Biomechanical analysis of bone mineral density, insertion technique, screw torque, and holding strength of anterior cervical plate screws

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The bone mineral density (BMD) of 99 cadaveric cervical vertebral bodies (C3–7) was determined using dual x-ray absorptiometry. The vertebral bodies were randomly assigned to receive either a unicortical (51 bodies) or bicortical (48 bodies) Caspar cervical plating screw. The initial insertion torque was measured using a digital electronic torque wrench, and the force required to withdraw the screw from the vertebral body was determined. The mean BMD for the total group of 99 was 0.787 ± 0.154 g/cm², the mean insertion torque was 0.367 ± 0.243 newton-meters, and the mean pullout force was 210.4 ± 158.1 newtons. A significant correlation was noted between BMD and torque (p < 0.0001, r = 0.42), BMD and pullout force (p < 0.0001, r = 0.54), and torque and pullout force (p < 0.0001, r = 0.88). Although the BMD of the unicortical and bicortical groups was equivalent (p = 0.92), the insertion torque and pullout force differed significantly (p = 0.02 and p = 0.008, respectively) for the unicortical and bicortical groups. A holding index for each screw and insertion technique was defined as the product of the BMD and insertion torque. The calculated holding index and resultant pullout force were significantly correlated with both techniques of screw insertion (r = 0.92), and a significant difference in holding index was observed with unicortical versus bicortical screw placement (p = 0.04). The determination of BMD and measurement of insertion torque to create a unique holding index provides an assessment of bone–screw interaction and holding strength of the screw, both of which impact on the resultant stability of cervical instrumentation. As the number of cervical plating systems increases, the determination of a holding index for various screws and insertion techniques may assist in the comparison of cervical instrumentation.

KEY WORDS • biomechanics • bone mineral density • cervical spine • torque • instrumentation

The anterior approach to the cervical spine has been successfully used to treat degenerative disease, vertebral body fractures, tumors, and infection. When necessary, plates of various sizes and shapes have been secured to the anterior vertebral body surface to provide stability until fusion occurs. Anterior cervical plating systems may use either bicortical or unicortical screws. Over the past several years, we have been involved in the biomechanical evaluation of instrumentation in cadaveric cervical spines. Previously we have compared various anterior and posterior constructs to assess stability immediately after fixation and after repetitive flexion–extension stress. Anterior cervical plate stabilization is dependent on the holding strength of the bone screws, and inadequate holding strength may result in failure of the stabilization procedure. A significant factor in the holding strength of this type of instrumentation is the quality of vertebral bone, and a major contraindication for placement of plate and screw devices is the presence of osteoporosis. A variety of techniques have been used to assess bone quality; however, recently dual x-ray absorptiometry (DXA) has been recognized in multicenter longitudinal studies of osteoporosis as the modality of choice for determination of bone mineral density (BMD).

This experimental study was undertaken to evaluate DXA as a means of obtaining a reproducible assessment of cervical vertebral bone quality and to examine the relationship of bone quality to the peak insertion torque and holding strength of anterior unicortical and bicortical cervical plating screws. The BMD and insertion torque were used to define a mathematical holding index that can accurately predict the holding strength of these screws.

Materials and Methods

Thirty cervical spines were harvested from formalin-fixed cadavers obtained from the University of Iowa Department of Anatomy. The average age of the donors was 75.2 years (range 59 to 95 years). The paravertebral musculature and fascia were removed and the
Biomechanical analysis of anterior cervical screws

Screw Placement

Screws were inserted using the instrumentation from the anterior cervical plating system (Caspar Trapezoidal Osteosynthetic system donated by Lesch, South San Francisco, CA). The guide hole traversed the central region of the vertebral body and, for the bicortical screws, pierced both the anterior and posterior cortices. Each vertebral body received only one screw to avoid stress artifacts from repeated testing. The anterior cortex was tapped, and each screw was inserted through a pullout cylinder (described below) into the vertebral body. Unicortical or bicortical placement was assured by measuring the depth of the vertebral body prior to insertion and by visual inspection of the posterior cortex after placement. All unicortical screws were 16 mm in length, and none of these penetrated the posterior cortex. The bicortical screws ranged from 21 to 28 mm and posterior cortical penetration was visually confirmed for all screws. After insertion, the peak insertion torque was determined by tightening the screw with a digital electronic torque wrench (Snap-On, Inc., Kenosha, WI). Peak insertion torque values were measured and recorded in units of newton-meters (Nm).

Determination of Screw Pullout Force

A specially designed stainless steel holding frame was used to immobilize the vertebral body. A 4-mm titanium rod was placed through the transverse foramen or against the anterior tubercle on either side of the vertebral body to mount the specimen in the holding frame. The level of the two rods could be varied to maintain perpendicular alignment of the screw, despite minor anatomical irregularities between sides of an individual specimen. Motion in the rostral-caudal direction was minimized by tightening a screw clamp onto the spinous process of the body through the sides of the holding frame. The base of the frame contained a threaded recess to allow direct coupling to a hydraulic servo-controlled material testing system device (MTS Systems Corp., Minneapolis, MN). A threaded stainless steel screw pullout cylinder was designed to allow perpendicular pullout of the screw, thus avoiding coupling of motion with pullout. The inner and outer surfaces of the distal end of the cylinder were machined to the exact specifications and thickness of the Caspar anterior cervical plate to ensure accurate reproduction of the clinical placement of the screws. Inserting and withdrawing the screw using this pullout cylinder assured alignment perpendicular to the anterior surface of the vertebral body. After the body was secured in the holding frame and the screw inserted through the pullout cylinder, the entire construct was mounted in the materials testing system machine (Fig. 1). A distraction load was applied perpendicular to the anterior surface of the vertebral body with a displacement rate of 0.25 mm/sec. The maximum force achieved in newtons (N) was plotted as a function of displacement (mm) with a standard chart recorder.

Data Management and Statistics

Comparisons between the unicortical and bicortical groups were made using standard two-tailed unpaired Student’s t-tests and a mixed-model multivariate analysis of variance (MANOVA). A multiple regression model and a MANOVA were performed to analyze correlations between variables for each of the unicortical, bicortical, and total groups.

Results

Insertion Torque and Pullout Force

The average values for BMD, torque, and pullout force for the total group after stratification into unicortical and bicortical groups are presented in Table 1. The two groups had statistically equivalent BMD (unpaired two-tailed Student’s t-test, p = 0.92). A significant difference was noted between the peak insertion torques of the unicortical and bicortical groups (unpaired two-tailed Student’s t-test, p = 0.02). The difference between

J. Neurosurg. / Volume 83 / August, 1995
the unicortical and bicortical pullout forces was highly significant (unpaired two-tailed Student’s t-test, p = 0.008). A representative force-versus-displacement curve is shown in Fig. 2. The mean displacement was not significantly different between the unicortical (1.02 ± 0.32 mm) and bicortical groups (1.10 ± 0.35 mm, p = 0.38).

**Interaction of Bone Mineral Density, Torque, and Pullout**

Regression analysis of BMD with peak insertion torque yields a significant linear relationship (p < 0.0001); however, the correlation coefficient is low (r = 0.42). This plot has an x-intercept value of 0.225, which suggests that as the BMD approaches 0.225, the insertion torque becomes negligible. The linear regression analysis of BMD with pullout force for the group also yields a significant linear relationship (p < 0.001), the correlation coefficient of which is 0.54. The plot has an x-intercept value of 0.405, implying that as BMD approaches 0.405, pullout force approaches zero. Linear regression analysis of peak insertion torque with pullout force results in a p value of 0.0001 and a correlation coefficient of 0.88.

A multiple regression analysis was performed to evaluate the relative contribution of BMD and torque on the variability observed in pullout force. Bone mineral density accounted for 28.3% and peak insertion torque accounted for 76.9% of the observed variability in pullout force. The relative differences in the effects of BMD and torque on pullout strength that were identified with multiple regression analysis are consistent with the correlation coefficients obtained using the simple linear regression models. Overall, these results indicate that although both BMD and insertion torque are statistically significant variables, torque has the greater influence.

**Holding Index**

Torque and BMD were examined using a series of mathematical equations, including a weighted sum of BMD and torque, in an attempt to improve their predictive power of pullout strength. We found that the simple multiplicative index obtained as the product of BMD and torque yielded the best improvement in the correlation coefficient of the multiple regression model. We therefore defined a holding index as the product of the BMD and the peak screw insertion torque. This creates a torque value that is weighted by the BMD of the bone in which the screw is being inserted. The linear plot of the defined holding index and pullout force is given by the equation: pullout force = 647.3 × holding index − 13.52 (p < 0.0001, r = 0.92) (Fig. 3). The improvement in the correlation coefficient (r = 0.92) reflects the reduction in scatter of the data around this linear plot.

Including this holding index in the multiple regression analysis improves the predictive power of the model, with holding index alone accounting for 84% of the variability observed in pullout force. The linear relationships obtained by separately plotting the unicortical and bicortical subgroups do not significantly alter the slope, intercepts, or correlation coefficients of the plots (r = 0.91 and r = 0.93, respectively); however, the mean holding indices for the unicortical and the bicortical groups do differ significantly, comparing 0.258 ± 0.211 and 0.354 ± 0.228, respectively (p = 0.04). For these groups, the comparison of holding indices can be used to assess the ability of similar screws placed with different techniques to withstand pullout.

**Discussion**

**Bone Mineral Density and Pullout Force**

Osteoporosis is a relative contraindication for anterior cervical plate implantation, and in some cases, failure of these devices has been ascribed to poor bone quality; therefore, we believe that any experimental study concerned with biomechanical characteristics of plate and screw implants, such as anterior cervical plates, must quantitatively control for bone quality.

Dual beam or DXA has become the method of choice for determination of BMD based on ease of use, high reliability, and limited radiation exposure. Large multicentered clinical trials have produced reference values for BMD of the lumbar spine and hip, and in these devices has been ascribed to poor bone quality; therefore, we believe that any experimental study concerned with biomechanical characteristics of plate and screw implants, such as anterior cervical plates, must quantitatively control for bone quality.

Unfortunately, we are not aware of similar reference values for the cervical spine, and comparison of cervical bone density to lumbar spine reference values may not be valid. In fact, we have found variations of up to 15% between cervical and lumbar BMD in a limited number of volunteers undergoing DXA scanning of both regions (our unpublished data). This difference may be the result of differences in load bearing by the vertebral bodies at different spinal levels. Until absolute reference values for BMD in the cervical spine are available from large clinical or experimental trials, BMD in the cervical spine must

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**Table 1**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No.</th>
<th>BMD (g/cm²)</th>
<th>Torque (Nm)</th>
<th>Pullout (N)</th>
<th>Holding Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>all specimens</td>
<td>99</td>
<td>0.78 ± 0.154</td>
<td>0.367 ± 0.243</td>
<td>210.4 ± 158.1</td>
<td>0.304 ± 0.224</td>
</tr>
<tr>
<td>unicortical</td>
<td>51</td>
<td>0.785 ± 0.152</td>
<td>0.312 ± 0.239</td>
<td>170.1 ± 152.6</td>
<td>0.258 ± 0.211</td>
</tr>
<tr>
<td>bicortical</td>
<td>48</td>
<td>0.788 ± 0.158</td>
<td>0.426 ± 0.246</td>
<td>253.3 ± 154.1</td>
<td>0.354 ± 0.228</td>
</tr>
<tr>
<td>p value</td>
<td></td>
<td>0.92</td>
<td>0.02</td>
<td>0.008</td>
<td>0.04</td>
</tr>
</tbody>
</table>

* Data are presented as means ± standard deviations. BMD = bone mineral density; Nm = newton-meters; N = newtons. Holding index is defined in the Results section. Probability values shown compare unicortical and bicortical groups, using the unpaired two-tailed Student’s t-test.
be used empirically, either to allow comparison between experimental groups to ensure equivalence, or for comparison with other biomechanical parameters.

In DXA, the bone mineral content in grams of a projected area in square centimeters is measured to compute an areal BMD (grams per square centimeter). This value differs from a true density value as it is calculated from a projected two-dimensional plane rather than a three-dimensional volume; therefore, comparative scans must be done in similar projections. In the lumbar spine, BMD determination in both the anteroposterior and lateral view yields reproducible results; however, the absolute BMD value of the anteroposterior as compared to the lateral view differs. Thus, the orientation of BMD imaging needs to be defined for meaningful interpretation. We chose the lateral projection in this study to facilitate identification of cervical level.

To obtain a sufficient number of specimens for testing, we elected to use formalin-fixed vertebral bodies and measure BMD, ensuring equivalence between the unicortical and bicortical groups. We have examined the effect of fixation on BMD in cervical vertebral bodies by comparing the BMD of 20 cervical vertebral bodies before and after 6 months of formalin fixation. These studies indicated that 6 months of fixation in 10% formalin resulted in a decrease of approximately 5% in BMD (our unpublished data); however, the BMD was equivalent between the unicortical and bicortical groups in this study and should not affect comparison between the two groups other than to reduce the overall BMD of the study group.

In a study done by HS An, et al. (unpublished data), the BMD, insertion torque, and pullout force were determined for 20 lumbar vertebrae using 6.5-mm Kaneda screws (Acromed Corp., Cleveland, OH). The mean lateral BMD was 0.58 ± 0.14 g/cm², and the mean pullout force was 211 ± 125 N; BMD and pullout force correlated significantly (r = 0.75, p < 0.001). Although this study differs significantly in design and sample number, the general relationship among BMD, torque, and pullout force reported by these researchers supports our observations. In our study, BMD accounted for approximately 28% of the overall variability observed in pullout force.

**Torque and Pullout Force**

Although the interaction between torque and pullout force has been examined in thoracic and lumbar pedicle fixation, this interaction has not been reported in cervical vertebral bodies. We found peak insertion torque to be the most significant single factor for predicting the holding strength of cervical screws. Our data suggest that peak insertion torque can, to a limited extent, predict the potential holding strength of the cervical vertebral body screw; in fact, insertion torque accounted for 76% of the variability observed in screw pullout force. An, et al., (unpublished data) also found a significant relationship between torque and pullout strength in lumbar vertebral bodies (r = 0.50, p = 0.03).

**Unicortical Versus Bicortical Placement**

Maiman, et al., compared the pullout strength of Caspar screws placed unicortically and bicortically in cervical (C3–T1) vertebral bodies. Twenty-one screws were placed unicortically and 22 were placed bicortically. Two screws were placed in each vertebral body, and the required pullout force determined. The mean for the bicortical group was greater than for the unicortical group, comparing 412 N with 371 N, although the difference was not statistically significant. In the present study, the difference in pullout strength between these two groups was significant, possibly because of the larger sample size examined. Placing only one screw in each vertebral body also may have reduced error introduced by repeated testing of the same vertebral body. In comparing the observed mean pullout values for the present study to those reported by Maiman, et al., and An, et al. (unpublished data), it appears that the vertebral bodies used by Maiman, et al., were of a higher bone quality based on the higher mean pullout force reported. Unfortunately, BMD measurements were not included in the report by Maiman, et al.

It is possible that as bone quality, or BMD, increases, the effects of posterior cortical purchase become less prominent. Certainly, clinically successful outcomes have been obtained with systems using unicortical screws. In a recent report, Gallagher, et al., compared unicortical and bicortical Caspar screw placement in a single-body motion fatigue model undergoing 200 cycles of simulated flexion–extension. Although deformation or “screw toggle” developed with cyclic loading in both groups, a significant improvement in stability was observed with bicortical placement, supporting the observations of the current study.

**Holding Index**

The creation of a multiplicative index of BMD and insertion torque improved the predictive value of our exper-
The linear correlation coefficient of holding index with pullout force was greater than 0.9 and accounted for 84% of the variability in pullout force in a multiple regression analysis. A significant difference in holding index between unicortical and bicortical screw placement was demonstrated (Table 1).

This index is calculated from values that could be determined pre- and intraoperatively to help assess the potential holding strength of the bone–screw interface. Ideally, a general range of acceptable bone quality should be predictable from the BMD determination; however, our results indicate that prediction of holding strength based on the BMD alone is associated with substantial variability. At best, a minimum acceptable range is suggested by the BMD alone. Until cervical spine BMD reference values have been correlated with clinical outcome, these predictive values should be interpreted with caution. The calculation of the holding index value requires determination of insertion torque, which must be determined at the time of screw placement. The holding index may play a role in decisions regarding alternate fusion technique or the need for postoperative external immobilization. As the number of cervical plating systems increases, the determination of a holding index for various screws and insertion techniques may also assist in the comparison of cervical hardware. As with the BMD alone, insertion torque and holding index values must be interpreted with discretion until clinical follow-up evaluation of these values is available.

Conclusions

We have found the determination of cervical bone density using DXA to be a reliable indicator of bone quality in the cervical vertebral body. Both BMD and torque play a role in the holding strength of cervical vertebral body screws. In this study, bicortical placement improved the holding strength of anterior cervical plating screws. Studies involving bone quality, torque, and screw holding strength begin to analyze the complex interaction at the bone–screw interface (Fig. 4). Future improvements in screw design and insertion technique will undoubtedly enhance screw holding strength and safety of insertion. The extension of BMD and holding index determination into clinical practice may result in guidelines for minimum acceptable values prior to consideration of anterior cervical plating constructs. Our report analyzes only one type of cervical screw. Extensive variability in screw design exists between manufacturers, and these results cannot be extrapolated to other cervical screws without further testing.

Acknowledgments

The authors thank the University of Iowa Clinical Research Center, Iowa City, Iowa, for use of the bone densitometer, and Hologic, Inc., Waltham, Massachusetts, for technical support.

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Biomechanical analysis of anterior cervical screws


Manuscript received June 20, 1994.
Accepted in final form December 6, 1994.
This work was funded in part by National Institutes of Health Grant AR40166-01.
This paper was presented in part by the first author as the 1994 Mayfield Award Lecture at the Tenth Annual Meeting of the Joint Section of the American Association of Neurological Surgeons and Congress of Neurological Surgeons on Disorders of the Spine and Peripheral Nerves in Fort Lauderdale, Florida, on February 11, 1994.
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