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Experimental evaluation of the holding power/stiffness of the self-tapping bone screws in normal and osteoporotic bone material

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Abstract

Objective. The goal of this study is to compare the holding power of the self-tapping bone screws in normal and osteoporotic bone materials.

Background. Self-tapping screws are increasingly being used in orthopaedic surgery due to their advantages over the other bone screws.

Methods. Screws were divided into five groups (six screws per group) based on the depth of insertion in the bone coupons that represented normal and osteoporotic bones. Screws were randomly inserted into the bone coupons with tips of the screws being -1 mm, 0 mm, 1 mm, 2 mm and 3 mm relative to the far cortex. Biomechanical testing was performed using an Instron 8511 in accordance with the American Society for Testing and Materials standards for bone screws. Two-factor analysis of variance (ANOVA) was used to determine if the holding power of the screws were different with respect to insertion depths and bone materials.

Findings. The bone materials had a significant difference (P < 0.05) in the holding power and depths of insertion past the far cortex were significantly different from one another in holding power. The affect of the screw material on the holding power of the self-tapping screws in different bone materials was also examined. The performance of stainless steel screws was superior to that of titanium screws in the osteoporotic material.

Interpretation. Based on the results it can be concluded that the depth of insertion of the tip of the screw for adequate fracture fixation in normal bone is 1 mm or more past the far cortex and in osteoporotic bone it is at least 2 mm past the far cortex. © 2006 Elsevier Ltd. All rights reserved.

Keywords: Biomechanical testing; Screw pullout; Holding power; Osteoporosis; Self-tapping screws; Depth of insertion

1. Introduction

Osteoporosis, often referred to as the "silent disease", has been characterized by low bone mass and structural deterioration of bone tissue making it fragile and liable to fail. This often results in fractures of the hip, spine, etc. after a normal fall (Takahashi et al., 1999). Osteoporosis has gradually become a major public health threat for postmenopausal women and aging individuals of both

* Corresponding author. *E-mail address:* bsuneel@uakron.edu (S. Battula). sexes. More than 10 million people are estimated to have the disease and 34 million more are at a risk for osteoporosis due to low bone mass. Osteoporosis is also responsible for more than 1.5 million fractures every year that include 700,000 vertebral fractures, 250,000 wrist fractures, 250,000 hip fractures and 300,000 other limb site fractures. The estimated national direct expenditure for osteoporosis and associated fractures was \$17 billion in 2001 and the cost is increasing (National Osteoporosis Foundation, 2005; Riggs and Melton, 1998).

There is an increased need to prevent osteoporosis and also for effective osteosynthesis for associated fractures. In

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osteoporosis the normal connective network of trabecular bone is reduced to a weak lattice framework with a comparable reduction occurring in the thickness of cortical bone. These alterations predispose patients to fracture and present a problem in osteofixation. The reduction in regional modulus of elasticity, tensile modulus and tensile strength in osteoporotic bone clearly impacts the fixation strength, stiffness and durability of orthopaedic biomaterials.

Cortical bone screws are commonly used implants for fixation of fractures and also for the stabilization of bone transplants. These days the self-tapping cortical bone screws (STS) are used more frequently than other types of bone screws (non-self-tapping, etc.). The use of STS reduces the operation time, number of instruments required and blood loss (Yerby et al., 2001). The STS also have a higher screw-to-bone interface compared to the non-self-tapping screws. The STS have cutting flutes that eliminate the need to use a tap and facilitate insertion. But the presence of these cutting flutes is thought to reduce the holding power in the region of the flutes compared to the fully threaded region, hence for maximum holding power it has been recommended that the screws be inserted with cutting flutes penetrating the far bone cortex (Neto et al., 1999). Based on anecdotal recommendations STS are usually inserted 2 mm beyond the cortex to obtain maximum holding power but this may lead to patient discomfort due to protuberance within muscle or soft tissue (Battula et al., 2004 (unpublished data) and Neto et al., 1999).

Berkowitz et al. (2005), demonstrated that there was no significant difference between the pullout strengths of the screws inserted to depths penetrating the far cortex of a normal bone coupon by 1 mm, 2 mm and 3 mm. But that study showed that there was a significant increase in the pullout strength when the screw penetrated the far cortex when compared to those inserted to a depth short of the far cortex. Battula et al. (2005, unpublished data) performed a similar study, to determine the pullout strength of the bone screws in an osteoporotic bone coupon but

no comparison was made between the pullout strengths of the bone screws in normal and osteoporotic bone.

The purpose of this study was to compare the holding power (HP) of the STS in bone materials representing normal and osteoporotic bone. HP has been defined as the maximum tensile force required to pull the screw out of the bone coupon per unit length of screw engagement. This study also compares the effect of the screw material, titanium (Ti) and stainless steel (SS), on the HP of the STS in both the bone materials.

2. Methods

Bone coupons (Fig. 1) from Sawbones[®] (Pacific Research Laboratories, Vashon, WA, USA) made of polyurethane foam and e-glass epoxy sheets, each with uniform material properties, were used to have a more consistent model compared to cadaveric bone. Synthetic bone test specimens have low block-to-block variance and can be considered to be of uniform material properties but cadaveric specimens have a high variability among the specimens, which makes it difficult to maintain uniform material properties in test conditions. Synthetic bone also facilitates uncontaminated and clean test environment that is not possible in cadaver testing.

The synthetic bone coupons were modeled after human bone structure with compact outer layer (e-glass epoxy sheets) covering a porous inner layer (solid polyurethane foam). Solid polyurethane foam was used as a testing material according to the American Society for Testing and Materials (ASTM) F 1839-01 specifications (Annual Book of ASTM Standards, 2003). The ASTM standard specifies that polyurethane foam cannot be used to replicate the mechanical properties of human bone but can be used as a test medium for testing metallic bone screws when the material properties are uniform and in approximate range of the human cancellous bone. E-glass filled epoxy sheets were used to mimic the compact bone with 1.7 g/cc density



Fig. 1. Bone coupon comprising of polyurethane foam (for cancellous bone) and e-glass-filled epoxy sheets (for cortical bone) with its specifications and the dimension between the drilled screw holes.

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