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Biomechanical analysis of different types of pedicle screw augmentation: A cadaveric and synthetic bone sample study of instrumented vertebral specimens

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ABSTRACT

This study aims to determine the pull-out strength, stiffness and failure pull-out energy of cement-augmented, cannulated-fenestrated pedicle screws in an osteoporotic cadaveric thoracolumbar model, and to determine, using synthetic bone samples, the extraction torques of screws pre-filled with cement and those with cement injected through perforations. Radiographs and bone mineral density measurements from 32 fresh thoracolumbar vertebrae were used to define specimen quality. Axial pull-out strength of screws was determined through mechanical testing. Mechanical pull-out strength, stiffness and energy-to-failure ratio were recorded for cement-augmented and non-cement-augmented screws. Synthetic bone simulating a human spinal bone with severe osteoporosis was used to measure the maximum extraction torque. The pull-out strength and stiffness-to-failure ratio of cement pre-filled and cement-injected screws were significantly higher than the non-cement-augmented control group. However, the cement pre-filled and cement-injected groups did not differ significantly across these values ($p = 0.07$). The cement pre-filled group had the highest failure pull-out energy, approximately 2.8 times greater than that of the cement-injected ($p < 0.001$), and approximately 11.5 times greater than that of the control groups ($p < 0.001$). In the axial pull-out test, the cement-injected group had a greater maximum extraction torque than the cement pre-filled group, but was statistically insignificant ($p = 0.17$). The initial fixation strength of cannulated screws pre-filled with cement is similar to that of cannulated screws injected with cement through perforations. This comparable strength, along with the heightened pull-out energy and reduced extraction torque, indicates that pedicle screws pre-filled with cement are superior for bone fixation over pedicle screws injected with cement.

1. Introduction

The pedicle screw system is commonly used for spinal reconstruction, fixation, and other spinal disorder surgeries [1–3]. When the vertebral bodies are seriously affected by osteoporosis, most pedicle screws cannot provide sufficient strength at the screw-bone interface, and such unions carry a high risk of loosening or failure [4–6]. Previous research has demonstrated that the pull-out strength of the pedicle screw in osteoporotic bone decreases with lower bone mineral density (BMD) values [7,8]. Hence, the screw holding strength is not easy to improve during orthopedic surgery. Some in vitro studies have indicated that using cement-augmented pedicle screws significantly increases both pull-out strength and transverse bending stiffness [9–12]. In clinical practice, a cement-augmented screw enhances the holding strength of screws in osteoporotic bone have been demonstrated by orthopedic surgeons. This technique has been used to reduce interoperative screw-bone interface failure and to reinforce its strength [4,13–15].

Although the advantages of cement-augmented screws are clear, reports of their clinical use are limited. Worrisome side effects

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include cement leakage into the spinal canal, neural foramina and paravertebral veins. Bone cement and cannulated pedicle screws have been developed to provide cement augmentation primarily in the distal end of the screw. As this technique and screw design evolved, there are several potential problems existing, such as risk of cement leakage outside the vertebral body, the difficulty of injection with cannulated screw (it requires high-pressure cement injection using low-viscosity cement via cannulated screw) and a difficulty of removing the fixed screw if there are complications after the initial surgery [16].

Recent research has focused on the perforated screw with cement augmentation, which allows cement injection through the perforation to improve the holding strength of the screw [17]. Although studies [9–12] have shown increased pull-out strength with various types of screw augmentation, none yet compare cannulated screws pre-filled with cement and those with cement injected through the perforation. Comparing to cement injected through the perforation, cement pre-filled method is more convenient, and due to solid screw is the only equipment to prepare. If the biomechanical strength of pre-filled with cement is comparing to cement injection through the perforation, the method of cement pre-filled have more advantages.

In addition, the revision characteristics of these two types of screws remain unknown. Some have hypothesized that pre-filled screws provide more uniform cement distribution, resulting in better pull-out strength and revision characteristics than screws with cement injected through the perforation. Hence, the primary purpose of this study is to determine the pull-out strength, stiffness and failure pull-out energy of cement-augmented, cannulated-fenestrated pedicle screws, both pre-filled with cement and those with cement injected through perforations, in an osteoporotic cadaveric thoracolumbar model, as well as to determine the extraction torques of these screws in synthetic bone samples.

2. Materials and methods

2.1. Cadaver sample preparation and pull-out test

A total of 32 human vertebrae from four female thoracic and lumbar spines (mean age 62.3 years, range 55–71 years), spanning T10 to L5, were used. Prior to testing, each explanted spine was vacuum sealed, frozen and submitted for BMD testing with dual-energy X-ray absorptiometry (DEXA, Hologic QDR 4500C; Hologic Inc., Waltham, MA). In addition, each specimen received radiographic evaluation to exclude any tumors or significant disease. Before implantation, the sizes of the pedicles in both outer height and width were measured using a calibrated vernier caliper. All specimens were allowed to reach room temperature and were kept moist throughout the testing period. Spinal levels of T10-L5 were instrumented transpedicularly with two cannulated-fenestrated pedicle screws (6 mm × 40 mm; SmartLoc OMEGA Cannulated Screw, A-Spine Asia Co., Ltd., Taipei city, Taiwan) of the same length and diameter. Each screw had a 2 mm diameter center hole over the screw tip and nine 1 mm diameter side holes over its distal one-third (Fig. 1). Selected vertebral samples randomly, bilateral pedicles of a single specimen were received cannulated screws with non-cement-augmentation (group 1), cement pre-filled (group 2), cement injected after screw insertion (group 3) in turn; samples were excluded in conditions as below: undersize or pedicle fracture during screw implanting in this study. A needle and the guide wire were used for positioning, and holes were tapped prior to screw insertion using a tap with a diameter of 2.5 mm; the screw was then inserted into the cadaver specimen through the prepared path. The insertion rate of the screws was 3 rev/min, according to ASTM standards [18].

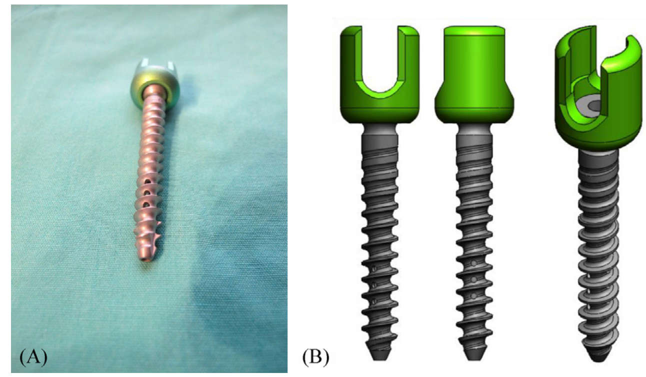

Fig. 1. (A) Photo and (B) schematic of 6 mm × 40 mm SmartLoc OMEGA Cannulated Screw, A-Spine.

Polymethylmethacrylate (PMMA) cement (2 ml, Stryker Surgical Simplex® P Bone Cement, Stryker Corp., Kalamazoo, MI) was mixed at room temperature and then injected through the cannulated screws into each vertebra and the cement was allowed to diffuse into the vertebral body. Finally, any cement remaining inside the screw was extruded by inserting a pin. For comparison, the pull-out strength of same-dimension pedicle screws was recorded for those pre-filled with cement and those not augmented with cement. The cannulated screws pre-filled with cement were inserted into the vertebra through the prepared pilot hole and then removed to create a tunnel. 2 ml of cement was then retrogradely injected to fill the created tunnel. After being pre-filled with bone cement, the screw was then fully inserted into the vertebra. Pull-out testing was performed using an Instron testing machine (model 8874, Instron Corp., Canton, MA). The specimen, with screws inserted, was placed on a specially designed universal fixture with a self-aligning function to ensure vertical pull-out (Fig. 2). The pedicle screw was attached to the apparatus by a rod threaded to the screw head. The specimens were mounted after the cement was allowed to set (60 min). A pre-load of 40 N with 30 s of accommodation time, followed by continuous and progressive load at a speed of 1 mm/min was applied. The first peak force (judged as the yield load in the force-displacement diagram) detected during the test was recorded as the failure pull-out strength. Stiffness was evaluated by the approximate slope of the linear region in each force-displacement diagram. The

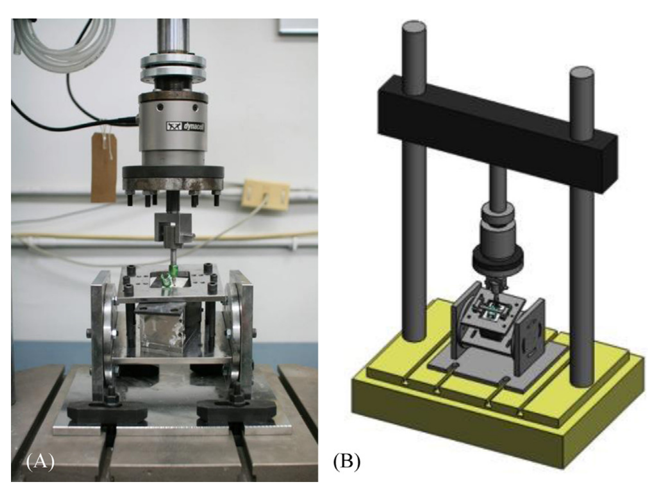

Fig. 2. (A) Photo and (B) schematic of material testing system and test specimen. The test specimen is connected with a metal segment that has an inner thread with the same dimension as the screw nut to lock the outer thread inside the screw head.