Biomechanical Evaluation of Relationship of Screw Pullout Strength, Insertional Torque, and Bone Mineral Density in the Cervical Spine

Charles Alan Reitman, MD, Lyndon Nguyen, and Guy R. Fogel

Background: Understanding of implant failure mechanisms is important in the successful utilization of anterior cervical plates. Many variables influence screw purchase, including the quality of the bone. The purpose of this study was to assess the relationship of screw pullout and screw insertional torque across a wide range of bone mineral densities (BMDs).

Methods: A total of 54 cervical vertebrae in 12 cervical spines were evaluated for BMD using dual-energy x-ray absorptiometry scanning. Actual and perceived peak torques of 3.5-mm anterior cervical screws were determined at each level followed by screw pullout strength testing.

Results: A high correlation was observed between screw pullout strength and BMD. However, there was a low correlation of peak insertional torque to pullout strength.

Conclusion: These findings suggest the quality of the bone is more instrumental in the success or failure of anterior cervical screws than is the insertional torque with which the screws are placed.

Key Words: cervical spine, bone mineral density, screw pullout strength, insertional torque, biomechanics

(*J Spinal Disord Tech* 2004;17:306–311)

Anterior cervical discectomy and fusion is frequently employed in the surgical management of the cervical spine. Recently, the benefit of the addition of anterior cervical plates has been established.[1,2] There are several plates available, each with their own characteristics, with variation in features such as implant thickness, rigidity, and dimensions.[3] Success of these implants is in part dependent on secure screw anchoring of the plate to the vertebral column.

These systems initially used bicortical fixation screws but have now evolved to safer unicortical cancellous screws. All of these screws are locked to the plate in some fashion to help prevent implant loosening and add rigidity to the plate-screw construct. Some screws actually lock to the plate, while in most cases, there is some kind of blocking plate or screw head expansion to secure the screw to the plate. In these cases, the screws are initially placed securely per the surgeon's own perception, in most instances without specific torque control.

Screw pullout and stripping (exceeding maximal insertional torque) are possible modes of failure. Some factors affecting the pullout strength of a cancellous bone screw are specific to the screw design and include the major diameter of the screw, the length of engagement of the thread, and screw thread depth and pitch.[4] Furthermore, tapping was found to reduce pullout force by an average of 8% compared with non-tapped holes. In addition to these characteristics of the instrumentation, the quality of the bone probably plays an important role in the strength of fixation. As a result, there is particular concern regarding implant failure when used in the osteoporotic spine. Since bone mineral density (BMD) is one clinical measure of bone quality, there is interest in determining the relationships between BMD and internal fixation. Although studies in the cervical spine in particular are limited, these data combined with more extensive reports in the thoracic and lumbar spine would suggest that there is a linear relationship of insertional torque and BMD to pullout force of vertebral body fixation screws.

The purpose of this study was to define the relationships of insertional torque and pullout strength of anterior cervical plate locking screws to a wide range of BMDs. In addition, the difference in maximum torque and the torque applied by the feel of the surgeon was evaluated. We hypothesized that screw pullout strength would be dependent on both BMD and peak insertional torque. Additionally, it was felt that a linear relationship of torque to BMD could be established such that optimal forces of screw application could be predicted based on BMD. Furthermore, it was suspected that a minimal BMD existed below which screw purchase would be unreliable.

MATERIALS AND METHODS

A total of 54 fresh-frozen human vertebral bodies from 12 different cadaveric cervical spines (3 female, age 59–88 years; 8 male, age 47–88 years) procured from ScienceCare Anatomic (Phoenix, AZ, USA) were used for this experiment.

Received for publication April 4, 2003; accepted July 29, 2003.
From the Baylor College of Medicine, Houston, TX, USA.
Reprints: Charles Alan Reitman, MD, Baylor College of Medicine, 6560 Fannin, Suite 1900, Houston, TX 77030, USA (e-mail: creitman@bcm.tmc.edu).

All 12 specimens contained C3–C7 vertebral bodies with parts of C2 and T1 and were kept frozen until the time of testing. Five screws failed to provide data owing to poor placement or a weak area of the bone consistent with a fracture, and one pullout test failed owing to failure of the coupling mechanism.

Prior to testing, each cervical spine was vacuum sealed, frozen, and submitted for BMD testing (Dexascan; River Oaks Imaging, Houston, TX, USA). In addition, each specimen was subjected to radiographic evaluation to rule out any tumors or significant destructive changes. All specimens were allowed to reach room temperature and kept moist throughout the testing period.

Two bone screws from the PEAK Polyaxial Anterior Cervical Plate System (DePuy AcroMed, Raynham, MA, USA) were inserted into each cervical vertebral body, C3–C7. All screws were inserted by a single orthopedic spine surgeon. These were cancellous screws specifically designed for unicortical placement in the cervical spine. All screws were 14 mm in length. At this length, all screws resulted in unicortical bone fixation in this sample of spines. Each screw was passed through an aluminum custom sleeve adapter prior to implantation to allow for mechanical pullout testing. The thickness of the adapter simulated the thickness of an average cervical plate. A special screwdriver with a torque transducer (Transducer Techniques, Temecula, CA, USA) mounted to the handle enabled continuous acquisition of torque measurements as the surgeon was placing the screws. Predrilled holes using a 2.5-mm bit were made in the vertebral bodies to accommodate each screw. One bone screw was inserted until it stripped the bone (actual peak insertional torque). A second screw was threaded until the physician felt that a sufficient amount of torque was achieved to maximize holding force without stripping the bone (perceived peak insertional torque). Torque values were documented and analyzed in Microsoft Excel (Microsoft, Redmond, WA, USA). During insertion of all screws, the surgeon was blinded to the BMD of the specimen as well as the torque being generated with each screw.

Destructive mechanical pullout testing was performed by means of a custom pneumatic testing apparatus (Fig. 1). One pneumatic cylinder (Parker Hannifin Corp., Cleveland, OH, USA) applied a uniaxial tensile load at a constant rate of 5 N/s. The pneumatic cylinder was powered by an individual pneumatic valve (Proportion-Air, McCordsville, IN, USA) and controlled by LabView (National Instruments, Austin, TX, USA). A universal "S" load cell fixed between the pneumatic cylinder and sleeve adapter noted the tension force at a rate of 30 Hz throughout the loading process. Each specimen was securely mounted to a multiaxial adjustable table vise and floating *x-y* table to permit self-alignment during the testing procedure. Use of the multiaxial vise allowed us to carefully adjust the alignment. Owing to the intentional and careful design of the sleeve and various adapters, the sleeve could be connected to load cell and testing apparatus only if it was positioned directly parallel to the configuration of the screw. High tolerances during the machining process required that the sleeve be within approximately 0.2° of vertical to couple with the load cell. This ensured that the pullout force was directed parallel to the alignment of the screw. The sleeve adapter was threaded to the force transducer and loaded to failure. Only screws placed by feel were tested for pullout. Stripped screws were not tested in this manner and were placed only to determine peak insertional torque. Maximum failure load was verified by graphing the force data over time and visually identifying the critical load.

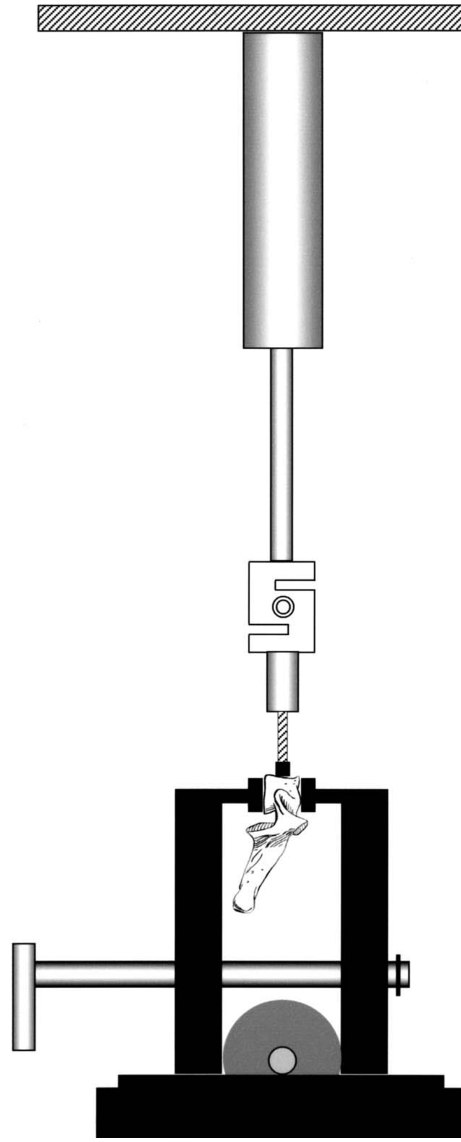

FIGURE 1. Screw pullout testing apparatus.

Average failure loads and statistical comparisons were calculated using a statistical analysis package to determine linear regression and square correlation coefficient as well as analysis of variance (ANOVA).

RESULTS

A total of 54 vertebra from 12 cervical spines were tested. This provided data for a broad range of BMDs from 0.256 to 1.273 g/cm^2.

The relationships of BMD, torque, and pullout strength were evaluated by linear regression analysis. Figure 2 demonstrates a high correlation of average BMD to pullout strength (R^2 = 0.710). There was also a strong relationship of average BMD to maximum torque (R^2 = 0.707) (Fig. 3). However, there was much less correlation of torque to pullout strength (R^2 = 0.422) (Fig. 4). ANOVA was also used to assess interactions of BMD, torque, and pullout strength (Figs. 5 and 6). Relationships of torque to average BMD were significant (P = 0.000087), while pullout strength to average BMD showed a trend (P = 0.093).

Maximum torque compared with the perceived peak torque results were assessed. On average, the surgeon's perceived peak torque was about 85% of the actual peak torque. Average maximum torque was found to be 2.56 ± 1.47 Nm, while average perceived torque was 2.16 ± 1.28 Nm (P = 0.003) (paired t test).

DISCUSSION

Screw pullout strength is a critical factor in the success of an anterior cervical implant. These data showed that screw pullout strength was substantially related to BMD as expected but had a much lower correlation with peak insertional torque. These relationships imply that the critical variable for screw purchase was the density of the bone into which it was placed, and not the force with which it was applied. Clearly, there was a correlation of torque to BMD, which was also expected. However, despite the fact that denser bone could accommodate more torque, the amount of torque did not appear to be critical in preventing screw pullout.

These findings are consistent with those of Lim et al.[5] They were based on biomechanical evaluation of 6.5-mm anterior lumbar screws, but results were similar in that pullout strength was strongly related to BMD but not to the peak insertional torque of the screws. Several other human and animal studies have been done in the thoracic and lumbar spine that support the high correlation of BMD to screw pullout force.[5–12]

Fewer studies have been conducted in the cervical spine. Zink et al[13] evaluated several variables including relationships of BMD and screw torque and axial forces for anterior cervical fixation of Caspar screws. They did not measure pullout strength directly. They found that torque was related to BMD. They also established that larger rescue screws generated higher torques than standard screws. They concluded that for BMD under 150 mg/mL, unicortical fixation with 3.5-mm screws was inadequate fixation without additional reinforcement and recommended that all patients get BMDs prior to surgery to help determine fixation and need for postoperative immobilization.

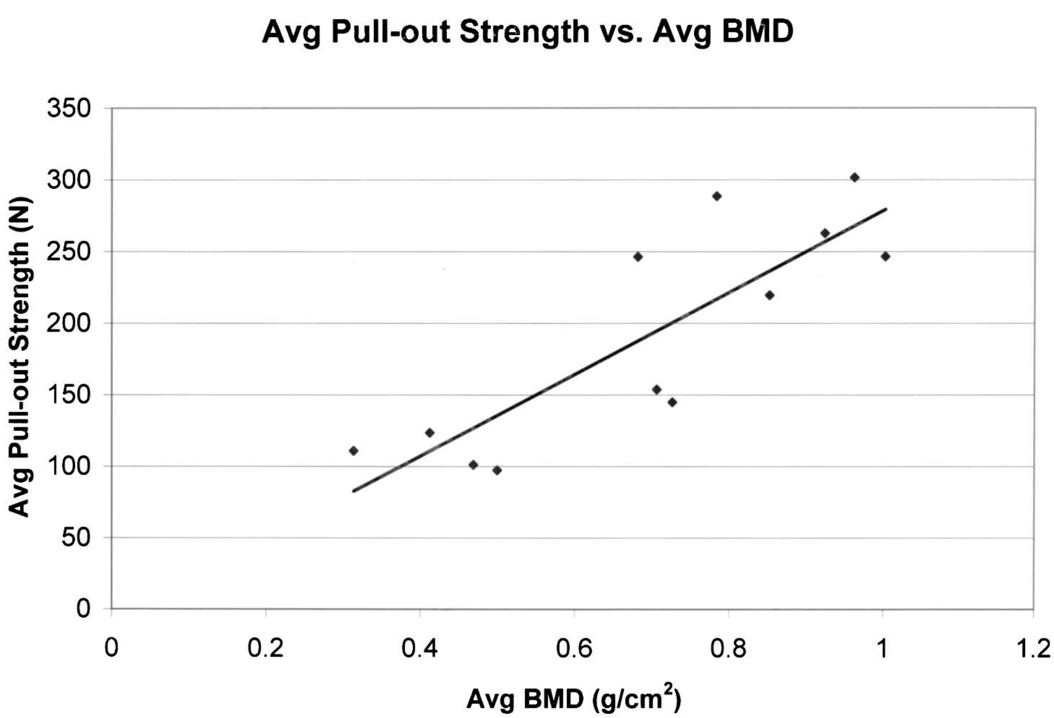

FIGURE 2. Relationship for BMD and pullout strength: $y = 64.049x + 1.5126$ (R^2 = 0.710).

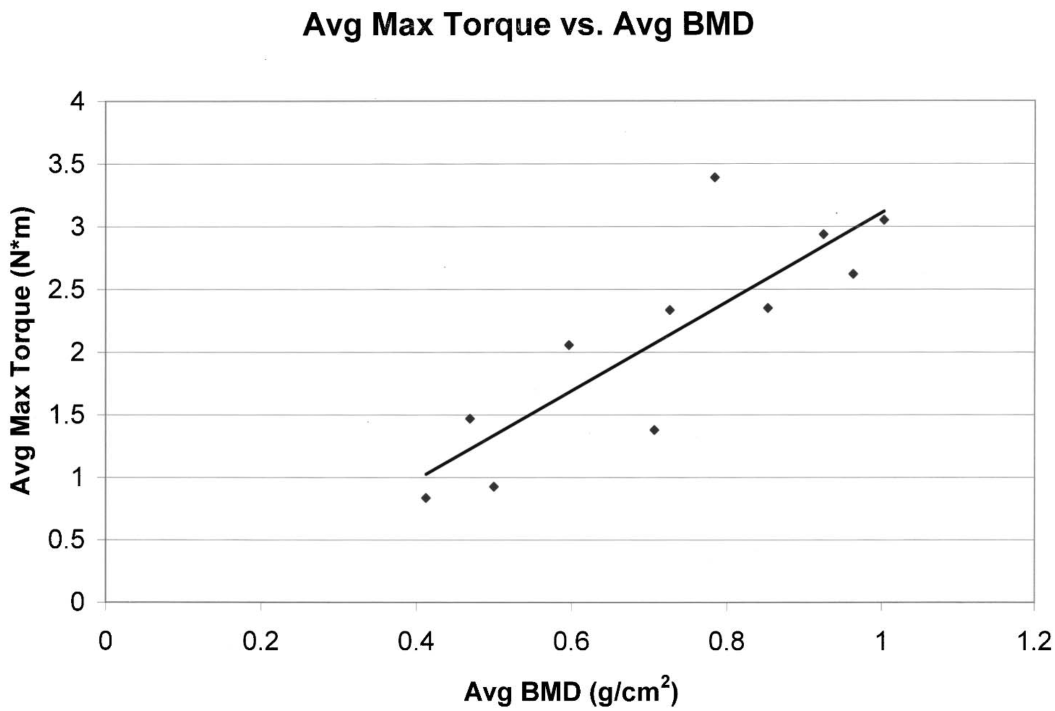

FIGURE 3. Relationship of BMD to torque: $y = 31.343x - 3.8488$ ($R^2 = 0.707$).

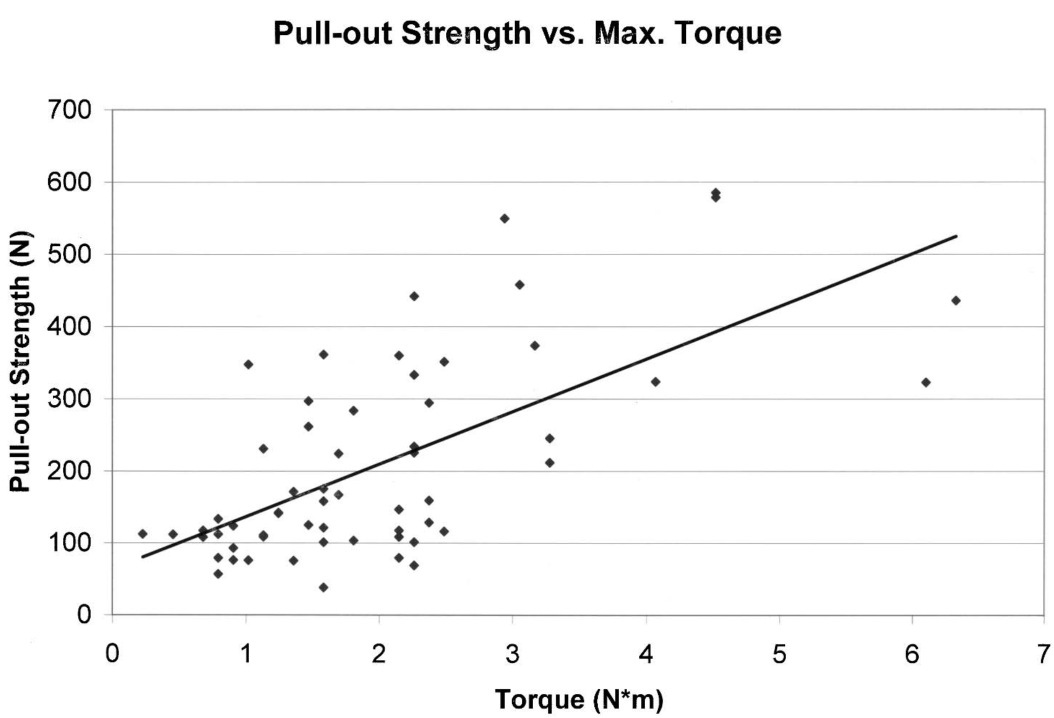

FIGURE 4. Relationship of pullout strength to torque: $y = 1.8503x + 14.363$ ($R^2 = 0.422$).

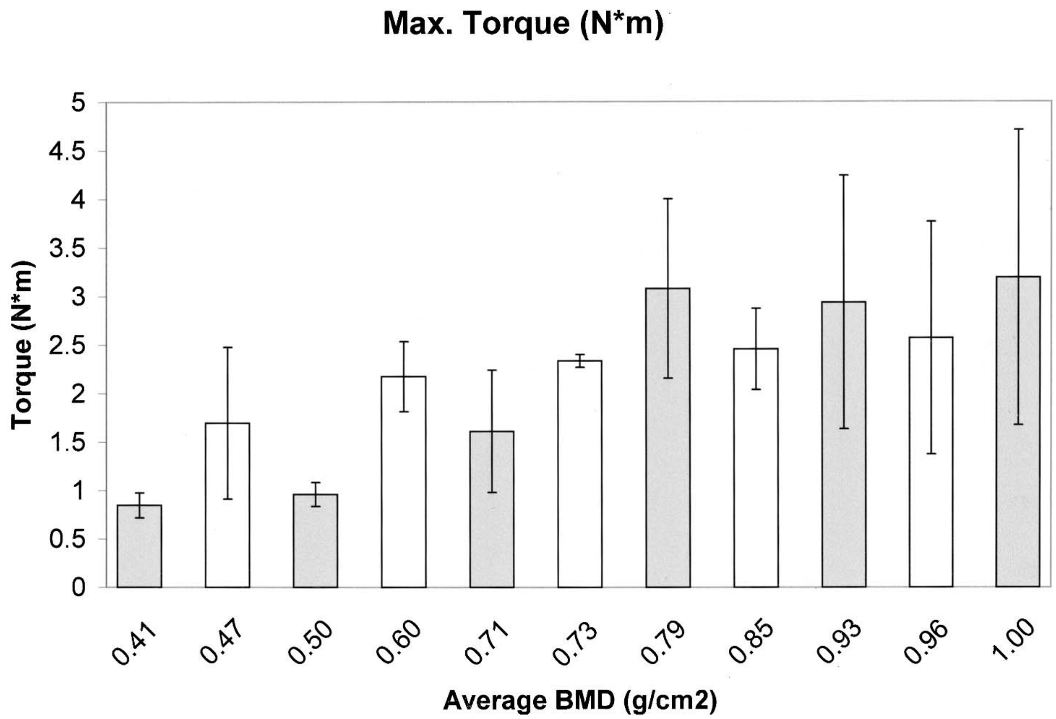

FIGURE 5. Relationship of maximum torque to average BMD ($P = 0.000087$).

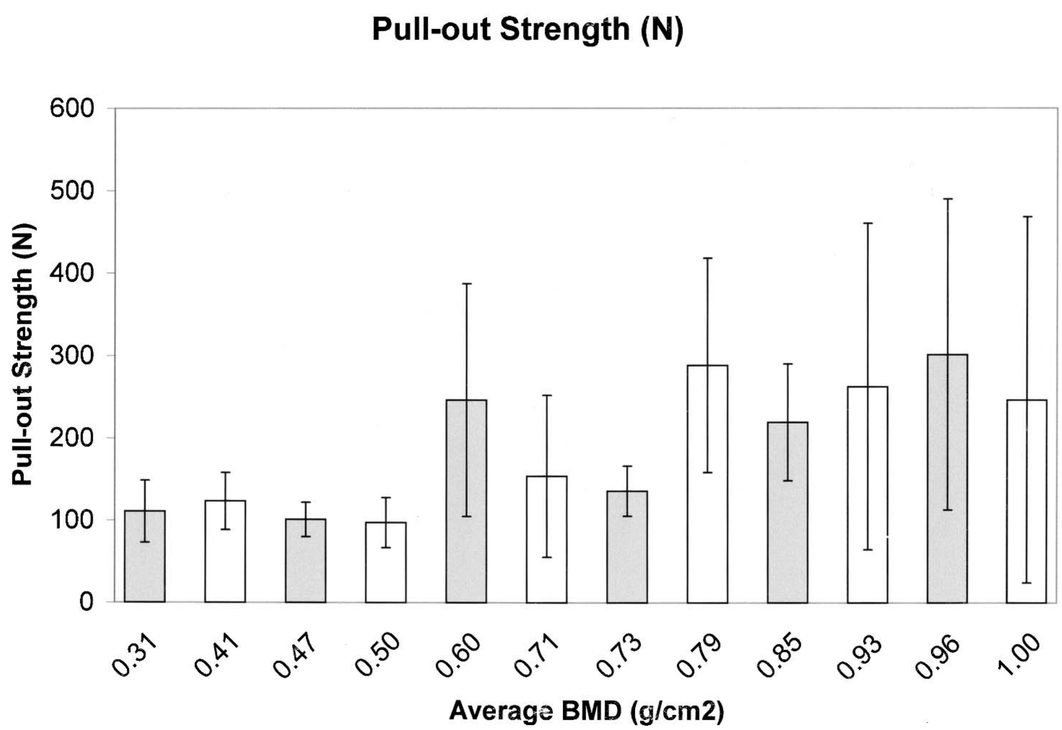

FIGURE 6. Relationship of pullout strength to average BMD ($P = 0.093$).

Ryken et al[14] also looked at properties of Caspar screws in the cervical spine. Contrary to our findings, they found a significant correlation of torque to pullout strength as well as BMD to pullout. These findings were more significant for bicortical purchase versus unicortical placement, and range of bone densities was fairly narrow (0.787 ± 0.154 g/cm^2). A recent report also found positive correlations with pullout strength and BMD as well as pullout strength and insertional torque of anterior unicortical cervical screws.[15] However, in this study, midrange insertional torque was evaluated rather than peak insertional torque. They additionally observed that longer screws (14 and 16 mm) had greater pullout strength than shorter screws (12 mm), and in general, their pullout strength findings were much more significant in the presence of longer screws. BMD has also been shown to be important in implant fixation in the posterior cervical spine.[16]

It appears to be clear that pullout strength is affected by BMD. This has been demonstrated in multiple studies. However, effects of insertional torque have been less well established for anterior cervical screws. While a recent study suggests a high correlation of insertional torque to pullout strength, they did not measure peak insertional torque, and the torque in the midranges of screw placement was probably more directly dependent on BMD. This is the first study to look at relationships of peak insertional torque to pullout strength of unicortical anterior cervical screws over a large range of BMD. Results of this study imply that it is not as important to attain near peak insertional torque values, and, in fact, care should be taken not to overtighten and strip the screw as this would more likely alter and weaken pullout properties. Of interest, we did look at the comparison of the surgeons' perceived peak torque versus the actual torque to failure. The average perceived torque was 85%. We initially hypothesized that peak insertional torque would be important and were set to establish optimal torque values for screw placement depending on the BMD. The study invalidated this hypothesis and supports placement of screws by feel without the need to reach a measured optimal torque.

We did observe a linear relationship between pullout strength and BMD down to about 0.4 g/mL. Below this density, pullout strength seems to reach a minimum of 106.8 N. Although we feel that the knowledge of BMD preoperatively is important to help determine the relative stability of internal fixation, this analysis does not establish a threshold safety value above which implant failure in pullout would reliably be decreased. This question would have to be answered with further study. Furthermore, we did not standardize torque values prior to pullout testing. One of the goals was to mimic the insertional torque that would be present during surgery and to assess the need for a torque feedback device in placing screws. Therefore, all pullout testing was done on screws placed by feel and not to a designated torque value. Although it was demonstrated that the surgeon was able to place the screws satisfactorily without the need for feedback, had we been able to standardize torque, there would have been further direct measure of pullout versus BMD, which would have provided additional support to our conclusions.

CONCLUSIONS

BMD significantly influences pullout strength of anterior cervical screws. Peak insertional torque is related to BMD but as an independent variable does not demonstrate a strong influence on pullout strength. It is important for the clinician to acknowledge that the critical factor contributing to pullout strength is the density of the bone and not the force with which the screw is placed into the bone. The surgeon is capable of placing a screw by feel that has adequate torque. Specific torque screwdrivers should not be necessary to ensure optimal bone purchase, and the surgeon then does not risk exceeding the peak insertional torque capacity of the bone. BMD should be considered when choosing a cervical implant.

REFERENCES

1. Wang JC, McDonough PW, Endow KK, et al. Increased fusion rates with cervical plating for two level anterior cervical discectomy and fusion. *Spine*. 2000;25:41–45.
2. Wang JC, McDonough PW, Kanim LEA, et al. Increased fusion rates with cervical plating for three level anterior cervical discectomy and fusion. *Spine*. 2001;26:643–644.
3. Fogel GR, Reitman CA, Nguyen L, et al. Cervical plates: comparison of physical characteristics and in vitro push out strength. *Spine J.* (in press).
4. Chapman JR, Harrington RM, Lee KM, et al. Factors affecting the pullout strength of cancellous bone screws. *J Biomech Eng*. 1996;118:391–398.
5. Lim TH, An HS, Evanich C, et al. Strength of anterior vertebral screw fixation in relationship to bone mineral density. *J Spinal Disord*. 1995;8:121–125.
6. Coe JD, Warden KE, Herzig MA, et al. Influence of bone mineral density on the fixation of thoracolumbar implants. *Spine*. 1990;15:902–907.
7. Hadjipavlou AG, Nicodemus CI, Al-Hamdan FA, et al. Correlation of bone equivalent mineral density to pullout resistance of triangulated pedicle screw construct. *J Spinal Disord.* 1997;10:12–19.
8. Oduyama K, Sato K, Abe E, et al. Stability of transpedicle screwing for the osteoporotic spine. *Spine*. 1993;18:2240–2245.
9. Shimamoto N, Kotani Y, Shono Y, et al. Biomechanical evaluation of anterior spinal instrumentation systems for scoliosis: in vitro fatigue simulation. *Spine*. 2001;26:2701–2708.
10. Snyder BD, Zaltz I, Hall JE, et al. Predicting the integrity of vertebral bone screw fixation in anterior spinal instrumentation. *Spine*. 1995;20:1568–1574.
11. Wittenberg RH, Shea M, Swartz DE, et al. Importance of bone mineral density in instrumented spine fusions. *Spine*. 1991;16:647–652.
12. Zdeblick TA, Kunz DN, Cooke ME, et al. Pedicle screw pullout strength: correlation with insertional torque. *Spine*. 1993;18:1673–1676.
13. Zink PM. Performance of ventral spondylodesis screws in cervical vertebrae of varying bone mineral density. *Spine*. 1996;21:45–52.
14. Ryken TC, Clausen JD, Traynelis VC, et al. Biomechanical analysis of bone mineral density, insertion technique, screw torque, and holding strength of anterior cervical plate screws. *J Neurosurg*. 1995;83:325–329.
15. Hitchon PW, Brenton MD, Coopes JK, et al. Factors affecting the pullout strength of self-drilling and self-tapping anterior cervical screws. *Spine*. 2003;28:9–13.
16. Lovick DS, Ryken TC, Traynelis VC, et al. Assessment of primary and salvage lateral mass screw insertion torque in a cadaveric model. *J Spinal Disord*. 1997;10:431–435.

