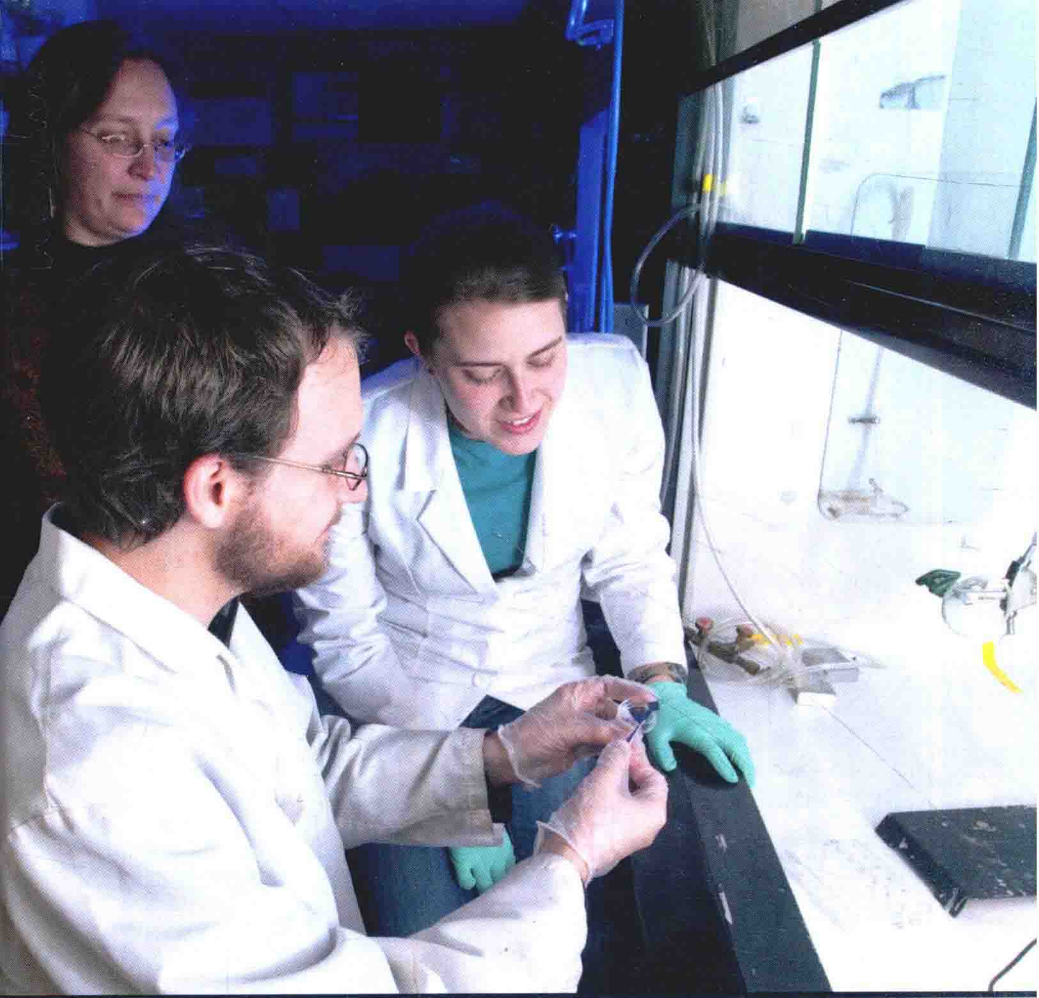

Biomedical Engineering

Applied Techniques in Medicine

Mark Walters

Biomedical Engineering – Applied Techniques in Medicine

Edited by **Mark Walters**

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Preface

The field of biomedical engineering has been illustrated in this book along with some applied techniques in medicine. Biomedical engineering is a diverse field of research. Its aim is to support and improve the clinical methods; be it therapy, diagnostics or rehabilitation. Biomedical engineering is available at nearly every technical university with many of them emphasizing on research and development in this field. The research works compiled in this book have been approved and appreciated by eminent European and international agencies. It provides comprehensive knowledge regarding biomaterials, bioelectronics and biomedical equipments applied in therapeutic and diagnostic processes of clinical trials. This book covers different aspects of biomedical engineering varying from fundamentals to its prospective applications in research and developments.

This book is a comprehensive compilation of works of different researchers from varied parts of the world. It includes valuable experiences of the researchers with the sole objective of providing the readers (learners) with a proper knowledge of the concerned field. This book will be beneficial in evoking inspiration and enhancing the knowledge of the interested readers.

In the end, I would like to extend my heartiest thanks to the authors who worked with great determination on their chapters. I also appreciate the publisher's support in the course of the book. I would also like to deeply acknowledge my family who stood by me as a source of inspiration during the project.

Editor

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Chapter 1

Fatigue of Ti-6Al-4V

Shabnam Hosseini

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1. Introduction

Metallic biomaterials have essentially three fields of use; these are the artificial hip joints, screw, plates and nails for internal fixation of fractures, and dental implants. Any of these devices must support high mechanical load and resistance of material against breakage is essential. High mechanical properties are needed for structural efficiency of surgical and dental implants. But their volume is restricted by anatomic realities what require good yield and fatigue strengths of metal [1].

The use of titanium alloys is due to their excellent corrosion resistance. Also, that is because of their tensile strength, a high strength to weight ratio and low elastic modulus. Titanium continues to be widely used in biomedical applications. Ti-6Al-4V alloy is the most frequently used these days [2].

Fatigue fracture and wear have been identified as some of the major problems associated with implant loosening, stress-shielding and ultimate implant failure. Although wear is commonly reported in orthopedic applications such as knee and hip joint prostheses, it is also a serious and often fatal experience in mechanical heart valves. Fig.1 illustrates some examples of fatigue fracture of implant devices in the hip prosthesis and a mechanical heart valve. It can be seen that fatigue-wear interaction plays a significant role in ultimate failure of these medical devices [3]. In orthopedic implants design, it is unavoidable the presence of geometrical fillets such as notches which cause stress locally. It's necessary to pay attention these notches, because they affect on fatigue resistance [4]. In addition about fatigue ratio, fatigue notch factor, notch sensitivity and effect of ultimate strength and notch size on the fatigue strength of Ti-6Al-4V will be discussed.

1.1. Orthopedic metal alloys

The main goal of design and fabrication of an orthopedic biomaterial is to restore the function and mobility of the native tissue that is considered to be replaced. In order to select an ideal biomaterial for orthopedic and dental applications specific property requirements must be fulfilled. The ideal materials for hard tissue replacement should be biocompatible and bioadhesive, possess adequate mechanical properties to tolerate the applied physiological load, be corrosion/wear resistant and finally show good bioactivity to ensure sufficient bonding at the material/bone interface. The materials used in orthopedic surgery can be divided into five major classes of metals, polymers, ceramics, composites, and natural materials [5].

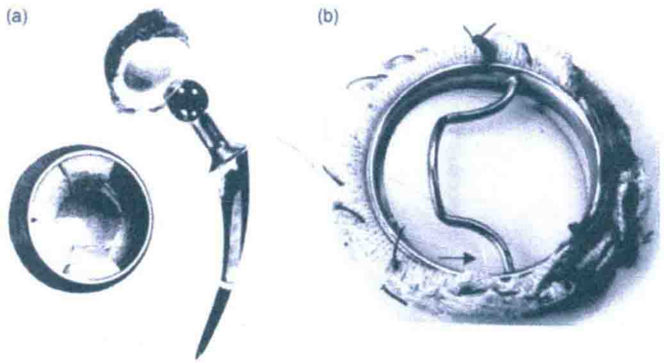

Figure 1. Some examples of fatigue failure of medical devices: (a) hip prosthesis; (b) explanted Bjo¨rk–Shiley polyacetal disc mechanical heart valve(arrow indicates fatigue-wear mark)[1].

Compared to other biomaterials like ceramics and polymers, the metallic biomaterials offer a wider range of mechanical properties such as high strength, ductility, fracture toughness, hardness, formability, as well as corrosion resistance, and biocompatibility. These are the required properties for most load-bearing applications in fracture fixation and bone replacement (total joint arthroplasty) [5].

Standard metallic orthopedic materials include stainless steels, cobalt-base alloys, and titanium base alloys (table 1), with an increasing number of devices being made of titanium and titanium alloys. The latter alloys are generally preferred to stainless steel and Co-alloys because of their lower modulus, superior biocompatibility and corrosion resistance [6].

1.2. Titanium and its alloy as orthopedic biomaterials

The need to find more reliable materials to replace broken or deteriorating parts of the human body is increasing with the increase in number of both younger and older recipients. Modern surgery and dentistry need metals and alloys of extreme chemical inertness and adequate mechanical strength. Metals and alloys in use include stainless steel, Co-Ni-Cr alloy, cast and wrought Co-Cr-Mo alloy, commercially pure titanium, Ti-6Al-4V alloy and other titanium alloys [7]. Recently, new titanium alloy compositions, specifically tailored for biomedical applications, have been developed. These first generation orthopedic alloys included Ti-6Al-7Nb and Ti-5Al-2.5Fe. Two alloys with properties similar to Ti-6Al-4V that were developed in response to concerns relating V to potential cytotoxicity and adverse reaction with body tissues. Further, biocompatibility enhancement and lower modulus has been achieved through the introduction of second generation titanium orthopedic alloys including Ti-12Mo-6Zr-2Fe (TMFZ), Ti-15MO-5Zr-3Al, Ti-15Mo-3Nb-3O, Ti-15Zr-4Nb-2Ta-0.2Pd and Ti-15Sn-4Nb-2Ta-0.2Pd alloys, as well as the completely biocompatible Ti-13Nb-13Zr alloy [6]. Commercially pure titanium is a material of choice as an implant because of its biocompatibility resulting in no allergic reaction with the surrounding tissue and also no thrombotic reaction with the blood of human body. The average yield strength of commercially pure titanium is approximately 480 MPa. If a higher strength of the implant is necessary, for example, in hip prosthesis, titanium alloys have to be used. The most widely used alloy, Ti-6Al-4V, reaches yield strength almost double the yield strength of commercially pure titanium [7].

	Stainless steels	Cobalt-base alloys	Ti & Ti-base alloys
Designation	ASTM F-138 (316 LDVM)	ASTM F-75 ASTM F-799 ASTM F-1537 (Cast and wrought)	ASTM F-67(ISO 5832/II) ASTM F-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 THRs 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)

Table 1. Some characteristics of orthopedic metallic implant materials [6]

Titanium is a transition metal with an incomplete shell in its electronic structure enables it to form solid solution with most substitutional elements having a size factor within ±20%. In its elemental form titanium has a high melting point (1678°C), exhibiting a hexagonal close packed crystal structure (hcp) α up to the beta (882.5°C), transforming to a body centered cubic structure(bcc) β above this temperature.

Titanium alloys may be classified as either α, near-α, $\alpha+\beta$, metastable β or stable β depending upon their room temperature microstructure. IN this regard alloying elements for titanium fall into three categories: α-stabilizers, such as Al, O, N, C, β-stabilizer such as Mo, V, Nb, Ta, Fe, W, Cr, Si, Ni, Co, Mn, H and neutral, such as Zr. A and near-α titanium alloys exhibit superior corrosion resistance with their utility as biomedical materials being principally limited by their low ambient temperature strength. In contrast, $\alpha+\beta$ alloys exhibit higher strength due to the presence of both α and β phases. Their properties depend upon composition, the relative proportions of the α/β phases, and the alloy's prior thermal treatment and thermo-mechanical processing conditions. β alloys(metastable or stable) are titanium alloys with high strength, good formability and high hardenability. β alloys also offer the unique possibility of combined low elastic modulus and superior corrosion resistance[8].

Ti alloys were first used in orthopedics in the mid-1940s and have continued to gain attention because of their unique properties, including high specific strength, light weight, excellent corrosion resistance and biocompatibility. Due to the aforementioned properties, this class of materials exhibits tremendous clinical advantages in terms of reduced recovery time and rehabilitation, and improved comfort for patients. However, for bone replacement components, the strength of pure Ti is not sufficient and Ti alloys are preferred due to their superior mechanical properties. In general, alloying elements would lead to an improvement in the properties of Ti for orthopedic applications. Ti-6Al-4V ELI and NiTi shape memory alloys (SMA) are the most commonly used Ti alloys in orthopedic applications because of their good combination of mechanical properties and corrosion resistance. However, the possible release of toxic ions from aluminum (Al), vanadium (V) and nickel (Ni) during in vivo corrosion of the implant remains the matter of concern. Al for exceeding content of 7% at low temperature would lead to possible embrittlement and it may also cause severe neurological, *e.g.* Alzheimer's disease and metabolic bone diseases, *e.g.* osteomalacia. Similarly, V can alter the kinetics of the enzyme activity associated with the cells and results in potential cytotoxic effects and adverse tissue reactions. Moreover, the oxide layer of Al_2O_3 and VO_2 are less thermodynamically stable than that of TiO_2, as their harmful debris may take place in living organism. Evident cytotoxic and allergic responses of Ni have also been reported. Thus, it is necessary to develop new Ti alloys that contain non-toxic elements [5]. New titanium alloys are being introduced to change the chemical composition and the mechanical properties. Some titanium alloys that are in use today or are being considered for use as implant materials are listed in table 1 along with their mechanical properties. The properties in table 2 result from specific heat treatments and will vary depending on their processing parameters. Information in this table permits a comparison of mechanical properties of pure titanium, some alpha/beta titanium alloys and some beta titanium alloys [7].

Type, Alloy, Nominal wt.%	E GPa	UTS MPa	YS(0.2%) MPa	% E1	%Red Area
Alpha	105	240-617	165-520	12-27	
Ti					
Alpha/Beta					
Ti-6a1-4V	88-116	990-1184	789-1013	2-30	2-41
Ti-5A1-2.5Fe	110	943-1050	818-892	13-16	33-42
Ti-6A1-7Nb	108	900-1100	910-970	11-14	
Beta					
Ti-13Nb-13Zr	79	550-1035	345-932	8-15	15-30
Ti-11.5Mo-6zr-2Fe	74-85	1060-1100	910-970	18-22	46-73
Ti-15Mo-5Zr-3Al	15-113	882-1312	870-1284	11-20	43-83
Ti-15Mo-3Nb	79	1035	993	15	60

Table 2. Mechanical properties of selected titanium alloys [7]

The biocompatibility performance of a metallic alloy is closely associated with its corrosion resistance and the biocompatibility of its corrosion products. Corrosion data show excellent resistance for titanium and its alloys though some precautions should be taken in order to optimize their composition [9].

Alloy design and thermo-mechanical processing control of titanium alloys has allowed the production of implant materials with enhanced properties. Titanium and its alloys areused in orthopedic surgery as implants in the shape of wires, nails, plates and screws for fixation and stabilization of fracture or in the form of artificial joints for the replacement of joints of the human body. Some implants are used for short time duration in the human body whereas others remain in place providing a continuous and trouble free function for decades. To avoid a reoperation caused by the implant material, the material must meet certain chemical and mechanical requirements. As previously mentioned, chemical requirement include high biocompatibility without altering the environment of the surrounding tissue even under deformation and sterilization. Mechanical property requirement relate to specific strength, modulus, fatigue, creep and fracture toughness which, in turn, relate to microstructures. The direct relation of the microstructure to properties and performance makes it necessary that the microstructural condition be part of the specification for a finished device [7].

In general, most of the Ti alloys offer appropriate mechanical properties for orthopedic applications. The modulus of Ti alloys is closer to those of bone and theoretically provides less stress shielding than those of stainless steel and Co-Cr alloys. Figure 2 present elastic moduli of some important materials used in bone tissue engineering. The Young's moduli of 316L stainless steel and Co–Cr–Mo alloy are much greater than that of cortical bone. The Young's moduli of biomaterials have been said to be desirable to be equal to that of cortical bone because if the Young's moduli of biomaterials are much greater than that of cortical bone, bone resorption occurs. The Young's modulus of $\alpha + \beta$ type titanium alloy, Ti–6Al–4V that is the most widely used titanium alloy for biomedical applications, is much lower than those of stainless steel and Co based alloy. However, its Young's modulus is still much greater than that of cortical bone [10].

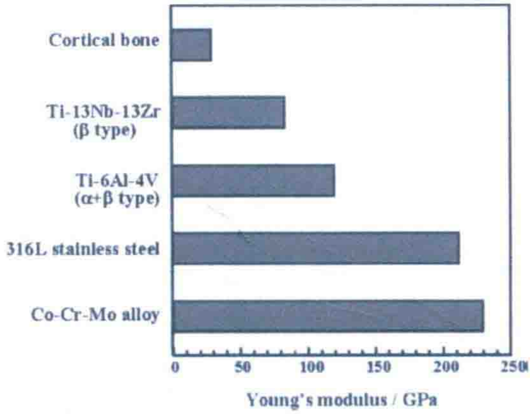

Figure 2. Comparison of Young's modulus of cortical bone, β type Ti–13Nb–13Zr, $\alpha + \beta$ type Ti–6Al–4V, 316L stainless steel and Co–Cr–Mo alloy for biomedical applications [10]

2. Fatigue of biomaterials

Safety is of concern for any biomaterial and its mechanical aspect, breakdown of a metallic implant, is a major complication. High mechanical properties are needed for structural efficiency of surgical and dental implants. But their volume is restricted by anatomic realities what require good yield and fatigue strengths of the metal. The yield strength fixes the forces above which a bone screw and a bone plate lose their shape and will no more fulfill a given function. The fatigue strength, less than yield in size, fixes the admissible load for any implant. On the other hand, an implant bridges the forces in bone, i.e. it may reduce the normal physiological level of forces, and effect an unwanted stress shielding. This would give advantage to a less-rigid bone plate, hip prosthesis or dental implant. Frequently this suggestion is associated with a low elastic modulus, near to that of bone. The conjecture is misplaced and convincing clinical evidence for it lacks. Flexible structure cannot guide and transport forces. But Young's modulus is connected to the ratio yield strength/Young's modulus, or fatigue limit/Young's modulus. The engineer calls this ratio the admissible strain; it is a design criterion. It equal 0.67% for human cortical bone and only titanium alloys can match this figure. Another concern of the engineer is damage tolerance [2].

Cyclic loading is applied to orthopedic implants during body motion, resulting in alternating plastic deformation of microscopically small zone of stress concentration produced by notches or microstructural inhomogeneteies. The interdependency between factors such as implant shape, material, processing and type of cyclic loading, makes the determination of the fatigue resistance of a component an intricate, but critical, task. Since testing an actual implant under simulated implantation and load conditions is a difficult and expensive process, standardized fatigue tests have been selected for initial screening of orthopedic material candidates, joint simulator trials being generally reserved for a later stage in the implant development process. Standard fatigue tests include tension/compression, bending, torsion, and rotating bending fatigue (RBF) testing, the latter, a relatively simple test, being widely used to evaluate orthopedic metallic materials. Unfortunately, no standard for fatigue evaluation of biomaterials testing has yet been established, a variety of testing conditions being encountered in reported fatigue studies of orthopedic materials [6].

One of the main reasons for concern about fatigue of biomaterials arises from the adverse host-tissue response to wear debris generated by the 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 wear 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 a highly acidic one (pH less than 3) [1].

Metal fatigue has been extensively studied [1,2,11]. The fatigue strengths of common metallic implant alloys used in hip replacements such as stainless steel, cobalt chrome and titanium, and their relationship to their microstructures, surface and corrosion properties have been reported [1].

Fig. 3 shows the fatigue strength (in air) of some common implant alloys using the S/N approach. It is of interest to note the importance of post processing treatment such as forging, which introduces compressive surface stresses. It can be seen that forged 316L stainless steel and forged cobalt–chromium have significant fatigue strengths over the cast components. The use of hot isostatic pressing (HIP) which introduces fine microstructures also has a pronounced improvement. The strength of the leg and arm bones is in the range of 100–200 MPa, the skull is about 97 MPa and that of the vertebral bodies is 1–10

MPa. It can be seen that the majority of these alloys (especially the HIP cobalt–chromium and titanium alloys) have fatigue strengths in excess of 500 MPa (in air) and hence have been deemed to be good for orthopedic implant applications such as those for the leg and arms [1].

The S/N approach has been used in a simulated body fluid environment with electrochemical and fretting devices incorporated. The combined mechanical and chemical processes play a vital role in crack initiation. The inability to repassivate quickly causes the electrochemical breakdown of the surface layers. Fig. 4 shows schematically how the formation of slip planes can break through the protective oxide film during fatigue [1].

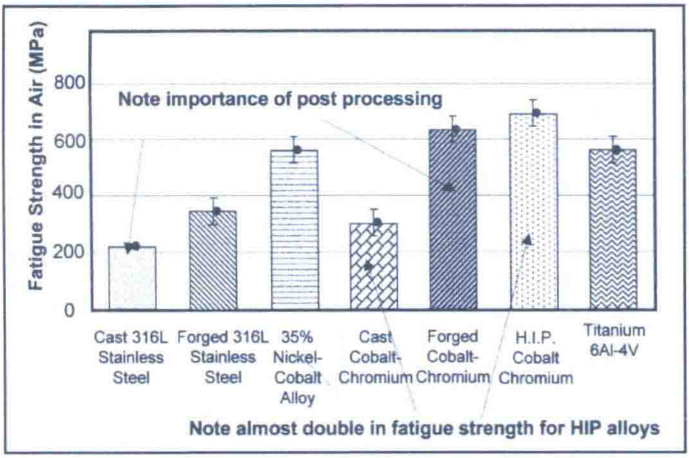

Figure 3. Fatigue strength of some common implant alloys [1]

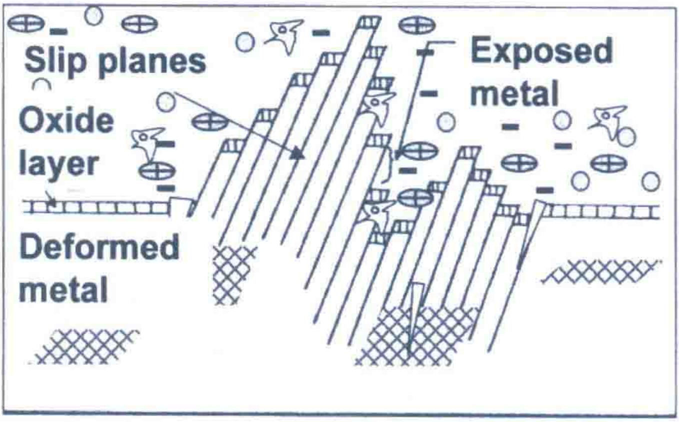

Figure 4. Schematic illustration of the formation of fresh slip planes in a body fluid environment during fatigue, exposing unprotected regions to electrochemical and biological activities [1].

Fretting fatigue of implant alloys based on the S/N approach has been studied [12]. In titanium implants, wear debris has given rise to blackening of surrounding tissue. Wear particles also cause implant loosening giving rise to severe 3 body wear. Fretting fatigue is essentially a micromotion phenomenon and often occurs at interfaces such as between the metal and the cement in the case of a hip prosthesis. This can result in a drastic reduction in fatigue strength. The fretting fatigue experiment in simulated body fluid is illustrated in Fig.5 for Ti-6Al-4V. The plain fatigue performance in air at 20 Hz and in pseudo-body fluid (PBS) at 2 Hz seems to be same. This is understood to be due to the ability of the titanium alloy to undergo rapid passivation. However, when fretting is carried out (artificially