A Biomechanical Comparison of the US Spine™ Facet Bolt™ and Pedicle Screw Fixation

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Report Prepared by:
Lisa Ferrara, DEng.
OrthoKinetic Technologies, LLC
2790 Creekbridge Court
Southport, NC 28461
Voice: 910.253.9883
Fax: 910.253.9884
Email: orthokinetic@ec.rr.com

Testing Conducted by:
Vijay Goel, Ph.D.
University of Toledo
Toledo, Ohio

Corporate Sponsor
Trace Cawley
US Spine
3600 FAU Boulevard
Suite 101
Boca Raton, Florida 33431

1. Study Objective

The goal of this study is to compare the biomechanical performance of three fusion fixation systems in conjunction with interbody graft.

TEST GROUPS:

1. Intact
2. Novel Facet Bolt Implants, bilateral
3. Pedicle Screw and Rod fixation, bilateral

2. Methods

2.1 Specimen Preparation

Eight fresh cadaveric lumbar spines (L1-S1) were obtained for this study. The bone mineral density for each spine was scanned using dual energy xray absorptiometry (DEXA). Specimens with a T score less than -1.0 were eliminated from the study due to their osteopenic nature. All specimens were under the age of 65 years and exhibited ideal bone quality. Following this, the surrounding musculature was removed from each spine leaving all ligamentous structures intact. The specimens were tested using a kinematic profiling apparatus, with the upper and lower vertebra embedded to their midbodies into a polyester resin. The disc and facet joints were free of any embedding material and accessible for the application of instrumentation. Each spine segment was instrumented in a sequential manner with one of the test groups discussed above. All specimens were non-destructively tested in flexion, extension, bilateral bending, and bilateral rotation for:

TEST GROUPS

1. Intact
2. Facet Bolt with intact disc and spinous process (USB + SPP)
3. Facet Bolt with intact disc and the spinous process removed (USB – SPP)
4. Facet bolt with a ventral allograft (Allograft + USB)
5. Pedicle screw fixation with a ventral allograft (Allograft + PS)

2.2 Biomechanical Testing Scheme

Motion was measured at the instrumented spinal level. The motion of the L1, L2, L3, L4, and L5 vertebrae relative to the sacrum were measured using an optoelectronic motion measurement system (Model 3020, Optotrak®, Northern Digital, Waterloo, Ontario). Each spine was embedded into customized testing jigs using Bondo (a 2-part epoxy resin) cranially at L1 and caudally at S1. The base was bolted to a test frame located in the field of measurement of an Optotrak Motion Measuring System (Northern Digital, Waterloo, Ontario, Canada). This system uses infrared cameras to track the spatial locations of three light-emitting diodes affixed to the each vertebral body in response to the applied loads.

The hybrid testing protocol for mechanical testing of the spine specimens followed the methods used in previous studies.[1-5] The hybrid test protocol involves applying moments until the overall motion equaled the intact specimen motion in a given loading mode. Using a system of loading arms, pulleys and weights, quasi-static loads were applied to the L1 vertebral body leading to sequential pure moments of 1.5, 3.0, 4.5, 6.0 Nm, 7.5 Nm, and 10 Nm. Moments were applied to generate the following 6 loading modes: flexion (Flex), extension (Ext), right and left lateral bending (RB, LB), and right and left axial rotation (RR, LR) without the application of a follower preload. Following this, a follower type preload of 400N was applied in flexion and extension. To overcome each spine's viscoelastic effects, the specimens were ranged maximally in all directions at least three times before data collection to precondition the tissue. In addition, after each load application, the system was allowed to stabilize for 30 seconds to minimize creep before data collection. All specimens were biomechanically and non-destructively tested intact initially, followed by implantation in the order described in Section 2.1.

The Descriptive statistics and a one-way analysis of variance with a Neuman Keuls comparison were used to evaluate any significant differences between the intact and instrumentation systems. The motion across the disc and/or grafted spinal segment was measured with the motion analysis system.

3. Results:

Figure 1: The hybrid testing protocol involved applying moments until the overall range of motion was equivalent to the intact specimen motion in a given loading mode. It does not involve a follower load (preload that simulates human muscular contribution). The bending moments for all test groups are illustrated below. Incremental bending moments were applied to each stage of testing for each specimen until the range of motion became equivalent to the intact state and the moment was recorded. Figure 1 demonstrates the mean bending moments for all the L1-L5 levels for each test group. The Pedicle screw with allograft exhibited the greatest bending moment to achieve the same range of motion as the intact spine (~16 Nm in extension, ~19 Nm in flexion). *The Facet Bolt (USB) required less bending moment to achieve the same range of motion. However, this can be attributed to the orientation of the insertion path of the bolt, which lies orthogonal to pedicle screw fixation.*

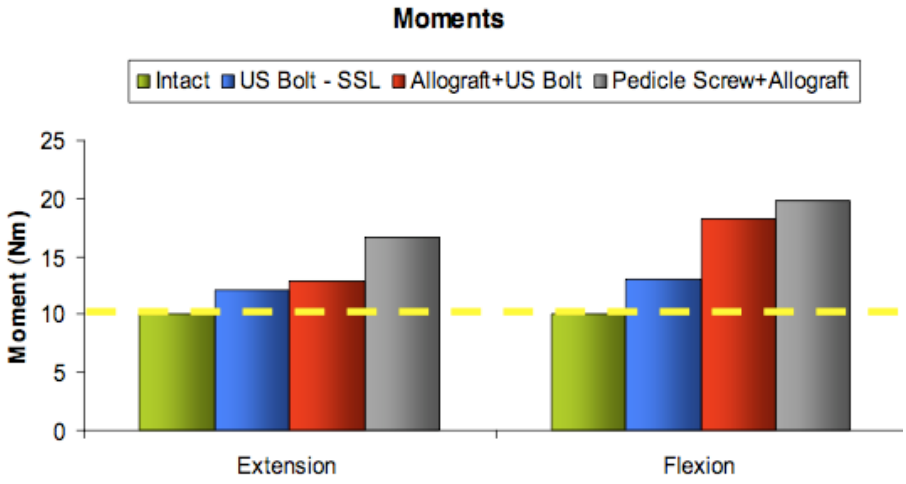
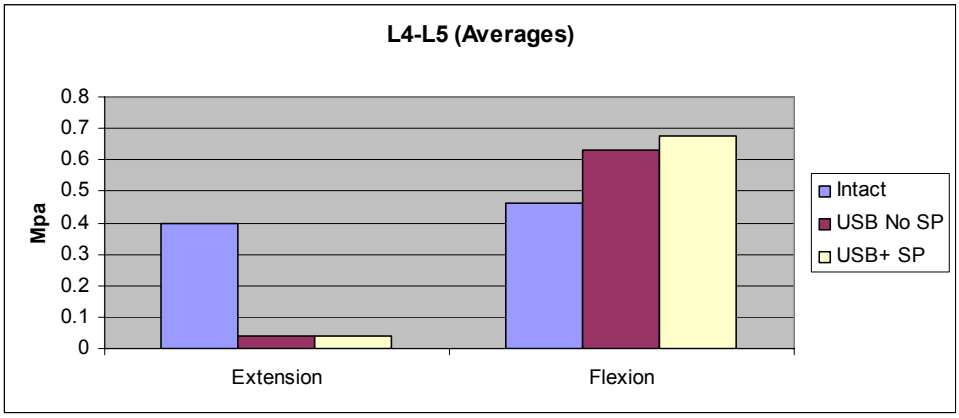


Figure 2: Implanted Segment Pressures:



Intradiscal pressure could not be recorded for the allograft intervention scenario due to placement of the bone graft into the interspace. Overall, the intradiscal pressures measured for the implanted Facet Bolt without the allograft demonstrated greater pressures along the anterior and middle column of the vertebral motion segments when compared to the intact situation (Figure 2). An increased disc pressure can be correlated with an increased loading or improved load sharing on the anterior and middle column of a motion segment if a bone graft or interbody device is in place. The improved load sharing will lead to improved bone incorporation and fusion at the interbody graft site. Therefore, this data clearly suggests that improved load sharing with the Facet Bolt would occur on an interbody fusion device as indicated by the increase in IDP, thus enhancing the probabilty of fusion incorporation.

Summary of Results

- Overall, the intradiscal pressures demonstrated greater pressures along the anterior and middle column of the vertebral motion segment in flexion for the spinal level implanted with the Facet Bolt, implying better load-sharing across an interbody fusion site when compared to pedicle screw fixation.

- The range of motion observed was greater for the Facet Bolt and Allograft for all modes of loading when compared to the Pedicle Screw Fixation System and Allograft. Although the bolt was not statistically different from the pedicle screw fixation and allograft, the Facet Bolt would provide improved micromotion across the interbody graft for optimal load sharing and enhanced fusion.

- There was no statistically significant biomechanical difference between maintaining or removing the spinous process. Removal of the spinous process for implantation of the Facet Bolt did not impact the motion across the spinal segment for all modes of testing. Thus, the spinous process can be removed for implantation of the US Facet bolt without impacting the mechanical behavior for the stabilized segment.

Figure 3: Graphical representation of the mean range of motions at 10 Nm for each test group for all load modes with a 400 N follower preload. No statistically significant difference was observed between the test groups. However, there was a trend of more motion observed in all modes for the Facet Bolt when compared to the Pedicle Screw Fixation and Allograft scenario. This implies that there is more motion, thus greater load sharing across the fusion graft for the Facet Bolt, than the Pedicle Screw Fixation System.

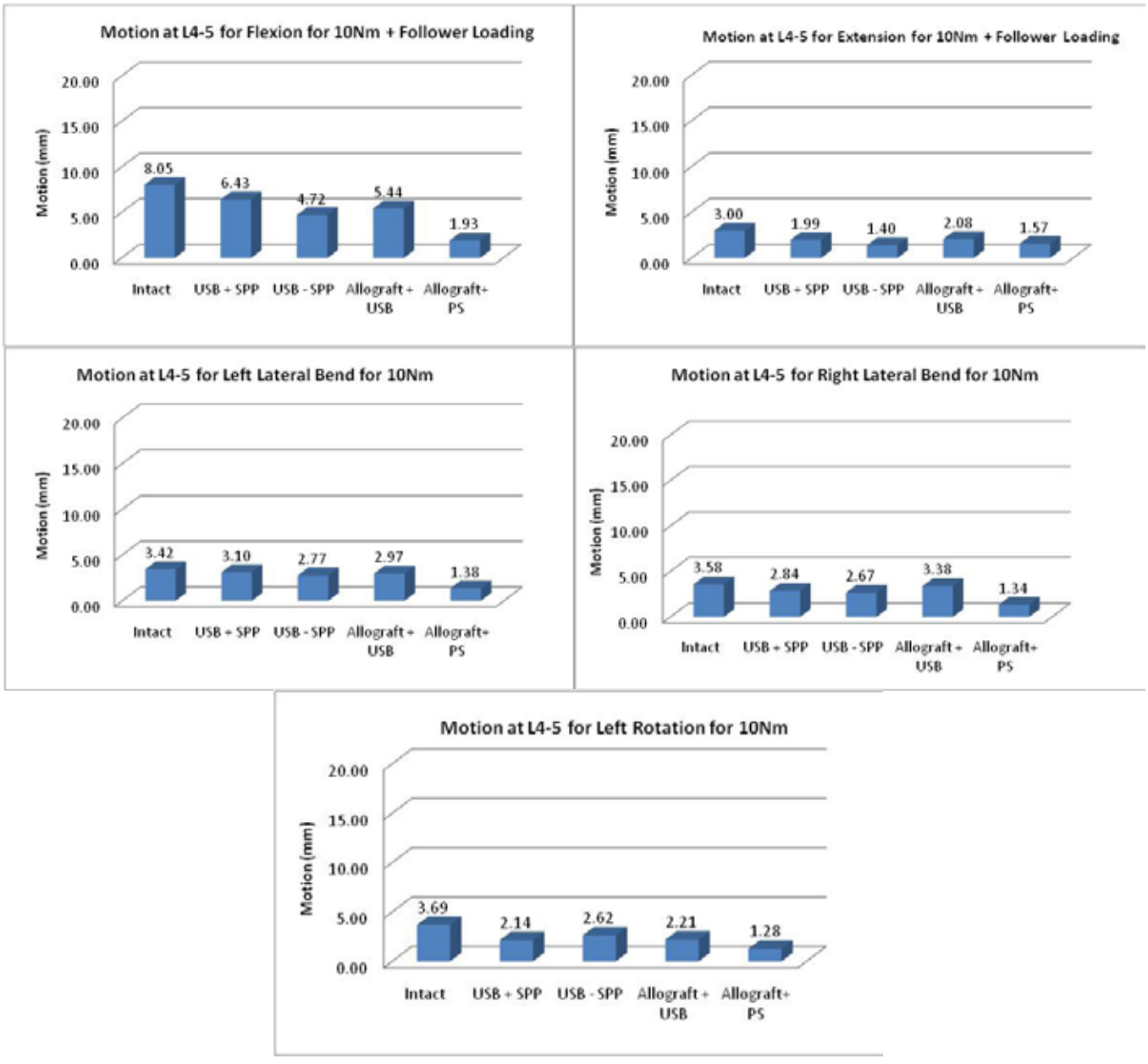
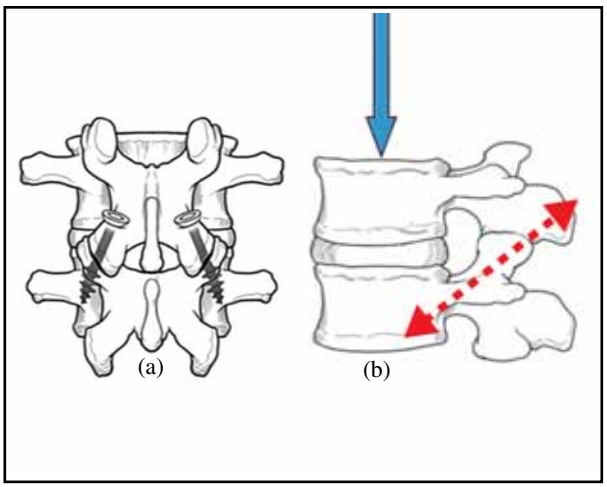
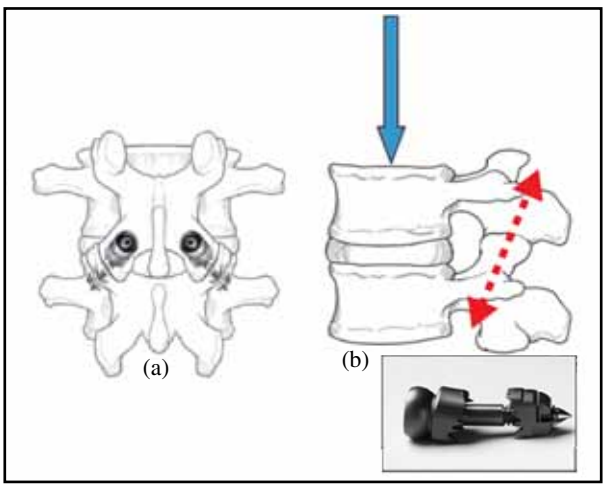


Figure 4: Left: Pedicle screw fixation and the orientation of the bending moments placed on the fixation during axial loading, provide risk to screw 'windshield wiper' effect with a pseudarthrosis. **Right:** The Facet Bolt is orthogonal to the axial loading, thus in flexion and extension, the bending moments are much less than what is shown for conventional rigid pedicle screw fixation (As demonstrated in Figure 1 also) which would elicit less risk to interface failure or bolt backout.



Traditional Trans-Facet Pedicle Screws: (a) Trajectory; (b) Loading



Trans-Facet Bolt: (a) Trajectory; (b) Loading

Study Limitations

Although this was an *in vitro* cadaveric biomechanical study and a solid fusion could not be simulated, the allograft provided a worst case scenario for the comparison of the immediate non-fused state. Although not significantly different, there was slightly greater motion observed for the US Facet Bolt (USB) with the allograft than when compared to the Pedicle screw fixation system. This can be attributed to one main factor;

The US Facet Bolt was implanted immediately after the intact spine, tested with and without the spinous process, followed by implantation of the allograft with the Facet Bolts in place. Therefore, implanting the allograft with the facet bolts inserted across the facet joint (after implantation) caused some disruption and loosening across the facet joint, contributing to greater motion than the pedicle screw fixation systems, as well as greater motion than the Facet Bolt in flexion with removal of the spinous process. In surgical practice, the fixation is applied after the interbody bone graft is inserted. For the purposes of this study, it was essential to perform the testing in the order described. Additionally, the pedicle screw fixation was placed following the Facet Bolt with Allograft testing.

Since the bolt is placed 90° from the plane of conventional pedicle screw fixation, (Figure 4), in flexion and extension it would require less bending moments to achieve the range of motion for the intact spine. This is a benefit of the Facet Bolt system, as it would reduce the incidence of increased stresses at the implanted and adjacent segments that are often observed with rigid pedicle screw fixation (Figure 1).

4. Summary and Conclusions

In summary, the data shown in this study demonstrated that the Facet Bolt will stabilize the spinal motion segment equivalent to that of rigid pedicle screw fixation, while providing improved load-sharing to the bone graft. Furthermore, removal of the spinous process for implantation of the US Facet Bolt will not impact the biomechanical performance or the stability of the fusion site, and can be incorporated into the surgical procedure if necessary.

Furthermore, the bending moments placed upon the spine in flexion and extension for the Facet Bolt are less than that of rigid conventional pedicle screw fixation. This suggests that the Facet Bolt allows for some posterior micro-elongation, greater than that of the pedicle screw system, as demonstrated by the reduced bending moments in Figure 1. Therefore, the stresses at the fusion site and at the adjacent segments would be lessened with Facet bolt supplementation, thus reducing the risk of early adjacent

segment degeneration often observed with rigid pedicle fixation. Although pedicle screw fixation has been the gold standard for fusion, the Facet Bolt will provide the same level of rigidity and immobilization to the interbody fusion site to allow for successful bone incorporation and fusion, while reducing the bending moments and stresses observed at the site of fixation. This in turn could reduce the risk of early adjacent segment disease related to fusion fixation.

Conclusions

- Statistically, the Facet Bolt performed equivalently with respect to range of motion and spinal segment stability when compared to conventional rigid pedicle screw fixation. However, when observing the trends for range of motion, the Facet Bolt with the allograft demonstrated greater range of motion in all modes of loading when compared to the Pedicle Screw Fixation system with an allograft. This implies that there is greater motion, and thus greater load sharing placed upon the anterior and middle portion of the grafted motion segment, which will enhance bone incorporation at the fusion site.
- The bending moments required to achieve the same range of motion of the healthy intact spine were less for the Facet Bolt than that of rigid pedicle screw fixation. This implies that there is less stress placed at the site of fixation (disc and bony interface) for the Facet Bolt than that for rigid pedicle screw fixation. These lower moments and stresses may lower the risk of implant failure at the bone interface and early adjacent segment degeneration than that of rigid pedicle fixation, since the Facet bolt allows for a minute amount of micro-elongation posteriorly due to the orthogonal orientation of bolt placement.

- The ideal benefit of the Facet Bolt is that the bolt is placed through the facet joint (90° from conventional pedicle screw fixation) and along the sagittal plane of flexion and extension rotation, thus allowing for some posterior elongation in flexion and extension and leading to less stress or bending moments than pedicle screw fixation, see Figures 1 and 3.

References

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