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The Effect of Repetitive Pilot-Hole Use on the Insertion Torque and Pullout Strength of Vertebral System Screws

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Study Design. *In vitro* biomechanical investigation of the screw-holding capacity.

Objective. To evaluate the effect of repetitive screw-hole use on the insertional torque and retentive strength of vertebral system screws.

Summary and Background Data. Placement and removal of vertebral system screws is sometimes necessary during the surgical procedures in order to assess the walls of the pilot hole. This procedure may compromise the holding capacity of the implant.

Methods. Screws with outer diameter measuring 5, 6, and 7 mm were inserted into wood, polyurethane, polyethylene, and cancellous bone cylindrical blocks. The pilot holes were made with drills of a smaller, equal, or wider diameter than the inner screw diameter. Three experimental groups were established based on the number of insertions and reinsertions of the screws and subgroups were created according to the outer diameter of the screw and the diameter of the pilot hole used.

Results. A reduction of screw-holding capacity was observed between the first and the following insertions regardless the anchorage material. The pattern of reduction of retentive strength was not similar to the pattern of torque reduction. The pullout strength was more pronounced between the first and the last insertions, while the torque decreased more proportionally from the first to the last insertions.

Conclusion. Insertion and reinsertion of the screws of the vertebral fixation system used in the present study reduced the insertion torque and screw purchase.

Key words: spine, bone screws, biomechanics, insertion torque, retentive strength. **Spine 2009;34:000–000**

The success of the spinal arthrodesis depends on the fixation of the operated segment, thus maintaining the correction and assuring future bone union. The mechanical stabilization relies on the performance of screws for anchorage into the bone which, in turn, is directly related to the purchase of the screw into the vertebrae.[1,2]

During the surgical procedure, insertion into, removal, and reinsertion of the screws is a recommended procedure to determine the pathway of the pilot hole and to detect possible violations of the lateral wall of the pilot hole that might damage adjacent structures of the vertebral canal.[3,4] However, this procedure may interfere with the hardware-holding capacity.

The effects of repetitive screw-hole use have been studied in bone osteosynthesis and in this situation removing a screw and reinserting it into the same hole was found not to cause loss of its holding capacity.[5,6] However, in this situation, the screws were inserted into cortical bone and the results obtained may not be applied to vertebrae that are mainly composed of cancellous bone surrounded by a layer of cortical bone. Thus, the purpose of the present investigation was to determine the effect of the repeated use of the pilot hole on pullout strength of vertebral fixation system screws with variation of the hole diameter and screw dimensions.

Materials and Methods

Pilot holes with different diameters were drilled into cylindrical blocks of different materials and screws with different diameters were driven through them with monitoring of the insertional torque and, later, performing mechanical pushing out tests. The variables studied were the number of screw insertions and the diameter of the screws in relation to the diameter of the pilot holes.

Cylinders made of wood, polyurethane, high molecular weight polyethylene, or cancellous bone were used. The wood blocks were obtained from a pinus variety (*Arauacaria angustifolia*), a native species from Brazilian woods, with a mean density of 0.57 g/cm^3. This parameter was obtained by the relation between mass and volume. The polyurethane samples consisted of expanded polyurethane that resulted from mixing isocyanate with polyol, with a density of 0.04 g/cm^3 (Nacional Ltda). The polyethylene was a polyolefin of ultrahigh molecular weight with a density of 0.93 g/cm^3 (Impactto Ltda), as recommended by the technical guidelines for the analysis of the spine fixation system.[1]

From 4- to 5-year-old healthy animals (*Bovis* spp.), bovine bone blocks were obtained from the metaphysis of the distal femur and stored frozen at −20°C. Later, this material was selected according to the mechanical resistance and mineral density. For this, first the bone blocks were thawed at room temperature and nondestructive mechanical compression tests were carried out in all the samples with a final selection of 300 samples that presented mean stiffness of (6.3–4.7) × 10^6 N/m.

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Table 1. Chart 1—Grouping and Subgrouping

Groups	Material	Screw Outer Diameter (mm)	Hole Diameter (mm)
Group 1	Wood polyurethane	5	3.0
(1 screw insertion)	polyethylene		3.8
	bovine bone		4.5
Group 2		6	4.0
(1 screw reinsertion)			4.8
			5.5
Group 3		7	4.0
(2 screw reinsertions)			4.8
			5.5
			6.5

Testing was performed in a safe limit in the elastic phase, as determined previously in pilot studies. Following this, the samples were submitted for mineral density assessment by dual radiograph absorptiometry and using the QDR system with software version 11 to 2:5 (Hologic 4500 W, Waltham, MA) with selection of the specimens in the interval 0325 ± 0097 g/cm^3 (mean ± standard deviation). The screws used were of the USS system (Synthes), with 45 mm in length and outer diameters of 5, 6, and 7 mm. The 7-mm screw has larger thread pitch and depth compared with 5- and 6-mm screws that have the same thread pitch and depth.

All the cylindrical blocks had a diameter of 30 mm and were initially prepared by drilling 1 perpendicular hole into its center. Holes measuring 3.0, 3.8, and 4.5 mm in diameter were drilled for screws measuring 5 mm in outer diameter (3.8 mm of inner diameter). Holes measuring 4.0, 4.8, and 5.5 mm in diameter were drilled for screws measuring 6 mm in outer diameter (4.8 mm of inner diameter) and holes measuring 4.0, 4.8, 5.5, and 6.5 mm in diameter were drilled for screws measuring 7 mm in outer diameter (4.8 mm of inner diameter). All screws had 45 mm in length and they were driven through the hole with a torque device (Makena, Brazil) that provided the mean torque on each turn. However, for analysis, it was considered the mean torque of the last turn that was reached when 10 mm of the screw tip protruded through the opposite side of the block. Then, the screw was removed and reinserted once or twice, according to the group, with measurements of the last turn insertional torque. Three experimental groups were established based on the number of insertions and reinsertions of the screws and subgroups were created according to the outer diameter of the screw and the diameter of the pilot hole used
T1 (Table 1).

The mechanical pushing-out tests were performed using an Emic universal testing machine working with a load cell capacity of either 2000 or 20000 N. The block was placed on a support positioned with the screw tip pointing upward and a pushing out load (F) was vertically applied to the tip of the screw at a rate of 2 mm/min. A stainless steel accessory fitted the screw tip to protect it and to provide an adequate surface
F1 for load application (Figure 1). After testing, samples of screws inserted into harder materials as wood and polyethylene were examined under the profile projector to discard damage to the threads. Data were processed by software that computed the pushing out strength. Data were analyzed statistically by multifactorial analysis of variance and by the *post hoc* Bonferroni test with level of significance set at 5% ($P \leq 0.05$).

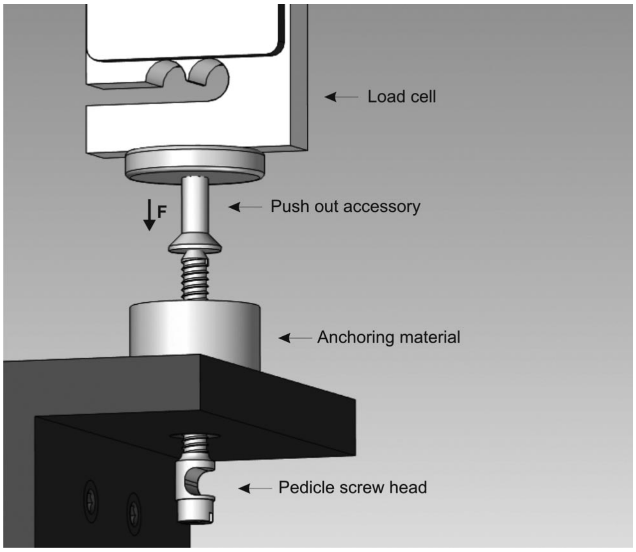

Figure 1. Schematic of the pushing out test. The block was placed on a support with the tip of the screw protruding 1 cm and pointing upward. A metal accessory protected the screw tip and provided an adequate surface for load application.

Results

Insertion Torque

Results of the insertion torque of 5- and 6-mm screws inserted into different material blocks and using different pilot holes are illustrated in Figures 2 and 3. The inser- F2–3
tion torque of screws measuring 5 and 6 mm in diameter inserted into the various blocks were significantly different between the first insertion and the following insertions ($P < 0.001$) for all pilot-hole diameters, except for the 4.5-mm hole in polyurethane.

The results of insertion torque of 7-mm screws placed into the different materials with different pilot holes are presented in Figure 4. The insertion torque of 7-mm F4
screws differed significantly between the first and the following insertions in all materials and all pilot-hole diameters ($P < 0.001$).

Pullout Strength

The results of maximum pullout strength for 5-mm screws driven into the different materials in different hole diameters are presented in Figure 5. The pullout strength F5
of 5-mm screws inserted into the wood, polyurethane and bovine bone blocks was significantly different between the first and the following insertions for all pilot-hole diameters ($P < 0.001$). However, for bovine bone a statistically significant difference was observed between the first and third insertion for all pilot-hole diameters ($P < 0.001$).

The maximum pullout strength of 6-mm screws inserted into different materials with different pilot holes is presented in Figure 6.The pullout strength for 6-mm F6
screws inserted into the wood was significantly different between the first and the following insertions for all hole diameters ($P < 0.001$). In polyurethane, polyethylene, and bovine bone, there was a significant difference be-

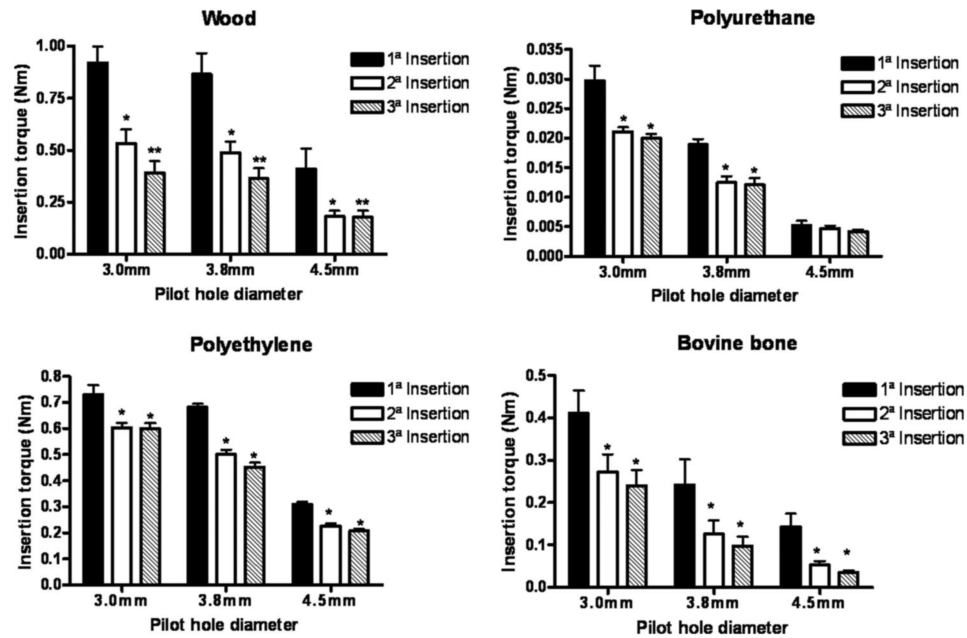

Figure 2. Histograms of the insertion torque of 5-mm screws driven into pilot holes of different diameters. The asterisk (*) indicates a statistically significant difference to values of the fist insertion into the specific diameters of the pilot hole. ** Indicates significant difference to values of first and second insertion into the specific diameters of the pilot hole.

tween the first and the third insertions into holes of different diameters ($P = 0.02$, $P < 0.001$, $P = 0.006$, respectively).

The results of maximum pullout strength of 7-mm screws inserted into different materials with different
F7 hole diameters are presented in Figure 7. The maximum pullout strength in wood, polyurethane, and polyethylene samples were significantly different between the first and the following insertions for all hole diameters ($P < 0.001$). In the bovine bone, a statistically significant difference was observed between the first and third insertion in all hole diameters ($P = 0.01$).

■ Discussion

Vertebral screws play a prime role in the initial holding capacity of the vertebral fixation system that has been designed to provide immediate stability and rigid immobilization.[7–9] The initial stability of the vertebral system relies on the purchase achieved in the interface between the screw and bone, whose strength can be described in terms of screw pullout resistance,[7,10–12] which in mechanical tests is the same of the pushing out strength.[6,13]

The screw pullout strength is a parameter that results from the interaction of bone mineral density, screw thread, and pilot hole.[10,11,14,15] Considering these factors the pilot hole is the only variable that can be controlled during the operation and depends on the attitude of the surgeon. Parameters related to the preparation of the pilot hole in the vertebrae have been studied, with emphasis on its diameter and mode of preparation.[2,11,14–17] Screw-hole preparation can be varied to maximize the holding power of the screw.[2,11,14–16] However, the effects of the

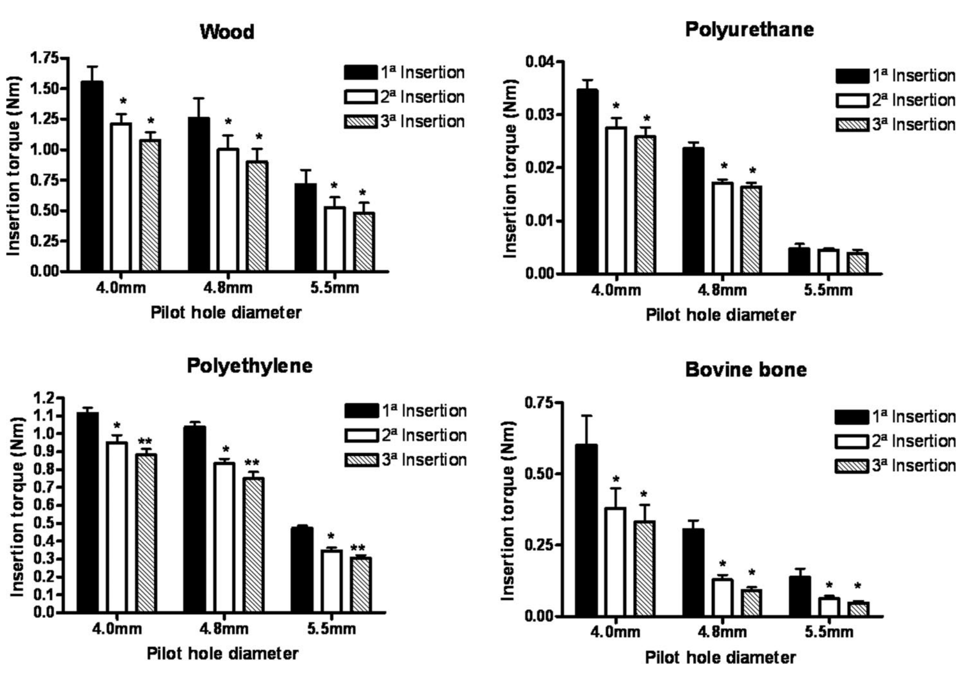

Figure 3. Histograms illustrating the insertion torque of 6-mm screws driven into pilot holes of different diameters. The asterisk (*) indicates a statistically significant difference to values of the fist insertion into the specific diameters of the pilot hole. ** Indicates significant difference to values of first and second insertion into the specific diameters of the pilot hole.

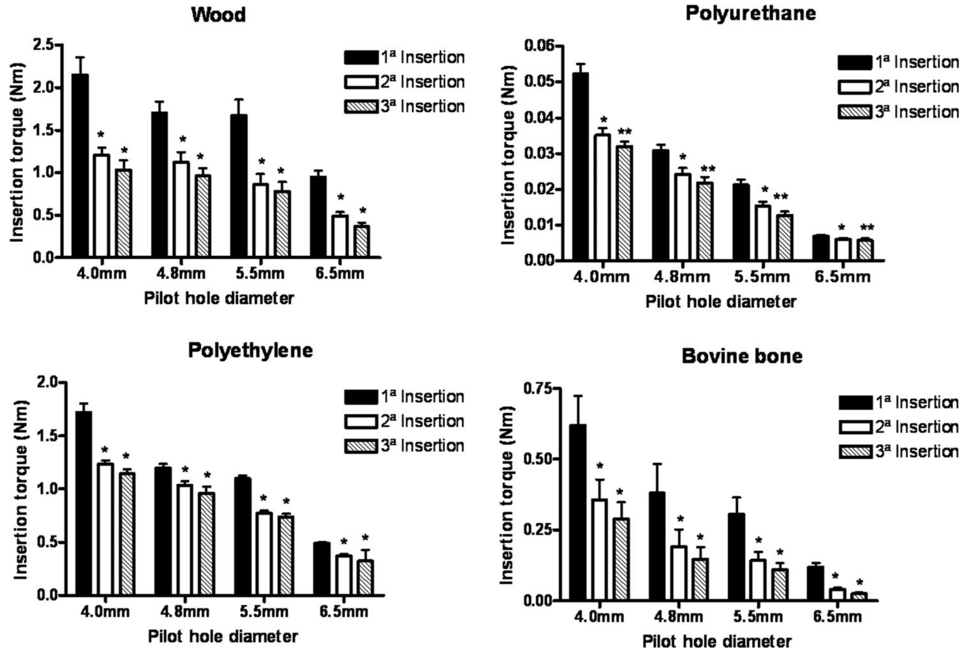

Figure 4. Histograms illustrating the insertion torque of 7-mm screws inserted into pilot holes of different diameters. The asterisk (*) indicates a statistically significant difference to values of the fist insertion into the specific diameters of the pilot hole. ** Indicates significant difference to values of first and second insertion into the specific diameters of the pilot hole.

repetitive pilot-hole use on the pullout strength of the vertebral screw have not been reported, although this surgical maneuver is performed and recommended to increase the safeness of the technique.[5,6]

Our study design presents some limitations and our results may not be totally transferred to human conditions. In fact, we do recognize that a more realistic study design should include human vertebrae. However, due to medical-legal limitations, human vertebrae are not always available in a sufficient number of specimens to carry out a proper study. Another problem regarding the use of human material is the considerable variation in bone quality that may compromise the results or cause a limitation in sample size.[6,7,18] Therefore, many researchers have employed cancellous bone or samples collected from natural or synthetic materials[12,19–21] so that a consistent and representative model could be used to replace the human vertebrae, thus allowing for a large number of trials. Furthermore, the use of different materials provides a combination of parameters that may compensate for some limitation of the model. In our investigation, the main purpose was to study the relationship between screw reinsertion and the pullout strength. The materials that received the implants differ in terms of isotropy (polyurethane and polyethylene) and anisotropy (cancellous bone and wood) and in terms of density.

Our overall results confirm intuitive acceptations, that is, reinsertion of the screws compromise the holding

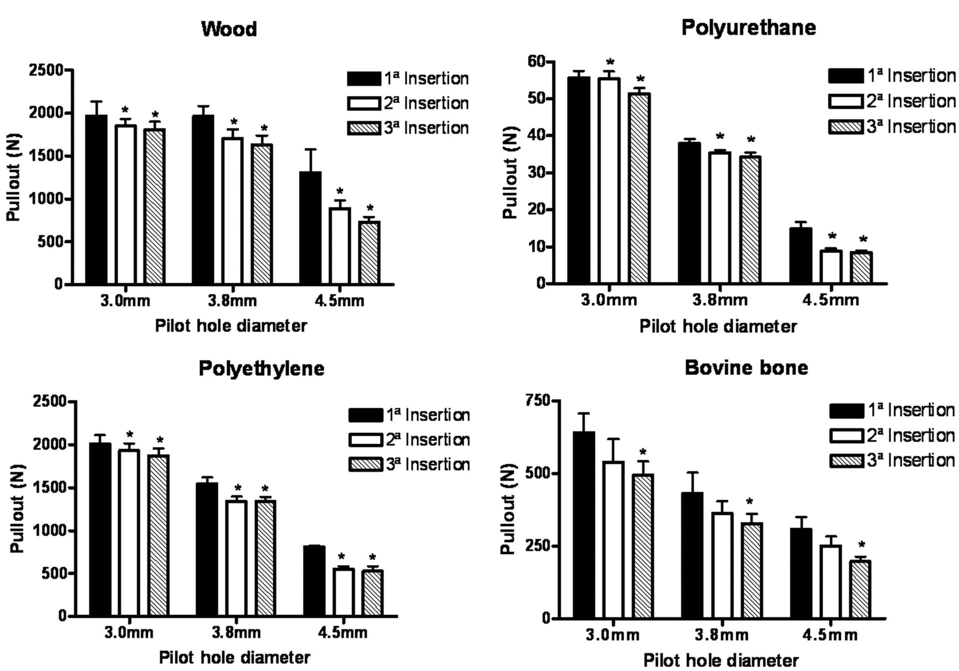

Figure 5. Histograms illustrating the pullout strength of 5-mm screws inserted into pilot holes of different diameters and different materials. The asterisk (*) indicates a statistically significant difference to values of the fist insertion into the specific diameters of the pilot hole. ** Indicates significant difference to values of first and second insertion into the specific diameters of the pilot hole.

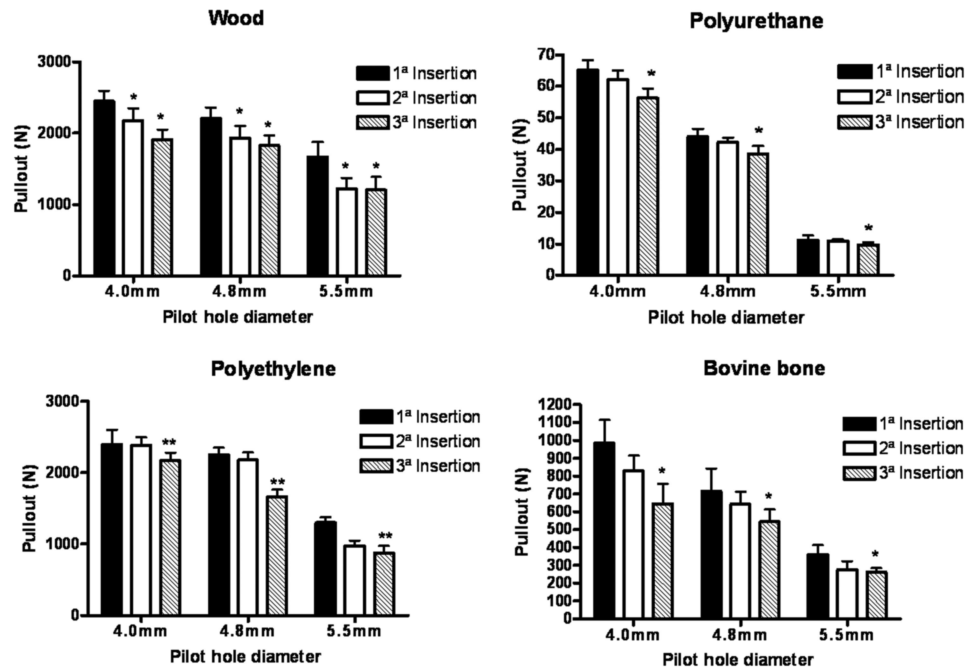

Figure 6. Histograms illustrating the pullout strength of 6-mm screws inserted into pilot holes of different diameters in different materials. The asterisk (*) indicates a statistically significant difference to values of the fist insertion into the specific diameters of the pilot hole. ** Indicates significant difference to values of first and second insertion into the specific diameters of the pilot hole.

capacity of the implant but, this side-effect may be partially compensate for using a screw with a larger outer diameter in relation do the original pilot-hole diameter. Moreover, this finding is true even when receptor materials vary in terms of homogeneity and density and, in last instance, would suggest that this is also valid for bones of different microarchitecture. Another point is the use of cancellous bone model to replicate the trabecular bone found in the vertebral body. The source of our bone blocks was the cancellous bone from the distal metaphysis, which was probed in terms of structural defects and density variation, but may present dissimilarities with the core bone of the vertebral body.

Even with the above mentioned methodologic limitations our results show very repetitive results from one material to another, thus suggesting that the results may be applicable to different bone conditions either for the pullout strength or the insertion torque. Pullout testing is thought to be a good predictor of screw fixation strength.[10] Axial pullout tests have generally been used as a method to evaluate the holding strength of various screw designs in a previous study.[15] Our results confirm the ideas that mechanical pullout strength tests illustrate the concept that the holding power of the screw is dependent on the screw major diameter, on the shearing strength of the material and pilot hole,[12,14,22] with a different behavior of the same

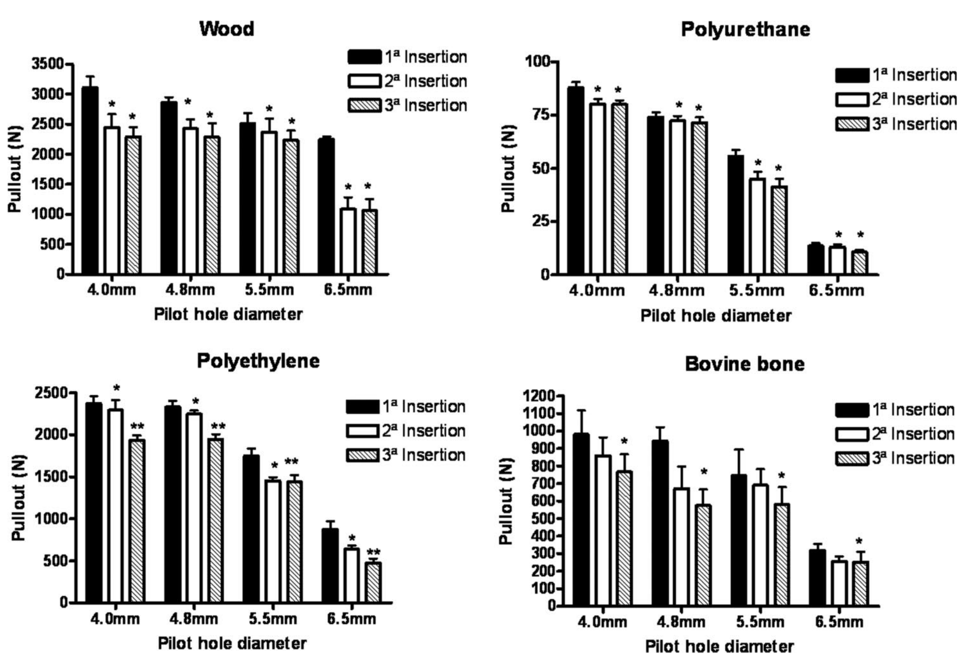

Figure 7. Histograms illustrating the pullout strength of 7-mm screws inserted into pilot holes of different diameters in different materials. The asterisk (*) indicates a statistically significant difference to values of the fist insertion into the specific diameters of the pilot hole. ** Indicates significant difference to values of first and second insertions into the specific diameters of the pilot hole.

screw being observed regarding the variables mentioned. This parameter is directly related to the holding capacity of a screw and tended to increase with reduction of the pilot-hole diameter in relation to inner screw diameter. Kuklo and Lehman[23] also observed that undertapping of the thoracic pedicle by 1 mm increased the maximal insertional torque.

The insertion torque has been considered the best predictor of ultimate screw interface failure[24] and is correlated with pullout strength.[12,24,25] The insertion torque results observed in the present study cannot be fully extrapolated to pullout strength, in agreement with other reports.[22] However, in some mechanical tests, the pullout strength of vertebral screws was evaluated on the basis of insertional torque.[12,24–27]

Our results showed that, in contrast to what has been observed in studies on cortical bone, removal and reinsertion of screws of the vertebral fixation system may reduce the pullout strength of the implants. Screw placement into and removal from the vertebra may correspond to the tapping effect on vertebral bone, which reduced the pullout strength of screws inserted into the vertebrae[28] and into synthetic materials.[29] Although tapping is desired in cortical bone, it is less desirable in cancellous bone. Cancellous bone tapping weakens the implant-bone interface, and since the vertebra essentially consists of cancellous bone, the repetitive screw-hole use may be related to weakening of the interface between cancellous bone and the screw.[22]

The insertion of the screw involves the application through the screwdriver of an end load on the screw. If the load is applied axially along the length of the screw the stress induced in the screw will be a pure compressive stress. In practice, the load is probably applied at an angle to the screw length and will introduce bending shear stress into the screw. This can be high at the start of the insertion when most of the screw length is unsupported.[30] This angular movement occurring during screw insertion may also contribute to the reduction of insertion torque and screw pullout strength after repeated insertions.

■ Key Points

- Reduction of insertion torque and screw pullout strength was observed between the first and the following insertions.
- The pattern of reduction of pullout strength was not similar to the pattern of reduction of the insertion torque.
- Insertion and reinsertion of the screws of the vertebral fixation system used in the present study reduced the insertion torque and screw pullout strength.

References

1. Pfeiffer M, Gilbertson LG, Goel VK, et al. Effect of specimen fixation method on pullout tests of pedicle screws. *Spine* 1996;21:1037–44.
2. Zhang QH, Tan SH, Chou SM. Effects of bone materials on the screw pull-out strength in human spine. *Med Eng Phys* 2006;28:795–801.
3. Daubs MD, Kim YJ, Lenke LG. Pedicle screw fixation (T1, T2, and T3). *Instr Course Lect* 2007;56:247–55.
4. Kim YJ, Lenke LG. Thoracic pedicle screw placement: free-hand technique. *Neurol India* 2005;53:512–9.
5. Foley WL, Frost DE, Tucker MR. The effect of repetitive screw hole use on the retentive strength of pretapped and self-tapped screws. *J Oral Maxillofac Surg* 1990;48:264–7.
6. Schatzker J, Sanderson R, Murnaghan JP. The holding power of orthopedic screws in vivo. *Clin Orthop Relat Res* 1975;115–26.
7. Ansell RH, Scales JT. A study of some factors which affect the strength of screws and their insertion and holding power in bone. *J Biomech* 1968;1:279–302.
8. Heller JG, Shuster JK, Hutton WC. Pedicle and transverse process screws of the upper thoracic spine. Biomechanical comparison of loads to failure. *Spine* 1999;24:654–8.
9. Seller K, Wahl D, Wild A, et al. Pullout strength of anterior spinal instrumentation: a product comparison of seven screws in calf vertebral bodies. *Eur Spine J* 2007;16:1047–54.
10. Abshire BB, McLain RF, Valdevit A, et al. Characteristics of pullout failure in conical and cylindrical pedicle screws after full insertion and back-out. *Spine J* 2001;1:408–14.
11. Carmouche JJ, Molinari RW, Gerlinger T, et al. Effects of pilot hole preparation technique on pedicle screw fixation in different regions of the osteoporotic thoracic and lumbar spine. *J Neurosurg Spine* 2005;3:364–70.
12. Daftari TK, Horton WC, Hutton WC. Correlations between screw hole preparation, torque of insertion, and pullout strength for spinal screws. *J Spinal Disord* 1994;7:139–45.
13. Bolliger N, Rossi J, Leivas T. Experimental determination of bone cortex holding power of orthopedic screw. *Rev Hosp Clin Fac Med Sao Paulo* 1999;54:181–6.
14. Defino HLA, Wich C, Shimano A, et al. Influência do diâmetro do orifício piloto na resistência ao arrancamento dos parafusos do corpo vertebral. *Acta Ortop Bras* 2007;15:76–9.
15. Wittenberg RH, Lee KS, Shea M, et al. Effect of screw diameter, insertion technique, and bone cement augmentation of pedicular screw fixation strength. *Clin Orthop Relat Res* 1993;278–87.
16. George DC, Krag MH, Johnson CC, et al. Hole preparation techniques for transpedicle screws. Effect on pull-out strength from human cadaveric vertebrae. *Spine* 1991;16:181–4.
17. Halvorson TL, Kelley LA, Thomas KA, et al. Effects of bone mineral density on pedicle screw fixation. *Spine* 1994;19:2415–20.
18. DeCoster TA, Heetderks DB, Downey DJ, et al. Optimizing bone screw pullout force. *J Orthop Trauma* 1990;4:169–74.
19. Burney MU, Mukherjee DP, Ogden AL, et al. A biomechanical study of posterior spinal instrumentation using pedicle screws with and without cross-links. *J Spinal Disord Tech* 2005;18:364–8.
20. Hsu CC, Chao CK, Wang JL, et al. Increase of pullout strength of spinal pedicle screws with conical core: biomechanical tests and finite element analyses. *J Orthop Res* 2005;23:788–94.
21. Kuhn A, Mc Iff T, Cordey J, et al. Bone deformation by thread-cutting and thread-forming cortex screws. *Injury* 1995;26:S-A12–S-A20.
22. Öktenoglu BT, Ferrara LA, Andalkar N, et al. Effects of hole preparation on screw pullout resistance and insertional torque: a biomechanical study. *J Neurosurg* 2001;94:91–6.
23. Kuklo TR, Lehman RA Jr. Effect of various tapping diameters on insertion of thoracic pedicle screws: a biomechanical analysis. *Spine* 2003;28:2066–71.
24. Zdeblick TA, Kunz DN, Cooke ME, et al. Pedicle screw pullout strength. Correlation with insertional torque. *Spine* 1993;18:1673–6.
25. Zindrick MR, Wiltse LL, Widell EH, et al. A biomechanical study of intrapeduncular screw fixation in the lumbosacral spine. *Clin Orthop Relat Res* 1986;99–112.
26. Brantley AG, Mayfield JK, Koeneman JB, et al. The effects of pedicle screw fit. An in vitro study. *Spine* 1994;19:1752–8.
27. Soshi S, Shiba R, Kondo H, et al. An experimental study on transpedicular screw fixation in relation to osteoporosis of the lumbar spine. *Spine* 1991;16:1335–41.
28. Krag MH, Beynnon BD, Pope MH, et al. An internal fixator for posterior application to short segments of the thoracic, lumbar, or lumbosacral spine. Design and testing. *Clin Orthop Relat Res* 1986;75–98.
29. Pfeiffer FM, Abernathie DL, Smith DE. A comparison of pullout strength for pedicle screws of different designs: a study using tapped and untapped pilot holes. *Spine* 2006;31:E867–E870.
30. Hughes AN, Jordan BA. The mechanical properties of surgical bone screws and some aspects of insertion practice. *Injury* 1972;4:25–38.

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