Biomechanical Analysis of a Novel Pedicle Screw Anchor Designed for the Osteoporotic Population

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OBJECTIVE: **The biomechanical study was performed to investigate the effect of a novel pedicle screw anchor in increasing the pullout strength of pedicle screws.**

METHODS: **Ten lumbar vertebral bodies with a weighted average T-score of -2.13 were used. Pedicle screws of 4.5 mm diameter and 25 mm length were inserted in to one pedicle randomly and matched with an anchor in the corresponding pedicle. Fatigue testing was performed by applying an axial load of ±200N to the screw tulip, along the axis of the rod, at a rate of 0.5 Hz for 1,000 cycles. After fatigue loading was completed, all screws underwent axial pullout testing at a rate of 0.1 mm/sec until failure. A paired two sample for means t-test was performed to determine a significant difference between the two groups ($p \leq 0.05$).**

RESULTS: **Following fatigue testing, the axial displacement at the 1,000 cycle point for the anchor and non-anchor group was 1.4 ± 0.7mm and 2.9 ± 1.2mm, respectively. The anchor group had significantly lower axial displacement compared to the non-anchor group ($p \leq 0.01$). The group with the anchor reached an average maximum load of 702 ± 373N. The average yield load for the non-anchor group was 421 ± 293N. The anchor group yield load was significantly greater than the non-anchor group ($p \leq 0.01$).**

CONCLUSIONS: **A novel anchor for standard pedicle screws resulted in significantly less axial movement during fatigue and a greater failure force compared a screw with no anchor. The anchor may provide a stronger bone-to-screw interface, than a non-anchor screw, without the complications of cement augmentation.**

INTRODUCTION

Osteoporosis, or loss of bone density, is a common problem occurring with natural aging and after menopause in women. It manifests itself through weakening of bones and ultimately the development of fractures (4, 15, 19). This bone matrix weakening also is seen as a complication of other pathologies, such as osteogenesis imperfecta, rheumatoid arthritis, and HIV infections (5, 21, 24). Poor bone quality poses challenges to surgical intervention, because any type of fixation or anchor point is at an increased risk of failure (18). Failure of instrumentation is more dangerous in the spinal column because of the proximity of the spinal cord and other neural structures, compared to extremities.

After spinal instrumentation, metal hardware often is used to provide stability and support to the anatomy until a fusion occurs (13). Pedicle screws must be seated firmly within the remaining bony anatomy to provide the necessary stability. The presence of weak bony architecture such as is seen in osteopenia and osteoporosis can cause failure of the metallic construct and ultimately lead to further neural compromise and reoperation (12).

When performing surgery for spinal stenosis, degenerative discs, or spondylosthesis, pedicle screw instrumentation is often required. All indications are likely to occur or worsen with age and have a high potential to overlap with other comorbidities, such as osteoporosis (15). In previous studies researchers have attempted to reduce this risk of hardware failure by augmenting the hardware with bone cement or through expandable screws (2, 4, 25). These methods, although useful at times, could create permanent changes to the bone and may make revision at a cement-augmented level difficult. In this study, we examine a novel approach to preventing hardware failure and pullout in low bone density vertebra through the use of a fully removable pedicle screw anchoring sleeve. The hypothesis is that a screw with an anchor will fail during pullout testing at a greater load than a screw without an anchor.

Key words
- Anchor
- Osteoporosis
- Pedicle screw pullout

Abbreviations and Acronyms
PEEK: Polyetheretherketone

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Citation: World Neurosurg. (2015) 83, 6:965-969.
http://dx.doi.org/10.1016/j.wneu.2015.01.057

Journal homepage: www.WORLDNEUROSURGERY.org

Available online: www.sciencedirect.com

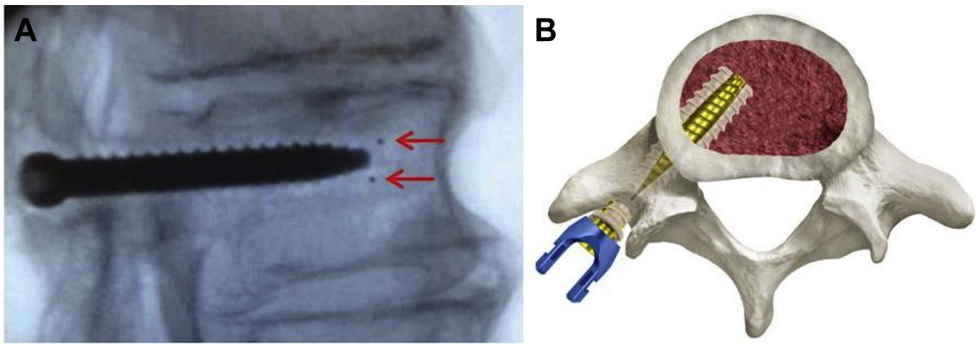

Figure 1. (**A**) Radiography of polyetheretherketone anchor and pedicle screw placed in a vertebral body. The anchor is radiolucent and can be seen by the radiopaque markers at the distal end of the pedicle screw (*arrows*). (**B**) Artistic interpretation of anchor and screw instrumented inside a vertebral body.

Second, our goal is to determine the displacement of a screw with an anchor during fatigue loading compared with a screw without an anchor.

METHODS

Specimen Preparation

Ten lumbar vertebral bodies (mean age 61 ± 8.8 years; 1 male, 3 female patient) from four fresh human lumbar spines were used in the study. The spines were radiographed in both the anteroposterior and lateral planes to ensure visual lack deformity. The specimens were stored in double plastic bags at −20°C. All specimen were defrosted overnight at room temperature with a consistent defrost period. The lumbar spines were then separated into individual vertebral bodies by removing the musculature and intervertebral disc material. The weighted average T-scores, from dual-energy X-ray absorptiometry scans, for the 10 vertebral bodies was −2.13 (range −1.67 to 3.1).

The anchor (Globus Medical Inc., Audubon, Pennsylvania, USA) is made out of polyetheretherketone (PEEK), a medical-grade organic polymer thermoplastic and functions by being introduced down a predrilled hole in the pedicle until it fits snuggly against the bone. The center is designed to fit the desired screw diameter and length of any manufacture. As the screw is advanced into sleeve, the superficial portion of the device expands in a cranial/caudal fashion within the pedicle, whereas the far end of the sleeve located within the vertebral body flairs in a medial/lateral fashion. These 2 changes are designed to help compress the screw tightly within the pedicle and vertebral body. There is no difference to the length of the pedicle screw and approximately a 1-mm increase of diameter when used in conjunction with an anchor. The anchoring sleeve also is designed to be easily removed. No extra steps are required for anchor deployment other than insertion down the predrilled trajectory. If the pedicle screw is removed, the device collapses back to its original shape and can be simply pulled back out. Figure 1 shows the anchor and screw placed in a vertebral body. The anchor is radiolucent and can be seen by the radiopaque markers at the distal end of the pedicle screw (arrows). A standard REVERE$^{(R)}$ (Globus Medical Inc., Audubon, Pennsylvania, USA) pedicle screw was inserted through the anchor. The anchor is not cleared or approved by the Food and Drug Administration for this or any other indication.

Fatigue Pullout Strength Testing

Fatigue loading was performed with the use of an MTS mechanical test machine (Figure 2). Standard REVERE polyaxial pedicle screws were inserted into the right and left pedicles of the same vertebral bodies matched with and without an anchor. To simulate a worst case screw pullout scenario, 4.5-mm diameter and 25-mm length pedicle screws were used for all groups.

An axial load of ±200N was applied to the screw tulip, along the axis of the rod, at a rate of 0.5 Hz for 1000 cycles. Axial displacement was measured by the MTS machine. After fatigue loading was completed, all screws underwent axial pullout testing

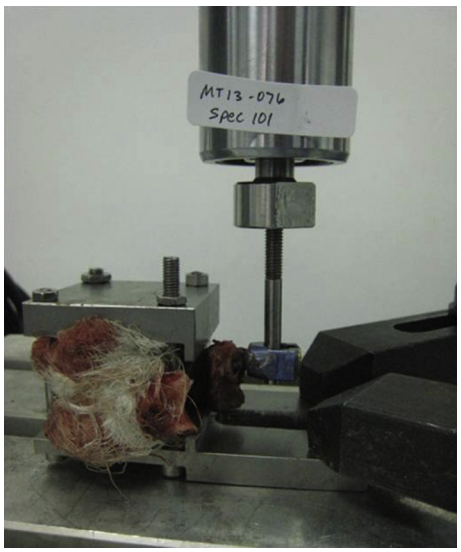

Figure 2. Screw toggle setup. Applied load of ±200N at 0.5 Hz for 1000 cycles.