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Correlations Between Screw Hole Preparation, Torque of Insertion, and Pullout Strength for Spinal Screws

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Summary: The bone–screw interface is critical in the use of spinal instrumentation. The purpose of these experiments described here was twofold. First, to determine whether a correlation existed between torque generated during screw insertion and the pullout strength. Second, to determine how differing surgical methods of screw hole preparation influenced torque of insertion and screw pullout strength. A series of experiments were carried out in which screws were inserted into synthetic bone (experiment 1) and into calf vertebrae (experiment 2). The method of screw hole preparation (i.e., diameter of entrance hole and pilot hole) was varied while the resulting torque of insertion and the pullout strength of the screw was measured in each case. A torque screwdriver was used to measure the torque of insertion of the screws. Screw pullout strength was measured using a materials testing machine. Two important results emerged from these experiments. First, a higher torque of insertion correlated with a higher screw pullout force. This correlation may be useful intraoperatively in evaluating fixation. Second, torque of insertion and pullout force were more influenced by cortex overdrill diameter than pilot hole diameter. These experiments show the importance of the dorsal cortex in pedicle screw fixation. **Key Words:** Screws—Torque—Cortex—Pullout strength.

The success of spinal fusion using instrumentation depends, among other things, on the stability of the construct. The bone–screw interface is critical (5,6), and loosening of any screws inserted into the vertebrae could compromise that stability. The surgeon generally estimates the adequacy of an inserted screw by subjective assessment, noting which screws give a "good bite" during tightening. Torque of insertion is defined as the angular moment of force required to advance the screw into bone. If torque of insertion of a screw could be correlated with the pullout strength of a screw, then torque could be used interoperatively as an objective measure of screw holding power.

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Previous studies have discussed torque of insertion in relation to the material properties of bone and fatigue of bone screws (1,4,8,10,11). In a study by Ansell and Scales (1), a screwdriver was adapted to measure torque during screw insertion. Based on a series of experiments, recommendations were outlined for optimal screw design in terms of core diameter for self-tapping or non-self-tapping, and for technique of insertion, in terms of drill size. To avoid failure of a screw during insertion, a "torque limiting" screwdriver was proposed for use. However, a relationship between measured torque and pullout strength was not described.

The properties of the bone into which the screw is inserted are prime determinants of screw pullout strength. In a given patient these properties are constant and generally cannot be altered. However, certain variables, such as the type of the screw and the method of screw hole preparation, can be varied to maximize the holding power of a screw.

The purpose of the experiments described here was twofold: first, to determine whether a correlation existed between torque generated during screw insertion and the pullout strength; second, to determine how various methods of screw hole preparation affected torque of insertion and screw pullout strength.

MATERIALS AND METHODS

Overview

The results from mechanical testing on human vertebrae can be obscured by the considerable variation in bone quality (1,3,9). We wanted both a consistent and representative model for testing that would not introduce large variability. A synthetic bicortical "bone block" with uniform material properties resembling those of human bone was developed as the testing material for screw pullout tests in the first part of this investigation (experiment 1).

Morphological studies (7,12) have revealed that the pedicle is a tunnel composed of a core of cancellous bone surrounded by cortical bone. However, because of the variability in diameter of lumbar pedicles, pedicular screws may have varying purchase on the inner cortical bone that surrounds the pedicle. Thus, to correlate the findings from a consistent synthetic substrate to transpedicular fixation, further testing (experiment 2) was conducted with screws inserted into the left and right pedicles of lumbar vertebrae from fresh, frozen calf spines. In both experiments pedicle screw failure is defined in terms of axial pullout force. This is an accepted biomechanical model that does provide reproducible results (13).

Experiment 1

Synthetic Bone Material

The synthetic bone (Pacific Research, Vashon, WA, U.S.A.) was supplied in blocks made to simulate corticocancellous bone found anatomically at the sites of screw insertion in the spine such as the vertebral body and the sacral ala (2). The synthetic bone was manufactured in rectangular cubes with a 15 × 15-cm² surface area; the thickness consisted of 40 mm of polyurethane foam sandwiched between 2-mm top and bottom layers of epoxy laminate (Fig. 1). The polyurethane foam (141 kg/m³) simulated cancellous bone, and the fiberglass epoxy laminate simulated cortical bone. This particular synthetic bone substrate was selected based on data from a pilot study whereby the substrate was compared in mechanical tests with fresh human cadaveric sacrums. The strength of the substrate was similar to that of bone at standard screw sites in the sacrum.

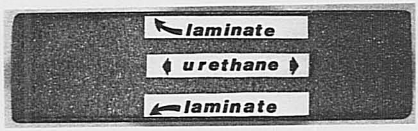

FIG. 1. A cross section through the synthetic bone used in experiment 1.

The Screws and the Hole Preparation

The screws were 40-mm Danek TSRH screws with 6.5-mm major diameter and 4.2-mm minor diameter. The screw holes were drilled using a vertical drill-press. A pilot hole was initially drilled completely through the blocks. The top "cortex" (the 2-mm-thick laminate) was then overdrilled. This "cortex" simulates the entrance site or dorsal cortex, for vertebral screw insertion. This overdrilling was to simulate various hole dimensions that could be created with various techniques using a pedicle probe, drill, or burr. Eight different combinations of pilot drill and cortex overdrill diameters were used: (a) 2.5-mm pilot/4.0-mm overdrilled; (b) 2.5 mm/4.5 mm; (c) 2.5 mm/5.5 mm; (d) 3.5 mm/4.0 mm; (e) 3.5 mm/4.5 mm; (f) 3.5 mm/5.5 mm; (g) 4.5 mm/4.5 mm; and (h) 4.5 mm/5.5 mm. The pilot drill diameters of 2.5 and 3.5 mm were chosen to represent the clinical situation in which a K-wire, pedicle probe, or drill is used for initial probing of the screw hole. The pilot drill diameter of 4.5 mm was chosen because it is larger than the minor diameter of the screw. For overdrilling of the entry cortex, drills of 4.0 mm and 5.5 mm diameters were chosen to represent sizes below and above the minor diameter, yet below the major diameter. These eight combinations were intentionally chosen to simulate different methods used in preparing the hole for the pedicle screw. By varying the hole preparation in a controlled fashion, we were able to observe the rela-

tive changes in torque of insertion and screw pullout using one constant type of screw. The length of the screws were such that they did not reach the bottom cortex.

Experiment 2

Calf Vertebrae

Screw pullout was tested using calf vertebrae with screws inserted into both pedicles. In an effort to minimize variability, comparison was made between screw pullout tests for the right and left pedicles of the same vertebrae.

Six fresh frozen lumbar spines from similar age calves were obtained from a local abattoir. They were stored at −20°C until the day before testing and were then slowly thawed at room temperature. After thawing, the spines were dissected free of all tissue, and the L2–L5 vertebrae (24 in all) were harvested. These vertebrae were then individually secured in a plastic mold using a wood screw and dental plaster. The wood screw was inserted into the body of the vertebra and the vertebra was placed in the wet plaster. This methodology ensured good fixation between the plaster and the vertebra (Fig. 2).

For each of the left and right pedicles, a pilot hole was drilled first, followed by overdrilling the dorsal cortex (i.e., the screw "entrance" hole). The dorsal cortex was defined as the most superficial cortical layer of bone of the vertebra over the pedicle when viewed posteriorly.

Because of the smaller size of the calf pedicle, the screws chosen were 40-mm Danek TSRH sacral screws with major diameter of 5.5 mm and minor diameter of 4.2 mm. The pilot drill size of 2.5 mm was constant in all tests. The dorsal cortex of the right and left pedicles were overdrilled with either 4.0 or 5.0 mm; the left or right was chosen in a random manner. The sizes for overdrilling were chosen to represent a size below and above the minor diameter.

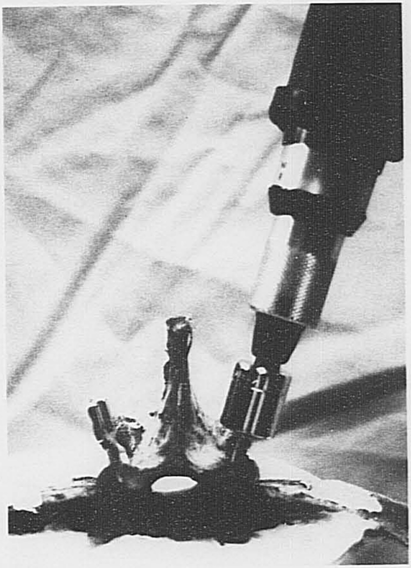

FIG. 2. The torque screwdriver is being used to drive a screw into the pedicle of a calf vertebra, which is embedded in dental plaster.

Torque Screw Driver

A commercially available torque screwdriver with a calibrated vernier scale was used to measure the torque of insertion of the screws (Fig. 2). The torque screwdriver was modified using an attachment to fit the heads of the sacral screws and it was scaled from 0 to 4 Nm in increments of 0.05 Nm. The torque was measured as the screw advanced in the material. The torque was found to progressively increase for two reasons: (a) the number of threads of the screw cutting through the bone increased as the screw advanced, and (b) the minor diameter of the Danek TSRH screw expanded in size from the tip to the head of the screw. The torque of insertion of a particular screw was defined in both experiment 1 and experiment 2 as the torque required to "bury" the last thread beyond the top cortex. In all cases this was the maximum torque.

Axial Pullout—Experiments 1 and 2

Screw pullout strength was measured using a uniaxial servohydraulic materials testing machine (model 810, MTS System Corp., Eden Prairie, MN, U.S.A.). A synthetic block was secured to the testing machine by means of C clamps. An adapter was made to fit securely around the head of the screw. The adapter was attached to the load cell of the testing machine by means of a 30-cm-long high-tension steel cable. As the ram of the testing machine moved down, the cable

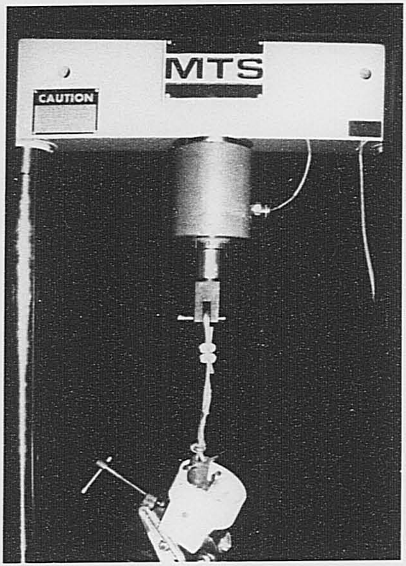

FIG. 3. The screw inserted into the pedicle of a calf vertebra is being pulled out using an adapter to grip the screw head.

applied tension to the screws and the force exerted for screw pullout was recorded by the load cell. With the cable and screw coaligned, the long cable allowed axial pullout along the axis of the screw. The tensile force was applied to the screw at a constant displacement rate of 12.5 cm/min. A curve of pullout force (N) versus time was recorded. For each of the eight combinations in experiment 1, 14 pullout tests were conducted.

The calf vertebrae were tested in a similar manner except that each plastic mold was clamped to the ram of the testing machine by means of a vise. The plastic mold was orientated in the vise to align the long axis of the screw with the long axis of the cable to ensure straight axial pullout (Fig. 3).

Statistical Methods

The data were analyzed using regression analysis, including Tukey's Studentized range (HSD) test and analysis of variance. In cases in which two groups were compared, the *t* test was used. Statistical significance throughout the foregoing text is defined at $p < 0.05$ (except where stated otherwise).

RESULTS

Experiment 1

The results for the mean torque of insertion, mean pullout force, and the standard deviations are shown in Table 1. Multiple regression analysis revealed a positive correlation ($p \le 0.001$) between torque and screw pullout force, i.e., a higher torque correlated with a higher pullout force. The "best fit" line ($r = 0.65$) of the data points of pullout force versus torque was found to be a hyperbolic curve:

$$Y = \frac{X}{1{,}693 - 0.699X} \quad \text{where}$$

Y = torque (Nm) and X = pullout force (N)

Pullout force and torque of insertion were found to be dependent on cortex overdrill diameter ($p \le 0.001$) and pilot drill diameter ($p \le 0.001$). The relationship between pullout force to torque of insertion, cortex drill diameter, and pilot drill diameter was determined using covariant analysis. Based on a comparison of the ratio of their standard coefficients, pullout force was found to be more dependent on torque than on cortex overdrill diameter or pilot drill diameter by a factor of > 6.5.

Covariant analysis also revealed that if the effect of torque was removed from consideration, the pullout was found to be more dependent on the size of cortex overdrill diameter than on the pilot drill diameter by a factor of 2. Similar analysis, with screw pullout removed, revealed that torque was more dependent on

TABLE 1. *Synthetic bone: mean values of torque of insertion and pullout force for each of the eight combinations of tests carried out (n = 14 for each combination)*

Pilot drill (mm)	Cortex overdrill (mm)	Torque (Nm) Mean	Torque (Nm) SD	Pullout (N) Mean	Pullout (N) SD
2.5	4.0	1.32	0.12	1134	112
2.5	4.5	1.31	0.17	1076	85
2.5	5.5	0.96	0.14	996	123
3.5	4.0	1.30	0.08	1072	81
3.5	4.5	1.33	0.11	1102	124
3.5	5.5	0.90	0.10	1017	91
4.5	4.5	1.36	0.11	1071	96
4.5	5.5	0.75	0.08	958	99

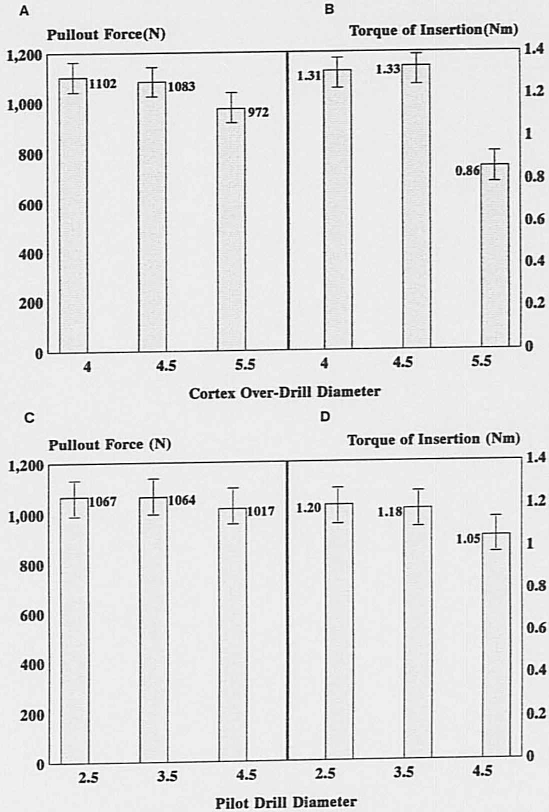

FIG. 4. The mean results with their standard deviations for the tests carried out on synthetic bone. **A and B:** Pullout force and torque of insertion for the three different cortex overdrill diameters; in both cases there is a statistical difference between 5.5 mm and the other two values, 4 mm and 4.5 mm. **C and D:** Pullout force and torque of insertion for the three different pilot drill diameters; in neither case is there a statistical difference between any of the three results. The results shown in these figures are combinations of results from Table 1 (e.g., the first result for pullout, 1,102 N, is the mean for all the values for cortex overdrill 4.0 mm, lines 1 and 4).

the cortex overdrill diameter than pilot drill diameter by a factor of 4.5.

Relative Effects of Combinations of Pilot and Cortex Drill Sizes

The effect of the various combinations of pilot hole diameter (2.5, 3.5, 4.5 mm) and cortex overdrill diameter (4.0, 4.5, and 5.5 mm) on mean screw pullout force and mean torque was determined. The mean screw pullout force versus size of the cortex overdrill diameter was plotted in a bar graph (Fig. 4A). Regression analysis revealed statistical difference for pullout force between cortex 5.5 mm and either cortex 4.0 or 4.5 mm. Mean torque versus cortex overdrill diameter was plotted in a bar graph (Fig. 4B). Similarly, the only significant differences were between the cortex overdrill diameter of 5.5 mm and either 4.0 or 4.5 mm.

Mean screw pullout force versus pilot hole diameter was plotted in a bar graph (Fig. 4C). No statistically significant differences in pullout force were observed between any of the three different pilot hole diameters. Mean torque versus pilot hole diameter was plotted in a bar graph (Fig. 4D). No significant

TABLE 2. *Calf vertebrae: mean values of torque of insertion and pullout force for each of the two combinations of tests carried out (n = 30 for each combination)*

Pilot drill (mm)	Cortex overdrill (mm)	Torque (Nm)		Pullout (N)	
		Mean	SD	Mean	SD
2.5	4.0	1.46	0.13	1488	378
2.5	5.0	0.97	0.09	1054	236

differences were observed between any of the three different pilot hole diameters.

Experiment 2

For the twelve calf vertebrae in each of the two groups (cortex overdrill of 4.0 mm and cortex diameter of 5.0 mm) the mean pullout force, the mean torque of insertion, and the standard deviations are shown in Table 2.

Regression analysis revealed a positive correlation ($p \leq 0.001$) between torque of insertion and screw pullout force, i.e., a higher torque correlated with a higher pullout force. The "best fit" line ($r = 0.83$) of the data points was a linear relationship (Fig. 5):

$$Y = \frac{X}{1{,}142} + 0.02 \qquad \text{where}$$

Y = torque (Nm) and X = pullout force (N)

The effect of screw hole preparation was also analyzed (Fig. 6). Analysis using a paired t test demonstrated that there was a significant difference in mean torque ($p \leq 0.001$, $t = 12.37$, $df = 29$), and mean pullout force ($p = 0.001$, $t = 3.82$, $df = 29$) between cortex overdrill diameter of 4.0 mm as compared with 5.0 mm. A significant decrease in both torque and pullout force was seen with the larger cortex overdrill diameter (i.e., the larger entrance hole).

DISCUSSION

Two important results emerged from these experiments. First, a higher torque of insertion correlated with a higher screw pullout force (from experiments 1 and 2). This confirms that the subjective tactile "feel" of torque during screw insertion is of relevance. More precisely, if torque is actually measured intraoperatively, an anticipated load-to-failure for that screw can be predicted using a mathematical relationship similar to the one that has been described. If the surgeon objectively measures the torque of insertion of a screw, he could then compare torque to the predicted range, and thus better answer certain questions: Is this screw able to withstand reasonable load to failure? Is this screw likely to loosen or fail in the postoperative period? How many intermediate screws are required? Should this screw be removed, upsized, or augmented? Without the objective information such as torque of insertion, the surgeon must resolve questions like these with only subjective information like "feel."

The second important result was that pullout force and torque of insertion were more influenced by cor-

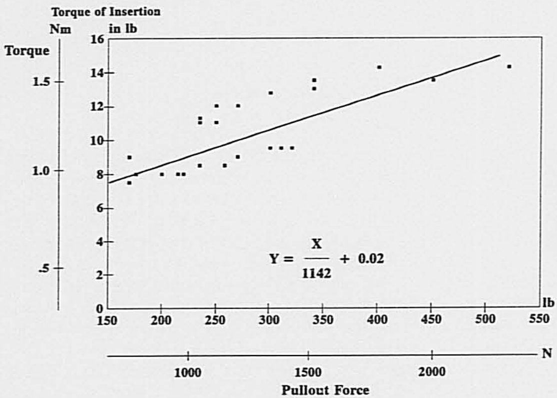

FIG. 5. The results for pullout force against torque of insertion for the tests carried out on the calf vertebrae. To avoid congestion some individual, overlapping points have been omitted. The regression line was linear; the constants shown in the equation relate to the outer axes (i.e., the SI system of units).

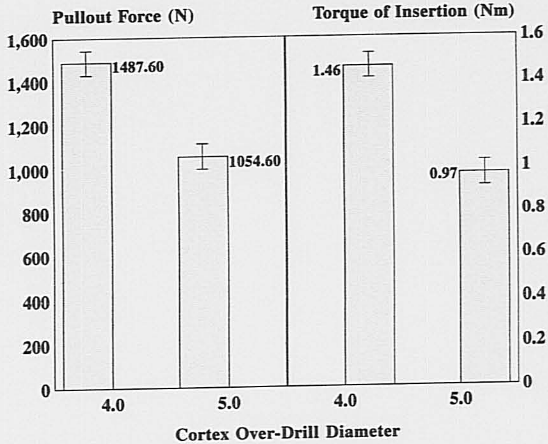

FIG. 6. The mean results and their standard deviations for the tests carried out on the calf vertebrae. Pullout force and torque of insertion for the two different cortex overdrill diameters are shown. In both cases, there is a significant difference between 4.0 and 5.0 mm.

tex overdrill diameter than pilot hole diameter (from experiment 1). The effect of cortex overdrilling was not decreased by using smaller pilot drills (from experiment 1). Thus, to ensure the most secure fixation, screws should be placed (if possible) in areas where the dorsal or "entrance" cortex is thickest. The bone stock at this entrance point appears to be critical to fixation. These data would suggest that preparation of the entrance hole should be precise and that the hole be as small as possible. The entrance hole (i.e., cortex overdrill diameter) should ideally equal the minor diameter of the screw or at least no more than 1 mm larger than the minor diameter. This implies careful localization of the entrance point and avoidance of extensive enlarging of the entrance hole through the use of oversize drills, burrs, or probes.

These experiments show the importance of the dorsal or "entrance" cortex in screw fixation. The strength of fixation of the screw is dependent on the combined strength of the cancellous bone and the cortex. If the cortex is removed, even in part, then the strength of fixation is more reliant on the strength of the cancellous bed, which is relatively weak.

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