This the final peer-reviewed manuscript is made available under the CC-BY-NC 4.0 license (http://creativecommons.org/licenses/by-nc/4.0/) The published version is available via https://doi.org/10.1097/BRS.00000000002611

Pullout strength of pedicle screws following redirection after lateral or medial wall breach

Toru Maeda¹, Kosaku Higashino¹, Hiroaki Manabe¹, Kazuta Yamashita¹, Fumio Hayashi¹, Yuichiro Goda¹, Yoshihiro Tsuruo², Koichi Sairyo¹

¹ Department of Orthopaedics, Institute of Biomedical Sciences, Tokushima University Graduate School, Tokushima, Tokushima, Japan ²Department of Anatomy, Institute of Biomedical Sciences, Tokushima University Graduate School, Tokushima, Tokushima, Japan

Corresponding Author: Kosaku Higashino, MD, PhD

Department of Orthopedics, Institute of Biomedical Sciences,

Tokushima University Graduate School

3-18-15 Kuramoto-cho, Tokushima 770-8503, Japan

Tel.: +81-88-633-7240; Fax: +81-88-633-0178

Email: kosahigasino@gmail.com

Key words: pedicle screw, thoracolumbar spine, pullout strength, redirection, larger screw, malpositioned screw

Mini abstract

Redirected pedicle screws of larger diameter after a lateral or medial pedicle breach show the recovery of pullout strength. However, the pullout strength of redirected pedicle screws of the same diameter after a medial pedicle breach is significantly less than that of correctly aligned screws.

Key points

A biomechanical study was carried out using fresh cadavers.

Redirected screws are about 20% weaker than correctly aligned screws.

Redirected pedicle screws with a larger diameter show the recovery of pullout strength compared with pedicle screws of the same diameter.

Abstract

Study Design: A cadaveric biomechanical study designed to test the pullout strength of pedicle screws. Objective: To evaluate the pullout strength of redirected pedicle screws with a larger diameter following lateral wall breach, redirected pedicle screws of the same diameter following medial wall breach, and redirected pedicle screws with a larger diameter following medial wall breach. Summary of Background Data: Screw malposition is one of the main pitfalls of inserting pedicle screws. Intraoperatively a malpositioned screw is re-directed and inserted along the correct axis.

Methods: Forty-seven vertebrae (T9–L5) were harvested from 8 fresh cadaveric spines. The 18 pedicle screws that breached the lateral wall were then removed and redirected using a pedicle screw of 1 mm larger in diameter. The 16 pedicle screws that had breached the medial wall were then removed and redirected using a pedicle screw of the same diameter. The other 13 pedicle screws that had breached the medial wall were then removed and redirected using a pedicle screws that had breached.

Results: Following lateral wall breach, mean pullout strength for the larger redirected screws was 46.9% greater than that of the correctly aligned screws. Following medial wall breach, mean pullout strength for the redirected screws of the same diameter was 20.6% less than that of the correctly aligned screws. Mean pullout strength for the larger pedicle screws following medial wall breach was 27.3% more than that of the correctly aligned screws.

Conclusion: Redirected pedicle screws of larger diameter after a lateral or medial pedicle breach show recovery of pullout strength. However, the pullout strength of redirected pedicle screws of the same diameter after a medial pedicle breach is significantly less than that of correctly aligned screws.

INTRODUCTION

Pedicle screw instrumentation is used in the treatment of many spinal diseases, including spondylolisthesis, scoliosis, kyphotic deformities, fractures, and tumors(1, 2). Although pedicle screw fixation is considered stronger than many other types of instrumentation, loosening can still be a problem(3). Screw malposition, such as lateral or medial wall breach, is one of the main pitfalls. When a malpositioned screw is identified intraoperatively, the screw is often removed and then redirected and inserted along the correct axis. A previous study by our group showed that the pullout strength for redirected screws of the same diameter following lateral wall breach was 24.0% less than that of correctly aligned screws(4). The biomechanical strength of a redirected pedicle screw with a larger diameter following lateral or medial wall breach is still not known(5).

The aim of this experiment was to determine the pullout strength of a redirected pedicle screw 1 mm larger in diameter following lateral wall breach, a redirected pedicle screw of the same diameter following medial wall breach, and a redirected pedicle screw 1 mm larger in diameter following medial wall breach.

MATERIAL AND METHODS

Forty-seven thoracic and lumbar vertebrae (T9–L5) were harvested from 8 fresh frozen cadaveric spines (4 male, 4 female, mean age 76.8 [range 61–91] years at the time of death). The cadavers were stored at -20°C. None of the cadavers had any medical history of metastatic disease, metabolic bone disease, fracture, or spine surgery. All muscle, ligament, and tendon was removed, preserving the normal osseous structure. Anteroposterior and lateral spinal radiographs were checked to eliminate any vertebrae with bone abnormalities that could compromise mechanical behavior during subsequent testing. Each pedicle in the vertebrae in which pedicle screws 5.5–7.5 mm in diameter were inserted had more than 80% of the occupation ratio taken up by the screw (as seen on radiographs). The specimens were removed from the freezer one day before testing and allowed to thaw slowly to room temperature.

On one pedicle of each vertebra, the screw was inserted correctly down the axis of the pedicle, while on the other pedicle the screw was inserted to breach the lateral wall (18 vertebrae) or the medial wall (29 vertebrae). The left and right pedicles were alternated on each successive vertebra. The 18 pedicle screws that breached the lateral wall were then removed and redirected using screws 1 mm larger in diameter along the correct axis of the pedicle. Of the 29 pedicle screws that breached the medial wall, 16 were removed and redirected using screws of the same diameter along the correct axis of the

pedicle and 13 were removed and redirected using screws 1 mm larger in diameter along the correct axis of the pedicle.

Pedicle screw insertion

A Cotrel–Dubousset system (Medtronic Sofamor Danek Manufacturing, Warsaw, IN) was used with pedicle screws that were 5.5–7.5 in diameter and 50 mm in length. Each vertebra was individually prepared for insertion of the pedicle screws. A pilot hole was made by decorticating the posterior cortex at each of the left and right entry sites. A screw was inserted into each pedicle using a free-hand technique. After the screw was inserted, the position and trajectory were checked on radiographs and computed tomography (CT) images.

The same depth was prepared for each screw by using a tap. The tap for each screw was of the same diameter as the screw. The screws were inserted to a depth of 60%-70% of the anteroposterior length (as determined by radiography and CT). Each pedicle screw projected about 1.5 cm from the vertebral body. Care was taken to ensure that this projection distance was the same on both the left and right pedicles.

On successive vertebra, if the right pedicle received a correctly aligned screw and the left pedicle received a lateral or medial wall breach screw, the right-left order was reversed on the next vertebra.

Correctly aligned pedicle screws

Correctly aligned pedicle screws were inserted using a center-center technique whereby the pedicle probe was used to develop the pedicle and the pedicle screw was inserted under direct visualization. Accuracy was confirmed on radiographs and CT scans.

Lateral breach pedicle screw orientation

The entry point and screw-hole preparation were the same as those used for the correctly aligned screw. However, in this case, the inserted screw was angulated to breach laterally at the junction of the pedicle and vertebral body (Figure 1). Eighteen screws were thus inserted, and were then removed and redirected to be correctly aligned using pedicle screws that were 1 mm larger in diameter.

Medial breach pedicle screw orientation

The entry point and screw-hole preparation were the same as those used for the straightforward screw. However, in this case, the inserted screw was medially angulated so that the tip of the screw penetrated the medial pedicle wall (Figure 2). Sixteen redirected screws were thus inserted, and were then removed and redirected to be correctly aligned using pedicle screws of the same diameter. A further 13 redirected screws were similarly inserted, and were then removed and correctly aligned using pedicle screws that were 1 mm larger in diameter (Figure 3).

Radiographic assessment

Axial images parallel to each vertebral body were obtained on radiographs and CT scans. Images with the optimal pedicle diameter were selected and the following parameters were measured: (a) the transverse diameter of the pedicle width, (b) the diameter of the lateral or medial breach screw, and (c) the diameter of the redirected medial or lateral pedicle screw. Using these values, the following ratios were calculated: the pre-occupied ratio (screw diameter divided by the transverse diameter of pedicle width) and the postoccupied ratio (redirected screw diameter divided by the transverse diameter of pedicle width). The increase in the occupied ratio was calculated from the post-occupied ratio minus the pre-occupied ratio (Figures 4).

Pullout testing

A special adaptor that had been made to fit around the head of the pedicle screw was applied (see Figure 5). This adaptor was attached to the ram of the testing machine through a steel cable. Using this method, each pedicle screw was pulled out along its long axis (at a displacement rate of 12.5 cm/min), and the pullout force was recorded using a universal testing machine (AG, Shimadzu, Tokyo, Japan).

Statistical analysis

The difference in pullout strength between the straight screw and the end-plate screw was tested for statistical significance using the Mann–Whitney U test. All analyses were performed using StatView version 5.0 software (Abacus Concepts, Berkeley, CA). A p-value < 0.05 was considered to be statistically significant. This study was approved by the ethics committee of the participating university hospitals.

RESULTS

Following lateral wall breach, the mean pullout strength for the larger redirected screws was 46.9% greater than that of the correctly aligned screws (P < 0.05; Figure 6). The mean \pm standard error pullout force was 929.1 \pm 121.2 N for the redirected screws and 701.0 \pm 91.2 N for the correctly aligned screws. The correctly aligned screws were superior in pullout strength at 2/18 vertebrae and the redirected screws were superior

in 13/18 vertebrae (**Table 1**). Mean pre-occupied ratio was 82.4% and mean post-occupied ratio was 96.8%. The mean increase in the occupied ratio was 14.4%.

Mean pullout strength for the redirected screws of the same diameter following medial wall breach was 20.6% less than that of the correctly aligned screws (Figure 7). The mean pullout force was 599.7 ± 108.9 N for the redirected screws and 751.2 ± 111.3 N for the correctly aligned screws. The correctly aligned screws were superior in pullout strength in 11/16 vertebrae and the redirected screws were superior in 2/16 vertebrae (**Table 1**). The mean pullout strength for the larger pedicle screws following medial wall breach was 27.3% more than that of the correctly aligned screws (Figure 8). The mean pullout force was 876.9 ± 90.1 N for the medial wall breach screws and 747.9 ± 91.8 N for the correctly aligned screws. The correctly aligned screws were superior in pullout strength in 4/13 vertebrae and the redirected screws were superior in 8/13 vertebrae (**Table 1**). Mean pre-occupied ratio was 82.0% and mean post-occupied ratio was 95.8%. The mean increase in the occupied ratio was 13.8%.

DISCUSSION

The main results to emerge from this experiment are that there is a significant recovery of pullout strength when redirected pedicle screws with a larger diameter are used after a lateral or medial pedicle breach and a significant decrease in the pullout strength of the redirected lumbar pedicle screw following medial wall breach when compared with the correctly aligned thoracolumbar pedicle screw.

Our previous biomechanical research showed a significant decrease in the axial pullout strength of a redirected lumbar pedicle screw following lateral wall breach when compared with a correctly aligned lumbar pedicle screw(4, 5). Compared with a correctly aligned screw that penetrated the lateral wall, a redirected screw of the same diameter was 26.7% weaker(4). Some reports have suggested that the incidence of medial wall breach using percutaneously inserted pedicle screws is relatively higher than that with pedicle screws inserted via the conventional open approach(6, 7). However, the newer techniques, such as the cortical bone trajectory and percutaneous pedicle screw systems have not overcome the problem of screw malposition(8-10).

A pedicle screw that breaches the lateral wall in the lumbosacral spine may cause radicular pain and neurological deficits(11). The exact rate of pedicle breaches that occur intraoperatively cannot be gleaned from the current literature because the reported accuracy rates for pedicle screw insertion are based on postoperative assessment, including radiography and CT. Postoperative assessment does not take into account the intraoperative pedicle breaches that are detected by the surgeon and managed with a redirected screw. However, it is reasonable to assume that the rate of pedicle breaches is higher than the 1%–10% reported in the literature(12-18). Although use of an intraoperative CT scan-assisted navigation system could increase the pedicle screw accuracy rate, the radiation exposure per patient is higher for navigated surgery than for fluoroscopy-guided surgery(19).

The question then arises as to whether it would be better to choose a screw with a larger diameter after a lateral or medial pedicle wall breach providing that nerve root injury can be avoided. Regarding the aforementioned numbers and considering pullout strength alone, it may be advisable to use a larger redirected replacement screw. One biomechanics study demonstrated that an expansive pedicle screw was as effective in terms of stability as the polymethylmethacrylate-augmented pedicle screw(20).

To our knowledge, there has been no study of the pullout strength of redirected pedicle screws after lateral wall breach when screws with a larger diameter are used. Furthermore, we are unaware of any studies that have tested the pullout strength of pedicle screws after medial wall breach when redirected screws of the same or larger diameter screw are used. In this study, the mean pullout strength for redirected screws 1 mm larger in diameter following lateral wall breach was 46.9% more than that of the correctly aligned screws, and that for redirected screws of the same diameter following medial wall breach was 20.6% less than that of the correctly aligned screws. However, the mean pullout strength for the larger pedicle screws following medial wall breach was 27.3% more than that of the correctly aligned screws.

In conclusion, the results of this study suggest that the pullout strength of larger redirected pedicle screws after a lateral or medial wall breach is significantly greater than that of correctly aligned screws(4), but that the pullout strength of redirected pedicle screws of the same diameter after a medial pedicle breach is significantly less than that of correctly aligned screws.

The biomechanical strength of a pedicle screw at the end of a construct procedure is important. The findings of this study suggest that surgeons should consider choosing larger redirected screws to ensure strength and stability, with the caveat that screws with a larger diameter may cause radicular pain and neurological deficits in the patient. Clearly, ensuring that the pedicle screw is correctly aligned in the first place is the best option. REFERENCES

Boucher HH. A method of spinal fusion. J Bone Joint Surg Br. 1959;41-B(2):248 PubMed PMID: 13641310.

2. Roy-Camille R, Saillant G, Mazel C. Internal fixation of the lumbar spine with pedicle screw plating. Clin Orthop Relat Res. 1986(203):7-17. PubMed PMID: 3955999.

3. Hackenberg L, Link T, Liljenqvist U. Axial and tangential fixation strength of pedicle screws versus hooks in the thoracic spine in relation to bone mineral density. Spine (Phila Pa 1976). 2002;27(9):937-42. PubMed PMID: 11979165.

4. Goda Y, Higashino K, Toki S, Suzuki D, Kobayashi T, Matsuura T, et al. The Pullout Strength of Pedicle Screws Following Redirection After Lateral Wall Breach or End-plate Breach. Spine (Phila Pa 1976). 2016;41(15):1218-23. doi: 10.1097/BRS.000000000001600. PubMed PMID: 27046637.

5. Stauff MP, Freedman BA, Kim JH, Hamasaki T, Yoon ST, Hutton WC. The effect of pedicle screw redirection after lateral wall breach--a biomechanical study using human lumbar vertebrae. Spine J. 2014;14(1):98-103. doi: 10.1016/j.spinee.2013.03.028. PubMed PMID: 23623630.

6. Santos ER, Sembrano JN, Yson SC, Polly DW, Jr. Comparison of open and percutaneous lumbar pedicle screw revision rate using 3-D image guidance and intraoperative CT. Orthopedics. 2015;38(2):e129-34. doi: 10.3928/01477447-20150204-61. PubMed PMID: 25665118.

7. Oh HS, Kim JS, Lee SH, Liu WC, Hong SW. Comparison between the accuracy of percutaneous and open pedicle screw fixations in lumbosacral fusion. Spine J. 2013;13(12):1751-7. doi: 10.1016/j.spinee.2013.03.042. PubMed PMID: 23647827.

8. Ohkawa T, Iwatsuki K, Ohnishi Y, Ninomiya K, Yoshimine T. Isthmus-guided Cortical Bone Trajectory Reduces Postoperative Increases in Serum Creatinine Phosphokinase Concentrations. Orthop Surg. 2015;7(3):232-8. doi: 10.1111/os.12189. PubMed PMID: 26311097.

9. Wood MJ, McMillen J. The surgical learning curve and accuracy of minimally invasive lumbar pedicle screw placement using CT based computer-assisted navigation plus continuous electromyography monitoring - a retrospective review of 627 screws in 150 patients. Int J Spine Surg. 2014;8. doi: 10.14444/1027. PubMed PMID: 25694919; PubMed Central PMCID: PMC4325487.

10. Wiesner L, Kothe R, Schulitz KP, Ruther W. Clinical evaluation and computed tomography scan analysis of screw tracts after percutaneous insertion of pedicle screws in the lumbar spine. Spine (Phila Pa 1976). 2000;25(5):615-21. PubMed PMID: 10749639.

11. Amato V, Giannachi L, Irace C, Corona C. Accuracy of pedicle screw placement

9

in the lumbosacral spine using conventional technique: computed tomography postoperative assessment in 102 consecutive patients. J Neurosurg Spine. 2010;12(3):306-13. doi: 10.3171/2009.9.SPINE09261. PubMed PMID: 20192632.

12. Boachie-Adjei O, Girardi FP, Bansal M, Rawlins BA. Safety and efficacy of pedicle screw placement for adult spinal deformity with a pedicle-probing conventional anatomic technique. J Spinal Disord. 2000;13(6):496-500. PubMed PMID: 11132980.

 Lehman RA, Jr., Lenke LG, Keeler KA, Kim YJ, Cheh G. Computed tomography evaluation of pedicle screws placed in the pediatric deformed spine over an 8-year period. Spine (Phila Pa 1976). 2007;32(24):2679-84. doi: 10.1097/BRS.0b013e31815a7f13. PubMed PMID: 18007244.

14. Karapinar L, Erel N, Ozturk H, Altay T, Kaya A. Pedicle screw placement with a free hand technique in thoracolumbar spine: is it safe? J Spinal Disord Tech. 2008;21(1):63-7. doi: 10.1097/BSD.0b013e3181453dc6. PubMed PMID: 18418139.

Kosmopoulos V, Schizas C. Pedicle screw placement accuracy: a meta-analysis.
 Spine (Phila Pa 1976). 2007;32(3):E111-20. doi: 10.1097/01.brs.0000254048.79024.8b.
 PubMed PMID: 17268254.

16. Gelalis ID, Paschos NK, Pakos EE, Politis AN, Arnaoutoglou CM, Karageorgos AC, et al. Accuracy of pedicle screw placement: a systematic review of prospective in vivo studies comparing free hand, fluoroscopy guidance and navigation techniques. Eur Spine J. 2012;21(2):247-55. doi: 10.1007/s00586-011-2011-3. PubMed PMID: 21901328; PubMed Central PMCID: PMC3265579.

17. Nottmeier EW, Seemer W, Young PM. Placement of thoracolumbar pedicle screws using three-dimensional image guidance: experience in a large patient cohort. J Neurosurg Spine. 2009;10(1):33-9. doi: 10.3171/2008.10.SPI08383. PubMed PMID: 19119930.

18. Silbermann J, Riese F, Allam Y, Reichert T, Koeppert H, Gutberlet M. Computer tomography assessment of pedicle screw placement in lumbar and sacral spine: comparison between free-hand and O-arm based navigation techniques. Eur Spine J. 2011;20(6):875-81. doi: 10.1007/s00586-010-1683-4. PubMed PMID: 21253780; PubMed Central PMCID: PMC3099154.

19. Noriega DC, Hernandez-Ramajo R, Rodriguez-Monsalve Milano F, Sanchez-Lite I, Toribio B, Ardura F, et al. Risk-benefit analysis of navigation techniques for vertebral transpedicular instrumentation: a prospective study. Spine J. 2017;17(1):70-5. doi: 10.1016/j.spinee.2016.08.004. PubMed PMID: 27503262.

20. Liu D, Zhang Y, Lei W, Wang CR, Xie QY, Liao DF, et al. Comparison of 2 kinds of pedicle screws in primary spinal instrumentation: biomechanical and interfacial

evaluations in sheep vertebrae in vitro. J Spinal Disord Tech. 2014;27(2):E72-80. doi: 10.1097/BSD.0b013e318299f4b1. PubMed PMID: 23732180.

Table 1

Comparison of pullout strength of correctly aligned pedicle screws and larger redirected screws after lateral breach of the pedicle wall

	Correctly aligned	Correctly aligned	Correctly aligned =
	> redirected	< redirected	redirected screw
Redirected screw	2 screws	13 screws	3 screws
following lateral breach			
(18 vertebrae)			

Comparison of pullout strength of correctly aligned pedicle screws and redirected screws of the same size after lateral breach of the pedicle wall

	Correctly aligned	Correctly aligned	Correctly aligned =
	> redirected	< redirected	redirected
Redirected screw of the same size	11 screws	2 screws	3 screws
following lateral wall breach			
(16 vertebrae)			

Comparison of pullout strength of correctly aligned pedicle screws and larger redirected screws after medial breach of the pedicle wall

	Correctly aligned	Correctly aligned	Correctly aligned =
	> re-directed	< re-directed	redirected
Larger re-directed screw	4 screws	8 screws	1 screw
following medial breach			
(13 vertebrae)			







Figure 1 Lateral wall breach screw; The screw diameter was 6.5 mm. The lateral pedicle wall breached.
Re-directed large diameter screw; re-directed using 7.5 mm pedicle screw of 1mm larger screw was inserted a correct screw path in the intra-cortex of the pedicle.



Medial wall breach screw

Re-directed screw

Figure 2 Medial wall breach screw; The screw diameter was 5.5 mm. The medial pedicle wall breached.
Re-directed the same screw; re-directed using 5.5 mm pedicle screw was inserted a correct screw path in the intra-cortex of the pedicle.



Medial wall breach screw





Re-directed screw

Figure 3 Medial wall breach screw; The screw diameter was 6.5 mm. The medial pedicle wall breached. Re-directed larger diameter screw; re-directed using 7.5 mm pedicle screw of 1mm larger screw was inserted a correct screw path in the intra-cortex of the pedicle.











Medial wall breach screw

Re-directed screw

Figure 3 Medial wall breach screw; The screw diameter was 6.5 mm. The medial pedicle wall breached.
 Re-directed larger diameter screw; re-directed using 7.5 mm pedicle screw of 1mm larger screw was inserted a correct screw path in the intra-cortex of the pedicle.



Figure 4 Axial images parallel to each vertebral body were obtained from X-ray and Computed tomography (CT). Those of the optimal pedicle diameter were selected and the following parameters were measured: (a) transverse diameter of the pedicle width, (b) the diameter of lateral or medial breach screw (c) the diameter of redirected medial or lateral pedicle screw.





Figure 5 Screw pullout testing; the testing special adaptors were made to fit securely around the screw head.



Mann-Whitney U test, alpha=0.05

Figure 6 As compared to correctly aligned screws the mean pullout strength of re-directed large diameter screws following lateral wall breach was 46.9% more.



Mann-Whitney U test, alpha=0.05

Figure 7 As compared to correctly aligned screws the mean pullout strength of re-directed the same screws following medical wall breach was 20.6% less.



Mann-Whitney U test, alpha=0.05

Figure 8 As compared to correctly aligned screws the mean pullout strength of redirected large diameter screws following medial wall breach was 27.3% more.