Clinical Study

Cortical bone trajectory for lumbar pedicle screws

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Abstract

BACKGROUND CONTEXT: Achieving solid implant fixation to osteoporotic bone presents a clinical challenge. New techniques and devices are being designed to increase screw–bone purchase of pedicle screws in the lumbar spine via a novel cortical bone trajectory that may improve holding screw strength and minimize loosening. Preliminary clinical evidence suggests that this new trajectory provides screw interference that is equivalent to the more traditionally directed trajectory for lumbar pedicle screws. However, a biomechanical study has not been performed to substantiate the early clinical results.

PURPOSE: Evaluate the mechanical competence of lumbar pedicle screws using a more medial-to-lateral path (ie, “cortical bone trajectory”) than the traditionally used path.

STUDY DESIGN: Human cadaveric biomechanical study.

METHODS: Each vertebral level (L1–L5) was dual-energy X-ray absorptiometry (DXA) scanned and had two pedicle screws inserted. On one side, the traditional medially directed trajectory was drilled and tapped. On the contralateral side, the newly proposed cortical bone trajectory was drilled and tapped. After qCT scanning, screws were inserted into their respective trajectories and pullout and toggle testing ensued. In uniaxial pullout, the pedicle screw was withdrawn vertically from the constrained bone until failure occurred. The contralateral side was tested in the same manner. In screw toggle testing, the vertebral body was rigidly constrained and a longitudinal rod was attached to each screw head. The rod was grasped using a hydraulic grip and a quasi-static, upward displacement was implemented until construct failure. The contralateral pedicle screw was tested in the same manner. Yield pullout (N) and stiffness (N/mm) as well as failure moment (N-m) were compared and bone mineral content and bone density data were correlated with the yield pullout force.

RESULTS: New cortical trajectory screws demonstrated a 30% increase in uniaxial yield pullout load relative to the traditional pedicle screws (p = 0.080), although mixed loading demonstrated equivalency between the two trajectories. No significant difference in construct stiffness was noted between the two screw trajectories in either biomechanical test or were differences in failure moments (p = 0.354). Pedicle screw fixation did not appear to depend on bone quality (DXA) yet positive correlations were demonstrated between trajectory and bone density scans (qCT) and pullout force for both pedicle screws.

CONCLUSIONS: The current study demonstrated that the new cortical trajectory and screw design have equivalent pullout and toggle characteristics compared with the traditional trajectory pedicle screw, thus confirming preliminary clinical evidence. The 30% increase in failure load of the cortical trajectory screw in uniaxial pullout and its juxtaposition to higher quality bone justify its use in patients with poor trabecular bone quality.

Keywords: Pedicle screw; Biomechanics; Spine fusion; Fixation; Osteoporosis

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Introduction

An estimated 44 million people in the United States suffer from osteoporosis, and as the constituent of the total population in industrialized countries over 65 is projected to increase by almost 30% within the next 20 years [1], the number of patients presenting with spinal conditions that involve osteoporotic bone will also concomitantly increase. Achieving solid implant fixation to osteoporotic bone presents a challenge to both spinal surgeons and hardware designers [2]. Loss of surgical construct stability as a result of screw loosening is a well-known complication [3–7], particularly in patients with poor bone quality [2,8–10]. Thus, the development of novel strategies to address the issue of obtaining enhanced bone-to-screw purchase to achieve necessary construct integrity is an important issue.

Vertebral bone quality and screw type are just a few of the important factors that contribute to successful pedicle screw instrumentation in the treatment of fractures or other clinical manifestations of osteoporotic etiology. A clear risk factor that may compromise the mechanical performance of spinal implants is low bone mineral density (BMD), as poor bone quality juxtaposed to internal hardware results in compromised implant–bone interface strength [2,8,11]. The lack of interfacial strength has been implicated in both pedicle screw loosening [8,12] and interbody device subsidence [13,14]. To date, approaches aimed at improving the longevity of spinal implants can, in general, be divided into two general areas: (1) modifying implant design and (2) augmenting vertebral bodies with reinforcing materials that improve the structural capacity of the deteriorated tissue.

Recent changes in implant fixation design include alterations in thread pitch and shape as well as surface modification of the screw to enhance bone apposition. Hydroxyapatite coating is one such surface modification that has been reported to improve the quality of bone–implant contact and reduce the frequency of screw loosening [15–19]. Other modifications in hardware design include the development of a novel expandable pedicle screw, which in recent reports has been reported to markedly increase the strength of the screw–bone interface in ex vivo biomechanical test of vertebral bodies with both normal and low BMD [20,21].

The use of milled or matchstick allograft bone as well as bone cement have gained clinical popularity in recent years as a means to mechanically augment the compromised bone and provide increased surface area for pedicle screw purchase [22–25] as well as to limit the frequency of interbody device subsidence [13]. Although allograft reinforcement may improve fixation by 70%, polymethylmethacrylate (PMMA) augmentation has been shown to increase pedicle screw pullout strength by up to 150% [25]. However, both allograft bone and PMMA suffer from a limited capacity to be remodeled, and PMMA is associated with a number of inherent disadvantages such as its high exothermic polymerizing temperature, toxicity of the monomer, poor fatigue performance, and its permanence in the body which can cause a large immunologic response [26–30]. Also, the introduction of pressurized cement into the pedicle raises the possibility of cement extravasation into the spinal canal. Calcium phosphate cements have recently been introduced with promising clinical results as an alternative to PMMA [22,24,31].

An alternative method proposed to increase screw–bone purchase of pedicle screws in the lumbar spine is to alter the currently accepted screw trajectory such that it experiences higher density bone. The current “traditional” pedicle screw trajectory uses a transpedicular path; either following the anatomic axis of the pedicle directed 22° in the cephalocaudal direction in the sagittal plane (ie, the anatomic trajectory) or instrumented parallel to the superior end plate of the vertebral body in the sagittal plane (ie, the straight-forward trajectory). Both cortical and trabecular bone are engaged with the traditionally directed trajectory. The new cortical trajectory follows a caudocephalad path sagittally and a laterally directed path in the transverse plane, engaging only cortical bone in the pedicle without the involvement of the vertebral body trabecular space. The theoretical advantage associated with this modified technique is increased cortical bone contact, providing enhanced screw purchase and interface strength independent of trabecular BMD. A new screw design that is shorter and smaller in diameter than the traditional trajectory pedicle screw has been proposed that seeks to maximize the thread contact with this higher density bone surface. It is hypothesized that this increase in cortical bone interference will directly relate to greater holding screw strength, and, thus, less opportunity for loosening. However, a biomechanical study has not been performed to elucidate whether the resulting screw purchase provided by this newly proposed technique results in a statistically significant increase in biomechanical performance. Thus, the goal of this investigation was to compare the mechanical performance and bone quality captured with the cortical bone and traditional pedicle screw trajectories in an in vitro human cadaveric model. The mechanical performance was determined using a standard pullout test and a novel screw toggle experiment. Associated gross and high fidelity measures of bone quality were also evaluated, and these data were correlated to the results of the mechanical data.

Materials and methods

Five fresh human spines were obtained for inclusion in this study (four male, one female). The average age of the donors was 80.8 years (range: 72–90 years). Lumbar vertebral bodies (L1–L5) with no evidence of infectious, neoplastic, traumatic, congenic, or developmental conditions were included for dual-energy X-ray absorptiometry (DXA) and quantitative computed tomography (qCT) scanning as well as biomechanical testing. Preliminary data
using a bovine model was used to determine the number of vertebral bodies required for inclusion in the current study. To detect a 30% difference in maximum pullout force between the traditional trajectory and the new cortical trajectory using an alpha value of 0.05 and a power of 0.8, a minimum of eight vertebral bodies were needed for each component of biomechanical testing. The vertebral specimens from the five donors were individually isolated and denuded of all muscular and ligamentous tissue.

**Bone quality determination using image analysis**

Bone densitometry measurements of a region of interest (ROI) within the center of each lumbar vertebral body were performed using standard DXA scans (QDR 1000W DXA scanner, Hologic Inc., Bedford, MA). To eliminate interoperator variability, the same operator (ASL) performed all measurements. Before BMD acquisition, the machine was calibrated using a standard phantom (coefficient of variation = ±1.5%). Cortical bone trajectory drill holes were generated line-to-line and unilaterally on each vertebral body by way of the pars interarticularis caudal to the sulcus of the facet complex. This trajectory was established free-hand with attention paid to vertebral body anatomy and followed both a medial-to-lateral and caudal-to-cephalad path. The contralateral side was prepared using the straightforward pedicle screw insertion technique in which the sagittal trajectory of the screw paralleled the superior end plate of the vertebral body. A small diameter burr was used to decorticate the posterior cortex to obtain the starting point. The screw path was then tapped using a cannulated tap 1.0 mm smaller than the diameter of the pedicle screw placed at that level. These trajectories did not interfere or intersect with one another (Fig. 1). Quantitative computed tomography (qCT) imagery of each drilled and tapped sample was collected (pQCT, Picker International, Cleveland, OH) at 1-mm thick slices and 0.5-mm spacing. Each vertebral body was subsequently wrapped in saline soaked gauze, double bagged, and stored at -20°C until biomechanical testing was performed.

**Mechanical experiments**

At the time of testing, each vertebral body was completely thawed and pedicle screws were inserted into their respective trajectories and digitally radiographed (MinXray HF 80T, MinXray, Inc. Northbrook, IL) to visualize screw placement and orientation (Fig. 3). Screw length was adjusted at each vertebral level for each trajectory to prevent bicortical purchase. Biomechanical integrity of the pedicle screw trajectories was compared using standard screw pull-out tests and screw toggle testing. Lumbar bodies from 3 cadaveric spines (n=14) were designated for pullout tests and screw toggle testing. Lumbar bodies from 2 cadavers underwent screw toggle testing.

For pullout tests, the vertebral body was coupled to a six degree of freedom (DOF) load cell (AMTI, MC5, Waltham, MA) via a custom-designed fixture that constrained the body (Fig. 4A). A standard pedicle screw driver (Medtronic Sofamor Danek, Memphis, TN) gripped by hydraulic clamps coupled the constrained vertebral body to the materials testing machine actuator (MTS, Eden Prairie, MN). Additional uniaxial alignment of the MTS actuator and the pedicle screw was accomplished through the use of an adjustable X–Y table. The driver was then withdrawn

![Fig. 1. (Left) Anterior and (Right) lateral views illustrating drilled hole volumes along traditional trajectory (purple) and new trajectory (red). Traditional screw is primarily oriented in the anteromedial direction, whereas the new cortical trajectory screw projects in the anteromediolateral direction. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)](image-url)
uniaxially at a rate of 10 mm/min [22,32] until a sharp drop in the monotonically increasing force profile was noted and/or there was clear observable bone failure. Stiffness was defined as the slope of the linear region of the uniaxial force versus displacement curve. After failure, the contralateral pedicle screw was tested in an identical fashion. Pedicle screw toggle testing was implemented to provide a more clinically relevant failure scenario (mixed loading regime) than the traditional pullout testing. Although the practical nature of the uniaxial pullout test cannot be understated, in vivo, pedicle screws are exposed to simultaneous combinations of bending moments, shear stresses, and axial stresses in multiple planes. This is especially true in the early stages of convalescence because most of the flexion/extension and lateral bending force and moment components are borne by the pedicle screw–rod construct [33]. To closely mimic the physiologic loading scenario, the vertebral body was potted in PMMA and rigidly constrained to the 6-DOF load cell via the adjustable X–Y table (Fig. 4B). A longitudinal rod was then attached to each screw head using a standard coupling mechanism (ie, set screw). The rod was grasped using a hydraulic grip while maintaining a constant lever arm of 40 mm. A quasi-static, upward displacement (10 mm/min) of the actuator delivered a mixed loading regime of tension, shear, and bending stresses to the implanted screw until failure. On construct failure, the contralateral pedicle screw was tested in the same manner. Force displacement data from the pedicle screw pullout and toggle tests were plotted and yield force (N) and stiffness (N/mm) were extracted and calculated, respectively, from the plots. The failure moment (N-mm) component from the screw toggle tests was also extracted. Biomechanical parameters for the two screw trajectories obtained from these two tests were compared with a paired t-test using SigmaStat (Systat Software, San Jose, CA). Bone mineral content (DXA) and bone density data (qCT) were...
correlated with pullout and toggle yield force using a standard Pearson’s correlation coefficient. All statistical comparisons were performed at a significance level of $\alpha = 0.05$.

Results

The global mean BMD (mean±standard error of the mean [SEM]), as determined from DXA, of the lumbar vertebrae undergoing pedicle screw pullout and toggle testing was 0.786±0.060 g/cm² (range: 0.538 – 1.52 g/cm²). A normal range for BMD for similar specimens from the lumbar spine is approximately 0.8 to 1 g/cm² [8,12]. Based on this reported range, 18 of the 24 tested lumbar vertebral bodies (75%) tested in either pullout or toggle were classified as “osteoporotic.” All specimens tested in uniaxial pullout were osteoporotic whereas half of the specimens designated to the toggle treatment group were osteoporotic. The mean overall length (29.00±2.89 mm) and diameter (4.66±0.24 mm) of the new cortical trajectory pedicle screws used in biomechanical testing were significantly less than that of the traditional trajectory screws ($p<0.001$, Table 1), representing a 42.5% and 28.3% difference, respectively.

Analysis of bone quality at the screw–bone interface obtained from qCT scans indicated significantly higher bone density adjacent to the new cortical trajectory screws ($p<0.001$). Digital radiographs taken before mechanical testing demonstrated consistent placement of the traditional pedicle screws in the straight-forward trajectory; however, 5 of the 25 (20%) new cortical trajectory screws indicated a breach of the medial wall of the pedicle using standard radiography and gross inspection.

A typical screw pullout load–displacement curve for the new cortical trajectory pedicle screw is illustrated in Fig. 5. The mean resistance against screw pullout for the new cortical trajectory was 367.54±23.65 N (mean±SEM) and 287.59±35.64 N for the traditional trajectory ($p=0.080$). No differences in construct stiffness were noted between the two trajectories (Table 2). Pedicle screw pullout force did not appear to depend on global bone quality as

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Fig. 3. Representative radiographs showing pedicle screws before mechanical testing. (Left) New cortical bone screw with cortical bone placement and (Right) traditional screw with traditional placement.

Fig. 4. Traditional trajectory screw undergoing (Left) pullout testing and (Right) toggle testing.
measured through DXA scans (traditional: \( r=0.154, \ p=0.614 \); new cortical: \( r=0.285; \ p=0.346 \)). However, positive correlations were demonstrated between trajectory and bone density scans and pullout force for both pedicle screws (Fig. 6).

In toggle testing, no significant differences (\( p>0.05 \)) were noted for the force traction component or the overall construct stiffness between the two trajectories (Table 2). The average failure moment component for the traditional trajectory (19.67 ± 3.25 N-m) was greater than for the new cortical trajectory pedicle screw (16.23 ± 2.16 N-m), although this difference was not significant (\( p=0.354 \)).

**Discussion**

Improving lumbar pedicle screw purchase in osteoporotic vertebral bone remains a serious clinical challenge as evidenced by a number of recent biomechanical studies aimed at developing new technologies to address this very issue [18,34–38]. Because of the increasing aging spine population and the every expanding number of patients with osteoporosis who require surgical intervention, improved bone–screw fixation is desirable due to historical complications of screw loosening, pullout and implant failure in this complex group of patients [2,8–10].

The current study sought to evaluate the biomechanical performance of a novel pedicle screw trajectory designed to purchase only higher density bone in the posterior aspect of the spinal column. The results presented herein demonstrate that yield pullout force, stiffness, and failure moment for the two trajectories under different loading conditions proved to be statistically equivalent. qCT image analysis revealed significantly denser bone juxtaposed along the entire length of the new cortical trajectory screw. Contact with denser tissue accommodates a screw design that is both shorter in length and smaller in diameter. This combination of smaller screw size and denser juxtaposed osseous tissue afforded by the new trajectory screw translated into a 100% increase in interface strength per unit screw length relative to the traditionally oriented screw. Therefore, the interface of higher bone density provided by the new trajectory screw achieves adequate fixation that is independent of the bone trabecular quality, as confirmed by the lack of significant correlation between uniaxial pullout force and BMD data collected from DXA scans. This is an important finding because osteoporosis has a far greater effect on cancellous bone (than cortical bone). Thus, the new cortical trajectory screw affords the spine surgeon an excellent alternative method of fixation in osteoporotic patients without the risk of complications associated with other augmentative modalities such as PMMA, including potential spinal cord and nerve root damage caused by the high exothermic (40–100 °C) polymerizing temperature, potential chronic foreign body response because of the limited remodeling of the cement, and the associated vertebral body destruction associated with removing PMMA during revision surgeries [26–30].

Of particular interest in the current study was the lack of a significant positive correlation between BMD measurements and pullout force in the traditional pedicle screw trajectory group. This finding is confounding and in disagreement with previously reported work [8]. The most likely reason for this observation was that the spread in our BMD data was small (0.786±0.060 g/cm²), with ~75% of the vertebral bodies biomechanically tested classified as osteoporotic. It is our contention that were we to test a separate group of vertebral bones with normal BMD and include them in our data set, we would have seen a strong, positive correlation between pullout force and BMD, similar to what has been previously reported by Halvorson and coworkers [8].

Pedicle screw–bone interface quality has traditionally been characterized through uniaxial pullout tests, as this testing method is simple and allows for ready comparison.
Table 2

<table>
<thead>
<tr>
<th>Trajectory</th>
<th>Pullout force (N)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean ± SEM</td>
</tr>
<tr>
<td><strong>Pullout</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traditional</td>
<td>14</td>
<td>287.59 ± 35.64</td>
</tr>
<tr>
<td>New cortical</td>
<td>14</td>
<td>367.54 ± 23.65</td>
</tr>
<tr>
<td><strong>Toggle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traditional</td>
<td>10</td>
<td>1041.61 ± 152.72</td>
</tr>
<tr>
<td>New cortical</td>
<td>10</td>
<td>1030.15 ± 94.89</td>
</tr>
</tbody>
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Pecial screw pullout and toggle results

Fig. 6. Yield screw pullout load (N) as a function of bone quality as measured from qCT scans. Bone density juxtaposed to the new cortical screw (outlined in the dashed circle) was significantly higher than bone in contact with the traditional trajectory pedicle screws (p<0.001).

References


