Medical Engineering and Physics 37 (2015) 746–751

Contents lists available at ScienceDirect

Medical Engineering and Physics

journal homepage: www.elsevier.com/locate/medengphy

Effect of different radial hole designs on pullout and structural strength of cannulated pedicle screws

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ARTICLE INFO

Article history:
Received 18 August 2014
Revised 11 February 2015
Accepted 3 May 2015

Keywords:
Cannulated screw
Radial hole
Finite element model
Pullout strength

ABSTRACT

Cannulated pedicle screws are designed for bone cement injection to enhance fixation strength in severely osteoporotic spines. However, the screws commonly fracture during insertion. This study aims to evaluate how different positions/designs of radial holes may affect the pullout and structural strength of cannulated pedicle screws using finite element analysis. Three different screw hole designs were evaluated under torsion and bending conditions. The pullout strength for each screw was determined by axial pullout failure testing. The results showed that when the Von Mises stress reached the yield stress of titanium alloy the screw with four radial holes required a greater torque or bending moment than the nine and twelve hole screws. In the pullout test, the strength and stiffness of each screw with cement augmentation showed no significant differences, but the screw with four radial holes had a greater average pullout strength, which probably resulted from the significantly greater mean maximum lengths of cement augmentation. Superior biomechanical responses, with lower stress around the radial holes and greater pullout strength, represented by cannulated pedicle screw with four radial holes may worth recommending for clinical application.

1. Introduction

Osteoporosis is characterized by a decrease in bone mass and density which can easily lead to fractures. Osteoporosis-related fractures most commonly occur in the hip, wrist or spine. Research has demonstrated that the risk of bone fractures increases by 1.5–3 times as the standard deviation of bone mineral density (BMD) decreases, and the lowest density is found at the fracture site [1,2]. When vertebral bodies are seriously affected by osteoporosis, most pedicle screws cannot provide sufficient holding power to the screw–bone interface, leading to greater risk of loosening or failure [3,4]. Previous research has found that the pullout strength of pedicle screws in osteoporotic bone decreases with lower BMD values [5,6]. To reduce screw loosening, cement-augmentation has been applied to pedicle screw fixation systems [6–8]. Using osteoporotic cadaveric thoracolumbar models, Chao et al. [6] implanted cannulated screws with nine 1 mm diameter radial holes located around the distal one-third and demonstrated that the pullout strength of cement-augmented screws is stronger (over 300%) than un-augmented pedicle screws in osteoporotic vertebrae. Ying et al. [9] inserted a cannulated screw with one radial hole located at the distal third of the screw thread into a low-density synthetic bone block. The pullout strength of such cemented augmented screws was found to increase fivefold in comparison to non-cemented screws. Similarly, the pullout strength is increased even when the screws are augmented with absorbable materials such as hydroxyapatite [10], calcium phosphate [11,12] and calcium sulfate [13]. Numerous authors have reported fracture of cannulated pedicle screws around the radial holed during insertion. Typically, breakage occurs in screws with at least nine holes (Fig. 1). Most commercial cannulated pedicle screws in Taiwan use 4, 9 or 12 radial holes and the number of radial holes is considered as a key factor in determining cement distribution and pullout strength. Chen et al. [14] indicated that the amount of cement exuded from the cannulated screws increased with the number of radial holes, leading to an increased average pullout strength. But the radial holes in Chen's study were

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http://dx.doi.org/10.1016/j.medengphy.2015.05.004
1350-4533/

Fig. 1. Ruptured cannulated screws with nine radial holes located in the distal one-third of the screw shaft (SmartLoc Evolution System: Cannulated Screw, 60 mm × 40 mm, A-Spine, Taipei, Taiwan).

located at 4-mm increments along the full length of the screw, not limited to the distal one-third of the screw shaft. Actually, the risk of cement leakage from the vertebral body may increase with the use of cannulated screws, especially when the radial holes are near the posterior cortex of the vertebral body. Hence, the radial holes are primary positioned at the distal one-third of the screw. However, a high density of radial holes near the distal end might influence the strength of the screw, and result in yielding failure during insertion or loading. There have been no related studies on how the positioning of radial holes near the distal one-third of the screw may influence its structural strength. Therefore, the authors made an assumption that the number and location of radial holes would affect the mechanical strength and, hence, this study used three typical cannulated screw types (4, 9, and 12 holes) as a reference. Finite element (FE) simulations and mechanical tests were used to determine the properties of interest. Pullout strength was determined for the cement augmented screws using osteoporotic synthetic bone blocks to analysis the relationship between pullout strength and radial hole distribution.

2. Materials and methods

2.1. Establishing 3D cannulated pedicle screw models

Three types of commercially available cannulated pedicle screws (SmartLoc Evolution System: Cannulated Screw, 60 mm × 40 mm, A-Spine, Taipei, Taiwan) were adopted to create the 3D models using SolidWorks 2014 CAD software (DS Solidworks Corp, Waltham, Massachusetts USA). The radial holes in the three designs were all located at the distal one-third of the screw. The cannulated screw with four radial holes was named S4 type; nine holes named S9 type; and twelve holes named S12 type (Fig. 2). Each screw had the same inner diameter (2 mm) and radial hole diameter (1.5 mm). The length of the screw thread was 60 mm, and the largest outer diameter of thread was 40 mm.

2.2. Finite element analysis of different cannulated pedicle screws

FE methods were used to analyze and compare the maximum torque and bending moments among the three screw types under torsion and bending conditions (Ansys workbench 14.0, ANSYS, Inc., USA) when the Von Mises stress reached the screw's yield stress. Titanium alloy (Ti–6Al–4V) with an elastic modulus of 113.8 GPa and Poisson ratio of 0.342 was selected for the pedicle screws (ASTM F138-06). Also, the material properties were assumed to be homogeneous and isotropic, and the yield stress was set at 790 MPa. Convergence tests in structural strain energy have been performed to determine the adequate element mesh densities for the three models (S4 model: 79,331 elements; S9 model: 87,956 elements; S12 model: 102,580 elements). The S4 type pedicle screw has been chosen for finite element model validation by performing a three-point bending test. With a distance of 30 mm at the inferior load span and a constant central compressive displacement (2 mm/min) from the top, a 7.9% difference in structural stiffness determined from the load-displacement diagrams of both practical test and the finite element simulation has been observed. In the torsion test, the screw tip was completely fixed in all directions. An initial torque of 1.29 Nm [15] was applied to the screw tip and then increased in increments of 0.3 Nm (Fig. 3) until the Von Mises stress reached the yield stress. For the bending test, the screw tip was again completely fixed in all directions and an initial bending moment of 1.29 Nm was applied. Similarly, the moment was increased in increments of 0.3 Nm until the Von Mises stress reached the yield stress.

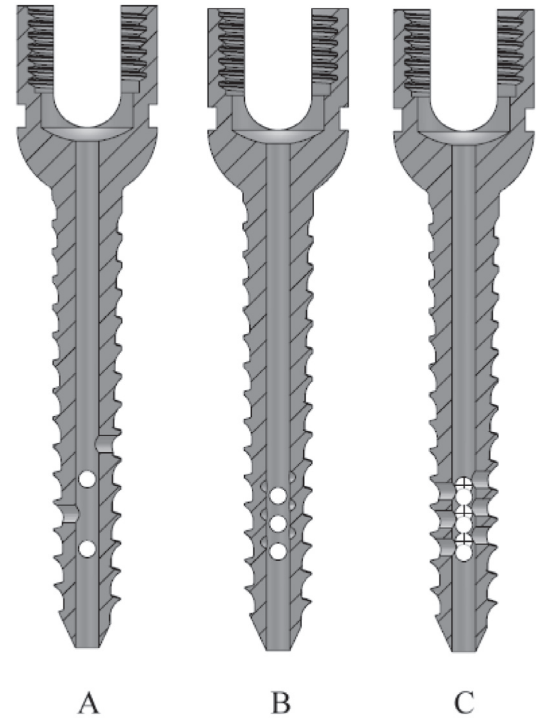

Fig. 2. (A) S4: Four radial holes positioned at 90° to each other, descending in a counterclockwise direction according to the thread. The first hole is located at the origin of the distal one third of the screw shaft. (B) S9: Nine radial holes positioned at 120° to each other. (C) S12: Twelve radial holes positioned at 90° to each other.

2.3. Synthetic bone preparation and pullout test

Titanium–6Aluminum–4Vanadium extra low interstitial (Ti–6Al–4V) alloy was selected as the material for the three pedicle screws on the basis of ASTM F138. To test the pullout strength, a commercially available synthetic bone (test block, model 1522-505, Pacific Research Laboratory Inc., Vashon Island, WA) was used to simulate human spinal bone with severe osteoporosis The synthetic bone, made from open-cell rigid polyurethane foam with a density of 0.09 g/cm^3, provides a homogeneous, uniform material with properties in the range