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A Biomechanical Comparison Evaluating the Use of Intermediate Screws and Cross-Linkage in Lumbar Pedicle Fixation

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Summary: In lumbar fusion, controversy remains regarding the effectiveness of cross-linking and the necessity of placing pedicle screws at the intermediate levels of the segment to be fused. The purpose of this study is to evaluate the stiffness of various rod/screw constructs used to instrument a three-level fusion with specific emphasis on the effect of cross-linking and the intermediate pedicle screws. Nine lumbar calf spines were mounted at L1 and L5. Pedicle screws (TSRH, Danek, Memphis, TN) were then placed bilaterally in the L2, L3, and L4 pedicles. Random sequence testing of the following constructs was then conducted: TSRH rods connected bilaterally to the L2 and L4 pedicles with and without a cross-link, and rods connected bilaterally at the L2, L3, and L4 levels with and without a cross-link. The tests were conducted on a modified MTS testing machine (MTS, Minneapolis, MN) and consisted of cyclic application of axial load, torsion, and flexion and extension. The tests yielded axial, sagittal, and torsional stiffness values. Statistical analysis was performed using log transformation and Fischer's test of least significant difference. In axial testing the use of additional screws in the intermediate pedicles increased stiffness an average of 160% ($p = .007$). The addition of a cross-link did not increase stiffness with axial loading. In flexion testing the six-screw construct was 84% stiffer when compared with the four-screw construct ($p = 0.0001$). There was no significant change in flexion stiffness with addition of cross-links. In torsional testing the six-screw construct was 38% stiffer than the four-screw construct ($p = 0.042$). The addition of a cross-link increased stiffness an average of 69% ($p = 0.0001$, four screw) and 61% ($p = 0.0037$, six screw). Our data show the increased multiplanar stiffness of the six-screw, cross-linked TSRH construct in immobilizing a three-level lumbar segment for fusion. **Key Words:** Lumbar pedicle fixation—Intermediate screws—Cross-linkage.

Pseudoarthroses after attempted lumbar spinal fusion have plagued surgeons since the first successful lumbar fusion was described by Hibbs in 1911 (11). This has fostered extensive experimentation in fusion techniques and the development of numerous internal fixation devices over the past 15 years (5). Several investigators have shown superior immobilization with pedicle screw devices versus hook or sublaminar wire systems (3,9), and many have shown the associa-

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tion of increased fusion rates with these improved methods of immobilization (14,16,18–20). There are currently several pedicle screw systems available that provide rigid immobilization of the fusion levels. Some controversies remain regarding effectiveness of cross-linking (8,13) and the necessity of placing pedicle screws at the intermediate levels in addition to those at the cranial and caudal ends of the segments to be fused (12,13).

The purpose of this study is to evaluate the stiffness of the TSRH system in various rod/screw constructs used to instrument a three-level fusion. Specific emphasis is placed on the effect of cross-linking and the intermediate pedicle screws. The calf spine was selected as a model because it is readily available and has little interspecimen variability, and although it has some anatomic differences, many investigators agree that it is a good, uniform model for comparison with the human lumbar spine (3,7,8).

MATERIALS AND METHODS

Nine lumbar calf spines of similar size and age were harvested from fresh carcasses. Each spine was prepared by separating the L1–5 portion through the T12–L1 and L5–6 disk spaces and facet joints. The soft tissue and paraspinal muscles were removed without violating the ligaments or facet joint capsules. The specimens were then sealed in plastic and frozen at −20°C until the day of testing. On the day of testing, the specimens were thawed and mounted in jigs by placing transfixing pins across the vertebral bodies of L1 and L5 and embedding L1 and L5 in polyester resin.

Nondestructive testing was performed using a modified servohydraulic materials testing device (Bionix 858; MTS, Minneapolis, MN). Each specimen was tested intact. Pedicle screws (6.5 × 45 mm; TSRH, Danek, Memphis, TN) were then placed bilaterally in the L2, L3, and L4 pedicles using an awl, probe, and appropriately sized tap. The screws were angled medially in the transverse plane, but no attempt was made to angle up or down in the sagittal plane. Each spine was then destabilized anteriorly by dividing the annulus with a sharp knife from foramen to foramen at the L2–3 and L3–4 levels. Testing was then conducted using the following constructs: TSRH rods connected bilaterally to the L2 and L4 pedicles with and without a cross-link at the L2–3 level, and rods connected bilaterally at the L2, L3, and L4 levels with and without a cross-link at the L2–3 level. These four tests were conducted in random sequence.

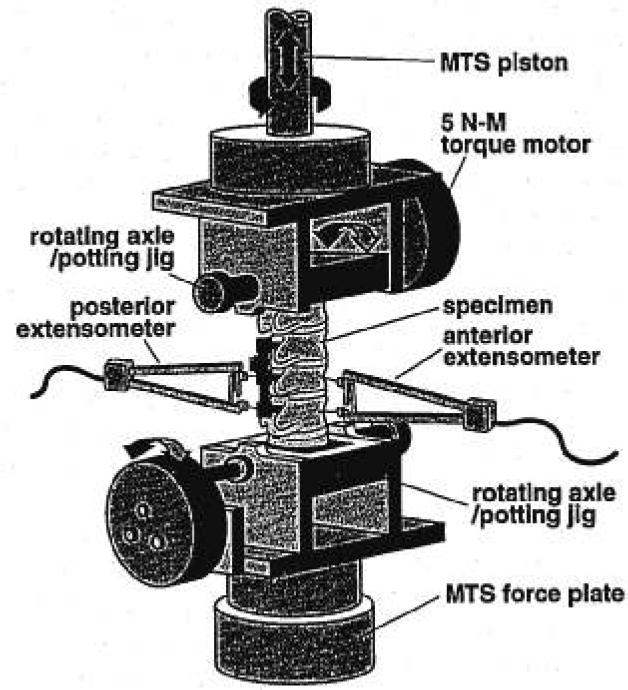

FIG. 1. Diagram of the MTS setup for testing the calf spine construct. Note the torque generators used at each end of the lumbar spine to simulate flexion and extension moments.

The tests consisted of cyclic application of load in three modes: an axial load of 200 N, a torsional moment of 5 Nm with 100 N of applied axial preload, and a 2-Nm flexion and extension moment. The materials tester was modified to allow pure moment application in sagittal rotation (flexion–extension). The superior and inferior mounting jigs were square aluminum blocks mounted in platforms. These platforms were connected to an axle and subsequently to computer-controlled electric motors, which were driven in rotation in the sagittal plane. During sagittal testing, both platforms were free to rotate, allowing application of the flexion and extension moment. The axial and torsional loads were kept at zero during sagittal testing, allowing unconstrained motion in these planes, although lateral flexion and translation were constrained. During axial and torsional testing, the spine was free to rotate or piston. However, the platforms were constrained in flexion extension, lateral flexion, and translation (Fig. 1).

Each test was performed over five full cycles of sinusoidal loading at a frequency of one cycle per 10 s. The first four cycles were regarded as conditioning cycles that allowed for stabilization of the viscoelastic properties of the spine. All data were derived from the fifth

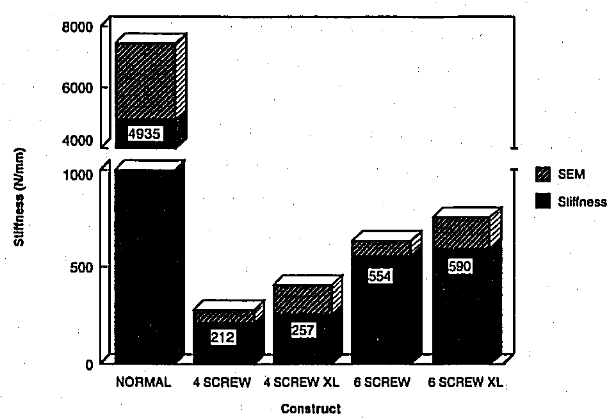

FIG. 2. Graph showing the change in stiffness and axial testing of various constructs. Note the large increase in stiffness with the addition of the intermediate pedicle screws, but minimal change with the addition of the cross-link. Shaded area is the standard error of the mean.

cycle. The data were collected on-line with the use of an IBM AT computer (Armonk, NY) and Labtech Notebook software (Version 5; Data Translation, Marlboro, MA). The data that were recorded included axial load, axial displacement, and torsional moment for each test. The sagittal torsion was recorded for the flexion–extension tests. Needle-tipped extensometers (MTS) placed anteriorly between the vertebral bodies of L2 and L4 were used to record anterior intervertebral displacement for axial and flexion–extension tests. A rotational extensometer was used to measure angular displacement during torsional testing. The data from the fifth test cycle were plotted as load-displacement curves. The slope of the neutral zone of each curve was measured with the use of a computer plotting analysis program (QuattroPro; Borland International, Scotts Valley, CA). This test yielded axial, sagittal, and torsional stiffness data. The data were averaged and log transformed to make variances more uniform. Statistical analysis was conducted by an independent statistician using an analysis of variance and Fischer's protected least significant difference test to compare means.

RESULTS

All tests were successfully completed without implant loosening or specimen failure.

In axial testing, the use of additional screws in the intermediate pedicles increased the average stiffness from 212 to 554 N/mm, an increase of 160% ($p = 0.007$). The addition of a cross-link to the four-screw construct increased the average stiffness from 212 to 257 N/mm, and a cross-link added to the six-screw construct increased the average stiffness from 554 to 590 N/mm. The increased stiffnesses in axial loading from addition of cross-links were not statistically significant ($p = 0.641$ and 0.662, respectively) (Fig. 2).

In flexion testing, the stiffness of the four-screw construct increased from 2.24 to 4.13 Nm/mm with the addition of an intermediate pedicle screw, an increase of 84% ($p = 0.0001$). There was no statistically significant change in flexion stiffness with addition of cross-links to either the four- or six-screw construct ($p = 0.999$ and 0.662, respectively) (Fig. 3).

In torsional testing, the stiffness of the four-screw construct increased from 1.19 to 1.56 Nm/degree with the addition of an intermediate pedicle screw, an increase of 38% ($p = 0.042$). The stiffness of the four-screw construct increased from 1.19 to 2.26 Nm/degree with the addition of a cross-link, an increase of 69% ($p = 0.0001$). Cross-linking the six-screw construct increased the stiffness from 1.56 to 2.59 Nm/degree, an increase of 61% ($p = 0.0037$). (Fig. 4).

DISCUSSION

The purpose of this study was to evaluate the benefits of using an intermediate pedicle screw and cross-link in a three-level lumbar fusion construct. Our data showed significant increases in stiffness in all planes tested with addition of the intermediate pedicle screw and significant increases in torsional stiffness only with addition of a cross-link.

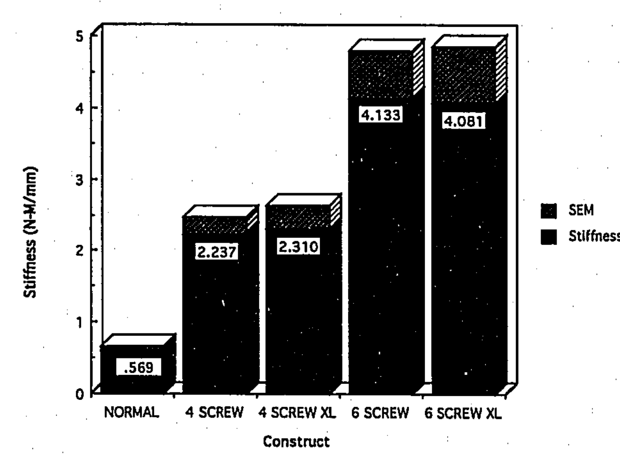

FIG. 3. Graph showing the change in stiffness with flexion testing of various constructs. Again note the large increase in stiffness with the addition of the intermediate pedicle screws, but minimal change with the addition of the cross-link. Shaded area is the standard error of the mean.

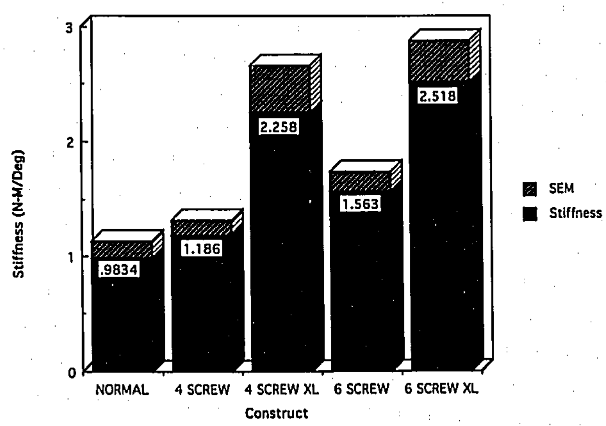

FIG. 4. Graph showing the change in stiffness with torsion testing of various constructs. Note that the addition of both intermediate screws and a cross-link gives large gains in torsional stiffness. Shaded area is the standard error of the mean.

The lumbar calf spine is a useful model for biomechanical testing. It has several anatomic differences, such as six lumbar vertebrae, persistent ring apophyses, and differences in orientation of the facet joints. Even so, many investigators agree that it has less interspecimen variability and is more readily available than the human cadaver spine (3,8,9). The specimens in this study were destabilized by dividing the annulus and disk at the L2–3 and L3–4 levels. This destabilization procedure is not clinically relevent but is actually much more unstable than most clinical conditions for which stabilization with a six-pedicle screw construct would be indicated. It represents a worst-case scenario of instability to test the various four- or six-screw constructs. A corpectomy defect would not be appropriate in this case because it would be impossible to use the intermediate pedicle screw.

The loads used in this study are relatively small when compared with loads placed on the human lumbar spine during normal activity. These loads were preferred for two reasons. Each specimen was tested without instrumentation and with four instrumentation constructs, three tests per construct, and five cycles per test for a total of 75 cycles. The use of a smaller load minimized any specimen degradation that may have occurred during testing. Additionally, the main purpose was to calculate the construct stiffness from the load-displacement curve. As long as the load remains in the elastic range, the slope of the load-displacement curve is independent of the load. Therefore, a smaller load gives equivalent information without the risk of damaging the specimen.

Significant modifications were made to the materials testing device, which allowed fewer constraints to motion during flexion–extension testing. The specimens were still constrained in anterior–posterior and lateral translation and in lateral flexion during all three modes of testing. During axial and torsional testing, the specimens were constrained in flexion–extension to prevent buckling of the specimen. A perfect testing device would be unconstrained in 5° of freedom while a load was applied in the sixth degree of freedom. The materials testing device used in this study will require further modifications to achieve complete freedom from constraints; even so, it is a significant improvement over past biomechanical testing devices.

Over the years, surgeons have noted improved fusion rates with superior immobilization. Many new techniques and hardware designs have been developed. This is evident by the changes in the design of implants, progressing from Knodt rods, Harrington rods, sublaminar wires, hooks, and semi-rigid pedicle screw and plate systems to rigid pedicle screw and rod constructs. Gurr et al. have demonstrated the superior immobilization achieved with pedicle screw devices compared with hook or sublaminar devices (9). Ashman et al. demonstrated the superior stiffness of constructs where the connecting rod or plate is rigidly connected to the pedicle screw over those that rely on bone contact for fixation of the plate or rod to the screws (3,4). McAffee et al. demonstrated higher fusion rates in animals when stiffer internal fixation devices were used (17), and Zdeblick demonstrated increased clinical fusion rates, comparing these rigid constructs to semi-rigid constructs (20). There are currently several instrumentation systems on the market that fit into this rigid category and are similar in their biomechanical properties. This study emphasizes that it is not only the design of the instrumentation but also appropriate technique in its use that can increase stiffness and improve outcomes in lumbar fusion surgery.

Pedicle screw fixation was popularized by Roy-Camille in the early 1970s and later by Steffee (18,19). It gained popularity because of its ability to control all three columns of the spine, a clear advantage over hook and wire fixation. Since its introduction, most surgeons have recommended that screws be placed in each pedicle for maximum control of each vertebral body (14,15,18,19). Horowitch reported occasionally leaving an intermediate level uninstrumented when using pedicle screws in a longer fusion (12). Recently Krag suggested that screws are only necessary in the

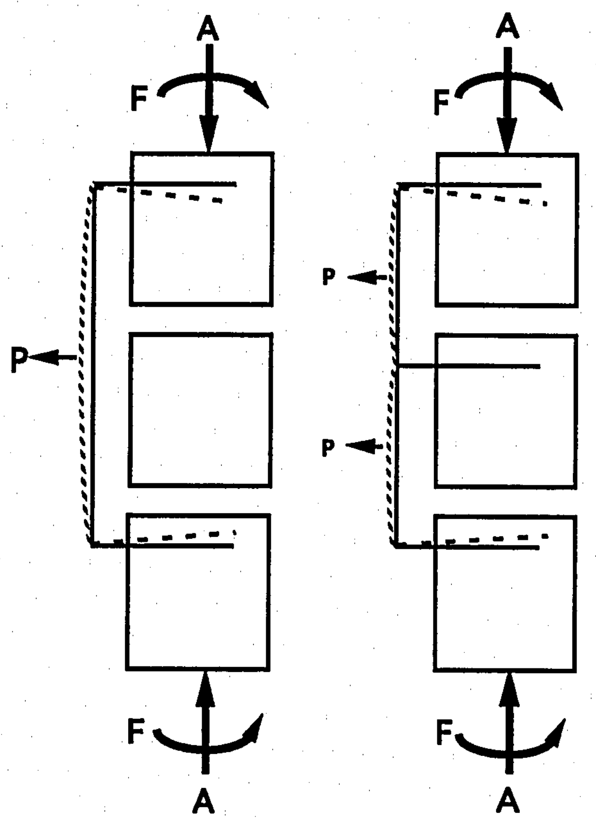

FIG. 5. Schematic diagram showing the slight flexibility of the rod, the screws, and the rod–screw coupling when the intermediate screw is left out. Addition of the intermediate pedicle screw resists the posterior motion of the rod through the intact anulus, ligaments, and facet capsules of the intermediate level. The forces are similar for both axial and flexion loading. The dotted lines demonstrate micromotion of the hardware under stress. A, axial load; F, flexion load; P, posterior force caused by the moment at the screw–rod coupling. Posterior motion of the intermediate vertebral body is not depicted but is certainly present.

top and bottom vertebrae of a fusion segment regardless of its length (13). To our knowledge, Krag's theory has not been previously tested. His theory is supported only by a low incidence of clinical hardware failure. It is based only on the forces of axial load, neglecting flexion, extension, and torsion loads. In his axial model there is no consideration of the flexibility of the rod, the screws, or the rod–screw attachment. Our data show an increased stiffness of 160% under axial load, 84% under flexion load, and 38% under torsional load when the intermediate screws are used. There is some flexibility of the rod-screw construct but this is lessened by the use of additional pedicle screws. This is true in all the planes of motion that we tested: axial, flexion–extension, and torsion (Fig. 5).

The use of a cross-linked system was first described by Armstrong and Connock in 1970. They used it to apply an additional lateral force when used with a Harrington distraction–compression system in scoliosis surgery. They reported that the cross-linked system demonstrated increases stability in axial loading compared with conventional systems (1). In 1983, Cotrel and Dubousset introduced their instrumentation with its device for transverse traction (DTT). They reported that the DTT produced a railwaylike construct that is particularly resistant to torsional stresses (7). Herndon et al. prospectively evaluated the DTT in conjunction with the Harrington compression and distraction system. They found that it did not significantly increase the amount of curve correction, but they did report a subjective increase in stability (10). Using mechanical testing, Asher et al. and Ashman et al. independently showed a significant increase in torsional stiffness when cross-links were added to Harrington/Luque constructs (2) and CD and Luque II constructs (3).

Krag has suggested that cross-linking is unnecessary if the pedicle screws are placed medially and superiorly in what he calls the "up and in" method (13). Carson partially tested this hypothesis using the Variable Screw Placement (VSP) system by testing two level constructs with and without cross-links while varying the pedicle–pedicle screw angle from 0 to 60°. He found that the constructs were more resistant to lateral shifting if the pedicle–pedicle angle was >30°, but the use of a cross-link added still more resistance regardless of the orientation of the pedicle screws (6). Both Carson and Krag have emphasized preventing lateral shift of one vertebrae on another as the major reason to angle the pedicle screws or use a cross-link (6,13). Limiting the lateral shift movement is much more important in cases of fracture–dislocation where the normal anatomy is disrupted. The spine that is not traumatically disrupted is resistant to the lateral shift motion through the action of the facet joints, longitudinal ligaments, and annulus. The physiologic motion that is most limited by the addition of a cross-link is torsional movement of one vertebral body on another (2,3,7). Our tests showed a 61–69% increase in torsional stiffness with the addition of the cross-link. With angled pedicle screws alone, the cancellous bone of the vertebral bodies must resist the lateral shifting and torsional movements. We feel that it is preferable to augment this bony resistance with the use of a rigid cross-link.

CONCLUSION

Our data clearly show the improved multiplanar stiffness of the six-screw, cross-linked TSRH con-

struct in immobilizing a three-level lumbar segment for fusion. These data in combination with those reported by McAffee lead us to expect higher fusion rates in three-level lumbar fusions when screws are placed in all six pedicles and a cross-link is used. Specifically, when sagittal instability is a concern, placing the intermediate screws is important. When torsional instability is a concern, the cross-link assumes an important role. We suggest that placing pedicle screws in each pedicle and using cross-links will lead to the most rigid construct. In cases where there is not room for both intermediate pedicle screws and a cross-link, using the intermediate pedicle screw creates a more rigid construct.

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