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Biomechanical Analysis of Different Techniques in Revision Spinal Instrumentation

Larger Diameter Screws *Versus* Cement Augmentation

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Study Design. Biomechanical analysis.

Objective. To determine the relative strengths of 2 different forms of revision spinal instrumentation using a validated, constant load, cyclic testing mechanism.

Summary of Background Data. Spinal fusion with instrumentation procedures are on the rise. As such, so are revision procedures. A few studies have looked at revision instrumentation techniques. Both increased pedicle screw diameter as well as cement augmentation of pedicle screw fixation have been proposed, used clinically and tested biomechanically. To our knowledge, no comparative study exists between these techniques.

Methods. Using an instron servohydraulic loading machine, we tested pedicle screws inserted in both the anatomic (angled) and Roy-Camille (straight) insertion technique with both larger diameter (8 mm) pedicle screws, as well as standard diameter (6 mm) pedicle screws augmented with polymethylmethacrylate bone cement. Each of these techniques was subjected to constant load under cyclic conditions for 2000 cycles at 2 Hz. Computerized data collection was used at all time points. Comparisons were made between primary instrumentation data (previously published) and large diameter screws for revision. Further comparisons were made between large diameter screws and cement augmented screws.

Results. The larger diameter screws compared with the cement augmented screws showed significant differences in: initial stiffness with straight insertion technique ($P < 0.01$), stiffness damage with straight insertion technique ($P < 0.01$), and creep damage with straight insertion technique ($P = 0.01$). There was also a significant difference between large diameter and primary instrumentation technique all calculated values ($P </= 0.05$).

Conclusion. The larger diameter screws were equivocal or significantly more resilient than the cement augmented standard diameter screws at the strongest of the insertion angles for all values. Since rigidity of the instrumentation construct is one of the very few factors that is surgeon controlled, this could influence the choice of instrumentation in revision spinal arthrodesis.

Key words: biomechanics, revision, pedicle screw, cement augmentation, cyclic loading. **Spine 2008;33: 2618–2622**

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Pedicle screw instrumentation has become the standard for stabilization of the posterior lumbar spine. The technique was first described by Boucher in 1959[1] and later refined by Roy-Camille[2,3] in his European work. Segmental pedicle screw instrumentation has been widely validated in numerous biomechanical studies and has now become the standard for stabilization of the lumbar spine in all types of applications.

The biomechanical studies that have examined pedicle screw fixation have generally used pullout strength as their measure of strength and durability.[4–8] Failure by pure pullout is very rarely described in the clinical setting for lumbar pedicle screws. Loosening due to fatigue loading and screw breakage are much more commonly cited reasons for failure.[9–11] The few study designs that used cyclic loading to test their constructs used constant displacement testing rather than constant load testing to evaluate rigidity and strength of the constructs.[11] Based on our group's previous work,[12] as well as the work of others,[10] constant load testing is a more clinically applicable testing mode. Our group's previous work validated a refined load control cyclic loading technique to evaluate the relative biomechanical properties of differing pedicle screw insertion angles in the lumbar spine.[12] This study determined that pedicle screw insertion nearly perpendicular to the coronal and sagittal axes of the vertebrae, using a 3 point fixation approach, results in a more stable pedicle-screw construct. The angled screw insertion technique resulted in more scattered values of damage indicating that the outcome from the angled screw fixation is less predictable. This validates the use of this technique to implant pedicle screws across the axis of the pedicle rather than along the axis, and has broad implications in instrumented posterior lumbar spinal surgery.

As the indications and application of pedicle screw constructs widen, the number of failures requiring revision will likewise increase. Many studies, both clinical and biomechanical, have evaluated methods of securing and improving screw purchase in a revision pedicle screw circumstance.[11,13–15] The 2 most commonly used methods include augmenting the screw tract with polymethylmethacrylate (PMMA) to increase bony purchase or to increase the diameter of the pedicle screw itself. Both PMMA screw tract augmentation as well as larger diameter pedicle screws have been tested and found to be biomechanically stronger than primary pedicle screw instrumentation. As with the literature testing primary instrumentation, most of these models used pullout strength as their testing mode.[7,8,13–16] Wittenberg and colleagues[11] used a cyclic model to test the differences between PMMA augmented screws and larger diameter screws. Again, as with the primary instrumentation literature, a constant displacement model was used.

Our intent with the current study was to examine the biomechanical differences between these two most frequently used methods of revision pedicle screw insertion using a cyclic load control model.

■ Materials and Methods

Specimen Preparation and Screw Implantation: Large Diameter Screw

Five fresh frozen cadaveric spines were obtained (4 male, 1 female, average age 67 year). Gender, age, corresponding medical comorbidities, and cause of death were documented. None had a history of metastatic disease. The vertebral bodies of L3, L4, and L5 were dissected free of soft tissue and were disarticulated from their corresponding segments. All disc material was removed and the endplates were cleaned. One of the L5 vertebral bodies had been damaged during cadaveric extraction and was removed from our sample group, resulting in a total of 14 specimens for testing. Fluoroscopic imaging confirmed absence of pathologic process other than osteoarthrosis, which was evident in 3 of the 5 specimens. Computer tomography confirmed the absence of underlying bony disease as well as the lack of cortical penetration of any of the primary screw tracts. Computer tomography reconstructed images also confirmed that adequate space was available along each tract for the insertion of a screw 2 mm larger than the first.

The vertebral bodies previously used in our primary instrumentation study[12] were examined here (1 specimen was lost due to experimental error resulting in n = 11). Primary instrumentation consisted of fluoroscopic visualization in the axial, sagittal, and coronal planes to determine the appropriate insertion point for each respective pedicle. Using a drill press and a 2.7 mm drill bit, a pilot hole was made in each pedicle for the straight and angled approaches. Using these pilot holes and fluoroscopic guidance, 6.0 mm Schantz screws (Synthes, Paoli, PA) were then inserted by hand. On completion of all straight and angled pedicle screw insertion, axial, sagittal, and coronal images were once again obtained to confirm placement of the screws within the pedicle and vertebral body. No specimens experienced cortical disruption of the pedicle wall or the anterior cortex of the vertebral body. Following testing of the primary instrumented specimens, examination of these vertebrae revealed that they loosened and "failed" by levering about the intact outer cortex, thus widening the cancellous channel and decreasing overall purchase.

For this study, the first round of testing on each vertebral body involved the insertion of the larger diameter pedicle screws (8 mm *vs.* 6 mm in the primary study) into the screw tracts from the primary instrumented specimens. Each vertebral body was held in a vice apparatus as previously described. A depth gauge was used to determine the depth of insertion of each screw hole. This depth was then transferred as a mark onto the 8 mm screws and the screws were then inserted to that depth. Each vertebral body was then subject to the first round of testing.

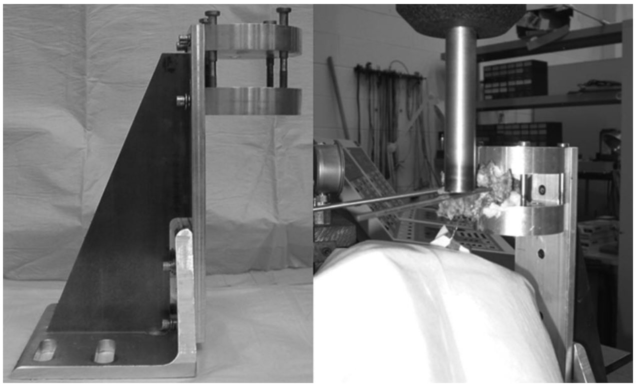

Figure 1. Left, Custom fixture used to grip vertebral specimens. Right, Picture of specimen potted in custom fixture placed in Instron for testing.

Biomechanical Testing

Using the same custom fixture as in our previous study (Figure 1), the vertebral bodies were held in place and PMMA (Zimmer, Warsaw, IN) bone cement was used to pot each specimen.[12] Cement was used to ensure uniform contact between the grip and the uneven vertebral endplates, to prevent motion, and to evenly distribute forces during loading. The vertebrae were placed in the grip and firmly secured, while the cement was in the doughy state. Each specimen was placed in an upright anatomic orientation and care was taken to prevent contact of the inferior or superior facets with the grip. On instrumentation, each pedicle screw was marked 2 cm from the initial point of bony contact. This marker allowed for a repeatable load contact point, ultimately resulting in a consistent bending moment applied to each specimen throughout testing.

Once the bone cement had cured (20 min at room temperature according to package insert), the construct was placed in a servohydraulic materials testing machine (8501 M, Instron, Canton, MA) for fatigue testing (Figure 1). Specimens were maintained at room temperature and were kept moist throughout testing. A cylindrical loading rod attached to a load cell was then aligned with the screw such that the point of contact was at the 2 cm mark. The cylinder was brought down to the screw until initial contact was made. The load control testing protocol was programmed for 2000 cycles at 2 Hz, with a peak load of 50 N and a load ratio $R = 0.1$ (min 5 N/max 50 N). A haversine waveform was used for compression in a caudal direction. Neither preconditioning nor tensile load were used. Data were acquired at a rate of 100 Hz.

Specimen Preparation and Screw Implantation: PMMA Augmentation

On completion of the large diameter screw testing, the screws were carefully removed to avoid damage to the vertebral bodies. A second batch of PMMA was mixed and allowed to assume a doughy consistency (6 min of hardening at 75 F). The cement was then loaded into a Toomey syringe and injected into the empty 8 mm screw tracts until significant resistance was met, completely filling the tracts. Although still in this doughy state, 6 mm Schantz screws (identical to those used in our primary instrumentation study) were carefully inserted into the cement so as not to toggle the screws or enlarge the hole. Screws were inserted to the previously mentioned 2 cm depth as indicated by a mark on the Schantz screw. Once the bone cement had cured, biomechanical testing was performed on the

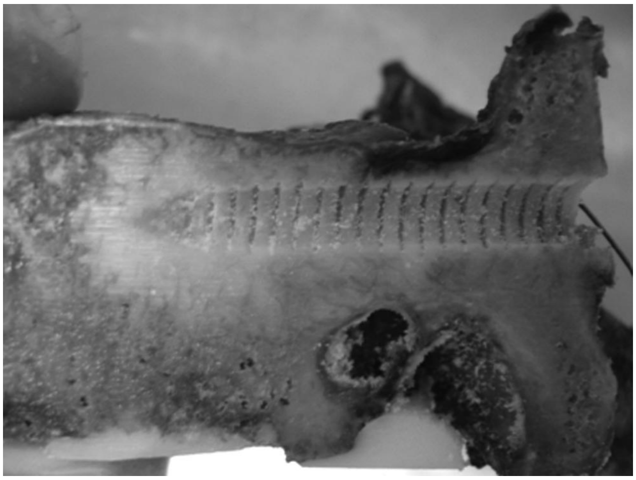

Figure 2. Sample vertebra showing complete interdigitation of PMMA into the cancellous bone as well as absence of cortical penetration.

PMMA augmented screws using the same protocol previously described. At the completion of all testing, each vertebrae was sectioned with a fine kerf bladed band saw directly along the screw paths to determine the cement penetration as well as to verify the screw depths (Figure 2).

Data Analysis

Initial stiffness, stiffness damage, creep damage, and total damage were the variables used for comparison of the 2 techniques. Undamaged initial secant stiffness was measured by dividing the applied force (50 N) by the maximum displacement at the first cycle. Stiffness damage was determined by subtracting the amount of cyclic displacement at the first loading cycle from that for the last cycle, as previously described.[13] Creep damage was defined as the displacement at the minimum applied load (5 N) in the last cycle. Note that the change in displacement due to change in stiffness was used as a measure of stiffness damage, rather than the change in stiffness, to compare with creep damage. Total damage was calculated as the sum of the stiffness and creep damage. Differences between the primary, large-diameter, and cement augmentation screws were examined using a mixed-model analysis. Each vertebra was introduced as a subject (random effect) with screw placement (straight or angled) and revision type (primary, secondary, *i.e.*, large-diameter screw or tertiary, *i.e.*, cemented augmentation) as fixed effects. For the analysis of stiffness, pre- and postfatigue status was introduced as an additional effect (with levels of initial and final stiffness). When a significant effect was found, *post hoc* analysis was performed using Tukey's HSD test (or Student t test if the effect has binary levels). All statistical analyses were performed using JMP software (SAS Institute Inc., Cary, NC) and statistical significance was set at $P < 0.05$.

Results

The mixed-model analysis of variance resulted in revision and pre/post fatigue effects as being significant ($P < 0.0001$, $P < 0.02$), while screw placement and all interactions being nonsignificant ($0.13 < P < 0.80$) on stiffness. Elimination of nonsignificant effects and interactions from the model did not change this result. The *post hoc* analysis revealed that large diameter screw fixation was stiffer than cement augmentation in values of both initial and final stiffness ($P < 0.05$, Figure 3). Similarly, cement augmentation was greater in initial and final stiffness when compared with primary instrumented screw fixation ($P < 0.05$, Figure 3). Further, final stiffness was found to be greater than initial stiffness ($P < 0.05$) within each respective test condition (primary, large diameter, cement augmentation).

As the resulting statistical analysis found no significant interaction, the difference between initial and final stiffness does not depend on which condition is present (primary, large diameter, or cement augmentation). Equally, the difference between conditions does not de-

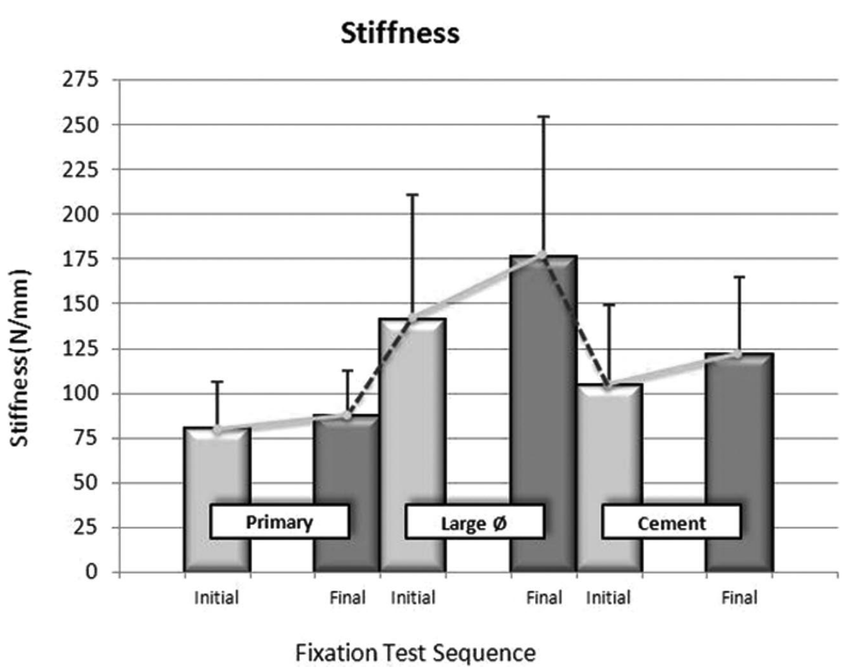

Figure 3. Initial and final stiffness values for primary, large diameter, and cement augmented screws.

Table 1. Creep Damage, Stiffness Damage, and Total Damage Values for Primary, Large Diameter, and Cement Augmented Screws

Fixation	Screw Insertion	Creep Damage	Stiffness Damage	Total Damage
Primary	Straight	0.430 ± 0.370	−0.032 ± 0.051	0.398 ± 0.380
	Angled	0.673 ± 0.920	0.017 ± 0.049	0.690 ± 0.960
Large	Straight	0.196 ± 0.098	−0.128 ± 0.074	0.069 ± 0.056
	Angled	0.330 ± 0.375	−0.128 ± 0.101	0.100 ± 0.079
Cement	Straight	0.386 ± 0.200	−0.271 ± 0.137	0.113 ± 0.095
	Angled	0.301 ± 0.227	−0.268 ± 0.234	0.098 ± 0.077

pend on whether initial or final stiffness is considered. These results indicate that the change from the end of one test to the beginning of the next is significant, *i.e.*, revision with the large-diameter screw makes the construct stiffer whereas revision with cement makes the construct more compliant immediately.

No differences in creep damage were present between primary, large diameter, or cement augmented fixation ($P > 0.45$, Table 1).

The effect of revision on total damage was significant ($P < 0.01$) but the effect of screw placement was not ($P > 0.54$). No significant interaction between revision and screw placement was found ($P > 0.63$). *Post hoc* analysis revealed that both large diameter and cement augmentation had less total damage than the primary fixation but a difference between the large diameter and cement augmentation was not demonstrable ($P > 0.05$, Table 1).

Lastly, we found significant correlations between stiffness damage and creep damage (Figure 4). The regressions suggested changes in stiffness with increases in creep damage, however, the sign and the slope of these regressions were different between the primary, large-diameter and cement-augmented screw revisions.

Stiffness damage increased with increasing creep damage for the primary revision (stars and solid line; SD = 0.0435 CD-0.0269; $r^2 = 0.42$, $p_{slope} < 0.002$; $p_{intercept} < 0.02$) and decreased with increasing creep damage for the large-diameter (squares and dashed line; SD = −0.309 CD-0.0607; $r^2 = 0.81$, $p_{slope} < 0.001$; $p_{intercept} < 0.004$), and cement-augmented screw revisions (circles and dotted line; SD = −0.677 CD-0.0072; $r^2 = 0.89$, $p_{slope} < 0.001$; $p_{intercept} > 0.73$). The slopes were significantly different between all cases ($P < 0.001$). Using absolute values for stiffness damage did not change the significance of regressions and comparison of slopes.

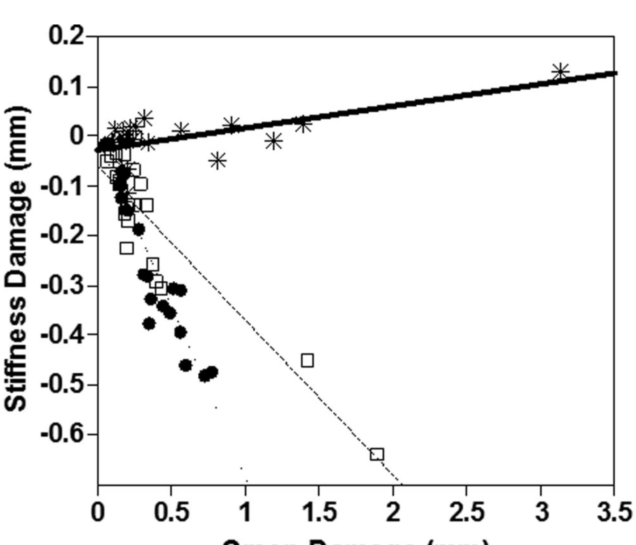

Figure 4. The correlation between stiffness damage and creep damage.

Discussion

Many studies have examined the biomechanical characteristics of primary posterior lumbar spinal fixation instrumentation. After failure of primary spinal instrumentation a method of supplementing, replacing or augmenting the screw purchase must be used to secure adequate purchase in the vertebral body. Studies designed to evaluate the biomechanical characteristics of revision instrumentation are much less common. Most of the available biomechanical studies for both primary and revision instrumentation systems use pullout strength as the determinant of failure. This is felt to poorly mimic the mechanism of failure of pedicle screw constructs *in vivo*.

In a study that most closely mirrors ours, Wittenberg *et al*[11] compared axial pullout strength and transverse bending stiffness of multiple screw diameters both with and without cement augmentation. Their transverse bending stiffness tests used a single push constant distance loading protocol to arrive at their results. In their results they found that increasing the diameter of the screw 1 mm had no significant impact on the bending stiffness of the construct. They also found that bending stiffness was significantly higher in screws augmented with PMMA.

In our present study, we conclude that larger diameter screw constructs offer a significantly more rigid construct than both the primary instrumentation construct, as would be expected, as well as the PMMA augmented screw constructs. This conclusion largely agrees with those of other authors. In the previously mentioned study by Wittenberg *et al* a single push or constant displacement technique was used, whereas in our work a constant cyclic load technique was used. We believe, as have others, that a cyclic loading technique most closely mimics the forces encountered *in vivo*, and therefore, provides a more relevant analysis of the usable biomechanical properties of these implants.

The larger-diameter screw construct also sustained less damage than the primary instrumentation construct in the current study. Although creep seems to constitute the larger portion of damage in these constructs, the difference in the total damage is largely attributable to differences in the stiffness-damage behavior. Stiffness damage is usually considered as a loss of stiffness with fatigue; however, we observed an increase in stiffness in a significant portion of our constructs. Potential mechanisms for stiffening, such as compaction of trabecular bone, were discussed in our earlier work. Our results indicate that stiffness damage is correlated with creep damage (Figure 4); however, the mechanism of stiffness damage is different between constructs.

The damage behavior in the primary revision can be explained by the creep and stiffness loss (stiffening if a state of compaction is reached) in the cancellous bone. The damage behavior in the large-diameter screw revision is likely originated from the replacement of cancellous bone with the metal and a larger and quicker involvement of pedicle bone cortex in the fatigue process. The behavior of the cemented revision would be similar to that of the large-diameter screw due to the replacement/compaction effect of the cement on cancellous bone. However, the less stiff and more viscoelastic nature of PMMA than the metal would result in reduced stiffness of the construct (Figure 3) and an increased ability to distribute creep deformations during fatigue than the large-diameter construct as suggested by the different slopes of creep damage *versus* stiffness damage regressions (Figure 4). The role of these different damage mechanisms on the longevity and failure strength of the revision as well as on the host tissue response should be further evaluated.

This study is certainly not without limitations. It is a cadaver-based biomechanics study. It therefore has all of the limitations imposed by that design. Our technique of cyclic loading is not a perfect mimic of *in vivo* spinal loading; however, we believe it to be the best model thus far. Our sample size was also small. Effects other than those found to be significant and interactions between main effects may become significant if a larger sample size is used.

A downside to this series of testing was the fact that secondary large diameter screw instrumentation was always followed by the cement augmentation technique. It is possible that further damage may have occurred during testing of the large diameter screw series, however, we believe that by using the cement augmentation after the large diameter series, the cement was adequate in filling the entire cavity caused by the large diameter screw and added further stability in a form-fitting fashion. The ideal testing conditions would alter the order in which the cement augmentation and large diameter screw series were tested; however, on insertion of the cement augmentation, it would be nearly impossible to remove this cement/screw construct without doing significant damage to the vertebral body being tested. With a larger sample size, alternating the order of application for these 2 secondary revision techniques may have been possible. Nonetheless, the distinctly different changes in the stiffness and damage behavior on application of one method compared with the other underscore the effect of revision methods rather than the cumulative effect of fatigue due to the sequential application of the revision methods.

Conclusion

This study shows that the use of larger diameter screw constructs for revision lumbar instrumentation offers a significantly more rigid construct and results in less bone damage than the primary instrumentation construct. Our data also shows that PMMA to augment screw fixation is superior to the primary constructs. Differences found in the damage behavior between constructs may be important in predicting revision success and design of new interventions.

Key Points

- Larger diameter pedicle screws offer a more rigid construct than PMMA augmented pedicle screw fixation in revision spinal instrumentation.
- PMMA augmentation does offer greater rigidity than primary instrumentation pedicle screws.
- Cyclic loading of instrumentation constructs is a useful and valid mechanism to test fixation constructs and is a more clinically relevant parameter than pull out strength.

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