Biomechanical comparison of single- and dual-lead pedicle screws in cadaveric spine

Laboratory investigation

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Object. The pedicle screw (PS) is the cornerstone of spinal instrumentation, and its failure often entails additional surgery. Screw pullout is one of the most common reasons for screw failure, particularly in the elderly population. In this study the authors undertook a biomechanical comparison of the maximum pullout force (MPF) required for single- and dual-lead PSs in cadaver vertebrae.

Methods. Radiographs of 40 cadaveric vertebrae (T11–L5) were obtained, and bone mineral density (BMD) was measured in the lateral plane using dual-x-ray absorptiometry with a bone densitometer. One screw of each design was implanted for side-by-side comparison. Vertebrae were potted and mounted on an MTS test frame for accurate measurement of MPF. A total of 80 PSs were tested, 40 each of single- and dual-lead design types.

Results. The average MPF for dual-lead screws (533.89 ± 285.7 N) was comparable to that of single-lead screws (524.90 ± 311.6 N) (p = 0.3733). The BMD had a significant correlation with MPF for both dual-lead (r = 0.56413, p < 0.0001) and single-lead screws (r = 0.56327, p < 0.0001).

Conclusions. Barring the effect of BMD, this in vitro biomechanical test showed no significant difference in MPF between single- and dual-lead PSs. Dual-lead PSs can be used to achieve a faster insertion time, without compromising pullout force. (DOI: 10.3171/SPI-08/01/052)

Key Words • biomechanical study • bone mineral density • dual-lead pedicle screw • pullout force • single-lead pedicle screw

The role of spinal instrumentation is to provide mechanical stability, obtain and maintain anatomical alignment, and promote bone fusion. Traditionally there have been 3 fusion devices used in spinal instrumentation: PSs, hooks, and sublaminar cables. Of these, PSs have been shown to be the most rigid and hence are the preferred device for fixation compared with hooks and cables.5,12 Although PSs form the mainstay of spinal instrumentation, cases of PS failure have been documented repeatedly in the literature. The mechanism of failure has consisted of screw bending or breakage, loosening, and pullout.2,3,8,11,16 Pedicle screw loosening and pullout resulting from failure of the fixation remains a significant clinical problem, particularly in the elderly population in whom bone is osteoporotic; the instrumentation failure rate in the overall population ranges from 0.6 to 11%.7,24

The utility of PSs is based on their ability to retain osseous purchase until the fusion mass is stable. By virtue of their length, screws can engage all 3 columns of the spine: anterior, middle, and posterior. Factors shown to be associated with increased PS pullout strength include higher insertion torque,26 higher BMD,9,24 increased depth of screw insertion,13 and increased outer thread diameter.21,23

The speed with which the screw is inserted can be increased by adding an additional thread to the screw shaft (see Fig. 1). Various double-thread designs have been tested previously. Mummaneni et al.18 showed that, compared with single-threaded screws, dual-threaded PSs with 2 parallel threads of differing heights are not associated with higher pullout strength, energy to failure, or stiffness. There have been no published reports on the biomechanical performance of PSs with parallel dual-lead threads of the same height. The rationale for dual-lead PSs is to expedite the insertion time compared with single-lead screws without compromising the pullout strength.

The goal of our study was to test the hypothesis that dual-lead PSs placed in cadaveric vertebrae have a pullout force comparable to that of single-lead screws. The effects of the spinal level and BMD on the MPF were also studied.

Abbreviations used in this paper: BMD = bone mineral density; MPF = maximum pullout force; PS = pedicle screw; PSF = PS fixation; TSRH = Texas Scottish Rite Hospital; VB = vertebral body.
Materials and Methods

Eight fresh-frozen human cadaveric spine specimens (T11–L5) were obtained from the deeded body program at the University of Iowa’s Department of Anatomy. Specimens were stored double bagged at −20°C and allowed to thaw at room temperature for 8 hours prior to any manipulation. The donor population included 2 males, 4 females, and 2 of unknown sex and age, with a mean age (± standard deviation) of 78 ± 18 years (range 44–98 years) at the time of death. Prior to experimentation, the specimens were examined radiographically in the anterior and lateral planes to ensure the absence of fractures, deformities, and metastatic disease. The BMD of each vertebra was measured in the lateral plane using dual–x-ray absorptiometry with a bone densitometer (QDR-2000, Hologic Inc.).

The spines were denuded of soft tissue and disarticulated into separate vertebrae. The pedicles were probed and tapped using a 5-mm tap, and engaged with 6.0-mm-diameter, 40-mm-long PSs. Both screw types were made of Ti6AL-4V alloy and had a minor diameter of 4.0 mm, pitch (distance between the thread apices) of 3.0 mm, and thread angle of 60°. The helix angle or the angle between the thread and the perpendicular plane to the long axis of the screw was 21° for the dual-lead screw, and 11° for the single-lead screw (Fig. 2). Each screw was meticulously inserted using the recommended technique appropriate for that screw type. Each of the 40 vertebrae had a single-lead screw (Moss Miami SI, DePuy Spine) and a dual-lead screw (Expedium, DePuy Spine) randomly assigned (Figs. 1 and 2).

Deck screws were placed into the VB to aid in securing it to the potting mixture. The instrumented vertebrae were then potted in a 70:30 mixture of Bondo (Bondo/MAR-HYDE Corp.) autobody filler and fiberglass resin. Radiographs were taken to confirm appropriate PS placement (Fig. 3).

Two custom-designed fixtures were developed—one for fixing the VB construct and another for fixing the screw head (Fig. 4). Locations of the screws from the radiographs were transferred to the specimens in order to determine the location for a hole (9.794 mm) that traversed the potting from the rostral endplate of the VB to the caudal endplate. This drilled hole allowed the vertebra to be held in the test fixture and ensured a purely axial pullout force on the PSs.

The pullout test was performed using a servohydraulic MTS machine (Bionix 858 Biaxial Test Star II, MTS Systems Corp.). One of the 2 custom-engineered test fixtures was secured to the ram of the MTS machine, while the other test fixture was secured to the load cell (Fig. 5).

Test parameters on the MTS machine were set at a displacement rate of 0.1 mm/second and a displacement limit of 45 mm, slightly higher than the length of the screw. Load and displacement data were obtained continuously at a frequency of 0.5 Hz until the end of the test. The MPF was defined as the point at which the specimen was maximally loaded directly prior to a precipitous drop in the load–displacement curve (Fig. 6) indicating that the specimen had lost its ability to resist the distraction force. The distance from the point of application of the distraction force to that of MPF was measured and referred to subsequently as “displacement at maximal load.” In the event of failure due to fracture, the result of that particular screw was omitted. Testing was conducted in an overall random order as to which screw was tested first in each VB.

Statistical analysis was done using Pearson correlation coefficients between BMD and pullout force. Comparisons of screw type were conducted using general linear models analysis of variance utilizing the SAS (Statistical Analysis System) version 9 software. Mean results are presented ± the standard deviation.

Results

Forty vertebrae (mean BMD 0.684 ± 0.197 g/cm², range 0.365–1.060 g/cm²) were used for this study. Five specimens failed as a result of fracture. Three of the failures re-

Fig. 1. Diagrams of single-lead and dual-lead screws. Note that the distance traveled by the dual-lead screw for 1 turn is twice the distance traveled by the single-lead screw for the same turn.

Fig. 2. Diagrams of the 2 screw types. The single- and dual-lead screws differ in helical angle: 11° for single- and 21° for dual-lead screws. The pitch of 3 mm, major diameter of 6.0 mm, minor diameter of 4.0 mm, and thread angle of 60° are the same for both designs.
sulted in loss of data for both screws, whereas in the remaining 2 cases the data for the single-lead screw could be used. This resulted in 35 usable results for the Expedium (dual-lead) screws and 37 usable results for the Moss Miami (single-lead) screws. Data were normalized and then analyzed for MPF for each spine and vertebral level.

The mean MPF for the dual-lead screw was $533.89 \pm 285.7\ N$ (range 126.695–1210.755 N), whereas that for the single-lead screw was $524.90 \pm 311.6\ N$ (range 88.773–1203.174 N). These values did not differ significantly ($p = 0.3733$). General linear model analysis of variance by specimen showed that the vertebral level did not influence the MPF ($p = 0.057$). The BMD correlated with the MPF significantly for both single-lead ($r = 0.56327, p < 0.0001$) and dual-lead ($r = 0.56413, p < 0.0001$) screws (Fig. 7). After adjustment for BMD, MPF still did not differ significantly between the dual- and single-lead screws.

Analysis of each vertebral level showed that the order of testing had no significant effect on the MPF. The BMD had a significant correlation with the MPF for L-2 ($p = 0.0076$), L-3 ($p = 0.0488$), L-4 ($p = 0.0091$), and L-5 ($p = 0.0231$). The BMD did not significantly affect the MPF for L-1 ($p = 0.6790$). Correcting for the BMD and order did not affect the MPF between the 2 screw types.

Displacement—that is, the distance of screw pullout during the loading cycle—was measured continuously. The typical load–displacement curve (Fig. 6) exhibited an initial sharp rise in load at a very small displacement. After the MPF was reached, there was a gradual decrease in load with increasing displacement. The mean displacement at the MPF for double-lead screws was $2.452 \pm 0.604\ mm$. 

Fig. 3. Axial (left) and lateral (right) radiographs showing PS and VB screw placement.

Fig. 4. Photographs showing the custom-designed fixture. The top portion holds the VB construct and the bottom portion locates the PS head.

Fig. 5. Photograph of the test setup showing the 2 fixtures and VB secured on the MTS machine.
whereas the MPF for the 0 single-lead screws was 2.667 ± 0.819 mm. There was no significant difference in the displacement values for the two screws (p = 0.2492).

Discussion

Transpedicular PS instrumentation for fusion is a well-established and widely accepted surgical technique. The PS instrumentation has 3 main advantages over other spinal fixation constructs: 1) it provides 3-column fixation, 2) it facilitates the instrumentation of short spinal segments, and 3) it maintains anatomical or desired sagittal alignment with increased rigidity. These advantages depend on the screws’ ability to retain osseous purchase until the fusion mass has become stable. Clinically, failure of PSF is most commonly the result of screw loosening at the bone–screw interface. The bone–screw interface strength has been shown to be dependent on BMD.$^9$$^{24}$ Screw design parameters influence the fixation strength, and a number of studies have shown this.$^4$$^5$$^{12}$$^{18}$ It is thus essential that any change in the screw design parameters to facilitate surgical technique should at least not compromise the bone–screw fixation strength.

Various devices have been used to improve PSF such as expandable screws,$^4$$^5$ bigger and longer screws,$^{12}$$^{21}$$^{23}$ self-tapping and self-drilling screws,$^{12}$ bone shims,$^{19}$ methylmethacrylate,$^{17}$ bone graft,$^{10}$ and various types of cement.$^{15}$$^{17}$$^{20}$$^{23}$$^{25}$ Expansive PSs have been designed to increase biomechanical fixation in osteoporotic bone. The mean pull-out force, when using an expansive design, was increased by approximately 50% compared with a self-tapping screw inserted into osteoporotic bone.$^4$$^5$ Studies have compared the pullout strength of self-drilling and self-tapping anterior or cervical screws of the same length in cadaveric spines.$^{12}$ No difference was observed in pullout strength between designs. Mummaneni et al.$^{18}$ designed and tested double-threaded screws with unequal height in embalmed vertebrae. In that study single-threaded TSRH PSs (with a taper-

![Fig. 6. Line graph showing mean load–displacement curves for the dual- and single-lead screws (p = 0.3733). There was no significant difference between the MPFs for the 2 devices. Values on the x axis are in millimeters and those on the y axis are in Newtons.](image)

![Fig. 7. Line graph demonstrating comparison of BMD and maximum load to failure for each of the 2 groups. There is a positive correlation between BMD and maximum load for both the single-lead screws (r = 0.56327, p < 0.0001) and dual-lead screws (r = 0.56413, p < 0.0001).](image)
ing inner diameter) were compared with double-threaded PSs (with uniform inner diameter throughout). The outer diameter of the 2 screw types was 6.5 mm and the double-threaded screw had a second parallel thread of lower height (5.2 mm). The inner diameter of the 2 screws differed by 0.0 to 0.7 mm because of the tapered nature of the TSRH screw. No significant difference in pullout strength was noted between the 2 screw designs. Conical or tapered screw designs with a tapering core diameter have been designed to increase the bending strength at the proximal level of the pedicle. Insertion torque and pullout strengths of conical and cylindrical screws have been compared in cadaveric pedicles by Kwok et al.14 These authors concluded that, although the tapered screw design increased the insertion torque, it had little effect on screw pullout. According to Weinstein et al.,22 approximately 60% of the screw fixation strength is in the pedicle. The choice of PS diameter is one that most closely matches the pedicle diameter without violating the cortex. Screws with too large a diameter will fracture the pedicle cortex, risking nerve injury.

The aim of the present study was to compare single-lead and parallel dual-lead PSs of the same outer diameter. Axial pullout tests were performed. The mechanism of PS pullout failure and methods to accurately reproduce the clinical situation are debatable, and several methods have been described. Previous studies have used both axial pullout and cephalocaudal toggling to estimate the PSF strength.3 In long-instrumentation constructs the PSs are subjected to a large bending moment and a large axial pullout force that is directly proportional to the length of the implant.1 Axial pullout simulates the loads placed on the PSs at the ends of long instrumentation and on PSs used in the reduction of spondylolisthesis.20 Thus, axial pullout tests are valid in determining PSF strength and have been used extensively in biomechanical testing.

In our present experiment, single- and dual-lead PSs of similar diameter and length were selected to prevent these design variables from influencing the results. Analysis showed that the MPF had a significant correlation with the BMD for both single-lead (r = 0.56327, p < 0.0001) and dual-lead (r = 0.56413, p < 0.0001) screws (Fig. 7). This result is in agreement with previous studies.7,9,11 A positive correlation between BMD and pullout strength has been shown in similar, but not identical, in vitro tests. We have shown a significant correlation between MPF and BMD for PSs when comparing the performance of PSs, sublaminar hooks, and sublaminar cables.15 Halvorson et al.9 have observed a significant correlation (p < 0.0001) between screw pullout strength and BMD when comparing the axial pullout force in normal and osteoporotic human lumbar spines to evaluate the effects of BMD on the quality of fixation. A similar correlation was observed by Cook et al.3 when comparing the pullout strength of an expansive PS design and conventional PSs placed in fresh unembalmed cadaveric vertebrae. Although there was a significant correlation between BMD and MPF in our study, there was no statistically significant difference between the MPF of the dual- and single-lead screws. A significant correlation between BMD and MPF was demonstrated at all levels except L-1. This is attributed to the fact that there were fewer useful L-1 vertebrae than other vertebrae available and utilized for the study (Table 1).

### Conclusions

We found no significant difference in MPF between single- and dual-lead PSs. Pullout strength had a significant correlation with BMD, and this is of concern in the elderly population. Dual-lead PSs designed to achieve shorter insertion times maintain an MPF comparable with the conventional single-lead screws.

### Disclosure

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### References

12. Hitchon PW, Brenton MD, Copes JK, From AM, Torner JC:

### Table 1

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<tr>
<th>Vertebral Level</th>
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