hydrogen and metal ions in the solution, together with a decrease in oxygen. The highly mobile chloride ion migrates into the crevice, and by a similar mechanism to that observed with pitting, the attack becomes accelerated. Titanium is generally considered to be biocompatible and highly corrosion resistant. On the other hand, titanium is also prone to crevice corrosion if fixed with PMMA. This is why titanium is recommended to be used in cementless implants (Tiainen, 2001).

As crevice attack occurs at interfaces, multicomponent devices, notably bone plates and screws, suffer from this type of attack.

4.3.2.4. Grain Boundary Attack (Intergranular Corrosion)

All metals crystallize from the molten state to form thousands of grains (regions of regular atomic arrangements). Where grains meet there is a region of mismatch, the grain boundary.

These regions are less ordered and possess higher energy than the body of the grains and may suffer preferential attack, resulting in intergranular corrosion. The attack may be due to the higher energy of the boundaries or to alloy segregation, resulting in a potential drop between the boundary and the body of the grain sufficient to lead to the development of corrosion currents of considerable magnitude.

Stainless steels made of 18Cr-8Ni are susceptible to intergranular corrosion when heat treated in the temperature range 500 to 800°C, as can occur, for example, in regions adjacent to welds or as a result of insufficient thermal control during forging. In this temperature range, chromium carbides Cr_{23}C_6 are precipitated at the grain

boundaries and the immediately adjacent areas become depleted in chromium, as shown in Figure 4.2. These chromium-depleted regions become active with respect to the body of the grain, and in the presence of an electrolyte can lead to the formation of an electrochemical cell. The low anode/cathode area ratio leads to corrosion under anodic control and the possibility of very severe attack.

This phenomenon can be remedied by the addition of strong carbide formers to the steel, for example, niobium or titanium. These will then form carbides preferentially to Cr_{23}C_6 , thus preventing the formation of the chromium-depleted region. Steel in this condition is said to be stabilized. Low carbon grades of steel, for example, AISI 316L also reduce the problem by limiting the carbon available to form carbide. Phosphorous and sulfur segregation have also been proposed as being responsible for weld decay, i.e., attack close to welds.

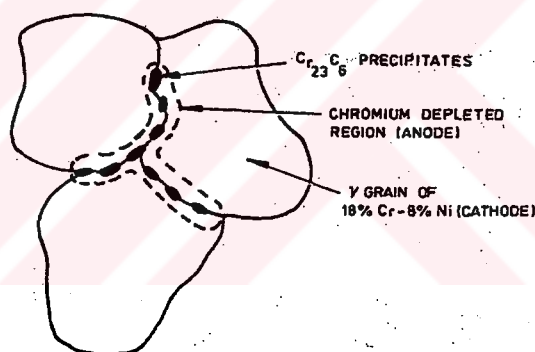


Figure 4.2. Carbide particles at grain boundaries leading to the setting up of electrochemical cell and grain boundary dissolution. (Ducheyne & Hastings, 1984).

4.3.3. Role of Corrosion on Mechanical Failure

Many alloys when subjected to the conjoint action of tensile stress and a corrosive solution will suffer cracking and premature failure. The process is a synergistic action since in many cases both the stress level and the solution themselves are relatively harmless and only induce premature failure when acting together. Three basic examples of the phenomenon will be considered here, stress corrosion cracking (SCC), corrosion fatigue, and fretting corrosion.

4.3.3.1. Stress Corrosion Cracking

Stress corrosion cracking (SCC) is a general term describing stressed alloy failures that occur by the propagation of cracks in corrosive environments. SCC has the appearance of brittle fracture, yet it can occur in highly ductile materials. SCC requires the presence of a tensile stress, either residual, applied, or a combination of both, and the presence of specific corrodent. The cracks form and propagate roughly at right angles to the direction of the tensile stress at stress levels much lower than those required to fracture the material in the absence of the corrodent. On a microscopic scale, the cracks that run across grain called “transgranular” and those that follow grain boundaries are termed “intergranular” (Sedriks, 1996).

The typical sequence of events in stress corrosion cracking of steel aptly depicted by Brown as consisting of the following stages: localized breakdown of the oxide film, crack nucleation from the pit, stress corrosion crack propagation and termination of crack by mechanical rupturing

Therefore, the failure of the intramedullary nail was a result of stress corrosion cracking due to the propagation of cracks radiating from a corrosion pit or pits. The crack was aggravated by the high inclusion content and large grain size of the implant (Sivakumar, 1992).

In 18Cr-8Ni stainless steel, failure can be either transgranular or intergranular, the latter frequently being associated with sensitized material. Transgranular cracks can, however, be initiated, by intergranular cracks. Elevated temperatures favor transgranular cracking in stainless steel so that care must be taken during sterilization procedures to avoid critical combinations of stress, temperature, and environment.

In titanium alloys, failure is transgranular and is due either to hydrogen embrittlement or a dissolution mechanism. Although chromium cobalt alloys are most unlikely to suffer from SCC in the body, premature failure can result due to the chemical sharpening of notches, which may already be present in the design of the

component, cast chromium cobalt alloys in particular having very low resistance to notch impact failure.

SCC of stainless steels is dealt with in an attempt to understand the mechanism of failure. The suggested mechanisms can be categorized according to the following unit process thought to be responsible for the propagation of the stress corrosion crack.

There are basically two different unit process: (a) the removal of material at the crack tip and (b) the separation of the material at the crack tip. These unit processes provide the basis for the classification of the SCC mechanisms shown in the following list:

(a) Removal of Material by Dissolution or by Film Formation

Stress-Accelerated Dissolution: The crack propagates by dissolution of the metal along an active path. The role of plastic deformation is to accelerate the dissolution mechanism.

Brittle Film Rupture: The crack propagates by the repeated formation and rupture of a brittle film that grows into the metal at the crack tip. The crack is confined to the brittle film and does not extend into the metal.

Film Rupture Plus Dissolution: The crack propagates by repeated formation and rupture of a brittle film at the crack tip and by some dissolution of the adjacent metal before the film re-forms.

(b) Separation of Material

Hydrogen Embrittlement: The crack propagates by the mechanical fracture of a region weakened by hydrogen accumulation.

Adsorption: The crack propagates due to species absorbing and reducing bond strength at the crack tip.

Film Rupture Plus Mechanical Fracture: The crack propagates by the repeated formation and the rupture of a brittle film at the crack tip and by some mechanical fracture of the adjacent metal before the crack is arrested by the plastic deformation and the film re-forms.

4.3.3.2. Fretting Corrosion

Fretting corrosion is most probably a combination of abrasive and corrosive wear acting conjointly, and abrasion, caused by the entrapment of the worn off oxide film and oxidized wear particles between the surfaces, ruptures the oxide film, thus allowing further corrosion to occur.

Fretting is a small amplitude oscillatory movement that may occur between contacting surfaces and may cause surface damages. If a relative movement is the consequence of a cyclic loading of one or both the contacting components, fretting will act conjointly with the cyclic stress, and the fatigue strength of the component will be much reduced. This phenomenon is referred to as fretting fatigue. Since fretting fatigue is a surface phenomenon, engineering the surface to produce a hard and wear resistant layer is believed to be an effective palliative. Attempts have been made in the past to modify the contact surfaces so as to improve the fretting fatigue strength of materials. These investigations have ranged from traditional surface techniques such as electroplating, thermochemical treatments and cold working, to the modern surface coating and surface modification techniques such as PVD, CVD and ion implantation (Li et al., 2000). Fretting Corrosion is the combination of the surface degradation occurring due to relative oscillatory tangential slip of small amplitude between components and the action of a corrosive environment. The relative amplitude is low ($< 75 \mu\text{m}$) and relative velocities are much lower than in wear, giving rise to the trapping of fretting debris between the surfaces.

Mechanism of fretting corrosion:

Three mechanisms are thought to occur in fretting corrosion, the relative importance of each depending on the nature of the two surfaces and the circumstances:

Removals of metal particles from the cold welds, which are formed at the relatively few points of intimate metallic contact, are ruptured. This mechanism is similar to the process occurring when two metals slide in contact with each other, which has been demonstrated by Bowden and Tabor. The subsequent oxidation of the metal powder to the oxide is assumed to play no part in the process.

The metal particles initially produced by the first mechanism are oxidized to a hard abrasive oxide, and the action is further intensified by this abrasive.

The continual rupturing of oxide films on the surface, which, in the absence of any mechanical disturbance, would be protective. The clean metal, which is continually being exposed, is highly deformed and therefore more chemically active.

Corrosion fatigue and fretting corrosion are both to some extent the result of increased chemical activity brought about (a) by the rupture of oxide films on the surface, and (b) the altered electrode potential, and possibly chemical potential, of plastically deformed metal (Fuchs, 1980).

In stainless steel implants, fretting corrosion produces scars with a pitted or granular appearance as distinct from the more polished wear traces. Angular corrosion pits are found at the periphery of the fretting scars. Deep corrosion tunnel-pits are observed in some scars, and chemical attack occurs along selected crystallographic planes leading to etch pitting,

By contrast, chromium-cobalt-molybdenum alloys show evidence of polished scars, corrosive activity varying from intense local attack to more general corrosion. The scars possess a rippled appearance possibly caused by grooves worn in the

material by an abrasive wear process. Some grooves may contain fine rounded particles, possibly the result of a breakup of brittle carbide particles exposed to the fretting surface.

Titanium alloys possess poor wear properties and finely divided metallic titanium is believed to be a product of the wear process. Fretting scars have a plowed appearance rather than polished or pitted, and cratering may also be observed.

4.3.3.3 Corrosion Fatigue

A material subjected to repeated stress cycle may be susceptible to fatigue cracking, depending on the amplitude and the number of the stress cycles. If the material is also exposed to a corrosive environment, then the fatigue cracking may be accelerated as a result of a process termed corrosion fatigue.

The process of failure by corrosion fatigue comprises two stages. During the first stage the combined action of corrosion and cyclic stresses damages the steel by pitting and crack formation to such a degree that fracture by cyclic stressing would occur ultimately even if the corrosive environment were removed altogether. The second stage is essentially a fatigue stage in which failure proceeds by propagation of the crack and is controlled primarily by stress concentration effects and physical properties of the steel (Uhlig, 1955). General aspects of corrosion fatigue of 316L are dealt with in details in Chapter 4.4.4.

Factors Influencing Corrosion Fatigue:

The corrosion fatigue properties of a material are naturally closely linked with its corrosion resistance. In general it is found that pure metals and solid solutions are superior to compositions containing two or more phases. The fatigue curves for the first two are almost identical in corrosive and non-corrosive environments.

The extent of the damage depends on the corrosive nature of the environment. Ordinary dry fatigue in air may be regarded as corrosion fatigue under rather mild

conditions. Tests carried out on various materials in a partial vacuum showed that the fatigue properties were improved, a fact which has been confirmed in tests performed with the test piece immersed in a oil, covered with grease, and painted with rubber solution.

A mean compressive stress applied to the specimen during test results an endurance limit similar to the normal fatigue strength. The pressure tends to heal up cracks, which develop in the oxide film, and so to limit electrochemical corrosion. A compressive stress can therefore be regarded as making the metals and/or alloys more noble.

Corrosion is a chemical process and the amount of material removed depends on the length of time that the specimen is in contact with the corrosive. Since corrosion fatigue endurance limits are quoted for a given number of cycles, it is obvious that the lower the frequency of the applied stress the longer the specimen is in contact with the corrosive. Endurance limits are, therefore, very dependent on frequency, in contrast to normal fatigue where frequency effects are slight.

4.3.4. Contribution Factors on the Corrosion Process

The following features are frequently contributory factors in the initiation or acceleration of the corrosion process:

4.3.4.1. Effect of Metallurgical Variables

As type AISI 316L, the principal austenitic stainless steel used for surgical implant applications, is susceptible to corrosion in aqueous environments, it is of paramount importance that the chemical composition is maintained within the specifications laid down by the various standards organizations. The amounts of chromium, molybdenum, carbon, and nickel present in the steel are all important if the material is to have adequate corrosion resistance. The presence of molybdenum within the limits of 2.0 to 4.0% is of the greatest significance.

Variations in the nickel content affect both mechanical properties and the corrosion resistance. Reducing the concentration of nickel increases the possibility of galvanic corrosion in multicomponent devices. As discussed earlier, this phenomenon is not restricted to different materials, but may occur when components, made from different compositions or with different microstructures, are in electrical contact. This frequently occurs in bone plates and screws, where manufacturing techniques involving cold deformation can lead to martensitic transformations in screws which may then corrode preferentially when in contact with the austenitic plate. This process would be reduced if the nickel content were kept above 11% as this retards the martensitic transformation. High nickel contents, however, may result in screws of inferior mechanical properties due to the associated decrease in work hardening rate. These two effects of nickel concentration may imply that the range of concentrations allowed should be reduced. Concern for the corrosion properties of the steel has been shown by the increase in recent years in the minimum concentration of nickel allowed in the steel by BSI from 8 to 10%, although this may still be “top low” as 11% is felt by some workers to be a critical concentration. Very few cases of steel depleted in chromium have been reported possibly because this element is standard to all stainless steels.

4.3.4.2. Incorrect Metallurgical Condition

When considering incorrect metallurgical condition, sensitization, which has been discussed previously, is of paramount importance. A continuous network of grain boundary precipitates provides a path for corrosion and a means of deep penetration of the implant. Removal of whole grains may occur, resulting in serious weakening or fracture.

4.3.4.3. Poor Design and Use of Implants

Poor design or the incorrect use of implants is principally apparent in multicomponent devices, leading to the formation of crevices and notches which then promote corrosive attack. Bone and nail plates present particular problems in this area due to the multiplicity of design combinations available for plates and screws.

Although the design of the threadform would appear to have little effect upon corrosion behavior, the surface finish is of paramount importance, with electropolishing being necessary, especially if a thread rolling technique has been used, which may lead to a highly work hardened surface containing inclusions, folds, and rakes.

Many design problems relate to interfaces which can result in crevice formation, pitting attack, or fretting corrosion. Components which have many points of contact frequently exhibit evidence of corrosive attack. Reducing the amount of corrosion could be achieved either by redesigning the component, minimizing the number of points of contact, or by manufacturing it from a material less susceptible to pitting corrosion.

4.3.4.4. Effects of Surface Finish

There are two aspects of surface finish which are of importance to corrosion studies. These are the effects of surface treatments or blemishes upon the propensity for corrosive attack and the probability of initiating corrosion-stress interrelated phenomena.

One of the most important surface treatments applied to stainless steel implants is passivation in nitric acid which has long been recognized as giving improved corrosion treatment. The process which is also applied to titanium alloys and which has the additional advantage of removing any iron particles which may have become embedded in the implant surface during polishing consists of immersion in a 30% nitric acid solution at 40 to 60°C for approximately 15 min. More recently, it has been proposed that passivating in oxygenated isotonic saline solutions can give enhanced corrosion resistance.

Polishing either by mechanical or electrochemical methods is frequently used to improve the surface finish. The latter gives a superior corrosion resistant surface, possibly due to the method and nature of the treatment. Mechanical polishing leaves a slightly work hardened layer on the surface, while electropolishing (which may be

regarded as a controlled electrochemical corrosion process) preferentially removes high energy atoms, for example, kink sites or ledges, which might be expected to undergo accelerated attack.

After polishing, the effects of isolated scratches incurred, for example, during handling or insertion, depend significantly upon their position on the implant and the ability of the damaged area to repassivate. Where repassivation is possible, only a short-term increase in the corrosion rate would be expected. If, however, the damage were in a crevice a permanent site of attack might result. A further factor to be considered is how the scratch was formed; contact with a harder material, for example, leads to the possibility of fretting corrosion, metal transfer, and galvanic attack.

Surface finish is also of considerable importance when considering resistance to corrosion fatigue or SCC. Fatigue crack initiation is a surface phenomenon and usually occurs in a region of maximum stress. Once a crack has initiated it will, in most circumstances, continue to propagate until complete failure of the device occurs. Any surface defect, for example, polishing or grinding marks, may be sufficient to promote cracking if it occurs in a region of high stresses. The effect of the defect may be to act as a precrack or stress concentrator, increasing the stress intensity at that point. Examples have been noted of surface defects which have initiated fatigue cracks, notably in stems of artificial hip joint prostheses.

Lack of appreciation of the above has led to occasional examples of cracks starting at defects deliberately introduced into the implant in highly stressed regions. Two cases have been reported of failed artificial hip joint prostheses which have broken on the stem due to cracks initiated at spark-etched trade marks on the lateral surface of the stem in the region of the maximum stress. Marks induced by this method produce very sharp notches which consequently have large stress-raising effects. These examples together with other design features, sharply notched serrated edges, sharp corners, and sharply radiused edges, may all serve as suitable stress concentrations to damage the oxide film and so help initiate corrosion fatigue or SCC.

The incidence of failures is low, but what emerges from many of the examples of components that have failed due to excessive corrosion is that in many cases the factor or combination of factors which contributed to the attack could have been avoided. Failure to produce steel to the required compositional standards or in the required metallurgical condition implies insufficient control over the manufacturing processes and ineffective quality control which allows such implants to be passed as satisfactory. Quality control can also be questioned when surface defects in highly stressed regions remain undetected. Improvements in the quality of implants is being achieved as realistic standards are being produced and as a result of the cooperation and understanding being achieved between surgeons and materials engineers.

Marking of implants in highly stressed regions and in such a manner as to produce sharp notches indicates a deep-rooted lack of understanding of the problems involved which can only be overcome by increased awareness by all involved with surgical implants of the principles governing the mechanical properties and corrosion behavior of the product when in service. Where failure is the result of poor component design or incorrect material selection, the remedy lies with product improvement or use of a different alloy. In this area, new designs are continually being adopted frequently using computer aided designs. A detailed program of standardized testing may be required to prevent the large-scale production of implants containing fundamental design faults or which utilize unsatisfactory material. The frequency of failed devices due to excessive corrosion can be reduced, but only by greater vigilance and effort by all associated with surgical implants (Ducheyne & Hastings, 1984).

4.4. Fatigue

Fatigue is the progressive, localized; permanent structural change that occurs in materials subjected to fluctuating stresses and strains that may result in cracks or fracture after a sufficient number of fluctuations. Fatigue fractures are caused by the simultaneous action of cyclic stress, tensile stress and plastic strain. If any one of these is not present, fatigue cracking will not initiate and propagate. The cyclic stress starts the crack; the tensile stress produces crack growth (propagation).

The process of fatigue consists of three stages:

1. Initial fatigue damage leading to crack nucleation and crack initiation,
2. Progressive cyclic growth of a crack (crack propagation) until the remaining cross section of a part becomes too weak to sustain the loads imposed,
3. Finally, sudden fractures of the remaining cross section.

Fatigue cracking normally results from cyclic stresses that are well below the static yield strength of the material. (In low cycle fatigue, however, or if the material has an appreciable work-hardening rate, the stress may also be above the static yield strength).

It would seem, therefore, that surface cracking could occur in any of three ways, namely, as a continuation of surface roughening in broad slip bands, as a result of severe strain incompatibilities across grain boundaries, or because of the presence of inclusions or inhomogeneities in the surface. The type of cracking that occurs will depend on material, stress level, and environment, if the grain boundaries or inclusion-matrix interfaces can sustain the imposed strain incompatibilities across them without cracking, microcracks will develop from slip bands.

Fatigue cracks initiate and propagate in regions where the strain is most severe. Minimizing these strain concentrations must be the first rule for avoiding fatigue failure. Real structures contain discontinuities, which may develop into cracks with applications of stress, progressive crack extension following up to final failure. Because most engineering materials contain defects and thus regions of stress concentration that intensify strain, most fatigue cracks initiate and growth from structural defects. Under the action of cyclic loading, a plastic zone (or region of deformation) develops at the defect tip. This zone of high deformation becomes an initiation site for a fatigue crack. The crack propagates under the applied stress through the material until complete fracture results. On the microscopic scale, the most important feature of the fatigue process is nucleation of one or more cracks

under the influences of reversed stresses that exceed the flow stress, followed by development of cracks at persistent slip bands or at grain boundaries (Boyer, 1986).

Final catastrophic failure occurs when a crack has grown to a critical length such that the next application of load produces static failure of the remaining net section. Under service conditions of variable amplitude loading, the critical crack length must be defined of course, in terms of the highest expected load and the total load spectrum. Redundant structures, i.e. structures designed with “crack arrestors” stopping the rapid growth of critical cracks before they weaken the integrity of the total structure, represent an important advance in fatigue design based on the previously described crack growth mechanisms (Dieter, 1988).

In the presence of stress concentration, enhanced fatigue hardening will occur in proportion to the stress or strain concentration factor. One can expect this enhancement in the vicinity of notches, fasteners, welds, and most importantly, near the tip of a fatigue crack.

4.4.1. Initiation of Fatigue Cracks

The general and basic features of fatigue failure are the initiation of surface microcracks and their subsequent extension across and penetration into the body of the metal. The onset of damage and cracking is associated with the surface grains, only those grains in the body of a specimen through which a crack, formed in a surface grain, passes as it grows across the specimen being damaged (Frost, 1974). Defining a crack in terms of the highest resolving power instrument available (the electron microscope for instance) it is possible to establish a number of load cycles N_I , to generate an observable fatigue crack. It is usual to express the result in terms of the fraction of total life, N_I / N_T . It has been shown that this ratio is normally a small number in unnotched members, about 0.1, so that fatigue crack propagation occupies a large percentage of total life.

Fatigue cracks always begin at concentrations of plastic strain. Consequently if no other manufacturing imperfections are present fatigue cracks have their origins at the surface. The so-called slip band formation, extrusions and intrusions on the surface of an otherwise uncracked material form fatigue crack initiation sites.

An important structural feature, which appears to be unique to fatigue deformation, is the formation on the surface of ridges and grooves called slip-band extrusions and slip-band intrusions. Wood, who made many basic contributions to the understanding of the mechanism of fatigue, suggested a mechanism for producing slip-band extrusions and intrusions. Figure 4.4 illustrates Wood's concept of how continued deformation by fine slip might lead to a fatigue crack. Slip produced by static deformation would produce a contour at the metal surface similar to that shown in Figure. 4.3. In contrast, the back-and-fro fine slip movements of fatigue could build up notches or ridges at the surface. The notch would be a stress raiser with a notch root of atomic dimensions. Such a situation might well be the start of a fatigue crack. This mechanism or the initiation of a fatigue crack is in agreement with the facts that fatigue cracks start at surfaces and that cracks have been found to initiate at slip-band intrusions and extrusions.

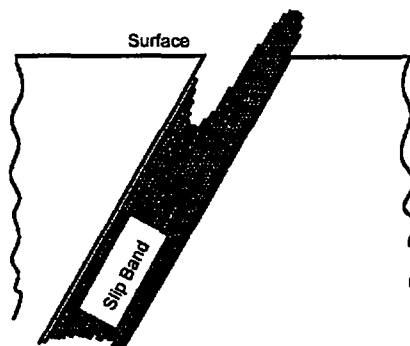


Figure 4.3. Notch-Peak geometry of slip bands at a free surface.

In general, slip lines formed under static loading appear, under low and moderate magnifications, as sharp, straight lines and are distributed evenly over each grain. Under high magnification, the individual lines appear as bands of parallel lines of various heights. The slip lines produced under cyclic stressing form in bands, which

do not necessarily extend right across a grain, new slip lines forming beside old ones as test proceeds, the intervening regions between the bands being apparently free from slip.

The increased life resulting from the removal of a surface layer at frequent intervals throughout a test, irrespective of whether the life is many millions or only a few thousand cycles demonstrates that crack initiation is confined to the surface grains. Electropolishing removed the roughness associated with a slip band, and most of them became visible. A few, however, became accentuated and were termed “persistent slip bands”; fatigue cracks grew eventually from these bands. If the polishing was continued until the persistent bands were removed, it was found that, on retesting, the slip bands reformed and became persistent. These persistent slip bands are embryonic fatigue cracks, since they open into wide cracks tend to propagate initially along the slip planes.

The fact that the initiation and development of microcracks are a consequence of cyclic plastic strain means that whether or not they form is dependent on the magnitude of the resolved maximum cyclic shear stresses in the loading cycle. Thus, the addition of a mean stress does not have a marked effect on the cyclic shear stress necessary to initiate a microcrack, and therefore they are able to form under a wholly compressive loading cycle. A compressive mean stress, however, tends to prevent a microcrack opening and so retards its development to the macrocrack stage. Of course, if the loading cycle is such that the crack faces are never opened, cracks can only keep developing as microcracks (provided the cyclic stress level is sufficiently high); they cannot grow as macrocracks. The introduction of surface compressive stresses of sufficient magnitude and depth therefore increases the fatigue strength of a specimen as a whole. On the other hand, a tensile mean stress tends to open in crack and so enhances its development to the macrocrack stage.

Under high amplitude loading fatigue cracks start at grain boundaries. In many commercial alloys the existence of large second phase particles, inclusions, play a predominant role in crack generation. They cause localised plastic deformation

leading to cracking usually at the inclusion matrix interface. Other flaws such as internal voids or large surface scratches may be the sites of fatigue crack generation. Such flaws need only the application of cyclic load to begin their growth as real fatigue cracks.

The combination of fatigue stresses and even a mildly corrosive environment accelerates the time for crack generation. The effects on later crack growth are even more pronounced. Previous load history can have two effects. First, if the material has been hardened, the yield stress is increased, and under constant stress conditions, the time to generate a crack would be increased. Secondly, prior loading can produce significant residual stresses at the root of a notch. For example prior tensile stress will leave a compressive residual stress, and cracks at the notch root will be very slow in developing compared to the annealed state. A similar situation may arise by superimposed stress conditions such as mean stresses due to external loads or to residual stresses. Treatments such as shot peening are used to induce compressive residual stresses on surfaces, so that N_I can be significantly increased.

There is indication that cracks must reach a minimum critical size before they can begin propagating. Nonpropagating microcracks, which have been observed at very low stress amplitudes, may be examples of cracks, for which the generation mechanism ceased to operate before they reached critical size. The value of N_I/N_T is dependent of the load amplitude, specimen geometry, material properties, the temperature, previous loading history, and the environment. The value of N_I/N_T decreases with increasing load amplitude, so that in the extreme low cycle range the entire life is consumed in crack propagation and in the extreme high cycle range a substantial portion of the entire life is consumed in crack initiation.

4.4.2. Growth of Fatigue Cracks

The direction of crack growth is now that which allows the maximum crack opening and closing during the fatigue cycle. Ideally, this approximately perpendicular to the nominal maximum cyclic tensile stress and is independent of

any crystallographic plane close to the ideal direction. The crack can now be termed a macrocrack; its growth rate is much faster than that of the initial microcrack, and it now spreads rapidly through the metal. The brittle appearance of a fatigue fracture follows from the fact that, during the macrocrack growth stage, the cyclic plastic strain occurring at any instant (at stress levels less than those causing general yielding) is confined to the small volume of material just ahead of the crack front.

Crack propagation occupies a major portion of fatigue life, especially at high load amplitudes. Final failure may be the result of the growth of one crack, or of many small cracks coalescing into a final crack. The higher the load amplitude, the more likely the production of multiple cracks. Corrosive environment also produces multiple cracking and accelerates failure.

There are two main stages of fatigue crack growth. The stage I crack propagates initially along the persistent slip bands. In a polycrystalline metal the crack may extend for only a few grain diameters before the crack propagation changes to stage II. Cracks forming in slip bands propagate along the active slip planes, which are inclined at $\pm 45^\circ$ with respect to the tensile stress axis. This shear mode propagation, Stage I growth, tends to continue more deeply into the specimen the lower the amplitude of loading. The crack soon begins to turn and follow a course perpendicular to the tensile axis. This tensile mode propagation as called Stage II growth, characterizing crack growth up to the critical length for which the next load peak produces tensile failure of the specimen.

Actually, the Stage I growth in a polycrystalline material involves hundreds of individual slip band cracks linking up to form a dominant crack at about the time when stage II growth begins. Stage II crack growth life increases with increasing load amplitude. Cracks formed at inclusions grow only a few micrometers in Stage I before changing to the Stage II mode. At low stress or strain amplitudes, very few inclusion cracks are generated and one such crack may grow all the way into the final failure crack. At higher amplitudes several inclusion cracks may joint together to form the final crack.

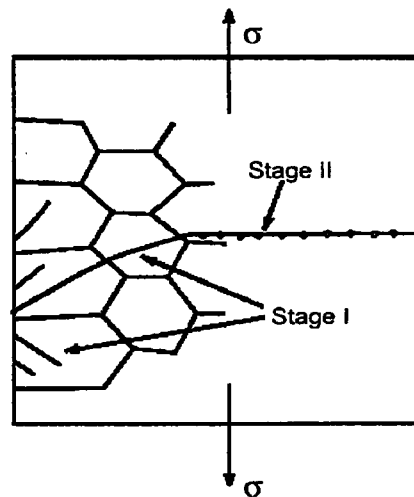


Figure 4.4. Stage I and II fatigue crack growth

Examination of fracture surfaces tells us a lot about the mechanism by which the crack advances. For all practical purposes the entire fracture surface formed is governed by the Stage II mode. Very near the crack nucleus, while the crack length is still small, conditions of plane strain hold at the crack tip. The fracture surface is microscopically flat and oriented perpendicular to the tensile axis. As the crack grows in length a shear lip begins to develop where the fracture surface intersects the specimen surface. This reorientation of the fracture surface to a 45° position with respect to the tensile axis is caused by the plane stress conditions at the crack tip intersecting the surface. As the plastic zone in front of the crack tip increases in dimension to become comparable to that of the specimen thickness, plane stress conditions hold everywhere at the crack tip and the fracture surface is one continuous shear lip or double shear lips. The flat, plane strain surface is especially rich in detail, exhibiting regularly spaced striations, even visible at optical magnification. Each striation represents the crack advance for one cycle of load and this was verified experimentally.

By marked contrast the fracture surface of stage II crack propagation frequency shows a pattern of ripples or fatigue fracture striations. Each striation represents the successive position of an advancing crack front that is normal to the greatest tensile stress. Each striation was produced by a single cycle of stress (Figure 4.5).



Figure 4.5. Beach marks on fatigue surface.

Stage II crack propagation occurs by a plastic blunting process that is illustrated in Figure 4.6. At the start of the loading cycle the crack tip is sharp (a). As the tensile load is applied the small double notch at the crack tip concentrates the slip along planes 45° to the plane of the crack (b). As the crack widens to its maximum extension (c) it grows longer by plastic shearing and at the same time its tip becomes blunted. When the load is changed to compression the slip direction in the end zones is reversed (d). The crack faces are crushed together and the new crack surface created in tension is forced into the plane of the crack (e) where it partly folds by buckling to form a resharpened crack tip. The resharpened crack is then ready to advance and be blunted in the next stress cycle. Cross sections comprising the crack tip formed at various parts of a load cycle have established that Stage II growth occurs by repetitive blunting and re sharpening of the crack tip (Colange & Heiser, 1987).

The effects of multiple load amplitude can be best understood in terms of crack tip plastic deformation. The two important concepts are localized work hardening and localized residual stresses at the crack tip.

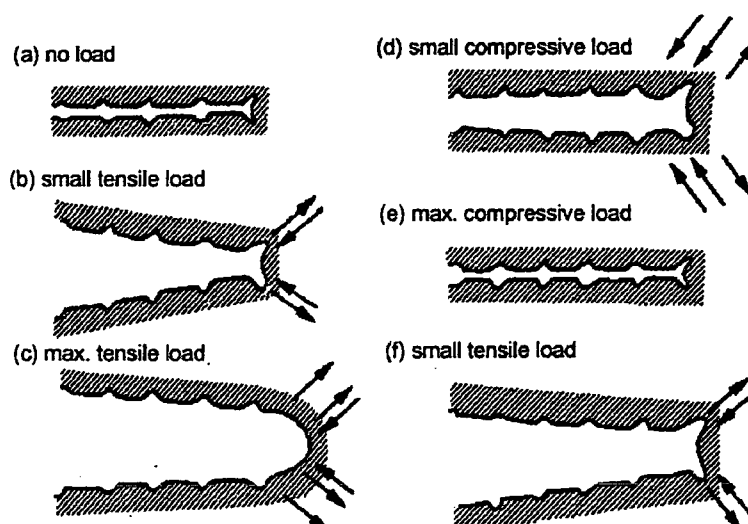


Figure 4.6. Fatigue crack growth by the plastic blunting mechanism.

Intermittent overloads can delay the subsequent growth of cracks at lower loads. On the other hand, such overloads are capable of generating new cracks, which can then grow on the lower amplitudes. The overall effect would be to shorten the effective service life of the member by linking together many individual cracks generated in this manner. An opposite case is the so called “coaxing”, in which fatigue at low amplitudes followed by high amplitudes leads to longer, overall lives, even though such a sequence can produce growth rates larger than normal crack. In this case nucleation of cracks is suppressed by the coaxing procedure, which hardens the surface layers.

4.4.3. Fatigue Failure of Stem

Although successful, total joint replacements do also fail. One of the reasons of clinical failure is fatigue fracture of the metal stem (Ducheyne et al., 1983). A common precursory mechanism to fatigue failure is loosening of the femoral component. The problems of loosening and fatigue failure of the stem are closely interrelated.

While several methods are presently being worked out to improve the long-term fixation of permanent implants, it is obvious that attention should still be focused on the availability of hip prostheses with sufficient mechanical properties. Most

manufacturers realized this aspect soon enough and came up with solutions which basically can be divided into three groups:

- a) use a prostheses material with a high fatigue limit
- b) use a prostheses design with a large cross section and thus a higher bending moment of inertia; and
- c) use a prostheses material with a lower modulus of elasticity.

Stem fracture usually occurs after proximal loosening with loss of medial support of the stem (Desmond et al., 1993). Fatigue failure of the stem is the product of repetitive cyclic load, which is normally initiated at a site of high tensile stress that usually resides at the lateral surface of the stem. Cracks usually start at places where the stress is concentrated, that is, at a defect such as a scratch, notch, or void.

Fracture is the result of “excessive tensile stress” at the lateral surface of the prosthesis owing to the bending moment and the load (patient’s weight and activities), it is important to consider the geometrical factors that may contribute to its appearance. They are as follows:

1. The neck shaft angle of the prosthesis; that is, the smaller the neck shaft angle, the greater the stress.
2. The neck length; that is, the longer the neck the greater the stress.
3. The orientation of the stem in the canal; that is, the greater the angle of varus, the greater the stress (Eftekhari, 1990).

In a two-dimensional stress analysis, the effect of some of the factors leading to early fatigue failure of the femoral stem in total hip arthroplasty was studied. This led to a similar conclusion: loss of proximal stem support at the level of the calcar femorale resulted in a level of stress on the stem that led to fatigue failure. The load (body weight) and the range of cyclic stress played an important part in fatigue life under test conditions. Increasing the stem dimension at the middle-third level of the stem (the critical level, where maximum tensile forces are found) was suggested,

although it should be emphasised that static testing in laboratories might oversimplify the three-dimensional geometry of the stem and the forces applied to it as they occur in the body. So this model would only partially explain the early failure of the metal.

Consequently, based on the clinical analysis of stem failures today, one may search for the cause of failure in the following categories: excessive load, failure of support by the bone, loss of fixation at the cement-bone-metal interface, uneven stress distribution throughout the cement column, metallurgical causes, and failure of surgery.

4.4.3.1. Failure Modes of Hip Stem

Classification of the modes of failure cemented stem-type femoral components is as follows;

4.4.3.1.1. Mode I: Pistoning Behaviour

This mode is characterized by pistoning of one material with respect to another, i.e. metal stem pistoning within the acrylic cement embedded stem pistoning within the bone (mode Ib). Mode Ia occurs as a result of incomplete cement encapsulation or subsequent loss of proximal-medial acrylic support from axial loading which tends to result in the stem being displaced distally. Close examination of the acrylic sheath indicates sufficient encapsulation everywhere except in the lateral midstem region allowed mode Ia to occur.

In mode Ib the applied stresses tend to disrupt the mechanical bond at the cement-bone interface with subsequent slip. This may be enhanced by inadequate interdigitation of acrylic cement into cancellous bone. This mode is the most familiar to orthopedic surgeons of loose total hip replacements.

4.4.3.1.2. Mode II: Medial Midstem Pivot

This mode is characterized by medial migration of the proximal stem coupled with lateral migration of the distal stem tip. It is caused by combined weak proximal-medial “calcar” support and lack of distal acrylic support. The loss of distal support may also occur following the distal punch-out of acrylic cement in cases of mode Ia failure. The progression continues with simultaneous proximal-medial migration and distal stem toggling followed by subsequent fracture, in some cases, of acrylic cement in the midstem region.

4.4.3.1.3. Mode III: Calcar Pivot

The action of this mode is a medial-lateral toggle of the distal end of the embedded stem due to lack of distal acrylic support with subsequent bone reaction. The prosthesis may have adequate proximal support or “hang up” on the medial femoral neck cortical rim upon which it pivots. This mode is analogous to the “windshield type” loosening of uncemented Austin-Moore or F.R. Thompson femoral head prostheses, where the large stage of these prostheses pivoted upon the transected femoral neck cortical rim and the distal part of the stem toggled within the intramedullary cavity.

4.4.3.1.4. Mode IV: Bending Cantilever Fatigue

This mode is characterized by partial or complete loss of proximal support with subsequent stem while the distal end remains rigidly fixed in acrylic cement encasement or from proximal cement-bone interface, the load transfer to the proximal femur is lost and the stem is then, consequently, transformed into a cantilever which must resist increased cyclic bending stresses (Jones et al., 1992).

4.4.3.2. Contributing Factors on Fatigue Failure of the Stem

There are five factors considered that contributed to the fatigue failure of the stem: cementing technique yielding inferior cement properties; varus position of the

femoral component; the prostheses material; the weight of the patient, and the lack of support at the level of the calcar femoralis (Ducheyne et al., 1983).

I	Ia	Pistoning: Stem within Cement	
	Ib	Pistoning: Stem within Bone	
II		Medial Midstem Pivot	
III		Calcar Pivot	
IV		Bending Cantilever (Fatigue)	

Figure 4.7. Schematic diagram of the 4 modes of failure characterizing the various mechanisms of hip stem.

4.4.3.2.1. Loss of Fixation

As indicated earlier, the most important cause of stem failure is initiation of the loosening of the prosthesis in the shaft, especially in the upper region (with the medial side of the prosthesis at the calcar region). Although most loosening may not terminate in failure by stem fracture, retrospective examination of most cases reveals early loosening before stem fracture. Improper cementing, that is, varus orientation of the stem and lack of support by the cement at the concave side of the prosthesis (in the compression side), increases stresses on the metal and the cement as well as the bone, leading to failure of fixation in this region.

Experimental studies coupled with studies of clinically failed prostheses can help determine the area of high-stress concentration and the location of the fracture. In both clinical and laboratory situations, loss of fixation by the cement precedes failure of metals; therefore it seems reasonable to assume that paying attention to the technical details of insertion and producing adequate support for the prosthesis at the calcar region to eliminate loosening are the first lines of defence against fatigue fracture.

If both proximal and distal fixation were poor, the femoral component would be expected to fail by subsiding. However, if the component is firmly fixed distally, so that it is not free to subside, but there is poor fixation which allows movement proximally, it would be liable to bend under the influence of excessive load. Jones et al. concluded that their results are consistent with the accepted mechanism that stem fracture of proximal fixation, while distal fixation is maintained suggesting that stem fracture can be avoided by careful fixation and the selection of appropriately sized prostheses.

4.4.3.2.2. Varus Position

Only few anatomical differences were found between the fracture and loose groups. Patients with fractured stems were reported to be significantly heavier than those with loose stems by an average of 10 kg. Features, which were determined by surgical technique, showed greater differences between the two groups. A significant difference in stem alignment was indicated such that; the fracture group tended to be inserted varus while loose group was in valgus. Valgus and varus were used to describe the inclination of the femoral component stem in the coronal plane, relative to the femur and are defined in Figure 4.8. Previous studies indicated that, the fractured stems were significantly more medial at the proximal, mid-stem and distal levels, but not at the stem tip. In keeping with the valgus inclination, the loose stems had significantly thicker medial cement at the proximal level. In the fracture group, the lateral cement thickness was found to be greater at the mid-stem and distal levels (Jones et al., 1992).

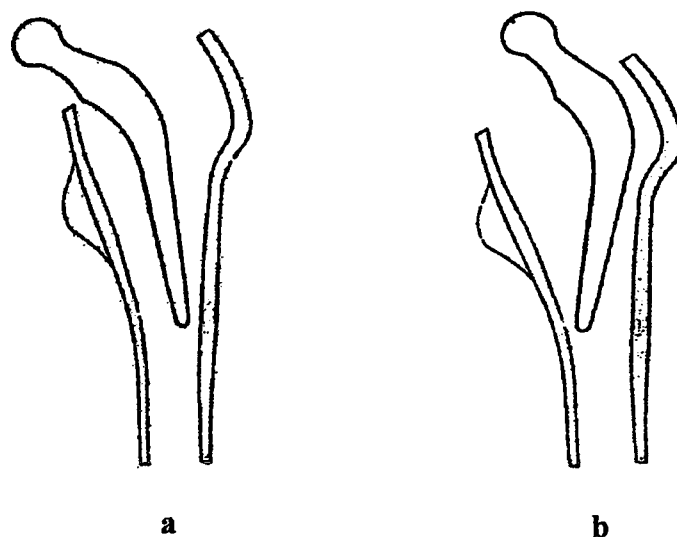


Figure 4.8. Schematic diagram showing; (a) a stem in varus, (b) a stem in valgus.

4.4.3.2.3. Metallurgical Causes

Fatigue is an engineering term used to describe the failure of material by a fluctuating stress, which if applied a sufficient number of times, produces failure in the material. The stress required to produce failure is often much lower than that required to fracture the same material on a single application. While this principle is applicable to most machine elements and laboratory tests may produce the basic information regarding fatigue properties of the materials, the stress cycles that cause fatigue failure in biological situations are usually extremely complex. The gross appearance of a fatigue-fractured surface of a metallic component such as the stem of a total hip prosthesis shows two distinct regions: (1) a relatively smooth surface area with concentric markings described as clamshell, beach, or ripple markings, and (2) a surface area of rough granular appearance with the appearance of a cross-section of a multifilament cord. The smooth area indicates slow propagation of the fatigue cracks, and the rough zone indicates the brittle, ruptured final fracture zone.

A new alloy used in Europe and the United States is a combination of cobalt, nickel, chromium, and molybdenum known as Protosul10 or MP36N. This alloy is made in a “multiphase” state. The mechanical properties of this alloy are outstanding with a yield strength of 400 MPa when fully annealed with elongation of 70%. With

work hardening, and heat treatment, the yield strengths rise to 2000 MPa with only 10% elongation. These characteristics make MP36N an ideal alloy, combining the good properties of stainless steel and chromium-cobalt.

A study of 35 stainless-steel and chromium-cobalt-molybdenum alloy devices showed that a very large numbers were defective or deficient; the effects were caused by the presence of delta-ferrite in 316L stainless steel, porosity in the cast-chromium alloy, and the presence of cracks and pits and in some instances a low molybdenum content in the steel. A number of other mechanical explanations have been proffered for the failure of metal in orthopaedic surgery. A brittle fracture owing to stresses exceeding the ultimate strength of the material, the use of an alloy not resistant to corrosion, brittle fractures as the result of combined mechanical and electrochemical defects, impact loading, fatigue crack propagation of 316L stainless steel, and weakness of the bone in the region of the femoral calcar. The effect of grain size on the fatigue life of 316L stainless steel has not been established, but it may be a significant factor in determining the strength of the stainless steel used for the stem of the femoral component. It is possible that a fine grain size is preferable and that a fine and uniform grain size could be maintained by manufacturers, Galante et al. (1975) feel that strings of shrinkage porosity in cast chromium and cobalt alloy should be considered flaws. When string length approaches an appreciable fraction of a millimetre, it must be considered as a progenitor of early failure, and large amounts of shrinkage porosity could impair the strength of the metal. Obviously maintaining the highest standards of microstructural quality in the metal used in the stem of the prosthesis is imperative.

In regard to metallurgical studies, the main morphological characteristic of most of these fractures is obviously fatigue. Failure, but in most of the cases examined so far, a premature fatigue failure was largely observed, probably because of a combination of circumstances. These include inadequate quality controls in manufacture and flaws in the metallic structures; for example 316 annealed stainless steel is unsuitable for a femoral stem, since this material can be expected to weaken

under loading conditions; wrought cold-worked 316 stainless steel should be the material of choice when stainless steel is used.

4.4.3.2.4. Excessive Load

Fatigue fracture of the femoral prosthesis was reportedly assumed to be the product of a “successful arthroplasty” in a heavy, athletic, active patient in which the dimensions of a standard prosthesis have been used. The valgus position of the prosthesis, while important in reducing bending stresses, is assumed inadequate to eliminate the fracture. The support of the prosthesis by the cement on the medial aspect is most important; use of an extremely heavy stem in the upper portion automatically reduces the amount of cement used, inviting further loosening problems that can initiate fatigue fractures. The anatomical advantages of a 130-degree shaft-neck angle are great enough to warrant its sole use in patients with a huge bony structure, to allow clearance between the neck and rim of the acetabulum. Obviously, heavier prostheses have now been designed for people who anticipate excess load from their weight or excess stress from the degree of their activities.

4.4.3.2.5. Failure of Support by Bone

The loss of support by the bone is now assumed to provide a substantial evidence for a fundamental cause of the failure of cement fixation in the calcar region, leading to eventual failure of fixation at the concave side of the stem. Therefore from histological evaluation of the calcar region, it seems reasonable to suggest that the cystic erosion of bone in this region is caused by slight movement between the cement and the bone. With the stress concentration at the calcar region and cement fragmentation causing tissue reaction such as bone resorption and necrosis, further varus subsidence of the prosthesis follows; the similarity between the periodontal disease and bone necrosis with the loosened cemented prosthesis is striking. In both instances, once loosening begins a vicious cycle is created. The cement loses support and permits increased motion in the upper end of the prosthesis between the bone and the calcar at the concave side of the prosthesis, while the remainder of the prosthesis (the distal portion) may remain fixed in the bone. To solve the problem,

surgical technique was suggested as such that should include, in addition to a slight valgus orientation for the prosthesis, removal of the loose cancellous bone of the calcar region to provide strong support by the cement. Poor support by the bone, despite a valgus orientation of the stem, has been occasionally observed (Azem, 1999).

4.4.4. Corrosion Fatigue of 316L Stainless Steel

When metallic materials are placed in the body two points of view may be considered. One is the effect of the corrosive environment upon the metal and its corrosion products upon the fluids and tissues of the surrounding environment (Bement, 1971). The environment of the body may not appear at first sight to be particularly aggressive. It is an aqueous environment, extremely well buffered so that the pH is maintained around 7.4 and it is held at a constant temperature of 37 °C. Two features control the corrosivity of this environment. Firstly, the saline solution is an excellent electrolyte and facilitates electrochemical mechanisms of corrosion and hydrolysis. Secondly, there are many molecular and cellular species in the tissues, which have the ability to catalyze certain chemical reactions or rapidly destroy certain components identified as foreign. Corrosion of metals within the body occurs by conventional and largely predictable mechanisms.

One of the main reasons for concern about fatigue of biomaterials arises from the adverse host-tissue response to wear debris generated by fatigue process. This appears to be a natural defence mechanism of the body. The wear debris often invokes an inflammatory and immunological response. This in turn causes blood clotting processes, leukocytes, macrophages and, for severe cases, giant cells to move in on the foreign particles resulting in interfacial problems between the implant and the host tissue. Numerous biochemical activities occur at this stage. These include a change in the local environment to highly acidic one (pH less than 3). In general, assuming that the wear debris is nontoxic, there are three scenarios: (i) the cells will try to digest the foreign debris by releasing chemicals and enzymes to dissolve and later absorb them so that the by-products can be eliminated through the blood circulation and lymphatic

system into the various organs such the kidney and liver; if this fails then (ii) the body will try to excrete them out of the body system; however, if (i) and (ii) cannot be achieved, then (iii) cellular fibrous linings will engulf the foreign bodies so as to keep them away (isolate) from the surrounding host tissue.

In order to understand the fatigue failure of biomaterials it will be essential to have some understanding of the surface substructure of biomaterials. Figure 4.9 shows a schematic picture of the cross-section of a deformed metallic biomaterial surface, surrounded in a physiological environment. Illustrated here physiological environment. Illustrated here are three distinguishable layers, namely (1) the molecular absorbed layer, (2) the passive oxide film, and (3) the deformed layer. How these layers interact with the physiological environment during the fatigue-wear process is of paramount importance to the behavior of the biomaterial and the long term fatigue performance of the medical device. Figure 4.9 exhibits this type of behavior under repeated impact loading.

However, the molecular absorbed layer is dependent on the underlying passive oxide layer, which protects the base material from corrosion. If the deformed layer has a high compressive stress field (for instance, in the case of forged stainless steel), the incident of crack initiation is reduced and hence the fatigue strength of the material is increased.

One can readily see that the process of removal of these layers (by wear) can greatly affect the fatigue of biomaterials.

In general, cracks initiate under tensile stresses. It is well known that the anterior and lateral surfaces of femoral prostheses are subjected to high tensile stresses during walking and stair climbing. These stresses are additive and generally peak at or near the anterolateral corner of the stem. Historically, analysis has shown that fractures most commonly emanate from the anterolateral corner in the middle third of the stem (Woolson et al., 1997). Fracture waves are similar to tide marks. As one might expect, they occur during different fatigue phases of the metals.

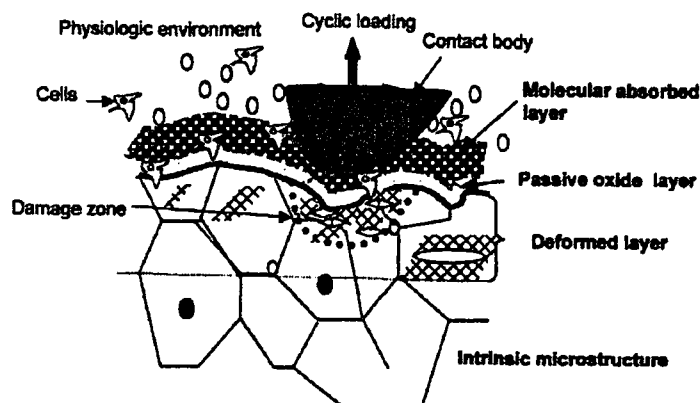


Figure 4.9. The cross-section of a deformed metallic biomaterial surface showing the complex interactions between the material's surface and the physiologic environment is schematically illustrated (Teoh, 2000).

Corrosion of retrieved stainless-steel hip stems has received little attention since early 1970s. Any subsequent reports of corrosion involving retrieved stainless-steel fracture fixation devices were not reported. Corrosion of these implants was investigated as the corrosion products of this alloy have been implicated in the generation of sensitivity reactions, the risk of local tumours, particulate debris leading to osteolytic implant failure and mechanical failure of the implant.

Austenitic stainless steel which has been used in the manufacture of hip prostheses since the earliest Charnley implants, consists mainly of gamma-iron (austenite) as a solution with less than 2% carbon, stabilized by the presence of nickel. The surface was treated to form a passivation layer of chromium oxide that imparts much of the corrosion resistance. Changes were initially made in response to reports of corrosion of retrieved fracture fixation plates and screws, and subsequently due to reports of hip arthroplasty stem fractures and reports of mechanical failure of 316L in vitro. Fracture of the stem of the early stainless steel hip arthroplasties was a major concern, but has only rarely been reported in association with corrosion. Refinements in manufacture, in particular, double-vacuum melting and cold working appear to have led to a satisfactory solution to stem failure, although corrosion fatigue leading to mechanical failure of fracture fixation devices is still reported.

The location of corrosion was specific to each design in their study. The proximal corrosion of the Charnley stems being contrasted with the distal corrosion of the grooves of the Müller stems. The area of the Charnley stems that was corroded is an area of high stress. This may weaken the passivation layer and also promote corrosion fatigue. This area is prone to fretting, which along with crevice corrosion, has been implicated as a major cause of corrosion of retrieved implants. Localized pitting corrosion, which could be attributed to implant surface defects, was only demonstrated in one implant series of Walczak et al., where the corroded area corresponded with the area of electroetched serial numbers. This process is recognized to be a risk factor for pitting corrosion and has been superseded by laser-marking. The distal location of the corrosion in the Müller stems may reflect the different stresses in the surface layers on a straight stem with increased valgus neck geometry. This results in relative reduction of stress and fretting at the proximal third and increased stress distally and medially. The most consistent site for corrosion in the Müller implants is at the distal end of the grooves that exist on the anterior and posterior surface of the prostheses. This may well be secondary to stem-cement debonding, which may, in addition, permit crevice corrosion.

Corrosion Products

The lamellar nature of corrosion plaques or scales on variety of alloys in industrial environments was well documented. Such compounds formed are insoluble and are relatively adherent to the alloy surface. There is also a lamellar structure to the corrosion scales in austenitic stainless steel.

EDX analysis of the elemental composition of corrosion plaques has been previously reported for stainless steels in industrial and dental environments. Plaques consisting of iron, calcium, chromium, sulfur, chloride and potassium were demonstrated following in vitro aqueous corrosion of 18-8 stainless steel and of chromium and oxygen following corrosion of 316L in seawater.

The change in appearance of the metal surface following black scale removal indicates disturbance of the passivation layer during the process of corrosion. It is

possible that accumulation of chromium in the black corrosion plaques may be resulted in a local depletion of chromium. This may result in repassivation occurring with a less protective oxide such as FeO. Occasional areas of high iron and oxygen content between the chromium-rich plaques and the pitted alloy may represent such a process. This may well lead to a self-perpetuating increase in the rate of corrosion and possibility the acceleration of any fatigue failure of the implant.

The sulfur, chloride, calcium and phosphorus in the plaques is assumed to arise from the interaction of the prostheses with the body, as these elements are present in microscopic amounts in the alloy.

When corrosion products were present on the stem-cement interface they had a similar composition to the plaques found on the stem. Of particular interest is the corrosion plaques found in the substance of one cement mantle. Their composition is similar to the chromium-rich stem plaques.

The biological significance of the corrosion plaques is at present unknown. Although the toxicity of certain of their elemental components is well established, their effect as a whole has yet to be identified. The clinical success of stainless steel hip implants has resulted in the implantation of such devices into a younger population with a longer life expectancy (Walczak et al., 1998).

4.5. Coating Applications Against Failures of Metallic Materials

In general, components used in engineering applications must possess the appropriate structural characteristics to provide stiffness or flexibility and to carry applied loads without macroscopic failure. Such properties are associated with the bulk material of the component. However, the majority of engineering failures are surface initiated and occur through such phenomena as friction, wear, corrosion, fatigue, or a combination of these factors as mentioned former sections. Surface related failures arise from two specific causes; in the first place, stress levels are often highest at the surface, and secondly, the surface is usually the only part, which is subjected to the external environment. An increasingly common way of coping

with such a situation is to provide different surface material properties from those of the bulk material. Surface treatment technology has advanced rapidly over the last few decades and has greatly assisted in meeting the ever-increasing demands placed on materials.

Since the early 1980s there has been a continuing and rapid development of advanced surface engineering practices for the optimisation of corrosion and wear resistance. It is now possible to produce coatings of novel composition and microstructure by a variety of sophisticated physical and chemical processes such as PVD (Physical Vapour Deposition), CVD (Chemical Vapour Deposition), Ion Implantation and Laser surface treatment methods.

Process, which deposits thin films and coatings of physically generated atoms or molecules from the vapour phase onto a substrate in a vacuum environment, is called PVD processes. This method of surface modification does not chemically alter bonding arrangements. PVD systems all incorporate a means of evaporating coating material from a solid source under a partial vacuum (Hübler et al., 2001).

In the basic CVD process gases containing volatile compounds of the elements or elements to be deposited are introduced into a reaction chamber, and condensed onto the substrate to form a coating. Most chemical reactions in CVD are endothermic, so that thermal energy must be supplied by heating the substrate or by the environment in the neighbourhood of the substrate. So, only systems, which do not undergo phase transformations within the temperature range required for deposition, can be employed by this coating method (Kuo, D. & Huang, K., 2001).

Ion implantation involves the bombardment of a target material with energetic ions (electrically charged particles). These ions penetrate the target to a depth dependent on the energy of the ion and the nature of the ion and the target. In a metallic substrate the neutralised ions come to rest in the lattice in interstitial and substitutional positions and remain there in a metastable solid-solution. The nature of the process allows any element to be introduced into the near-surface region of a

solid in a controlled and reproducible manner that is independent of most equilibrium constraints. Due to the non-equilibrium nature of this process, composition and structures unattainable through conventional methods may be produced. The chosen atomic species are first ionised and then accelerated in an electric field to level of energies, which lie in the range from a few tens to a few hundred kiloelectronvolts in a moderately high vacuum. These ions arrive at the work piece (target) with velocities around that of a rifle bullet and can penetrate the surface. The energetic ion comes to rest by displacing atoms from their normal lattice sites by ionising target atoms, thus producing a large number of point defects. Most defects are annihilated by recombination shortly after the passage of the bombarding ion, but some survive. The resultant structure consists of the host (target) material with an impurity (alloying) addition and a defect structure characteristic of radiation damage. Such a process does not require a high temperature, the penetration being achieved by high kinetic energy.

Laser processing utilises a laser to produce a source of energy which, when in contact with materials, can produce a large amount of heat in a very small volume of material. The amount of heat generated depends on the power density absorbed from the laser and the time of interaction with the surface. Laser-induced surface alterations include annealing, etching, deposition, welding, cutting, surface transformation and polymerisation.

Transition metal nitrides such as TiN, ZrN, VN, BN, and $\text{Ti}_{0.5}\text{Al}_{0.5}\text{N}$ are generally utilised as a protective coatings because of their complex bonding structure exhibiting characteristics of covalent, ionic and metallic bonds. The metallic character of these compounds is shown in their high thermal and electrical conductivities while the covalent nature give rise to high mechanical microhardness, typically in the range 20-30 GPa.

Protective properties of these films come especially from their hardness properties. The hardness of a material is determined both by its intrinsic hardness (the hardness characteristic of the material in the single-crystal form) and by

microstructural features that affect the deformation mechanisms. The intrinsic hardness of a material is determined both by the strength of the interatomic forces and the crystal structure. Materials exhibiting a high intrinsic hardness can be characterised as having high cohesive energy, short bond length and a high degree of covalent bonding (Sundgren, 1986). The strength of the interatomic forces and the bonding length plays an important role in determining the elastic properties of the material and thus also the hardness. A high resistance to dislocation propagation and multiplication is found in materials with high bond strength and thus a high Peierls stress (intrinsic lattice resistance to dislocation motion). Also highly directional bonds, such as covalent will restrict dislocation propagation. In general the hardness decreases as the proportion of covalent bonding decreases. Some typical microstructural features that influences dislocation movement, are grain boundaries, precipitates, and impurity atoms. Since thin films often have different microstructures compared to bulk materials, e.g., a much smaller grain size and a higher concentration of other defects it is understandable that thin films often show much higher hardness values compared to bulk materials (Rieu et al., 1991).

CHAPTER FIVE

EXPERIMENTAL STUDY

5.1. Purpose

The successful long term functioning of a hip replacement is influenced by many factors. Among all the others fatigue fracture and wear have been identified as the major problems associated with implant failure in forms of loosening, stress shielding and ultimate implant failure. The stem failure by fatigue is the consequence of several concurrent causes such as the surface or bulk material defects induced by technological processes, the high local stress concentration due to the stem design, the patient weight and activity, the stability of the stem-bone mechanical interface, the material properties, and corrosion (Raimondi & Pietrabissa, 1999). An important mechanical factor is the ability of the implant to withstand the continual application of load, which may exceed the body weight of the patient by several folds (Humphreys et al., 1990).

The development of THR combines three areas of investigation: theoretical, experimental and clinical. Component fatigue testing, the final step in the development of total joint replacements, is performed to validate the safety of these components against fatigue failure before clinical use, as part of the design approval. The fatigue test is one of the most common laboratory tests to evaluate the reliability of prostheses. In this manner, designs are tested to ensure that the minimum fatigue strength requirements are fulfilled. The first component fatigue test to be standardized was in response to the unacceptably high rate of in vivo hip stem fractures of the first generation hip stem designs. The fatigue test is usually performed according to the ISO 7206 standard. The international standard specified

vertical load application to the head of the stem and fixation of the distal stem in bone cement to a height of 80 mm below the center of the head.

The objective of this study was to generate CAD model and analyze stress distribution on the stem of Thompson hip prosthesis by IDEAS and, to perform fatigue test of prosthesis according to ISO 7206/4 with the purpose of comparing the experimental results of stress distribution measured by strain gauge system during the fatigue test with the calculated stress distribution of CAD modeling.

5.2. Material and Method

5.2.1. The Component

Implant quality 316L stainless steel is used in the field of implant surgery because of its relatively low costs, high machinability, and reasonable corrosion resistance but since it has some poor properties it requires to apply some coatings to withstand dynamic loads and aggressive body fluids in human body. Chemical and mechanical properties of 316L stainless steel are given in Table 5.1 and Table 5.2 respectively.

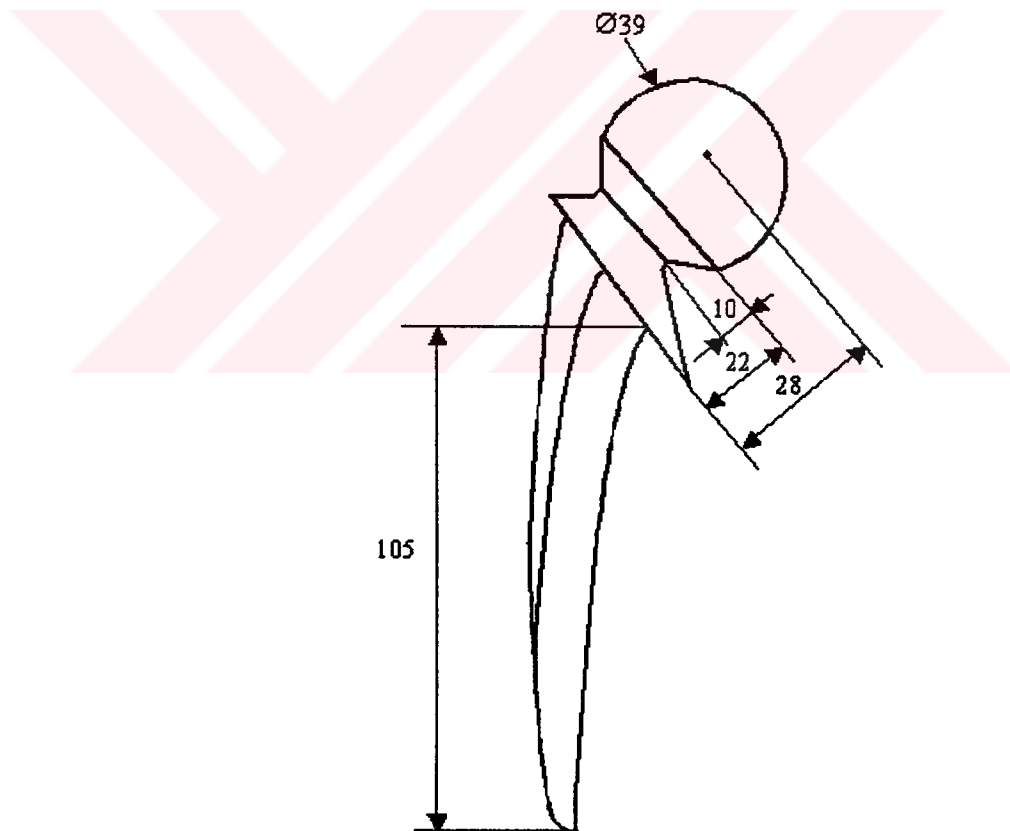
Table 5.1. Chemical properties of 316L stainless steel (Higo & Tomita, 1994).

% Element	Cr	Ni	Mo	C	Mn	P	S	Si	N	Cu	Nb	Fe
Wrought	17-20	1-17	2-4	0.03 max	2.00 max	0.03 max	0.03 max	0.75 max	0.10 max	0.50 max	-	Balance

In this study 316L stainless steel Thompson hip prosthesis supplied by HIPOKRAT A.Ş. was tested by double cantilever beams bending machine (DCBBM) designed at the Department of Metallurgy and Materials Engineering at Dokuz Eylül University. Dimensions of the original Thompson hip prosthesis are given in Figure 5.1.

Table 5.2. Mechanical properties of 316L stainless steel (Higo & Tomita, 1994).

Property	Wrought (ASTM F55 and F56)	Cast (ASTM A269)	Cold worked	Annealed
Elastic modulus (MPa)	$1.9\text{-}2.1 \times 10^5$	1.93×10^5	2.0×10^5	2.0×10^5
Shear modulus (MPa)	8.4×10^4	-	-	-
Yield strength (0.2%)	$2.05\text{-}2.41 \times 10^2$	2.06×10^2	$7.5\text{-}7.9 \times 10^2$	2.8×10^2
Ultimate tensile strength (MPa)	$5.1\text{-}5.5 \times 10^2$	4.82×10^2	$9.6\text{-}10.0 \times 10^2$	5.5×10^2
% Elongation	55	30	9-22	50

**Figure 5.1.** Dimensions of Thompson hip prosthesis.

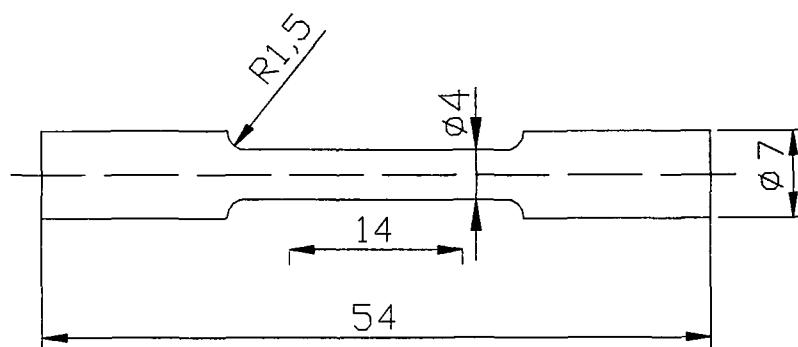


Figure 5.2. Dimensions of tensile test specimens.

Cylindrical tensile test specimens machined from the stem of the prostheses, 15 mm in gage length and 4 mm in gage diameter were prepared to determine mechanical properties of 316L stainless steel used (Figure 5.2).

5.2.2. The Apparatus and Set-up for Fatigue Test

The main aim of a standard for the fatigue testing of hip replacement is to specify test conditions, which, if satisfied, will give confidence that the prostheses will not break or fail under any expected circumstances during its service life. In order to satisfy this requirement, the test conditions should be similar to those, which are likely to be encountered in service (Humphreys et al., 1990).

In order to investigate the endurance properties of hip replacements, double cantilever beams bending machine was constructed (see Figure 6.6). This machine consists of two main units; mechanical parts that produce fluctuating forces and electronic parts that consist of amplification data acquisition system by which the load-cell generated data signals are pre-amplified and transferred to a PC where they are processed.

Mechanic Parts

This part of machine contain driving unit that supplies rotatory motion by means of 0.75 hp, 950-rpm electric motor. Force transmission system converts rotating motion to reciprocating one and forms varying force fluctuating on the prostheses

through the load-cell. This was provided by an eccentricity, which was adjusted by means of a sliding component moving along the V-sledge through screw on the V-belt pulley. Load fluctuating is transmitted to the prostheses by way of two lever arms with an amplification factor of 20 through a load-cell which measures alternating load on the prostheses that is directly proportional to the amount of displacement of the prostheses along its vertical axes.

On the other hand adjustment of the low load level was achieved with spring loading system, which is vertically positioned along the longitudinal axis of the prostheses. The setting of the low load level selected was adjusted by compressing the spring.

Electronic Parts

Data acquisition system that processes data obtained from mechanical parts is composed of a load-cell, a signal conditioner, a daughter board, and a data acquisition card.

The function of transducer such as a load-cell used in this study is energy conversion. In the context of instrumentation and measurement, the transducer provides a conversion of physical variable, which is representative of the process, to a proportional voltage or current. Load-cells have an analog output voltage, which could be measured using fairly traditional instrumentation including, for example, an oscilloscope or a voltmeter. Bonded foil type strain gauges are rigidly fixed to the strained member that embedded into a load-cell body and are electrically insulated from it. The principle embodied in a strain gauge is that a conductor, of initially uniform dimensions, will alter its proportions when subjected to an applied stress. In this study U-5000 series Load-Cell having 10 kN capacity, tension, compression and fatigue properties was used to measure alternating loads. Calibration of load-cell was carried out on a computerised Shimadzu testing machine.

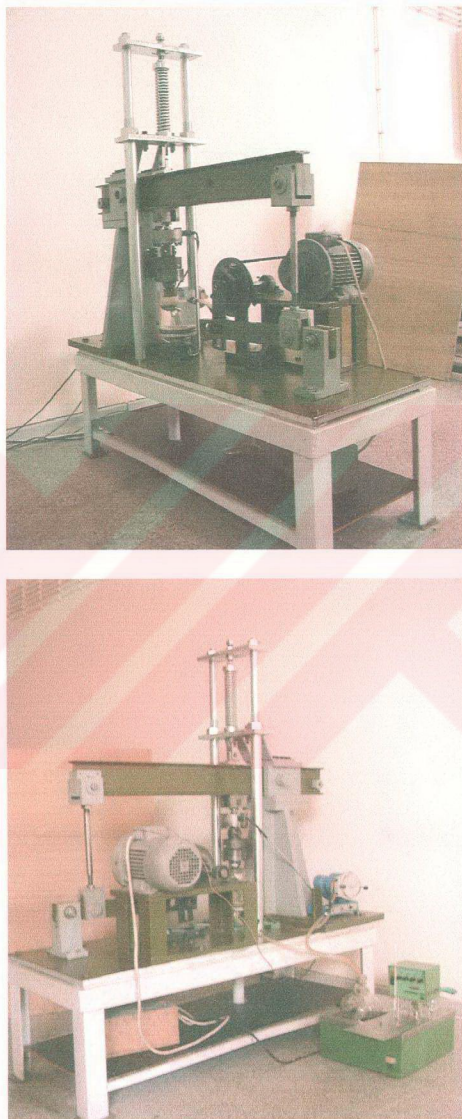


Figure 5.3. Front and back view of the double cantilever beams bending machine.

Signal conditioning circuits improve the quality of signals generated by transducers before they are converted into digital signals by the PC's data acquisition hardware. One of the most common signals conditioning function is amplification. In present study, Adam-3016 Strain Gauge Input Module that is trademark of Adventech-Taiwan is used as a signal conditioner.

The PCLD-8115 screw-terminal board provides convenient and reliable signal wiring among Data Acquisition Card, which have 20-pin flat cable connector, and Adam 3016 Signal Conditioner.

PCL- 818 HG PC- Lab Card was used to process the data coming from the wiring terminal board. It has a high gain, high performance multifunction data acquisition card for compatible PC.

By using Genie software, range of load is adjusted and loading cycle is counted and logged to the hard disk during processing.

5.3. Experimental Procedure of ISO 7206/4

The fatigue test is usually performed according to the ISO 7206 standard, which describes the test apparatus and procedure to assess the fatigue resistance of femoral stems without and with torque. In this study test procedure was executed in accordance with the ISO 7206/4, which includes determination of endurance properties of stemmed femoral components with application of torsion.

This part of ISO 7206/4 describes a test method for determining the endurance properties, under specified laboratory conditions, of stemmed femoral components of total hip joint prosthesis and stemmed femoral components used alone in partial hip joint replacement when subjected to a loading system which includes the combination of compression, bending and torsion. It is generally felt that the important factors are the application of cyclic stress, the value of the mean stress, the environment and the orientation of the femoral component in relation to the applied load. It also defines the conditions of testing so that the important parameters that

affect the components are taken into account, and describes how the specimen is set up for testing.

Each prostheses was prepared in the following manner:

The anatomical axis of the femur has been assumed to be at an angle of 10° (in adduction) to the load line, when viewed perpendicular to the plane that includes the stem and neck. The offset angle (which introduced the torsional component of force) has been set at $9^\circ \pm 1^\circ$ (in flexion). This orientation process was arranged by means of a gripping device. Furthermore, the test conditions are fixed on the assumption that the stem becomes unsupported proximally, remaining restrained at 80 mm from the centre of the head of the prostheses. This assumption is consistent with the clinical observations that failures generally occur in the middle third of the stem (Baleani et al., 1999).

Initially the head of the prosthesis was firmly clamped by gripping device.

The prosthesis was aligned according the orientation angles that mentioned above.

The specimen was embedded in the self-curing medium. As embedding medium, PMMA cement is used. To obtain final embedding medium, 50 g self-cure acrylic powder and 33 ml methyl methacrylate liquid are mixed rapidly in a pot and poured in the cavity of the specimen holder before polymerization. The prosthesis vertically plunged into specimen holder until the distance between the centre of the head and cement surface of 80 ± 2 mm is reached (Figure 5.5). Prosthesis was left for 24 hours whilst the embedding medium hardened.

Following step after the completion of setting the femoral component in testing rig, compressing test was applied on the specimen with an electromechanic tensile test machine with a loading capacity 5 tons Shimadzu, in order to determine the linear load-deflection curve of the test rig together with the fixed prosthesis.

Aim of this compression test was to provide an initial load-deflection curve of the system comprised prosthesis, embedding medium and the test rig prior to the test. The purpose of this test was of twofold: firstly to ensure that the prosthesis was firmly reset in the embedding medium as such that an immature sinking of the prosthesis is eliminated. Secondly a means of way to fully appreciate the range of loads that can be applied without causing a plastic deformation at first sight upon loading was obtained. An example of the load-deflection curve as such is given in Figure 5.4.

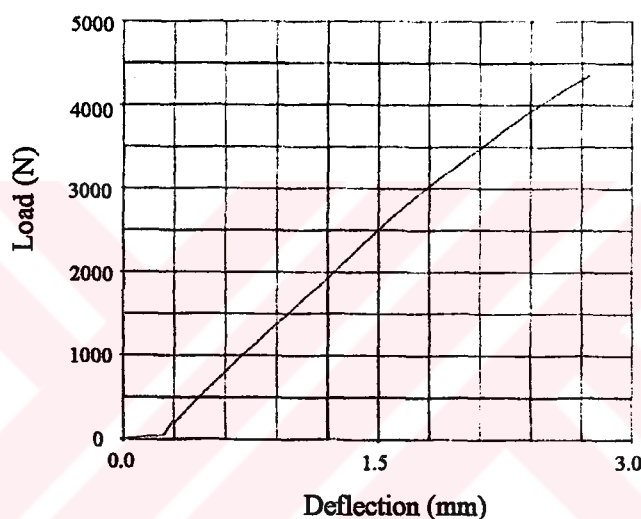


Figure 5.4. The load-deflection curve of the test rig together with the fixed prosthesis.

The specimen with test rig (Figure 5.6) was located in the testing machine with three clamps and partially immersed in the saline bath. Due to highly corrosive effect of the salt solution the hip implants were inserted in plastic holder. To maintain the specimens at 37 °C during testing temperature control unit was used. Peristaltic pump was used to control the flow rate of continuously aerated serum physiological solution (0.9 NaCl), which surrounded the specimen.

Testing machine is started and desired load ranges adjusted. Testing frequency was 10 Hz. A fatigue reliable stem must withstand 1×10^7 load cycles. The test was continued until:

- (a) yield or loose, fracture of specimen occurred,

(b) occurred the chosen number of load cycles was arrived.

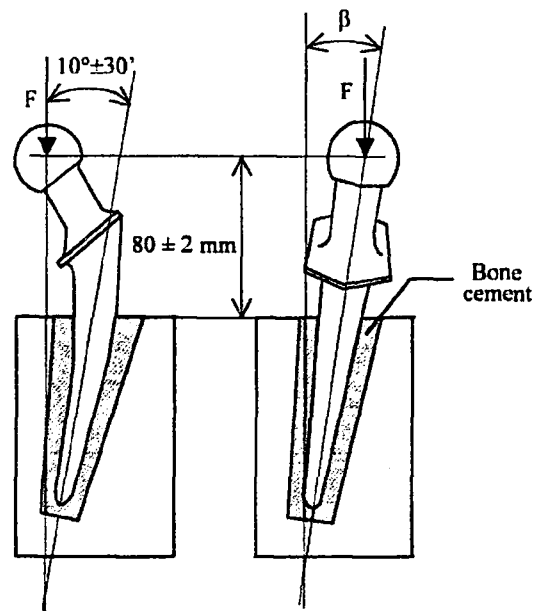


Figure 5.5. As indicated in the ISO 7206 standard position of the stem for the fatigue test. The flexion angle β is 0° for the set without torque and $9 \pm 1^\circ$ for the test with torque.



Figure 5.6. Specimen mounted on the test rig.

5.4. Orthopaedic Applications of FEA

Finite Element Analysis (FEA) has been applied to orthopaedic implants since the early 1970s. Faced with the task of understanding a complex system, it is often useful to extract its most essential features and use them to create a simplified representation of the system, or a model of the system. Finite element models are numerical mathematical models, numerical because they rely on computers to find approximate solutions to large sets of equations. According to the 1983 review of Huiskes and Chao, the first application of finite element analysis in orthopedics was in 1972. Since then, finite element models have been increasingly used for three main purposes; (i) for design and pre-clinical analysis of prostheses; (ii) to obtain fundamental biomechanical knowledge about musculoskeletal structures; (iii) to investigate time-dependent adaptation processes in tissues. The first application of finite element modelling is to obtain fundamental anatomical knowledge about the skeleton. The analysis of bones, cartilage, ligaments and tendons comes under this heading. The second field is the use of finite element modelling for orthopaedic implant design. Although quantitative accuracy can never be assured because of anthropometrical differences between patients, finite element analysis can be used to conduct parametric studies of implant material stiffness and geometric changes. The third field of use of finite element models is to investigate time-dependent biological processes in tissues (Prendergast, 1997).

The ability of FEA to model complex geometries initially modeling of bones encouraged, especially the proximal femur. It is a computer-simulation method suitable for determining stresses and strains at any given point inside a structure of arbitrary geometrical and material complexity. The model relies on accurate constitutive modeling of the material and material coefficients, 3-D geometric data, loading characteristics, and boundary and interfacial conditions. These models were often used for implant optimization by comparing the effects of implant design on bone stress patterns and magnitudes. FEA has also been applied to optimization of implants in terms of wear, fixation, and fatigue strength.

The FE mesh accounts for the geometry or shape of the arthroplasty components. In principle, every detail of the structure can be taken into account by using sufficiently small elements. For 3-D analysis, elemental volumes of a particular shape (e. g., bricks) are used and for 2-D analysis, elemental areas of particular shape (e.g., triangles or quadrilaterals) are used. When mesh has been constructed, FEA requires;

- A numerical description of external loads applied to structure (point of application, magnitude, direction)
- Each element must be assigned the appropriate elastic constants of the material. For an isotropic linearly elastic material, two material constants are required, e.g., Young's modulus and Poisson's ratio. This is the case for the metallic implant materials.

The boundary conditions for the FE models are imposed on the exterior surfaces (for 2-D models, curves) of the object. The boundaries can be divided into free, loaded, and fixed boundaries. At free boundary, no stress (or load) is transferred and its not constrained by a connecting structure. At a loaded boundary, external loads are applied. At a fixed boundary no motion is allowed or the motion is constrained by some surrounding structure. The last ones are usually those where the FE model is cut off from the environment with which it normally interacts (Mow & Hayes, 1991).

5.4.1. FEA of Femoral Stem According to ISO 7206/4 Standard

The solid modeling and meshing were performed for Thompson model hip prosthesis, with a stem having an antero-posterior symmetry, in order to measure the stress distribution with the intention of comparing with the experimental results. Model was generated, analyzed using the IDEAS finite element package (version 7m1). The reference set-up of the parameters used for stem structural analysis refers to the nominal testing condition indicated by the ISO 7206/4 standard. Model was oriented in 10° adduction and in 9° in flexion, using the following reference points: the center of the femoral head and the barycentre of the stem cross-sections located

at 10 and 80 mm from the tip. The stem mesh and stem with cement layer are shown in Figure 5.7 a and b, respectively.

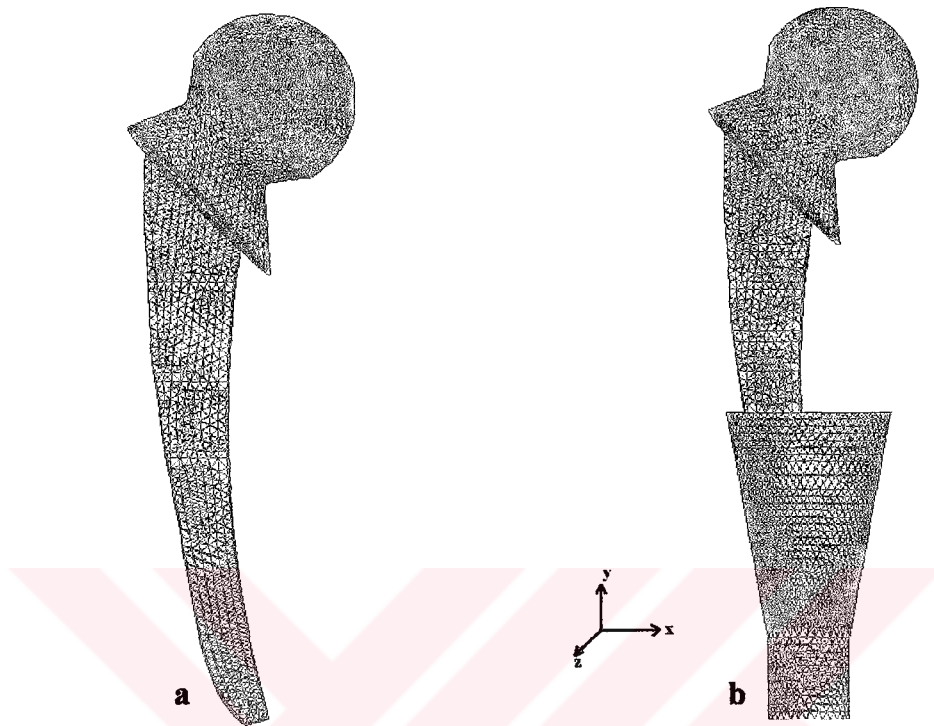


Figure 5.7. (a) The stem mesh, (b) The stem mesh with the cement layer.

The stem mesh consists of 30535 10-node parabolic tetrahedron elements (46127 nodes). Materials properties of wrought 316L stainless steel are; Young's modulus $E=200$ GPa and Poisson's ratio $\nu=0.3$.

The ISO 7206/4 standard states that the stem is fixed in testing apparatus using a bone cement-filling layer. The cement thickness is not indicated. A tapered sub-mesh is added to the stem model, with the max external diameter 40 mm (Figure 5.7 b) representing the cement surrounding the distal segment of the stem. The cement layer mesh consists of 27147 10-node parabolic tetrahedron elements (42837 nodes). Young's modulus and Poisson's ratio assumed for the cement elements are 2.3 GPa and 0.3, respectively.

The interface between the stem and cement was assumed to perfectly bonded. Solution was made as if two different material definitions are present in whole

geometry of model. All the external nodes in the model below 80 mm from the point of load application were constrained to have a displacement of zero to comply with the fixation of the stem in ISO 7206/4 standard for testing total hip prostheses.



CHAPTER SIX

RESULTS AND DISCUSSION

6.1. Mechanical Properties

6.1.1. Tensile Tests

Tensile tests were carried out on cylindrical tensile test specimens, machined from the stem of the prostheses, at a constant crosshead speed of 0.1 mm/min by Shimadzu tensile testing machine. Results of the test are given in Table 6.1. Specimen 1 and 2 extracted from the stems which were previously cyclic loaded at 400 and 700 kg respectively. The stem from which the specimen number 3 machined was in as received condition. Stress-strain curve of a tensile test result is given as an example in Figure 6.1.

Table 6.1. Mechanical properties of 316L stainless steel.

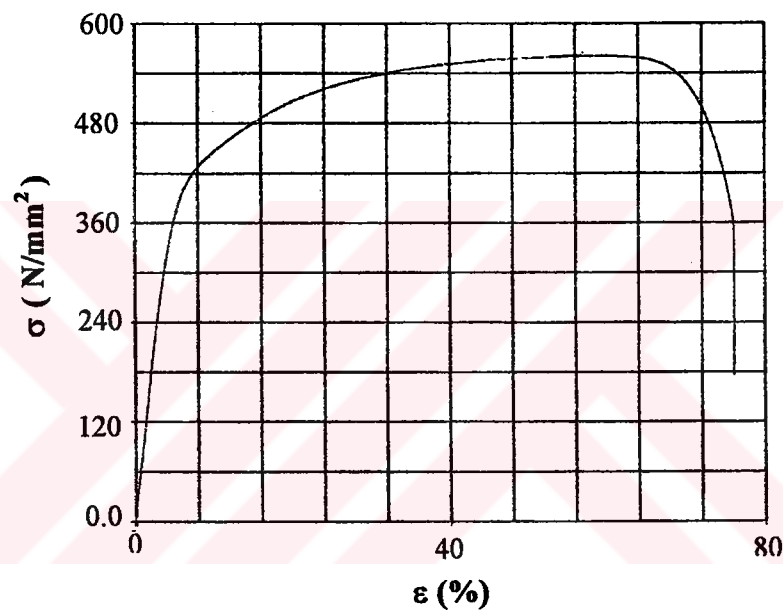
Specimen Number	Yield Stress $\sigma_{0.2}$ [N/mm ²]	Tensile Stress σ_t [N/mm ²]	Elongation ϵ [%]
1	302	561	60
2	269	596	42
3	312	595	57

6.1.2. Hardness Tests

Hardness tests were employed to the specimen and average micro-hardness values obtained by Shimadzu Dynamic Ultra Micro Hardness Tester are given in Table 6.2.

Table 6.2. Average micro-hardness values of 316L stainless steel specimens.

Specimen Number	Micro-hardness (80HV)	Dynamic Micro-hardness
1	186	164
2	192	149
3	181	170

**Figure 6.1.** Stress- strain behaviour of the specimen.

6.1.3. Microstructural Examination

Light microscopy was used to obtain the image of the microstructures of the 316L hip stem. Microstructure of the specimens 1 and 2 and 3 are given in Figure 6.2 a, b, and c respectively. Although all micrographs indicated an austenitic structure, specimen 2 and 3 seemingly contain more twins' formation, which reflected in a decrease and an increase in tensile strength and elongation respectively. Grain sizes of the specimens were determined by Lucia image analyzer. Average grain size of all specimens was found to be around 34 μm . Grains in specimen 1 are more equiaxed than others. Grain size distribution of specimen 1 is given in Figure 6.3.

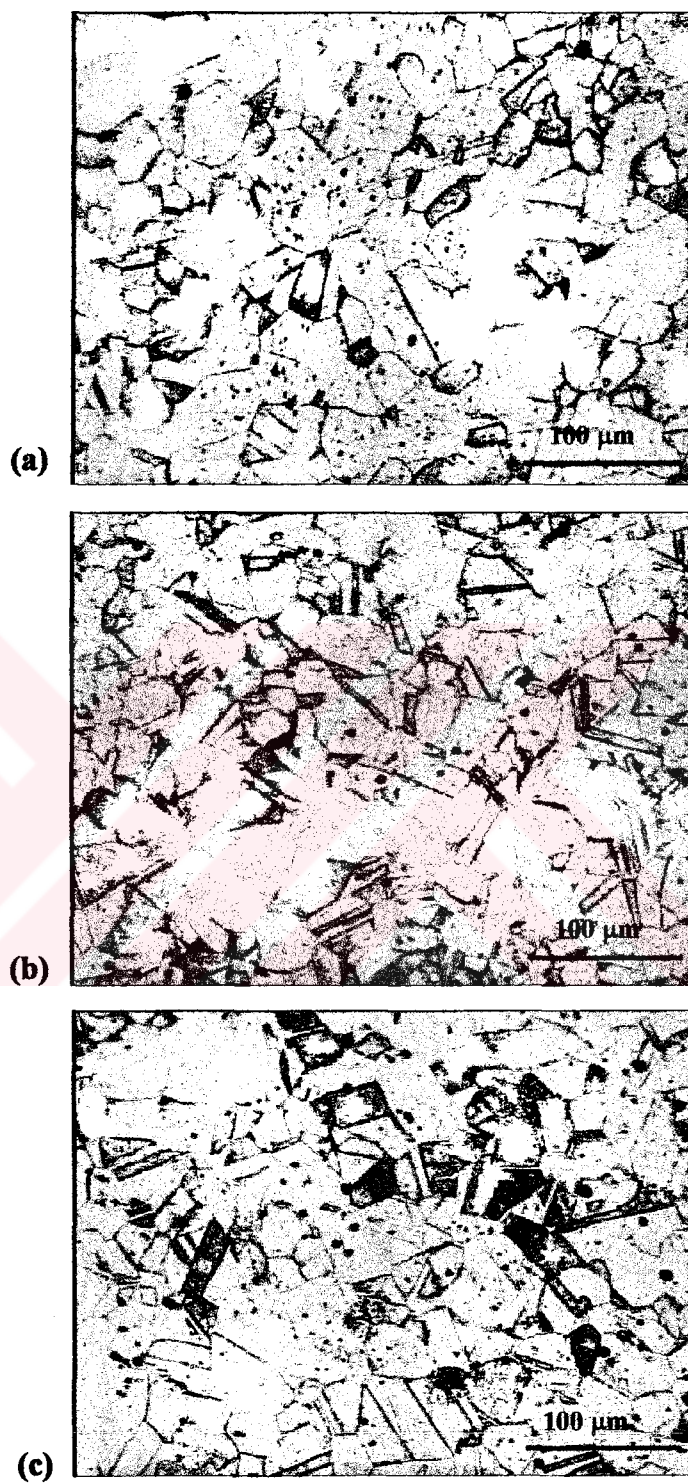


Figure 6.2. Microstructure of the specimen; (a) specimen 1, (b) specimen 2, (c) specimen 3.

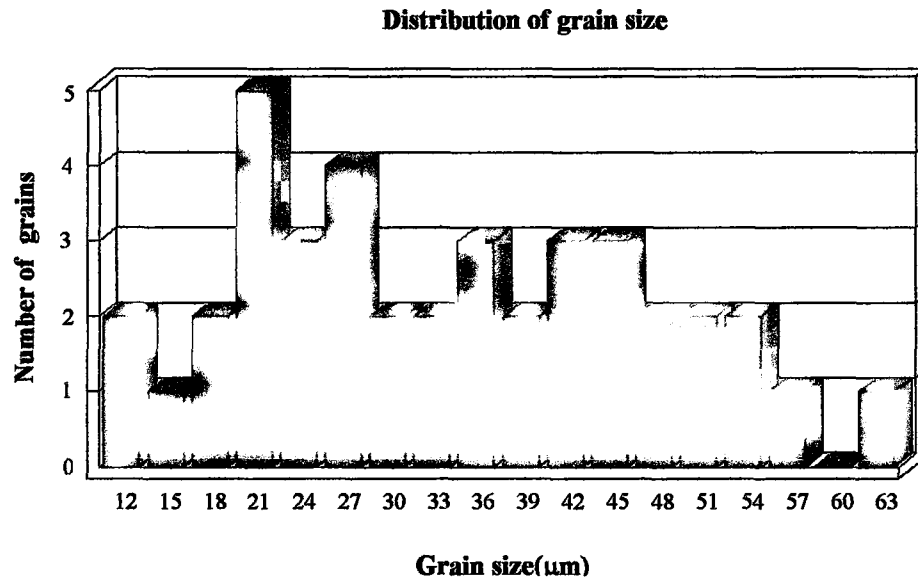


Figure 6.3. Graph of grain size distribution.

6.2. Stress Distribution of the Femoral Stem

A static point loading was applied vertically through the center of the head of the femoral component. Load data is given in percentage of the patient body weight (% BW). Baleani et al. reports that ISO test generally simulates quite well the in vivo load when normal body weight assuming 450-600 N. In this study 600 N was accepted as normal body weight. Depending on the activities within one year for active patients max load is about eight times of body (Baleani et al, 1999). Based on these, implant was sequentially loaded one to eight times of body weight under static conditions. The goal of finite element analysis is to determine peak stress on the stem surface. The Von Mises equation was used to calculate the maximum equivalent stress due to combined stresses on the stem. Von Mises stress distribution on the stem surface for 800 %BW is shown in Figure 6.4. A stress concentration area, corresponding to tensile stress, is present on latero-anterior stem portion, with a maximum located on the edge, approximately 10 millimeters above the cement surface according to the Figure 6.5. Stress distribution curves given in Figure 6.5 indicated that the maximum stress values computed under different loads were proportional to the applied loads (Figure 6.6.).

Raimondi was investigated the effect of cement thickness on stress distribution of the hip stem by means of FEM (Baleani et al., 2000). They found that the max stress measured decreased with increasing thickness of PMMA as seen in Figure 6.5 b. It is noteworthy to notice that the location of max stress, independent on PMMA thickness, corresponds to similar position close to cement surface found in our work. Although the materials used in each study are of different kind, stress distribution in each case are the same.

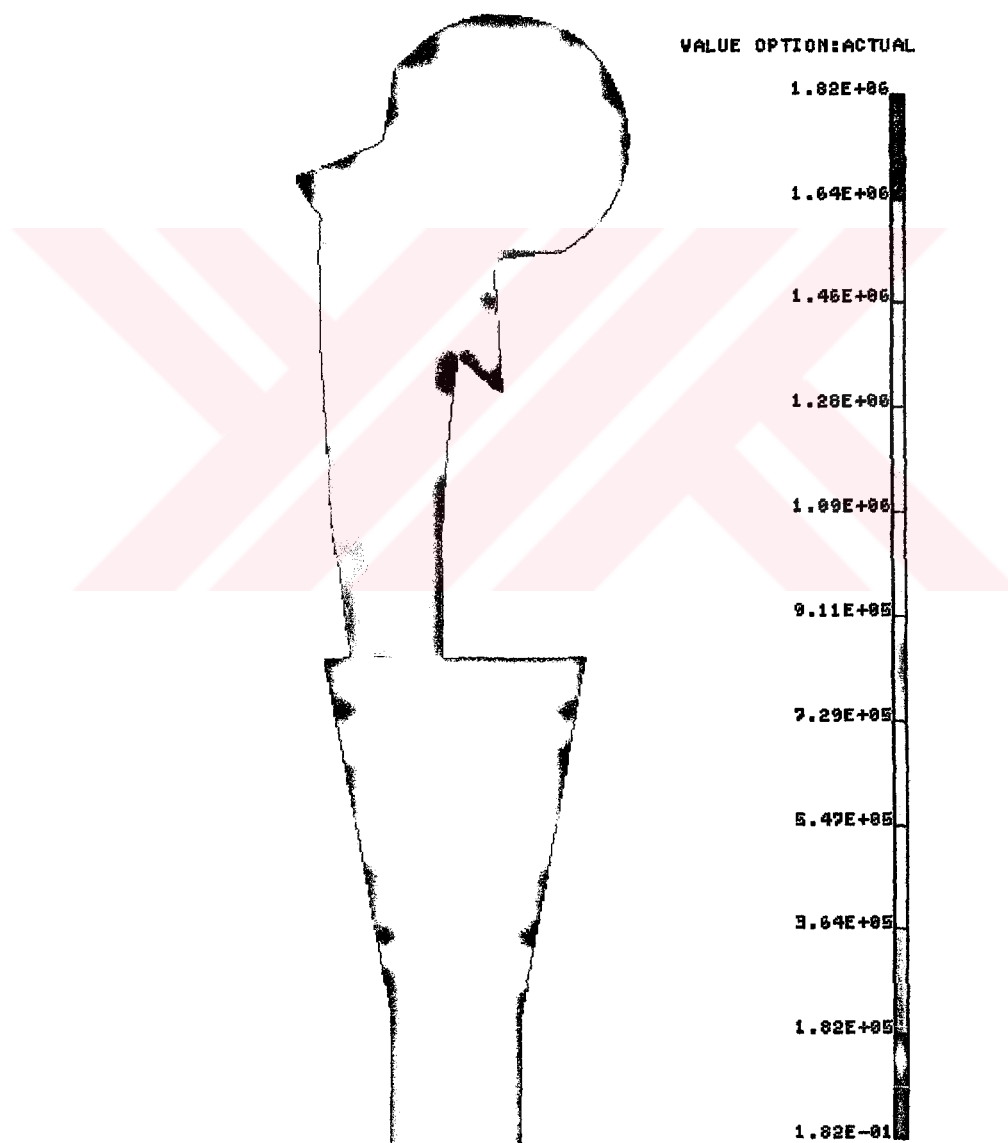
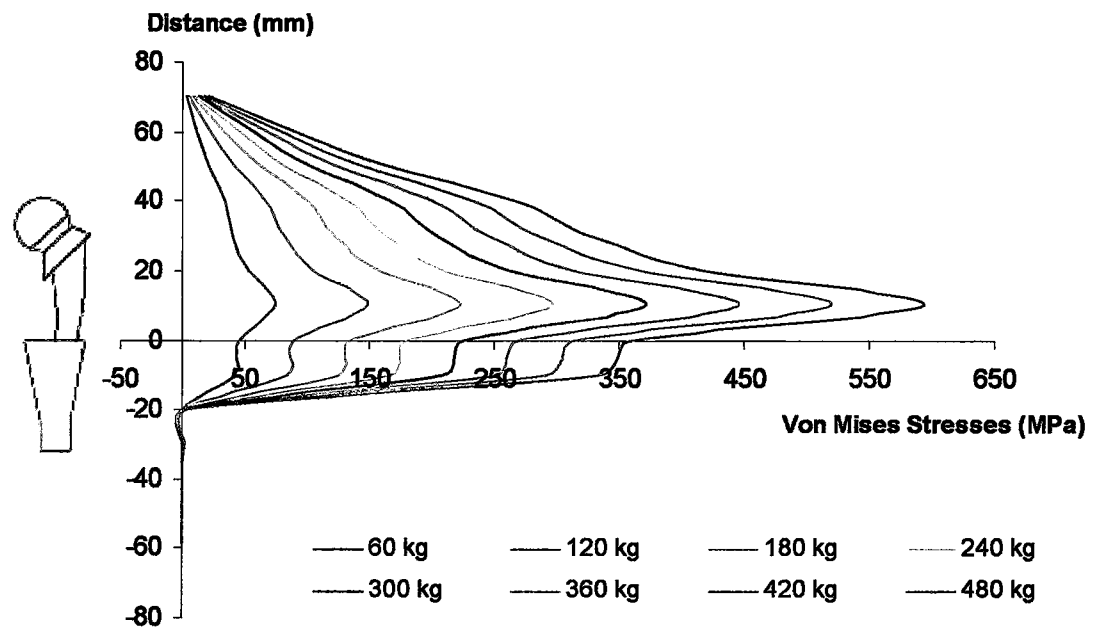
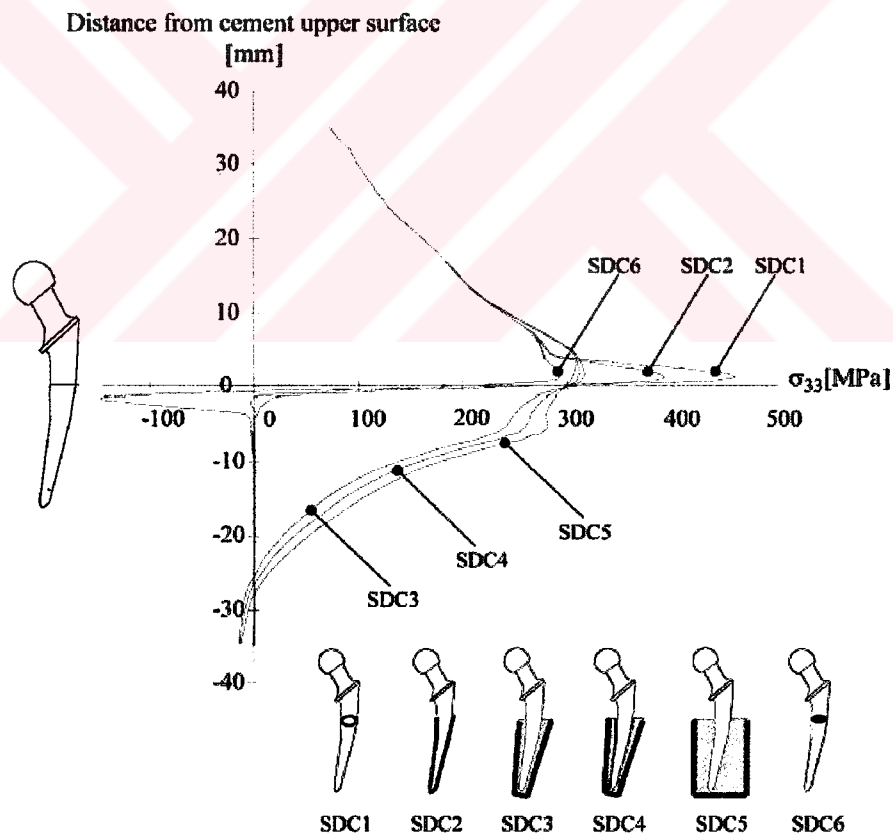


Figure 6.4. The stem with cement mesh stress distribution for 4800 N.



(a)



(b)

Figure 6.5. (a) Stress distribution at various load levels along the stem edge for all loads applied, (b) The σ_{33} (stress parallel to the stem axis) on the stem edge adjacent to the cement upper surface plotted for all stem distal constraints.

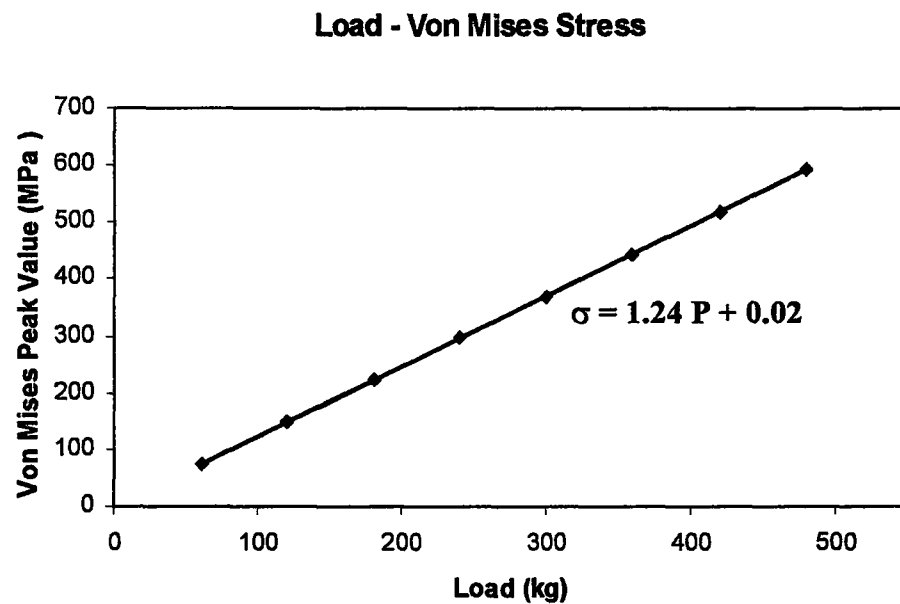
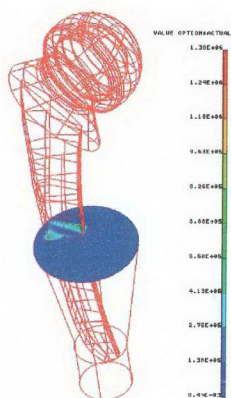
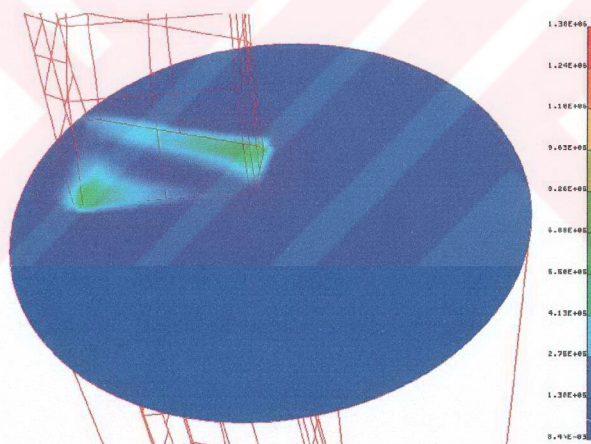


Figure 6.6 Correlation between Von Mises stress and load.

Stress intensification at one particular cross section along the stem is shown in Figure 6.7. As will be seen from this figure the maximum stresses were obtained on the latero-anterior and media-posterior sides of the stem, which corresponds to tensile and compression stresses respectively.



(a)



(b)

Figure 6.7. (a) and (b) stress distribution on cement surface for 4800 N.

CHAPTER SEVEN

CONCLUSION

In this study, fatigue tests of 316L stainless steel hip stems were investigated at different load levels. The following conclusions are obtained from the experimental works:

1. As a result of static loading of CAD model of prosthesis according to ISO 7206/4 by means of IDEAS, max stresses obtained on the stem originated 10 mm above from the cement surface. The max stresses values were increased by increasing the applied load for each loading levels.
2. 316L stainless steel Thompson hip stem was cyclic loaded with a stress rate of $R=0.1$. Specimen loaded at an ultimate load of 400 kg failed at a stress cycles of 6×10^5 , while the other with an ultimate load of 300 kg lasted for a number of cycles of 1×10^7 without failure. A max load of 700 kg caused an instant failure of the prosthesis indicated by its plastic deformation. Since no real stress measurement was conducted, no attempt was made to evaluate the stress levels in respect to fatigue limit. More fatigue tests are required to obtain a true S/N curve.

It is recommended that a further study should be carried out in order to obtain an experimental distribution of stresses along the stem by using strain gauges. Only then the theoretical stress distribution obtained by IDEAS could be compared and verified.

REFERENCES

- Azem, Z. (1999). Corrosion fatigue properties of 316L implant steel by double cantilever beams bending machine. M. Sc. Thesis.
- Baleani et al. (1999). Endurance testing of hip prostheses: a comparison between the load fixed in ISO 7206 standard and the physiological loads. Clinical Biomechanics, 14, 339-345
- Baleani et al. (2000). Endurance verification of custom-made hip prostheses. International Journal of Fatigue, 22, 865-871
- Bauer, T.W. & Schils, J. (1999). The pathology of total joint arthroplasty, II. Mechanism of implant failure. Skeletal Radiology, 28, 483-497
- Bement, A.L. (1971). Biomaterials: Bioengineering Applied To Materials for Hard and Soft Tissue Replacement. London: University of Washington Press.
- Bishop et al. (1996). Porosity reduction in bone cement at the cement-stem interface. Journal of Bone and Joint Surgery, 78-B, 1349-356
- Boyer, H.E. (1986). Atlas of Fatigue Curves. Metals Park, Ohio: American Society for Metals.
- Bronzino, J.D. (1995). The Biomedical Engineering Handbook. In J. B. Park Biomaterials.

- Bronzino, J.D. (1995). The Biomedical Engineering Handbook. In K. R. Kaufman & K. An (Eds.) Joint-Articulating Surface Motion. London: CRC Press.
- Bronzino, J.D. (2000). The Biomedical Engineering Handbook. In J. B. Park & Y. Kon Kim (Eds.), Metallic Biomaterials. London: CRC Press.
- Bronzino, J.D. (2000). The Biomedical Engineering Handbook. In J. B. Park, Hip Joint Prosthesis Fixation-Problems and Possible Solutions. London: CRC Press.
- Christel et al. (1988). Role of stem design and material on stress distributions in cemented total hip replacement. Journal of Biomedical Engineering, 10, 57-63
- Colange, V. J. & Heiser, F. A. (1987). Analysis of Metallurgical Failures (2nd Edition). New York: John Wiley & Sons, Inc.
- Cowin C.S. (2001). Bone Mechanics Handbook. In Prendergast P. J., Bone Prostheses and Implants. London: CRC Press.
- Crowninshield, R. (1988). An overview of prosthetic materials for fixation. Clinical Orthopaedics and Related Research, 235, 166-172
- Desmond et al. (1993). Fracture and loosening of Charnley femoral stems. Journal of Bone and Joint Surgery, 75-B, 259-265
- Dieter, E.G. (1988). Mechanical Metallurgy. London: Mc-Graw-Hill Book Company.
- Disegi, J.A. & Eschbach, L. (2000). Stainless steel in bone surgery. Injury, 31, S-D2-6

- Dowson, D. (1992). Friction and Wear of Medical Implants and Prosthetic Devices. ASM Handbook, vol. 18. Gereland: Materials Park, OH: ASM International, 656-664.
- Ducheyne et al. (1983). Fatigue properties of implant materials in hip prosthesis form: A standardized test. Journal of Biomedical Materials Research, 17, 45-57
- Ducheyne, P. & Hastings, G.W. (Eds.) (1984). Metal and Ceramic Biomaterials, Volume II: Strength and Surface. Florida: CRC Press.
- Edmonson, A.S. & Crenshaw, A.H. (1989). Campbell's Operative Orthopaedics. (6th ed.). U.S.A., Lea & Febiger.
- Eftekhari, N.S. (1990). Total Hip Arthroplasty. New York: Columbia University Press.
- Friedman et al. (1993). Current concepts in orthopaedic biomaterials and implant fixation. The Journal of Bone and Joint Surgery, 75-A, 1086-1109
- Frost, N.E., Marsh, K.J. & Pook, L.P. (Eds.). (1974). Metal Fatigue. Northern Ireland: Oxford University Press.
- Fuchs, H.O. (1980). Metal Fatigue in Engineering. New York: John Wiley & Sons, Inc.
- Greco, R.S. (1994). Implantation Biology: The Host Response and Biomedical Devices. London: CRC Press.
- Gross S. & Abel E.W. (2001). A finite element analysis of hollow stemmed hip prostheses as a means of reducing stress shielding of the femur. Journal of Biomechanics, 34, 995-1003

- Gruen, A.T. et al. (1979). Modes of failure of cemented stem type femoral components. A radiographic analysis of loosening. Clinical Orthopaedics and Related Research, 141, 17-29
- Hall, R.M., & Unsworth, A. (1997). Review: Friction in hip prostheses. Biomaterials, 18, 1017-1026
- Higo, Y., & Tomita, Y. (1994). Biomaterials Mechanical Properties, ASTM STP 1173. Kambic, H.E., & Yokobori, A.T. (Eds.). Evaluation of Mechanical Properties of Metallic Biomaterials. Philadelphia: American Society for Testing Materials.
- Huiskes et al. (1983). A survey of finite element analysis in orthopaedic biomechanics: The first decade. Journal of Biomechanics, 16, 385-409
- Huiskes et al. (1998). Migration, stem shape, and surface finish in cemented total hip arthroplasty. Clinical Orthopaedics and Related Research, 355, 103-112
- Humphreys et al. (1990). Testing of total hip replacements: endurance tests and stress measurements Part 1: endurance tests. Proceedings of the Institute of Mechanical Engineers, 204, 29-34
- Humphreys et al. (1991). An investigation into the fixation of hip replacements. Proceedings of the Institute of Mechanical Engineers, 205, 145-153
- Hübner et al. (2001). Wear and corrosion of 316L femoral implant by deposition of thin films. Surface and Coatings Technology, 142-144, 1078-1083.
- Ikeda et al. (2002). Effect of nitrogen plasma-based ion implantation on joint prosthetic material. Surface and Coatings Technology, 156, 301-305

- ISO 7206/4. (1984). International Standard. Implants for surgery – Partial and total hip joint prostheses – Part 4: Determination of endurance properties of stemmed femoral components with application of torsion. Switzerland.
- Jones et al. (1992). Bending and fracture of the femoral component in cemented total hip replacement. Journal of Biomedical Engineering, 14, 9-15
- Kuo, D. & Huang, K. (2001). Kinetics and microstructure of TiN coatings by CVD. Surface and Coatings Technology, 135, 150-157
- Lewis, G. (1997). Properties of acrylic bone cement: state of the art review. Journal of Biomedical Materials Research, 38, 155-182
- Ling et al. (1992). The use of a collar and precoating on cemented femoral stems is unnecessary and detrimental. Clinical Orthopaedics and Related Research, 285, 73-83
- Long, M. & Rack, H.J. (1998). Titanium alloys in total joint replacement—a materials science perspective. Biomaterials, 19, 1621-1639
- Macionczyk et al. (2001). Repassivating tantalum/tantalum oxide surface modification on stainless steel implants. Surface and Coatings Technology, 142-144, 1084-1087
- Mann et al. (1995). Coulomb frictional interfaces in modeling cemented total hip replacements: a more realistic model. Journal of Biomechanics, 28, 1067-1078
- McCormack et al. (1998). A statistical analysis of microcrack accumulation in PMMA under fatigue loading: applications to orthopaedic implant fixation. International Journal of Fatigue, 20, 581-593

- McCormack et al. (1999). Fatigue of cemented hip replacements under torsional loads. Fatigue and Fracture of Engineering Materials, 22, 33-40
- McGee et al. (2000). Implant retrieval studies of the wear and loosening of prosthetic joints: a review. Wear, 241, 158-165
- Mow, V.C. & Hayes, W.C. (Eds.). (1991). Basic Orthopaedic Biomechanics. New York: Raven Press.
- Papakyriacou et al. (2000). Effects of surface treatments on high cycle corrosion fatigue of metallic implant materials. International Journal of Fatigue, 22, 873-886
- Park, J.B. (1984). Biomaterials Science and Engineering. New York: Plenum Press.
- Pohler, O.E.M. (2000). Unalloyed titanium for implants in bone surgery. Injury, 31, S-D7-13
- Prendergast, P.J. (1997). Review Paper: Finite element models in tissue mechanics and orthopaedic implant design. Clinical Biomechanics, 12, 343-366
- Prendergast, P.J. (2001). The functional performance of orthopaedic bone cement. Key Engineering Materials, 198-199, 291-300
- Raimondi, M.T. & Pietrabissa, R. (1999). Modelling evaluation of the testing condition influence on the maximum stress induced in a hip prosthesis during ISO 7206 fatigue testing. Medical Engineering & Physics, 21, 353-359
- Raimondi, M.T. & Pietrabissa, R. (2000). The in-vivo wear performance of prosthetic femoral heads with titanium nitride coating. Biomaterials, 21, 907-913
- Ramakrishna et al. (2001). Biomedical applications of polymer-composite materials: a review. Composites Science and Technology, 61, 1189-1224

- Ratner, B.D. (1996). Biomaterials Science: An Introduction to Materials in Medicine. San Diego: Academic Press.
- Rieu et al. (1991). Ion implantation effects on friction and wear of joint prosthesis materials. Biomaterials, 12, 139-143
- Schmalzried, T.P. & Callaghan, J.J. (1999). Current concepts review: Wear in total hip and knee replacements. Journal of Bone and Joint Surgery, 81-A, 115-137
- Sedriks, A. J. (1996). Corrosion of Stainless Steels. New York: John Wiley & Sons, Inc.
- Sivakumar et al. (1995). Failures in stainless steel orthopaedic implant devices: A survey. Journal of Materials Science Letters, 14, 351-354
- Sivakumar et al. (1995). Investigation of failures in stainless steel orthopaedic implant devices: pit-induced fatigue cracks. Journal of Materials Science Letters, 14, 148-151
- Sivakumar, M. & Rajeswari, S. (1992). Investigation of failures in stainless steel orthopaedic implant devices: pit-induced stress corrosion cracking. Journal of Materials Science Letters, 11, 1039-1042
- Sloten et al. (1998). Materials selection and design for orthopaedic implants with improved long-term performance. Biomaterials, 19, 1455-1459
- Teoh, S.H. (2000). Fatigue of biomaterials: a review. International Journal of Fatigue, 22, 825-837

- Tiainen, V. (2001). Amorphous carbon as a bio-mechanical coating-mechanical properties and biological applications. Diamond and Related Materials, 10, 153-160
- Uhlig, H.H. (1955). The Corrosion Handbook. (5th Ed.). New York: John Wiley & Sons, Inc.
- Walczak et al. (1998). In vivo corrosion of 316L stainless-steel hip implants: morphology and elemental compositions of corrosion products. Biomaterials, 19, 229-237.
- Williams D.F. (1994). Titanium: epitome of biocompatibility or cause for concern. The Journal of Bone and Joint Surgery, 76-B, 348-349
- Woolson et al. (1997). Fatigue Fracture of a forged cobalt-chromium-molybdenum femoral component inserted with cement. Journal of Bone and Joint Surgery, 79-A, 1842-1848
- Zitter, H. & Plenk, H. (1987). The electrochemical behavior of metallic implant as an indicator of their biocompatibility. Journal of Biomedical Materials Research, 21, 881-896