Çukurova Üniversitesi Mühendislik Mimarlık Fakültesi Dergisi, 31(ÖS 2), ss. ÖS 221-ÖS 228, Ekim 2016
Çukurova University Journal of the Faculty of Engineering and Architecture, 31(SI 2), pp. SI 221-SI 228, October 2016

Pull out Performance of Medical Screws used in Orthopaedic Surgeries

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Geliş tarihi: 14.07.2016 *Kabul tarihi: 12.10.2016*

Abstract

In this study, a new medical bone screw was designed and manufactured by Ti6Al4VELI GR23 material and tested in accordance with the ATSM F 543-02 test procedure experimentally. This test is used to measure the axial tensile force required to fail or remove a bone screw from a defined material. Concurrently, 3-D Finite Element Analysis (FEA) models of these medical bone screws were developed to simulate and biomechanically evaluate the pull-out forces and stiffness of the screw samples using FEA software ANSYS. Obtained results from the FEA models are in reasonable agreement with the experimental data on the pull-out strength of the medical bone screw. Results from FE models are experimentally verified.

Keywords: Medical screws, Finite element analysis (FEA), Pull-out, Biomechanics

Ortopedik Operasyonlarda Kullanılan Medikal Vidaların Sıyırma Performansı

Öz

Bu çalışmada, Ti6Al4Veli GR23 malzemesi kullanılarak yeni bir medikal vida tasarlanmış, ASTM-543-02 test prosedürüne uygun test edilmiş ve üretilmiştir. Bu testte tanımlanan bir malzemeden vidanın kırılmasını veya kemik malzemeden ayrılmasına neden olan kritik eksenel kuvvet hesaplanır. Aynı zamanda, tasarlanan vidanın üç boyutlu sonlu elemanlar modeli ANSYS programı kullanılarak sıyırma kuvvetleri ve dayanımları değerlendirilmek ve simule edilmek için oluşturuldu. Sonlu elemanlar modelinden elde edilen sonuçlar deneysel sıyırma mukavemeti sonuçlarıyla uygunluk göstermiştir. Böylece sonlu elemanlar ile elde edilen sonuçlar deneysel olarak doğrulanmıştır.

Anahtar Kelimeler: Medikal vidalar, Biyomekanik, Sonlu elemanlar yöntemi, Sıyırma

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1. INTRODUCTION

Medical bone screws are commonly used in orthopaedic implants for internal fracture fixation [1]. They are placed into bone for the fixation of fractures in epiphyseal and metaphysical areas such as the femoral head and condyles, proximal and distal tibia, talus, calcaneus, pelvis and spinal vertebrae [2,3] (Figure 1).

Problems associated with medical screws include loss of fixation, improper placement, fatigue and bending failure, cerebral spinal fluid leaks, nerve root injury and infection. In addition, any problems such as loss of reduction, vertebral body fractures after screw fixation, or metallic failure after the use of pedicle screws in osteoporotic spines [4]. Metallic medical bone screws are tested according to ASTM F543 for solution of these problems, such as torsion, driving torque, axial pullout, and self-tapping performance testing.

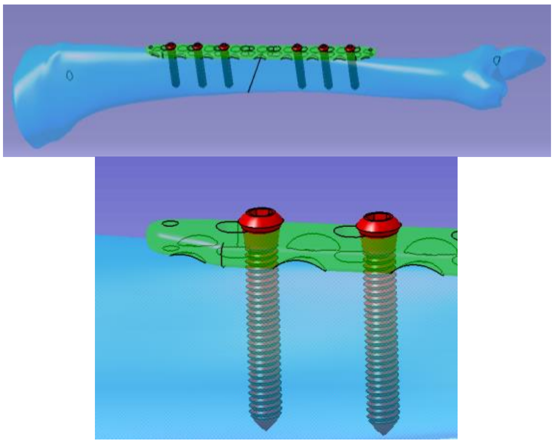

Figure 1. Assembly of the internal fracture fixation using bone plate and screw

Durability of fixation is important for life quality of patient. Biomechanical performance of fixation systems plays a major role in this manner. Pullout strength is one of the most important parameters that effect durability of fixation. Pullout strength can be used to measure loss of reduction of screw. This test is used to measure the axial tensile force required to fail or remove a bone screw from a defined material. Improving the pullout strength of the screw is complicated because the pullout strength is dependent on several factors, including the screw design, insertion technique, bone quality and shape of the bone [5]. In previous studies, different types of screws were designed for improving the pull-out performance. İnceoğlu studied that the effects of stress relaxation on the mechanical properties of the interface were different for different screw designs [6]. Yaman was conducted to measure the pullout strengths of newly designed transpedicular screws.

Transpedicular screws redesigned with modified helical angles exhibit higher pullout strength compared to the classical transpedicular screws and can be inserted more rapidly with the same number of screwing rounds result with doubled insertion depth [7]. It's important to find out the stress concentrations and deformation zones of implants, so FEA is the best method for analysis of stresses and deformations of Ti6Al4V [8]. Chatzistergos was aimed to the design of a FE model simulating accurately the pullout behaviour of cylindrical pedicle screws and predicting their pullout force. Three commercial pedicle screws, subjected to pure pullout from synthetic bone were studied experimentally. The results were used for the design, calibration and validation of a FE model [9]. Chao compared experimental study and FE analysis to investigate the bending strength and pullout strength of conical pedicle screws, as compared with conventional cylindrical screws [10]. Feerick has been studied the screw pullout from cortical bone using the UDMGINI subroutine with the extended FE method (XFEM) [11].

Pullout strength of a screw is significantly correlated with the screw designs like screws with radial holes, different core geometries, thread designs, cannulated and expandable screws [12]. Bone screws have almost a V or buttress shape of thread. Kim showed that the V-shaped thread had the highest pullout strength in osteoporotic bone and that the V and buttress shapes of threads maintained the highest pullout strength in a normal bone density [4]. By reducing the core diameter toward the tip while maintaining the same nominal diameter, achieves frictional connection, and better locking, by means of better pullout strength [13].

In this study, a new medical bone screw was designed and manufactured by Ti6Al4V ELI GR23 material and tested in accordance with the ATSM F 543-02 test procedure experimentally. Concurrently, 3-D FEA models of these medical bone screws were developed to simulate and biomechanically evaluate the pull-out forces and stiffness of the screw samples using FEA software ANSYS.

2. MATERIALS AND METHODS

2.1. Design of a New Medical Bone Screw

A screw is a device which converts 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. The two main thread types of surgical screws are for cortical bone and for cancellous bone. Each screw type is available in fully threaded and partially threaded format. Screws can also be cannulated. Such a screw can be introduced over a threaded-tip guide wire. The guide wire is inserted preliminarily, partly as temporary fracture stabilization, and partly so that the final orientation can be checked radiologically, prior to screw insertion.

A surgical screw is a device manufactured to high specifications, and is to be used with great care and precision. In order to select the correct instruments and technique for insertion of any screw, the surgeon needs to be familiar with its dimensions. The diameter of the core determines the minimal hole size for the screw to be accommodated in the bone and determines the drill used to create the pilot hole for the screw. An appropriate length of screw needs to be chosen. If it is too short, it will not gain full purchase in the bone. If it is too long: it may cause problems by irritating the soft tissues, or protruding subcutaneously.

The pitch of the screw is the length travelled by the screw with each 360° turn of the spiral. The shorter the distance, the “finer” the pitch; the longer the distance, the “coarser” the pitch. Cortical bone screws have a fine pitch; cancellous bone screws have a coarse pitch. The more threads engaged in the cortex, the greater the pull-out resistance. For a screw that crosses a fracture plane to produce interfragmentary compression, the thread must purchase in only the far cortex. A gliding hole is drilled in the near cortex. Special partially threaded cortical, or shaft-screws are also available for this purpose. If the screw that crosses the fracture plane purchases in both cortices, it cannot produce interfragmentary compression. Screws are also commonly used to attach implants to the bone by compressing them onto the bone surface using plates. As the plate hole is larger than the outside diameter of the conventional cortex screw and the screw has good purchase in the underlying bone, as it is tightened it compresses the plate to the bony surface.

In this study, a new bone screw was designed using CATIA Computer Aided Design (CAD) software package and technically detailed. General representation and designa1tions related to new developed bone screw can be seen in Figure 2.

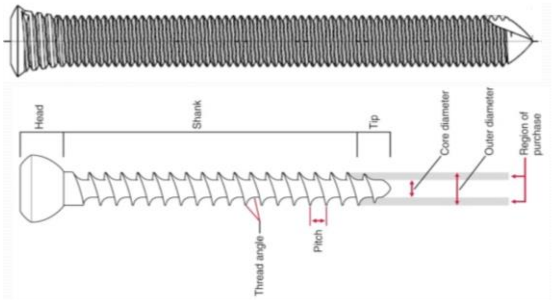

Figure 2. Engineering design of the medical bone screw

2.2. Material Properties

The high strength, low weight ratio and outstanding corrosion resistance inherent to titanium and its alloys has led to a wide and diversified range of successful applications which demand high levels 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. Designs made using the properties provided by titanium often result in reliable, economic and more durable systems and components.

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 and chemical properties for Ti6Al4V ELI can be seen in Table 1. and Table 2.

Table 1. Mechanical properties of Ti6Al4V ELI

Mechanical Properties	**Tİ6A14V 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

Table 2. Chemical properties of Ti6Al4V ELI

Chemical Properties	**Ti6A14V ELI**
Aluminum, Al	5.5-6.5%
Vanadium, V	3.5-4.5%
Carbon, C	< 0.08%
Iron, Fe	< 0.25%
Oxygen, O	< 0,13%
Nitrogen, N	< 0.05%
Hydrogen, H	< 0.012%
Titanium, Ti	Balance to

2.3. Pull out Test Procedure and Testing

The Medical Bone Screw test samples Ti6Al4V ELI were prepared (as shown in Figure 3.) and tested in accordance with the "F 543-02 Standard Specification and Test Methods for Metallic Medical Bone Screws" test procedure [14]. Samples were tested using 2,5 kN capacity tensile test machine at room atmospheric conditions. Pull out test method is used to measure the axial tensile force required to fail or remove a bone screw from a defined material.

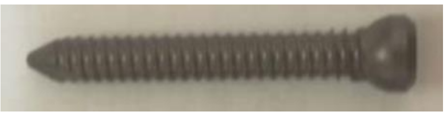

Figure 3. The medical bone screw test sample

Machines used for testing the axial pull out strength of screws conform to the requirements of F 543-02. A suitable test fixture as shown in Figure 4, used for testing. This fixture incorporate the test block which has material Ultra-High-Molecular-Weight Polyethylene (UHMW, UHMWPE) test block clamp, and bushing support. In addition to these requirements, the test block clamp and bushing support sufficiently rigid such that deflection under the required loading conditions is negligible. The test block clamp has a minimum grip span of five times the major diameter of the bone screw with the screw centered between the grips.

UHMWPE is a material better known as high performance polyethylene which is a thermoplastic polyethylene. Owing to its long chain like structure it can distribute loads more efficiently helping to reduce wear and increase stability. It has a high resistance to chemical attack and absorbs only minute amounts of moisture. In terms of medical applications UHMWPE is the preferred material when performing arthroplasty procedure for spine and orthopaedic implants.

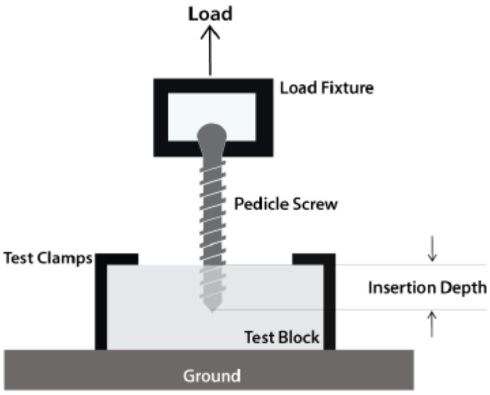

Figure 4. A test fixture for testing medical bone screw

The test block fabricated from a uniform material that conforms UHMWPE as shown in Table 3. The top and bottom surfaces have flat, smooth, and parallel as required to ensure that the test block will be supported in the fixture with the top surface at an angle of 90° to the centerline of the test specimen. The test block has a 25 mm diameter. The bone screws inserted into the standard material in accordance with the insertion torque test method. The screws inserted at a rate of 3 r/min to a depth of 20 mm.

Table 3. Typical average physical properties of UHMWPE [15]

Physical Properties	UHMWPE
Molecular weight (106 g/mol)	2-6
Melting Temperature (°C)	125-138
Yield Strength (Mpa)	21-28
Ultimate Tensile Strength (Mpa)	39-48
Poisson Ratio (%)	0,46
Young Modulus (Gpa)	0,8-1,6
Elongation (%)	350-525
Impact Strength (J/m)	>1,070(no break)

The test block and test block clamp fixed to the base of the load frame so that the longitudinal axis of the screw is aligned with the direction of the applied load. The screw's placed in the slot of the load fixture and seated in the recess. The load fixture then attached to the load frame. A tensile load applied to the test specimen at a rate of 5 mm/min until the screw fails or releases from the test block.

2.4. Finite Element Analysis (FEA)

CAD Model and Material Properties: The CAD software (CATIA V5R18) was used to create the solid model of the screw and test block as shown in Figure 5. The study includes FEA deformation simulations based on the standard of ATSM. The pullout experiments were simulated by FEA using ANSYS Workbench 16.0. The geometric model of the test sample was imported to ANSYS and mechanical properties of Ti6Al4V ELI and UHMWPE as screw and test block material shown in Table 1 and 3 are defined as material parameters.

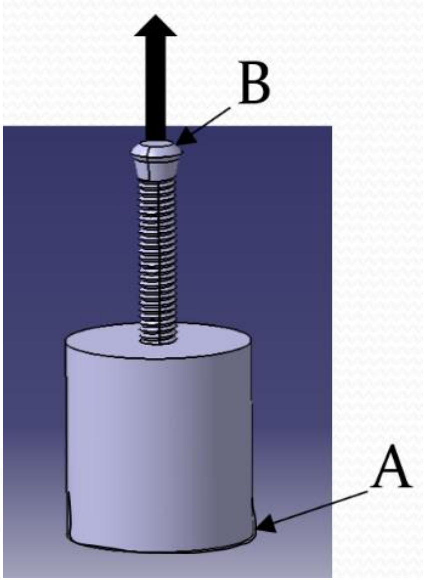

Figure 5. CAD model of the pullout test

Meshing: ANSYS software was used to generate meshes for the assembly. Tetrahedral elements of identical size and shape were employed for meshing. Mesh sensitivity was performed on the model using a workbench mesh tool called relevance.

Boundary Conditions: Boundary condition of FEA model was shown in Figure 5 using ANSYS. 3000N axial load was applied on B area and A was fixed area. These boundary conditions are similar to pullout test standards.

3. RESULTS AND DISCUSSION

3.1. Experimental Test Results

Typical Force (N) versus Elongation (mm) curves using UHMWPE block material and Ti6Al4V ELI medical bone screws created by the method of ASTM F 543-02 to determine axial pullout strength. In experiments; maximum load applied and the mode of failure executed (screw shaft, screw threads, or material failure). Pullout strength was analyzed using the Instron servo hydraulic materials testing system. All trials concluded with screw pullout. There were no screws visibly damaged during testing. There was also no evidence of cracking or fissuring of block or intrinsic block damage that extended into adjacent screw holes. Figure 6 demonstrates a typical profile obtained during the pullout test of a screw by plotting the force-displacement curve. The peak axial force and maximum deformation were determined as 2947 N and 15, 64 mm, respectively.

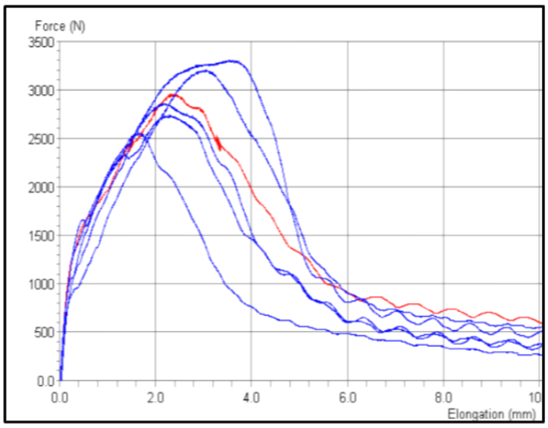

Figure 6. Force-deflection characteristics of medical bone screws

3.2. FEA Results

Reliable results can be obtained with experimental studies, but these studies do not give distribution of stress and deformation on test samples. If we want to achieve optimum design, must demonstrate these distributions for reliable interpretations. FEA was used for demonstration and simulation of stress, and deformation of designed model in boundary conditions. Also, it will guide for improving of design without time consuming and material waste. In this study, the FEA results are presented in Figure 7. It is clear from figure that for 3000 N applied force, deflection can be seen on solution model. This study shows that maximum and minimum deflections are distributed on the model. Thus, FEA results give some opinions such as critical area, minimum effected zone.

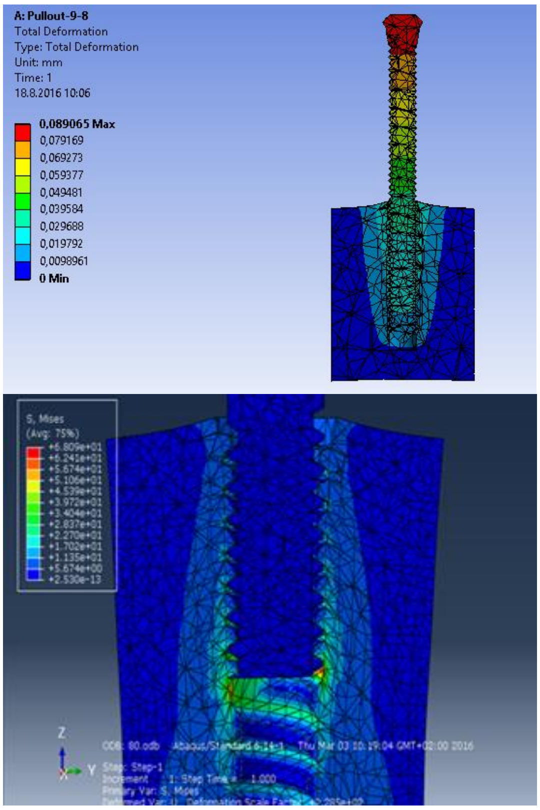

Figure 7. Total displacement on the screw and the bone

It was observed that at peak load the bone at the bone-screw interface experienced high stress gradient that led to the failure of the bone at edges of screw thread. The corresponding peak von Mises stresses (< yield stress) in the screw were also observed in the thread region at the bone-screw interface.

A decrease in stress values was observed as the bone was traversed from the bone-screw interface to the outer circumference of the bone illustrating a large stress gradient. Hence, it can be deduced that the failure of the model occurred in the bone around the outer diameter of the screw. The stress values were the highest in the first two threads at the ends and the failures stresses were evenly distributed at the bone-screw interface. It was observed that at peak load the elements representing cortical and cancellous bone near the thread tip region experienced high stresses.

The stress values in the screw were different from that of the bone in that they were not as evenly distributed as in the bone. It was observed that stress values in the screw decreased for threads away from the head as compared to those near the head. The stress experienced by the screw was much lower than its yield stress. Hence it can be concluded that failure during pullout testing occurs in the bone at the bone-screw interface without plastically deforming the screw threads. The displacement of the head of the screw was the largest as in the experimental evaluation.

4. CONCLUSION

In this study, a new medical bone screw was designed using Ti6Al4V ELI GR23 material and tested in accordance with the ATSM F 543-02 test procedure experimentally. Concurrently, 3-D FEA models of these medical bone screws were developed to simulate and biomechanically evaluate the pull-out forces and stiffness of the screw samples using FEA software ANSYS.

Pullout strength was determined by screw thread design. Thread designs that allow for greater screw purchase result in higher screw pullout strengths. The pullout strength of new design was measured and compared against the FEA results. Screw pullout was measured by inserting the screws into Ø2.5mm holes drilled into UHMWPE blocks. The strength is measured as the amount of axial load of the screw can endure until failure or removal occurs.

The main factors affecting the pullout force of a bone screw are its design, the material properties of the bone and the insertion technique followed by the surgeon. Conflicts still exist whether to perform experimental study using cadaver or synthetic foam blocks since results may vary within the materials. A continuous study is needed to gather information and knowledge as much as possible to enhance more stable and rigid spinal fixation system. Extra concern must be put on to the osteoporosis cases since major problems of fixation stability and rigidity.

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