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ORIGINAL RESEARCH

Screw Orientation and Foam Density Interaction in Pullout of Anterior Lumbar Interbody Fusion Plates

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ABSTRACT

Introduction: Previous studies demonstrated increases in single screw pullout strength with increases in material density. Recent anterior cervical interbody fusion plate pullout studies utilizing a polyurethane foam block model have shown that alterations in screw insertion angle from straight-in are not associated with an increase in pullout strength. The purpose of this study is to characterize the pullout strength of an anterior lumber interbody fusion (ALIF) plate when installed at various screw angles in different simulated bone densities.

Materials and methods: Ninety ALIF plate pullout tests were performed using three common screw insertion angles in polyurethane (PU) foam blocks of three densities: 0.08 g/cm^3, 0.16 g/cm^3 and 0.24 g/cm^3, simulating severely, mildly and nonosteoporotic cancellous bone, respectively. Plates were pulled out axially at 1 mm/min and pullout strength and stiffness compared.

Results: Doubling foam density yielded 2.6-fold and 3.0-fold increases ($p < 0.05$) in mean pullout strength and stiffness, respectively. Tripling foam density yielded 4.5-fold and 5.3-fold increases ($p < 0.05$) in mean pullout strength and stiffness, respectively. Screw angle placement contributed relatively less to pullout strength and stiffness compared to PU foam density.

Conclusion: In our model, ALIF plate pullout strength and stiffness appear to be more associated with increased foam block density than screw trajectory. Vertebral bone density should be a strong consideration in preoperative planning for ALIF with plating. Screw trajectory should be based on vascular anatomy and screw placement safety, rather than the classic lateral-to-medial trajectory.

Keywords: ALIF, Biomechanical, Polyurethane foam, Pullout strength, Screw angle, Spine.

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INTRODUCTION

Anterior lumbar interbody fusion (ALIF) has evolved over the last few decades to become a commonly used surgical treatment for instability, discogenic pain and spondylolisthesis.[1-3] Reducing movement within spinal motion segments facilitates bony fusion and can be achieved with transpedicular and/or anterior plate fixation.[4]

Although pedicle screw fixation has been shown to provide greater biomechanical stability in lateral bending, anterior plates have been shown to provide sufficient immobilization for fusion while obviating intraoperative repositioning of the patient and a second approach.[5-7] Anterior plate fixation in ALIF procedures has become increasingly popular over the last 7 years.[8] While the stability of lateral plates and posterior fixation has been previously studied, research regarding the stability of straight anterior plates remains relatively scarce.[7,9]

Based on biomechanical studies, screw length, screw diameter, screw thread pitch and bone density have been shown to influence construct stability.[10-14] Pullout tests, making use of cadaveric bone or foam block models, have been studied.[10,12-14] A polyurethane (PU) foam block model is advantageous because these blocks can be reproducibly manufactured to specified uniform densities.

Chapman et al[15] compared screw pullout strength using PU foam materials and cadaveric bone specimens and found that the coefficient of variance (CV) of foam (CV = 0.055) was smaller than that of bone (CV = 0.412). A PU foam model for screw pullout provides accurate and reproducible results. Furthermore, its material composition can be reliably altered to study various 'bone densities'. It has been shown that increasing foam density increases screw pullout strength.[11]

It is thought that placement of screws at an angle (i.e. inward or outward) versus straight in confers increased stability to the anterior plate construct. Despite the large body of research completed on screw pullout in a foam block model,[10,15-19] our understanding of the pullout strength of plates with multiple screws placed with varying trajectories is limited. Several studies have investigated the effect of screw orientation on plate pullout strength,[16,17] but the interaction between screw orientation and bone density has not been clearly defined.

In this study, we compared ALIF plate pullout strength using three different foam density models representing severely, mildly and nonosteoporotic bone. In addition, we used three common screw trajectories, including straight in, the classic '12° up and 6° in', and 6° up and 4° in (i.e. the trajectory of the fixed angle screws in this construct).

We hypothesized that plate pullout strength would increase with increasing density in the PU foam model and that this relationship would be maintained among the three different screw trajectories. We were interested in quantifying differences in pullout strength between groups and comparing those differences to variations in foam density.

MATERIALS AND METHODS

Closed-cell PU foam blocks of low density (0.08 g/cm^3), medium density (0.16 g/cm^3) and high density (0.24 g/cm^3) (Sawbones, Inc, Vashon, WA) were used to model severely osteoporotic, mildly osteoporotic and normal cancellous bone respectively.[18] The PU foam was purchased in blocks with original dimensions of 180 × 130 × 40 mm. For each density, three smaller, identical blocks measuring 60 × 130 × 40 mm were used and pull-out tests were performed on each long face of a block. Self-tapping, titanium alloy screws (20 × 6.0 mm) were used to affix the ALIF plate (LANX, Inc., Broomfield, CO) onto the foam block.

Custom insertion guides were used to ensure proper screw placement. Pilot holes were drilled at the desired trajectories including, 0° in both the sagittal and coronal directions, 12° diverging in the sagittal direction and 6° converging in the coronal direction, and 6° diverging in the sagittal direction and 4° converging in the coronal direction. The screws were then inserted into the predrilled holes by a single investigator and tightened to a predetermined torque for each respective foam density. One group at each of the three screw trajectories was tested in each of the three different density PU foam models.

After the ALIF plate was affixed, two clamps were used to secure the foam block in place. The plate was then attached to the actuator of a servo-hydraulic materials testing machine (Model 8521, Instron, Norwood, MA) (Fig. 1). A rod that threaded into the center plate hole was used to ensure uniform delivery of an axial load throughout testing.

A preload of 50 N was applied to the plate that was subsequently pulled out at a rate of 1 mm/min.[16,17] Load and displacement data were obtained during each test. Maximum pullout force was defined as the maximum load recorded prior to screw failure. Stiffness was calculated using the slope of the linear region of the load-displacement curve before yield. Ten samples were tested in each group. Two-factor ANOVA and one-way ANOVA with Tukey multiple comparison tests were performed to compare groups (SPSS, version 18).

RESULTS

Load-displacement curves were plotted for each of the three different foam density models (Fig. 2). The maximum pullout load was significantly higher ($p < 0.05$) for each increase in foam density (Fig. 3, Table 1). The average pullout strength was 289 ± 10 N for the low density foam, 873 ± 88 N for the medium density foam and 1518 ± 127 N for the high density foam. This corresponds to a 3.0-fold increase in pullout strength for a two-fold increase in foam density and a 5.3-fold increase in pullout strength for a three-fold increase in foam density (Fig. 3).

This relationship between pullout strength and foam density was maintained within each screw trajectory group (Table 1). Although significant differences were found between the 0° × 0° and 6° × –4° groups in the low density foam ($p < 0.05$), and the 6° × –4° and 12° × –6° groups in the medium density foam ($p < 0.05$), these were only on the order of 4 and 12% respectively.

Stiffness also increased with increased foam density ($p < 0.05$) (Fig. 4 and Table 2). The mean stiffness was 452 ± 34 N/mm for the low density foam, 1180 ± 150 N/mm for

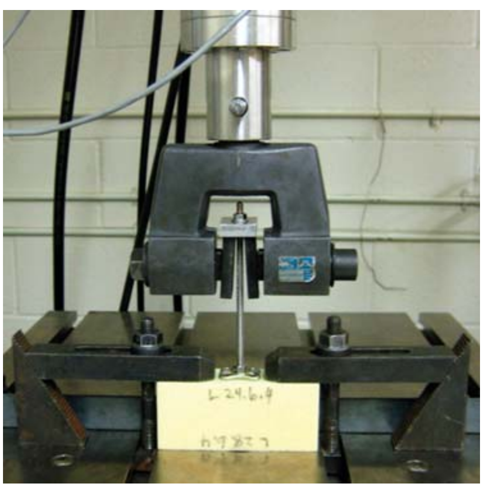

Fig. 1: Pull-out test setup. PU foam block with ALIF plate affixed by screws and secured by clamps. Threaded rod was inserted into center hole of ALIF plate to ensure uniform axial load

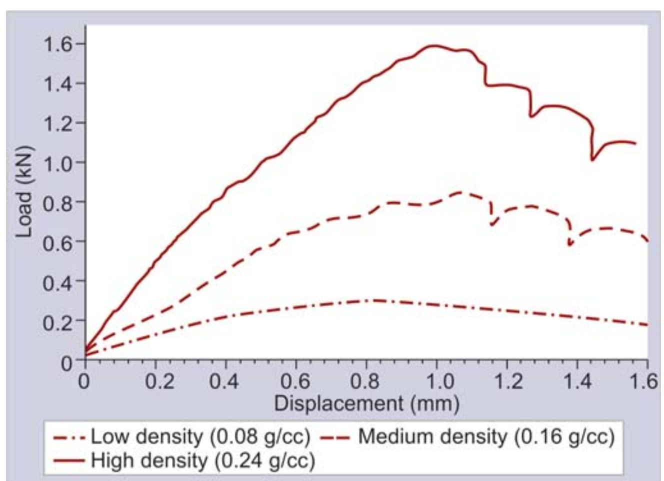

Fig. 2: Representative load-displacement curves for the straight in configuration in each of the three different foam density models. With higher densities, the area under the curve increases signifying increasing stiffness

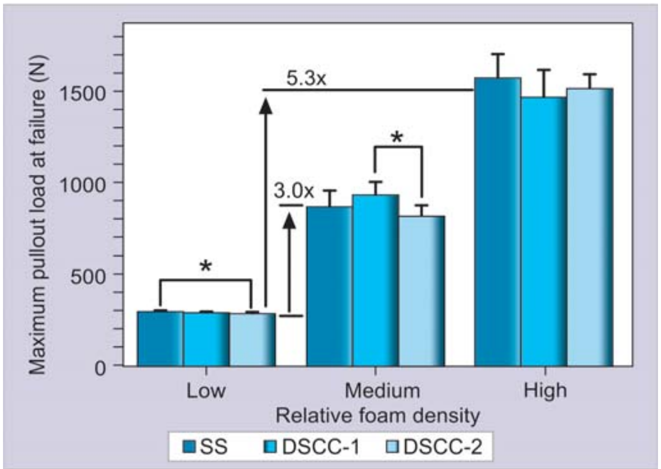

Fig. 3: Mean maximum pullout loads at failure (N) for each screw position and foam density (* = $p < 0.05$). SS = straight in, DSCC-1 = 12° diverging sagittal and 6° converging coronal, DSCC-2 = 6° diverging sagittal and 4° converging coronal. Low = 0.08 g/cm^3, Medium = 0.16 g/cm^3, and High = 0.24 g/cm^3

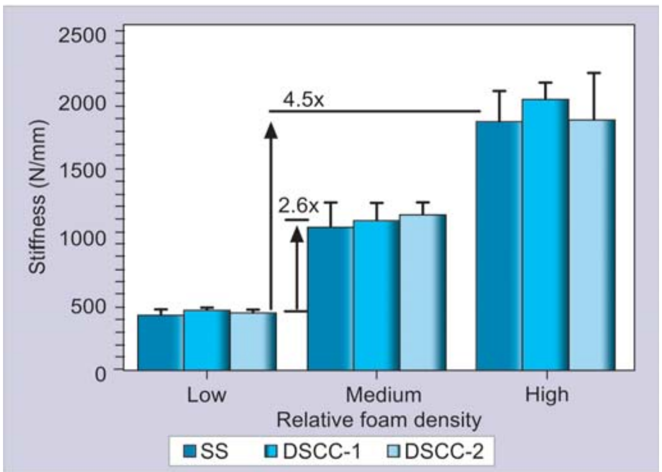

Fig. 4: Stiffness (N/mm) for each screw position and foam density (* = $p < 0.05$). SS = straight in, DSCC-1 = 12° diverging sagittal and 6° converging coronal, DSCC-2 = 6° diverging sagittal and 4° converging coronal. Low = 0.08 g/cm^3, Medium = 0.16 g/cm^3, and High = 0.24 g/cm^3

the medium density foam and 2027 ± 279 N/mm for the high density foam. Similar to the trend with pullout strength, this corresponds to a 2.6-fold increase in stiffness between the low and medium density foam, and a 4.5-fold increase in stiffness between the low and high density foam.

DISCUSSION

This study was performed to better define the influence of matrix density on ALIF plate pullout strength and stiffness with varying screw trajectories using a PU foam model. Our results confirmed our hypothesis that plate pullout strength and stiffness increases with foam density. In addition, the trend in pullout strength and stiffness with increases in matrix density was maintained among the three different screw trajectories. In some cases, a significant increase in pullout strength was obtained by varying the screw trajectory. However, these increases were relatively small and inconsistent across the varying matrix densities.

DiPaola et al[17] observed the pullout force of an anterior cervical plate from 0.16 g/cm^3 PU foam to be about 100 N ($p \leq 0.005$) higher when variable angle screws were placed straight into the foam as opposed to when the screws were placed 12°up and 12°in. The difference in pullout between different screw trajectories that DiPaola et al observed in their study, however, was similar to the difference in pullout seen in different screw trajectories in the present study, in that they were much smaller than the difference in pullout observed between densities. Other variables shown to change pullout strength include screw length, screw major diameter and screw thread pitch.[10-12,14,19] Increasing plate pullout strength and stiffness through manipulation of these factors is limited, as these variables are largely controlled by the manufacturer or vertebral anatomy of the patient.

Table 1: Pull-out loads (N) (mean ± SD)

Foam density	*Screw position*		
	0° sagittal, 0° coronal (N = 10 in each density)	*12° diverging sagittal, 6° converging coronal (N = 10 in each density)*	*6° diverging sagittal, 4° converging coronal (N = 10 in each density)*
0.08 g/cm^3	296 ± 9	286 ± 10	284 ± 8
0.16 g/cm^3	868 ± 86	936 ± 72	816 ± 66
0.24 g/cm^3	1571 ± 133	1468 ± 147	1515 ± 76

Table 2: Stiffness (N/mm) (mean ± SD)

Foam density	*Screw position*		
	0° sagittal, 0° coronal (N = 10 in each density)	*12° diverging sagittal, 6° converging coronal (N = 10 in each density)*	*6° diverging sagittal, 4° converging coronal (N = 10 in each density)*
0.08 g/cm^3	435 ± 42	467 ± 28	454 ± 25
0.16 g/cm^3	1130 ± 200	1191 ± 130	1220 ± 102
0.24 g/cm^3	1968 ± 258	2127 ± 152	1985 ± 380

In the preoperative ALIF planning stage for an osteoporotic patient, it is important to consider all means by which plate stability can be increased. As demonstrated in this study, increased matrix density contributes to improved ALIF plate pullout strength and stiffness. These data support the use of cement augmentation in some cases to increase matrix density.[20,21]

Additionally, consideration should be given to bone density variation within an individual vertebral body and the effect of trabecular disruption with age, that begins in the vertebral body center.[22] Strategic screw placement near or engaging with the vertebral body endplate may provide another surgeon-controlled means to enhance ALIF construct stability. Lowe et al[23] showed that a juxta-endplate screw with a staple had greater toggle resistance than a centrally placed vertebral body screw with a staple.

Horton et al[24] also demonstrated that screw position within the vertebral body influences fixation strength. Previous pullout studies of cervical plates in PU foam models, however, do not indicate that altering the screw position from 'straight in' increases construct stability.[16,17] This apparent discrepancy may be a result of the relative density homogeneity within each PU foam block specimen compared to the heterogeneous composition of cadaveric vertebral specimens.

A limitation of this study is the use of PU foam specimens rather than human vertebral specimens for biomechanical testing. Although PU foam does allow for increased homogeneity between specimens, the internal composition of each foam block may not adequately represent that of a human vertebral body. Another limitation of the current study is our use of only one type of plate. Indeed, other anterior lumbar plates may behave differently. Finally, while pullout testing in our PU foam model allows for a straight forward comparison of relative construct stabilities, it differs from *in vivo* construct failure, which more commonly involves cyclic loading mechanisms.

CONCLUSION

Our results suggest that matrix density (i.e. PU foam) has a greater impact on overall ALIF plate stability than screw position. This emphasizes the importance of preoperatively assessing whether or not a patient has adequate bone density to undergo an ALIF procedure. Screw position should be based on vascular anatomy and safety rather than on the traditional lateral-to-medial trajectory.

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REFERENCES

1. Li J, Dumonski ML, Liu Q, Lipman A, Hong J, Yang N, et al. A multicenter study to evaluate the safety and efficacy of a stand-alone anterior carbon I/F cage for anterior lumbar interbody fusion: Two-year results from a Food and Drug Administration investigational device exemption clinical trial. Spine 2010;35:E1564-70.
2. Mayer HM. The ALIF concept. Eur Spine J 2000; 9(Suppl 1):S35-43.
3. Mannion RJ, Nowitzke AM, Wood MJ. Promoting fusion in minimally invasive lumbar interbody stabilization with low-dose bone morphogenic protein-2-but what is the cost? Spine J 2011;11:527-33.
4. Burkus JK. Intervertebral fixation: Clinical results with anterior cages. Orthop Clin North Am 2002;33:349-57.
5. Nichols TA, Yantzer BK, Alameda S, Johnson WM, Guiot BH. Augmentation of an anterior lumbar interbody fusion with an anterior plate or pedicle screw fixation: A comparative biomechanical in vitro study. J Neurosurg Spine 2007;6: 267-71.
6. Tzermiadianos MN, Mekhail A, Voronov LI, Zook J, Havey RM, et al. Enhancing the stability of anterior lumbar interbody fusion: A biomechanical comparison of anterior plate versus posterior transpedicular instrumentation. Spine 2008;33: E38-43.
7. Beaubien BP, Derincek A, Lew WD, Wood KB. In vitro, biomechanical comparison of an anterior lumbar interbody fusion with an anteriorly placed, low-profile lumbar plate and posteriorly placed pedicle screws or translaminar screws. Spine 2005;30:1846-51.
8. Aryan HE, Lu DC, Acosta FL Jr, Ames CP. Stand-alone anterior lumbar discectomy and fusion with plate: Initial experience. Surg Neurol 2007;68:7-13.
9. Beaubien BP, Mehbod AA, Kallemeier PM, Lew WD, Buttermann GR, Transfeldt EE, Wood KB. Posterior augmentation of an anterior lumbar interbody fusion: Minimally invasive fixation versus pedicle screws in vitro. Spine 2004;29: E406-12.
10. DeCoster TA, Heetderks DB, Downey DJ, Ferries JS, Jones W. Optimizing bone screw pullout force. J Orthop Trauma 1990;4:169-74.
11. Dvorak MF, Pitzen T, Zhu Q, Gordon JD, Fisher CG, Oxland TR. Anterior cervical plate fixation: A biomechanical study to evaluate the effects of plate design, endplate preparation, and bone mineral density. Spine 2005;30:294-301.
12. Hitchon PW, Brenton MD, Coppes JK, From AM, Torner JC. Factors affecting the pullout strength of self-drilling and self-tapping anterior cervical screws. Spine 2003;28:9-13.
13. Pitzen T, Barbier D, Tintinger F, Steudel WI, Strowitzki M. Screw fixation to the posterior cortical shell does not influence peak torque and pullout in anterior cervical plating. Eur Spine J 2002;11:494-99.
14. Zhang QH, Tan SH, Chou SM. Investigation of fixation screw pull-out strength on human spine. J Biomech 2004;37:479-85.
15. Chapman JR, Harrington RM, Lee KM, Anderson PA, Tencer AF, Kowalski D. Factors affecting the pullout strength of cancellous bone screws. J Biomech Eng 1996;118:391-98.
16. DiPaola CP, Jacobson JA, Awad H, Conrad BP, Rechtine GR 2nd. Screw pull-out force is dependent on screw orientation in an anterior cervical plate construct. J Spinal Disord Tech 2007;20:369-73.

17. DiPaola CP, Jacobson JA, Awad H, Conrad BP, Rechtine GR 2nd. Screw orientation and plate type (variable- vs. fixed-angle) effect strength of fixation for in vitro biomechanical testing of the Synthes CSLP. Spine J 2008;8:717-22.
18. Patel PS, Shepherd DE, Hukins DW. Compressive properties of commercially available polyurethane foams as mechanical models for osteoporotic human cancellous bone. BMC Musculoskelet Disord 2008;9:137.
19. Conrad BP, Cordista AG, Horodyski M, Rechtine GR. Biomechanical evaluation of the pullout strength of cervical screws. J Spinal Disord Tech 2005;18:506-10.
20. Sarzier JS, Evans AJ, Cahill DW. Increased pedicle screw pullout strength with vertebroplasty augmentation in osteoporotic spines. J Neurosurg 2002;96(3 Suppl):309-12.
21. Steens J, Verdonschot N, Aalsma AM, Hosman AJ. The influence of endplate-to-endplate cement augmentation on vertebral strength and stiffness in vertebroplasty. Spine 2007;32:E419-22.
22. Mosekilde L. Vertebral structure and strength in vivo and in vitro. Calcif Tissue Int 1993;53 (Suppl 1):S121-25; discussion S5-6.
23. Lowe T, O'Brien M, Smith D, Fitzgerald D, Vraney R, Eule J, Alongi P. Central and juxta-endplate vertebral body screw placement: A biomechanical analysis in a human cadaveric model. Spine 2002;27:369-73.
24. Horton WC, Blackstock SF, Norman JT, Hill CS, Feiertag MA, Hutton WC. Strength of fixation of anterior vertebral body screws. Spine 1996;21:439-44.

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