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Determination of Fatigue Life of Titanium Alloys Used As a Locking Screw in Medical Applications

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Abstract

Titanium alloys are used in a wide range of applications including implant materials for the surgery and dental applications because of their outstanding mechanical properties such as superior strength, high corrosion resistance, lower modulus of elasticity and excellent biocompatibility. Ti6Al4V ELI is a typical Ti alloy accepted as an alternative metallic material for failed bone fractures because of good machinability and excellent mechanical properties, especially when direct contact with tissue or bone is required. During its service, most of the metallic implants are subjected to cyclic loading inside the human body which leads to the possibility of fatigue fracture. An evaluation of the fracture characteristics of fatigued implant materials can offer information about the fatigue life and the residual fracture resistance of these materials. In this study; Ti6Al4V ELI Grade 23 material medical screw test samples were designed and tested in accordance with the ASTM Bending Fatigue Test Procedure using 2,5 kN capacity test machine at room atmospheric conditions. Initial loading conditions determined based 75, 50, and 25 % of the bending strength found in accordance with the static 3P bending tests. The data generated from a series of tests were compiled and the results presented as a Fatigue Strength-the Number of Cycles (S/N) diagrams. For validation of the experimental studies; fatigue behaviors of screws were also analyzed with Ansys software using Finite Element Analysis (FEA) under dynamic loads.

Keywords: Fatigue Life, Biomechanics, Computer Aided Design, Locking Screw, Finite Element Analysis

INTRODUCTION

Medical bone screws are commonly used in orthopaedic implants for internal fracture fixation. They are placed into the bone for the fixation of fractures in epiphyseal and metaphysical areas such as femoral head and condyles, proximal and distal tibia, talus, calcaneus, pelvis and spinal vertebrae [1, 3]. Problems associated with medical screws include loss of fixation, improper placement, fatigue and bending failure, cerebral spinal fluid leaks, nerve root injury and infection. Implants used for fixation of fractures are subjected excessive forces during daily life. Variable stresses occur due to these forces on the implants. The amplitude, periodic changes and repeat of stresses instead of the maximum values are very important in terms of material life and safety. Periodically, varying stresses lead to a set of cracks and wears in the internal structure of the implant material. The cracks occurring in the internal structure of implant material under the repetitive forces lead to stress accumulations with time. As a result, implant material may be damaged even at a lower yield strength. One of these implant materials is the screws of internal fixators used to fix bone fractures.

In the literature, several studies are presented about the implant design and fatigue behavior in the skeletal system [4-8]. Colombi was developed three-dimensional finite element model for fatigue analysis of the hip implant [9]. Senalp et al. [10] modeled four stems of varying curvatures for the hip prosthesis. Static, dynamic and fatigue behavior of designed stems were analyzed by commercial FEA software. Kayabasi et al. [11] investigated the static, dynamic and fatigue behaviors of the implants. They have calculated fatigue life of the implants based on Goodman, Soderberg, and Gerber and mean-stress fatigue criteria.

A material subject to a cyclic loading can fracture far below its ultimate tensile strength and even below the yield strength of the material. Fatigue fractures are dangerous because they occur under normal service conditions with no warning prior to rupture. Indeed, medical devices manufactured from any material that are expected to survive millions of cyclic deformations over their lifetime require scrutiny of the fatigue and fracture resistance, with fatigue fracture being the major cause of premature failure in biomedical implants.

In this study, Ti6Al4V ELI Grade 23 material Intramedullary Fixation Devices (IMFDs) locking medical screw test samples were designed and tested in accordance with the ASTM test procedure using dynamic three point (3P) bending tests. The data generated from a series of tests were compiled and the results presented on the S/N diagram. For validation of the experimental studies; screws were also analyzed by Ansys software using FEA under dynamic loads.

METHODOLOGY

Design of a new medical bone screw

A medical screw is a device that drives rotational forces into linear motion. Thread design may vary according to the physical characteristics of the bone in which the screw is intended to gain purchase. There are two main types of the surgical screw for cortical and cancellous bone. Each type is available in fully and partially threaded format. Both can also be cannulated. A surgical screw is a device manufactured to high specifications, and is used with great care and precision. In order to select the correct instruments and techniques for insertion of any screw, the surgeon needs to be familiar with its dimensions and properties.

In this study, a new bone screw was designed using CATIA Computer Aided Design (CAD) software package and technically detailed. General representation and designations can be seen in figure 1.

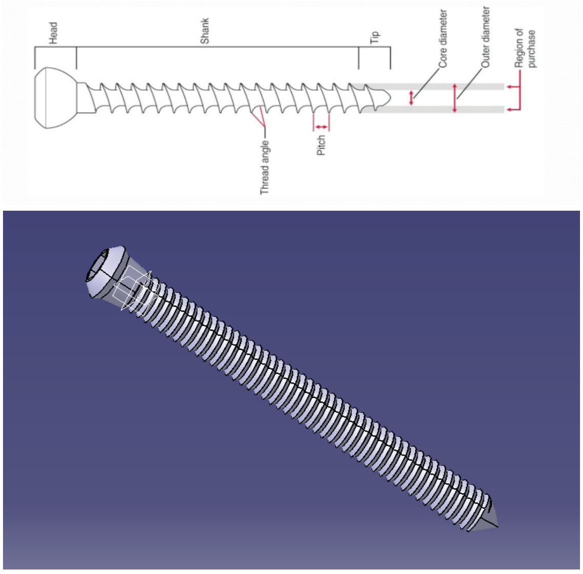

Figure 1. Engineering design of the medical bone screw

Material Properties

The high strength, low weight ratio and outstanding corrosion resistance inherent to titanium and its alloys have led to a wide and diversified range of successful applications which demand high level of reliable performance in surgery and medicine as well as in aerospace, automotive, chemical plant, power generation, oil and gas extraction, sports, and other major industries. In the majority of these and other engineering applications, titanium replaces heavier, less serviceable or less cost-effective materials.

Ti6Al4V ELI (Grade 23) is very similar to Ti6Al4V (Grade 5), except that Ti6Al4V ELI contains reduced levels of oxygen, nitrogen, carbon and iron. ELI is short for Extra Low Interstitials, and these lower interstitials provide improved ductility and better fracture toughness for the Ti6Al4V. The mechanical properties for Ti6Al4V ELI can be seen in Table 1.

Table 1. Mechanical and properties of Ti6Al4V ELI

Mechanical Properties	Ti6A14V ELI
Yield Strength (Mpa)	795
Ultimate Tensile Strength (Mpa)	860
Poisson Ratio (%)	0,24
Young Modulus (Gpa)	114
Rockwell Hardness (HRC)	30-35
Elongation (%)	>10
Reduction of Area (%)	>25
Fatigue Strength @ 600 Mpa (cycle)	10^6

Fatigue test procedure and testing

The IMFD Locking Screw test samples were prepared (Figure 2) and tested in accordance with the "ASTM F 1264-03 Standard Specification and Test Methods for Intramedullary Fixation Devices, A4. Test Method for Bending Fatigue Testing of IMFD Locking Screws" test procedure. Samples were tested using 2,5 kN capacity test machine at room atmospheric conditions (Figure 3) [12]. 3P bending fatigue test method covers the test procedure for performing cyclic bending fatigue test of locking screws.

Figure 2. The locking screw test samples

The three-point bend fixture is adjusted to the 18 mm span of the outer support rollers. The upper loading roller is centered between the outer supports rollers. The load and support rollers are manufactured using hardened steel and have a diameter of 8 mm. The screw is placed on the loading fixture such that the rollers sit between the crests of two adjacent threads.

Figure 3. Three-Point Bending Test

The locking screw is placed in a 3P bending fixture and is oriented in such a way that the locking screw section will normally bridge the fracture site to a uniform bending moment along the length of the section length. It is subjected to a constant frequency sinusoidal cyclic load waveform in 3P bending situation. Fatigue testing was done under axial loading with a constant amplitude. The termination criterion for the fatigue tests was either fracture of the specimens or the survival of 106 cycles. Initial loading conditions determined based on use initial fatigue loads corresponding to 75, 50, and 25 % of the bending strength determined in accordance with ASTM F 1264-03 standards.

Finite Element Analysis (FEA)

The CAD software (CATIA) was used to create the solid model of the screw as shown in figure 1. The study includes FEA fatigue strength-number of cycles simulations based on the same ASTM standard. The geometric model of the test specimen was imported to ANSYS and also mechanical properties of Ti6Al4V ELI as screw material, shown in Table 1, are defined as the material parameters. ANSYS software was used to generate meshes using tetrahedral elements of identical size and shape.

RESULTS and DISCUSSIONS

Standard fatigue tests include tension/compression, bending, torsion, and rotating bending fatigue testing is used to evaluate metallic materials. Unfortunately, no standard for fatigue evaluation of biomaterials testing has yet been established. An investigation on the mechanical properties and fracture characteristics of Ti alloys with fatigue damage under cyclic stress conditions are therefore beneficial.

Fifteen test sample of the new screw manufactured by CNC machining method was tested according to ASTM Bending Fatigue Testing of IMFD Locking Screws test standards. The results presented in a Fatigue Strength-Number of Cycles diagram (Figure 4.) that characterize the general fatigue life of the screw over a range of applied loads. As a result of fatigue analysis, minimum fatigue life has been determined as 12e+005 cycle under 100 MPa stress and 40e+006 cycle under 20 MPa stress. The numbers of cycles to failure were recorded and analyzed using an S-N diagram. From this diagram, the endurance limit was calculated from the linear relationship when plotted on a log scale.

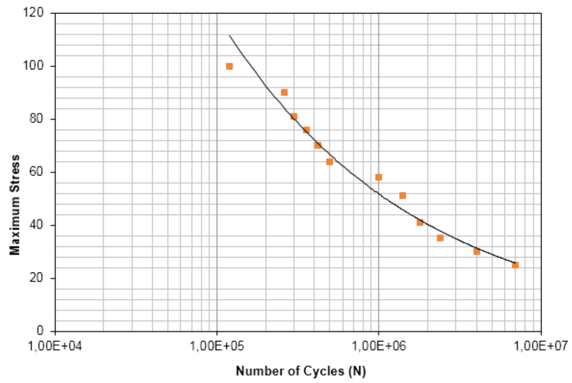

Figure 4. Fatigue Strength-Number of Cycles for 3P Bending experiments

In this study, fatigue analyses were conducted upon based on Equivalent (von-Mises) stress using ANSYS Workbench (Figure 5). Fatigue life is selected as analysis type and fully reversed is selected as loading type.

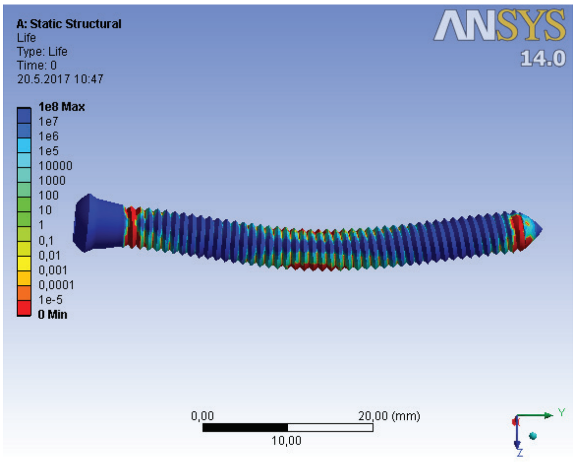

Figure 5. Bone screw life analysis in FEA

The results from the FEA simulations were validated with experiments based on ASTM F 1264-03 test method to detect the lifetime of the implant. Thus, this study shows that if boundary conditions set up correctly, FEA solution will be suitable for mechanical test standards. Figure 6. show us the validation of FEA solutions using 3P bending experiments. There were no significant differences in the number of cycles created both methods. It has been shown how the mechanical design for dynamic loading of biomaterials can be performed using FEA. A close coupling between test and analysis can be used to create a FE model and to verify its correctness. Then, the models are used to determine areas where failure would most likely to occur.

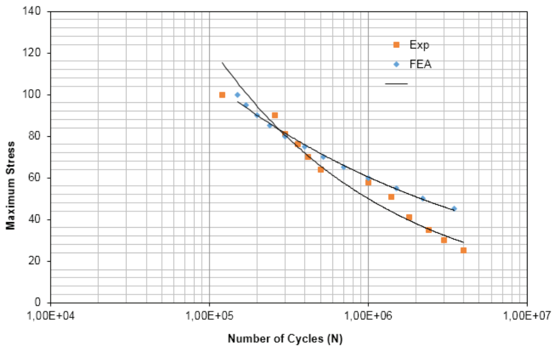

Figure 6. Medical bone screw life

CONCLUSIONS

In designing metal implants for use in the body, it is important to ensure the stress levels encountered are below this limit to avoid failure. Fatigue failures of metal implants occur in orthopaedic particularly if there are stress risers or local areas of stress concentrations in the implant. Stress risers are geometric features which raise the local stress in a structure they can be features of the design such as, screw holes, defects, notches in the implant. The fatigue behaviors of screws are very important for implant failure. If the implant failure occurs, the consolidation of fracture may delay or be off. Fatigue behaviors of the screws must be longer than the duration of fracture consolidation.

In this paper newly designed and manufactured bone screw was modelled and analyzed. Ti6Al4V ELI Grade 23 material IMFD locking medical screw test samples were tested in accordance with the ASTM standard. Fatigue strength-the number of cycles (S/N) diagrams have been created using both experimentally and FEA under dynamic loads. As a result of fatigue analysis, minimum and maximum fatigue life have been determined as 12e+005 cycle under 100 MPa stress and 40e+006 seconds under 40 MPa stress, respectively.

While it is not possible to avoid failure, recent works have focused on predictive tools to enable more accurate prediction to avoid catastrophic failure in a living body environment. The goal of biomaterial research has been continued to develop implant materials that induce predictable, control guided and rapid healing of interfacial tissues. Fatigue should become one of the major design criteria together with biological (biocompatibility) factors in the design of implants.

Acknowledgement

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