Biomechanical Comparison of a Novel Percutaneous Transfetad Device and a Traditional Posterior System for Single Level Fusion

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Abstract: Posterior spinal fusions are indicated for a variety of spinal disorders. Transfetad fixation minimizes soft tissue disruption and preserves the adjacent facet joint. This technique is uncommon due to concerns with biomechanical stability and proper implant placement. For these reasons, a length-adjustable implant may obviate the clinical concerns but necessitates biomechanical study. This study evaluated the in vitro biomechanical stability between a novel transfetad fixation device compared with standard pedicle screws during cyclic physiologic loading in a human cadaver model. Cadavere L4-L5 motion segments from 16 human spines were tested in cyclic flexion/extension, lateral bending, and torsion after insertion of either transfetad fixation devices or 5.5-mm pedicle screw instrumentation. A load cell was used to measure the compressive forces on the anterior column during testing. Motion segment stiffness and anterior screw-cage compression were analyzed with a 1-way analysis of variance (P < 0.05). The transfetad device demonstrated a statistically similar stiffness when compared with the pedicle screwsyst for each test direction. For anterior column loading during physiologic testing, there were no biomechanical differences between stabilizations of transfetad and pedicle screws when compared with the normal cadaveric spine system. The length adjustability of the device may alleviate concerns for precise device placement and the biomechanical stability may provide similar results and quality of posterior spinal fusion.

Key Words: posterior spinal stabilization, transfetad fixation, biomechanics, anterior column load, spinal fusion (J Spinal Disord Tech 2006;19:591–594)

Posterior spinal fusions are indicated for a variety of spinal disorders such as degenerative disc disease, trauma, and tumor. During spinal fusion procedures, it is desirable to minimize soft tissue trauma and retain the continuity of the spine’s anatomy. Numerous approaches to spinal fusion tend to reduce the exposure area and its associated morbidities such as blood loss, perioperative pain, and potential for infection. The technique of direct facet fixation provides an attractive option in this regard. Facet fixation can be performed percutaneously using the Boucher technique.1 This method of fixation avoids injury to the adjacent facet above the fused segment, which may decrease the incidence of adjacent segment disease. Although there have been concerns regarding the biomechanical stability of transfetad fixation, recent biomechanical studies have demonstrated that both short-term and long-term cyclic loading of segment motion segments instrumented with bilateral facet fixation had equivalent biomechanical performance to standard pedicle screw instrumentation.2 In a more recent study, Kandziora et al5 found that a translaminar screw and a facet interference screw were biomechanically superior to standard pedicle instrumentation in the single-level screw system. Thus, the stability issues related to facet fixation remain unclear. A novel transfetad device has been developed that allows for the adjustment of the screw length. The device is cumulated to allow percutaneous insertion using guide wires. This method length is adjustable in situ, allowing precise placement of the screw and compression at the fusion site. Finally, a double helical thread design along with the ability for axial compression increases the biomechanical stability of the transfetad system. The purpose of this study was to compare this new transfetad device with standard pedicle screw instrumentation for single-level posterior lumbar fusions.

METHODS
Sixteen human cadaveric L4-L5 single motion segments (9 male, 7 female, average age: 70 ± 11 y) were stripped of soft tissue saving the ligamentous structures. Each motion segment was inspected to ensure there were no gross abnormalities. Motion segments were randomly assigned to either 4.5-mm transfetad fixation (BONE-LOK Transfetad Fixation System, Triage Medical, Inc) or...
The technique for implantation of the transfacet device is described below. The implantation of the transfacet device was performed using an instrument kit provided by the manufacturer. An incision is made in the skin and fascia to allow adequate exposure to gain proper alignment for facet screw placement, as indicated by thorough preoperative examination. Once adequate alignment is achieved, a guide wire is placed to be used as a guide for drilling and device insertion. A device path is created by power drilling over the guide wire and the path is then hand tapped with the appropriate sized instruments. The device is installed using a custom driver. The distal tip of the device is placed as desired and its position confirmed using fluoroscopy (typically). The collar mechanism of the device is then advanced using a custom compression tool. The retaining ring is locked to the outer barrel and achieves compression by stepping down the ratchet on the inner shaft. Once compression across the facet joint is achieved, the compression tool is removed and the device stability may be checked by hand. After confirmation of proper position and adequate stabilization, the guide wire is removed, as is the redundant pin mechanism that is used as part of the compression process.

Transfacet fixation followed the technique described by Buehler, although the technique was slightly modified in its trajectory to obtain thread purchase within the pedicles of the inferior vertebral body (Figs. 2A, B). Motion segments 2 were tested intact and after posterior instrumentation and anterior interbody lumbar fusion. To simulate an anterior body cage, a compression load cell (Model no.: AE332, Senseonics, Columbus, OH) was inserted between 2 custom machined, anodized aluminum plates (diameter = 25 mm) (Fig. 3). The load cell was factory calibrated to be within 0.5% of full range, with a full-scale measurement range of 0 to 500 N. When necessary, additional plates were used to ensure that each cage experienced a press fit within the anterior column. Mechanical testing involved physiologic moments applied in flexion (5 Nm), extension (5 Nm), lateral bending (5 Nm), and axial torsion (2 Nm) to 100 N axial load over 5 cycles using an MTS858 sercopathic biaxial test frame (MTS, Co, Eden Prairie, MN). These loading levels approximated those previously used for in vitro investigation of transfacet fixation stability. System stiffness (Nm/degree) was calculated between 0.5 Nm and the end load. The compression load cell within the simulated anterior body cage provided real-time changes in the compressive force between vertebral bodies. These fluctuations in load (N) within the anterior column were calculated as the range from maximum to minimum for each cycle for each test (thus combining data for each direction of loading). For each test, the first 3 cycles were used to condition the specimen and data analyzed over the last 2 cycles. The statistical analysis occurred in 2 stages. Because no data could be collected for anterior column loading during the intact condition, the first analysis compared the stiffness and loading differences between constructs without any normalization to the intact state. The second stage of statistical analysis compared only the stiffness of each construct after normalization to the intact state, enabling each spine to act on its own control. For all comparisons, data were statistically analyzed using a 1-way analysis of variance (P < 0.05).

RESULTS

No differences were found between groups for testing of intact specimens in any direction. This indicated adequate randomization of specimens. For flexion stiffness, there were no significant differences between transfacet (1.3 ± 3.1 Nm/degree) and pedicle screw (2.6 ± 1.2 Nm/degree) constructs. After normalization, both systems reported slightly stiffer data than the intact. No significant differences were reported between transfacet fixation (+9 ± 37%) and the pedicle screw construct (+22 ± 57%) (P = 0.6). For torsion stiffness, there were no significant differences between the transfacet (3.9 ± 3.1 Nm/degree) and pedicle screw (2.6 ± 1.2 Nm/degree) constructs. After normalization, both systems were found to be stiffer on average than the intact condition. There were no differences between the transfacet construct (+84 ± 177%) compared with pedicle screws (+59 ± 123%) (P = 0.7).

Anterior Column Loads

The load fluctuations during flexion/extension were not significantly different between the transfacet (71.3 ± 51 N) and pedicle screw (91.1 ± 68.4) (Fig. 5). These data were not significantly different between systems for lateral bending, with the load fluctuations for the transfacet system being slightly lower for the transfacet system (17.7 ± 14.5 N) compared with the pedicle screw system (25.2 ± 24.8 N). The load fluctuations during torsion testing demonstrated the lowest magnitude of loading change during testing. As before, there were no significant differences between transfacet (13.4 ± 15.7 N) and pedicle screw (9.6 ± 9.5 N) constructs.