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Effect of the Total Facet Arthroplasty System after complete laminectomy-facetectomy on the biomechanics of implanted and adjacent segments

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Abstract

BACKGROUND CONTEXT: Lumbar fusion is traditionally used to restore stability after wide surgical decompression for spinal stenosis. The Total Facet Arthroplasty System (TFAS) is a motion-restoring implant suggested as an alternative to rigid fixation after complete facetectomy.

PURPOSE: To investigate the effect of TFAS on the kinematics of the implanted and adjacent lumbar segments.

STUDY DESIGN: Biomechanical in vitro study.

METHODS: Nine human lumbar spines (L1 to sacrum) were tested in flexion-extension (+8 to −6 Nm), lateral bending (±6 Nm), and axial rotation (±5 Nm). Flexion-extension was tested under 400 N follower preload. Specimens were tested intact, after complete L3 laminectomy with L3–L4 facetectomy, after L3–L4 pedicle screw fixation, and after L3–L4 TFAS implantation. Range of motion (ROM) was assessed in all tested directions. Neutral zone and stiffness in flexion and extension were calculated to assess quality of motion.

RESULTS: Complete laminectomy-facetectomy increased L3–L4 ROM compared with intact in flexion-extension (8.7±2.0 degrees to 12.2±3.2 degrees, $p<.05$) lateral bending (9.0±2.5 degrees to 12.6±3.2 degrees, $p=.09$), and axial rotation (3.8±2.7 degrees to 7.8±4.5 degrees $p<.05$). Pedicle screw fixation decreased ROM compared with intact, resulting in 1.7±0.5 degrees flexion-extension ($p<.05$), 3.3±1.4 degrees lateral bending ($p<.05$), and 1.8±0.6 degrees axial rotation ($p=.09$). TFAS restored intact ROM ($p>.05$) resulting in 7.9±2.1 degrees flexion-extension, 10.1±3.0 degrees lateral bending, and 4.7±1.6 degrees axial rotation. Fusion significantly increased the normalized ROM at all remaining lumbar segments, whereas TFAS implantation resulted in near-normal distribution of normalized ROM at the implanted and remaining lumbar segments. Flexion and extension stiffness in the high-flexibility zone decreased after facetectomy ($p<.05$) and increased after simulated fusion ($p<.05$). TFAS restored quality of motion parameters (load-displacement curves) to intact ($p>.05$). The quality of motion parameters for the whole lumbar spine mimicked L3–L4 segmental results.

FDA device/drug status: investigational/not approved (Total Facet Arthroplasty System).

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CONCLUSIONS: TFAS restored range and quality of motion at the operated segment to intact values and restored near-normal motion at the adjacent segments.

Keywords: Lumbar spine; Facetectomy; Facet arthroplasty; ROM; Quality of motion

Introduction

Degenerative lumbar spinal stenosis may be a debilitating condition affecting a measurable portion of the general population [1,2]. Initial treatment of spinal stenosis is usually nonsurgical; however, when symptoms are disabling and refractory to nonoperative care, surgical intervention may be considered. Surgical treatment of spinal stenosis typically involves decompression of the involved neural elements necessitating removal of the offending pathology including all or part of the posterior elements including the lamina, ligamentum flavum, and facet joints. These posterior structures, particularly the facet joints, are important stabilizers of the motion segment. Instability can either preexist or may be created by aggressive surgical decompression. Stability is usually restored with surgical fusion, often supplemented with pedicle-based posterior instrumentation. As an alternative to fusion in this situation, a facet joint arthroplasty may have the advantage of restoring the natural kinematics of the functional spinal unit while providing the stability of the removed native structures.

The orientation of facets in the lumbar spine allows flexion-extension and aids in resisting torsion and shear load. The Total Facet Arthroplasty System (TFAS; Archus Orthopedics Redmond,WA) has been designed to mimic the anatomic configuration and resembles the motion and restraint patterns of the natural facet joints at L3–L4 and L4–L5. The device allows for up to 15 degrees of total segmental flexion-extension, ±7.5 degrees of lateral bending, and ±2 degrees of axial rotation. However, it is critical that the artificial joints re-establish not only the ability to attain the limits of the natural range of motion (ROM), but also provide graduated resistance throughout the ROM to promote a quality of motion similar to that of the healthy, intact functional spinal unit. Ignoring the kinematic trajectory of the natural anatomy may compromise both the operated and the adjacent levels [3]. If healthy motion patterns are achieved by artificial joints in the spine, the risk of adjacent-level degeneration that has been reported after fusion may be mitigated.

The objectives of the present study were twofold: 1) to investigate the effect of the TFAS on the range and quality of motion at the L3–L4 segment and 2) to evaluate the effect of TFAS on the motion at the adjacent segments.

Materials and methods

Specimens and experimental set-up

Nine fresh-frozen human cadaveric spines from L1 to sacrum (age: 57±15 years; six males, three females) with no previous spinal surgery were used. Specimens were screened radiographically to exclude those with evidence of disc ossification and bridging osteophytes. The paravertebral muscles were dissected, while leaving the discs, ligaments, and posterior bony structures intact. All tests were performed at room temperature and the specimens were kept moist during testing with saline-soaked towels. The L1 vertebra and sacrum were anchored in cups using bone cement and pins.

The specimen was mounted on a six-component load cell (Model MC3A-6-250, AMTI Multi-component transducers; AMTI Inc., Watertown, MA) at the caudal end and was free to move in any plane at the proximal end. A moment was applied by controlling the flow of water into bags attached to loading arms fixed to the L1 vertebra. The apparatus allowed continuous cycling of the specimen between specified maximum moment end points in flexion and extension, lateral bending, and axial rotation.

The three-dimensional motions 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, Canada). In addition, biaxial angle sensors (Applied Geomechanics, Santa Cruz, CA) were mounted on each vertebra to provide real-time feedback for the optimization of the follower load path. Fluoroscopic imaging (GE OEC 9800 Plus digital fluoroscopy machine, GE Medical) was used during flexion and extension to monitor vertebra and implant motion.

A compressive preload was applied to the lumbar spine during flexion and extension using the follower load technique described by Patwardhan et al. [4]. The compressive preload was applied along a path that followed the lordotic curve of the lumbar spine. By applying a compressive load along the follower load path, the segmental bending moments and shear forces as a result of the preload application are minimized [5]. This allows the lumbar spine to support physiologic compressive preloads without damage or instability. The preload was applied using bilateral loading cables that were attached to the cup holding the L1 vertebra (Fig. 1). The cables passed freely through guides anchored to each vertebra and were connected to a loading hanger under the specimen. The cable guide mounts allowed anterior-posterior adjustments of the follower load path within a range of about 10 mm. The preload path was optimized by adjusting the cable guides to minimize changes in lumbar lordosis when a compressive load up to 400 N was applied to the specimen. A follower preload was not applied during lateral bending and axial rotation because of technical limitations of the current apparatus.

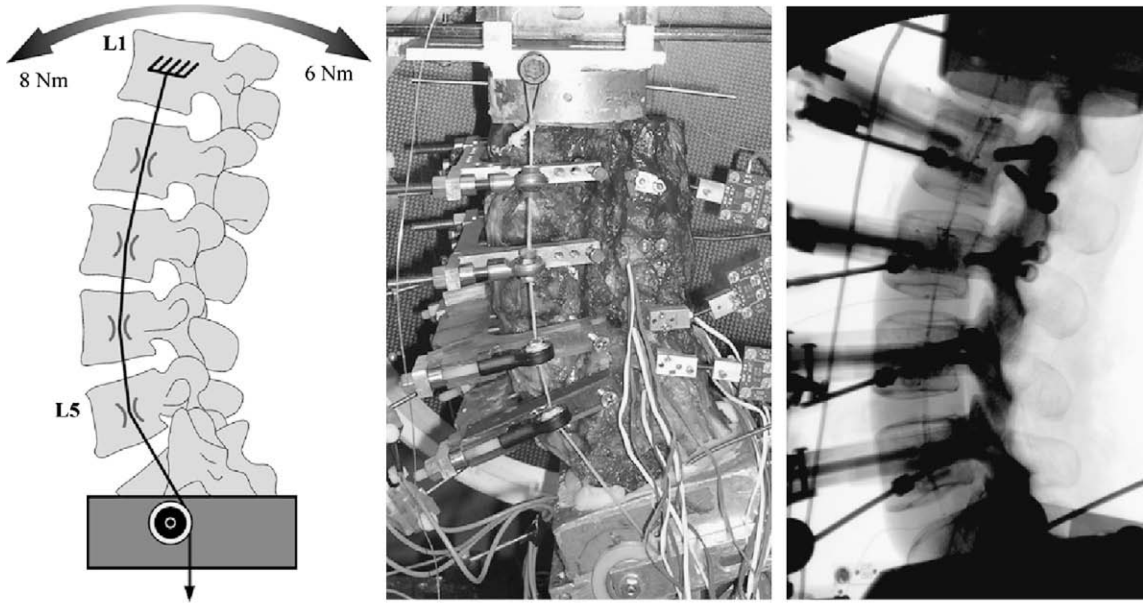

Fig. 1. Experimental set-up. (Left) Schematic; (Center) specimen photo; (Right) lateral X-ray.

Experimental protocol

Each specimen was subjected to flexion-extension, lateral bending, and torsional moments in random order. The load-displacement behavior of the specimen was recorded under flexion moments up to +8 Nm and extension moments up to −6 Nm. Lateral bending moments ranged within ±6 Nm, and axial rotation moments ranged within ±5 Nm. Flexion-extension was tested under 400 N preload. The load-displacement data were collected until two reproducible load-displacement loops were obtained.

After testing the intact specimen, a complete L3 laminectomy with complete resection of the L3–L4 facet joint was performed using standard instruments and techniques. The L3–L4 segment was then instrumented with a pedicle screw fixation construct. Next, the TFAS lumbar facet prosthesis (Fig. 2) was implanted at L3–L4 using specified instruments following manufacturer recommended procedures. Four metal stems were cemented at the pedicles of L3 and L4 using polymethylmethacrylate bone cement. Two caudal socket type bearings were connected to the caudal stems. A cross-arm component including the ball-shaped upper bearing surfaces was attached to the cephalad stems and fixed in the proper position on the caudal bearings. Fluoroscopy was used during the procedure to ensure proper sizing and placement of the TFAS device.

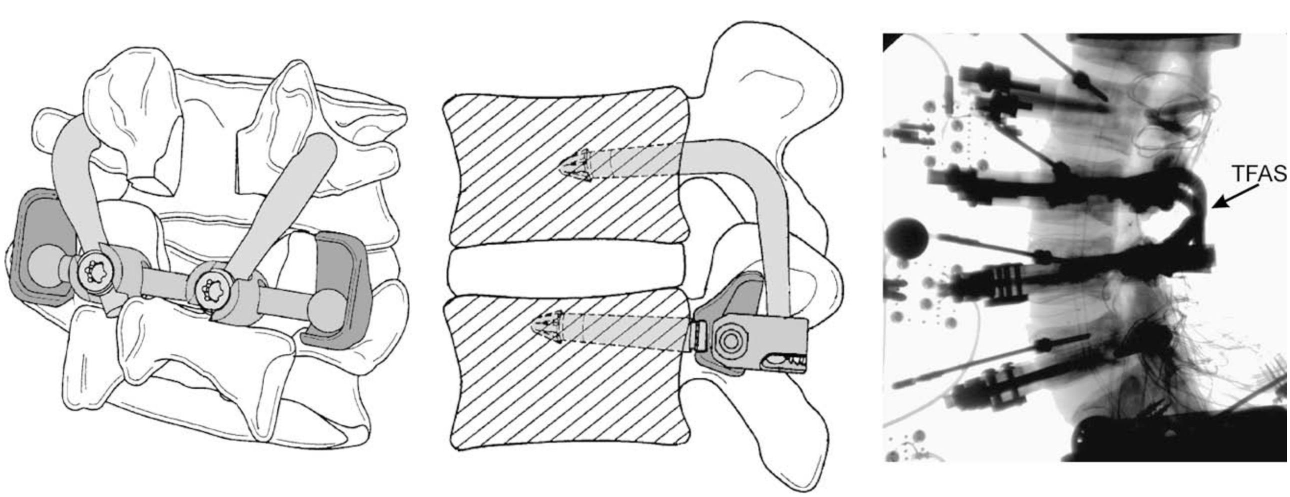

Fig. 2. Total Facet Arthroplasty System (TFAS) lumbar facet prosthesis. Artist's rendition of TFAS implanted in single functional spinal unit; (Left) posterior view; (Center) lateral cross sectional view; (Right) lateral fluoroscopic image of a test specimen implanted with TFAS (denoted by arrow).

Data analysis

The load-displacement data were analyzed to determine the ranges of angular motion at L3–L4 in flexion-extension, lateral bending, and axial rotation in the intact condition, after destabilization, after fusion, and after TFAS implantation. Load-displacement curves of the implanted segment in flexion-extension were further analyzed to measure quality of motion in terms of stiffness and neutral zone (Fig. 3). The L3–L4 segmental stiffness values (Nm/degree) in flexion and extension were calculated using slopes of the linear portion of the load-displacement curve around the neutral posture in flexion and extension, respectively. Neutral zone (degrees) was calculated as the difference in the segmental angle between the loading and unloading curves at 0 Nm bending moment.

The statistical analysis was performed using repeated measures analysis of variance (ANOVA; Systat Software Inc., Richmond, CA). Post hoc tests were done where indicated by analysis of variance results using Bonferroni correction corresponding to the number of multiple comparisons used for each analysis. The level of significance was set such that Bonferroni-adjusted one-tailed $\alpha=.05$. p Values between .05 and .1 were considered to show a trend for statistical significance.

The effects of surgical procedures on the ROM of the operative (L3–L4) segment were assessed using three pairwise comparisons in each loading mode (flexion-extension, lateral bending, and axial rotation): 1) intact versus destabilized spine, 2) intact spine versus simulated fusion, and 3) intact spine versus TFAS implantation. Comparisons of quality of motion parameters (stiffness and neutral zone in flexion and extension) for the L3–L4 segment were made to determine the effect of destabilization and TFAS implantation.

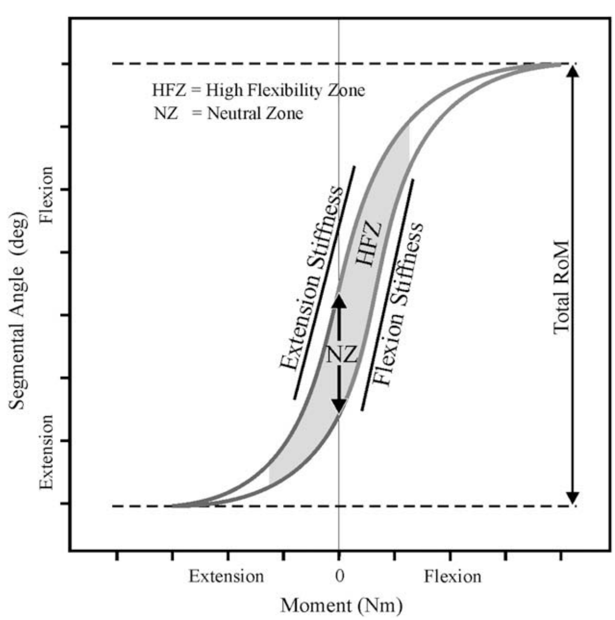

Fig. 3. Analysis of load-displacement curves in flexion-extension. The following parameters were quantified: 1) stiffness (slope of load-displacement curve) in the high-flexibility zone in flexion and extension (Nm/degree) and 2) neutral zone (degrees).

The effects of surgical procedures at L3–L4 on the distribution of flexion and extension ROM values at each remaining lumbar segment were assessed using two comparisons: 1) intact spine versus simulated fusion and 2) intact spine versus TFAS implantation. Because the specimens were tested in a load-controlled mode, the total lumbar motions were different depending on the specimen condition. Therefore, the ROM of each specimen (L1–sacrum) for each condition was normalized to 100%. The ROM of each lumbar segment was then expressed as a percent of the total lumbar motion (in flexion and extension). Comparisons were made on the flexion and extension ROM values as percent of total lumbar motion.

Results

Range of motion at the operative (L3–L4) segment

Flexion-extension

Under compressive follower load of 400 N, the baseline total flexion-extension ROM for the intact L3–L4 segment was 8.7 ± 2.0 degrees. Segmental ROM increased to 12.2 ± 3.2 degrees after destabilization with complete laminectomy and facetectomy ($p<.05$). After posterior fusion at L3–L4, the segmental ROM decreased to 1.7 ± 0.5 degrees, which was significantly smaller compared with intact ($p<.05$). The TFAS prosthesis at L3–L4 restored motion to 7.9 ± 2.1 degrees, which was not significantly different compared with intact ($p>.05$).

Lateral bending

The mean baseline total lateral bending motion for the intact L3–L4 segment was 9.0 ± 2.5 degrees. After destabilization, the total lateral bending at L3–L4 increased to 12.6 ± 3.2 degrees ($p=.09$). After fusion at L3–L4, the segment lateral bending decreased to 3.3 ± 1.4 degrees, which was significantly smaller than intact ($p<.05$). The TFAS prosthesis restored the lateral bending motion to 10.1 ± 3.0 degrees, which was not statistically different from the intact segment ($p>.05$).

Axial rotation

The mean baseline total axial rotation for the intact L3–L4 segment was 3.8 ± 2.7 degrees. After destabilization, the total axial rotation at L3–L4 significantly increased to 7.8 ± 4.5 degrees ($p<.05$). After fusion at L3–L4, the segmental axial rotation decreased to 1.8 ± 0.6 degrees, which showed a trend to be significantly less than intact ($p=.09$). The TFAS prosthesis restored the axial rotation to 4.7 ± 1.6 degrees, which was not significantly different than intact ($p>.05$).

Quality of motion at the operative (L3–L4) segment

The baseline stiffness values in the high-flexibility zone for the intact L3–L4 segment in flexion and extension were 0.89±0.46 and 1.01±0.64 Nm/degree, respectively. Surgical destabilization of the L3–L4 segment significantly decreased the flexion stiffness to 0.53±0.28 Nm/degree ($p<.05$) and extension stiffness to 0.58±0.38 Nm/degree ($p<.05$).

Fusion significantly increased segmental stiffness in flexion and extension compared with both the destabilized and intact spine ($p<.05$). TFAS implantation significantly increased the flexion and extension stiffness values compared with the surgically destabilized condition ($p<.05$), restoring them to the intact values ($p>.05$). The stiffness values of the implanted L3–L4 segment in flexion and extension were 1.11±0.38 and 1.10±0.69 Nm/degree, respectively. The load-displacement curve pattern in flexion-extension after TFAS implantation was sigmoidal and approximated the intact pattern (Fig. 4).

The neutral zone values for the intact, destabilized, and TFAS implanted segments were 0.60±0.51, 0.62±0.60, and 0.77±0.79 degrees, respectively. There was no significant difference in the neutral zone of the intact, destabilized, or implanted segments ($p>.05$).

Motion at the nonoperated segments

Fusion of L3–L4 significantly increased the normalized ROM at all remaining lumbar segments, whereas TFAS implantation resulted in near-normal distribution of normalized ROM at the implanted and at all the remaining lumbar segments (Table 1). The ROM at the L2–L3 level remained significantly larger than the intact value after the TFAS implantation.

The quality of motion parameters for the whole lumbar spine (L1–sacrum) mimicked the L3–L4 segmental results. The flexion and extension stiffness values in the high-flexibility zone were significantly smaller after destabilization when compared with intact ($p<.05$), and were restored to normal after TFAS implantation. In contrast, extension stiffness was significantly increased after fusion compared with intact ($p<.05$). The neutral zone (in degrees) of the lumbar spine was not significantly affected by either destabilization or TFAS implantation.

Discussion

With the advent of new, nonfusion surgical treatment modalities for the spine such as dynamic stabilization/motion preservation, and more recently motion restoration using total disc replacement and facet arthroplasty prostheses, novel and relevant in vitro testing methodologies must be used to best capture the implant loading, kinematics, and tissue load sharing of these complex systems [6]. The departure from traditional fusion implants necessitates a broader and more descriptive means to depict both the biomechanical function of the natural and pathological anatomy, as well as that of the surgically reconstructed spinal segment undergoing arthroplasty. Although recent biomechanical reports have confirmed that a number of spinal devices do accomplish their goals of preserving ROM at the treated level; little attention has been paid to the quality (ie, pattern) of this motion. In this context, quality of motion refers to the ability of the implanted device to replicate the characteristic kinematic signature of the intact spine in both its limits and its profile.

In a recent biomechanical study, Zhu et al. [7] showed that the kinematics (ROM and helical axis of motion) of

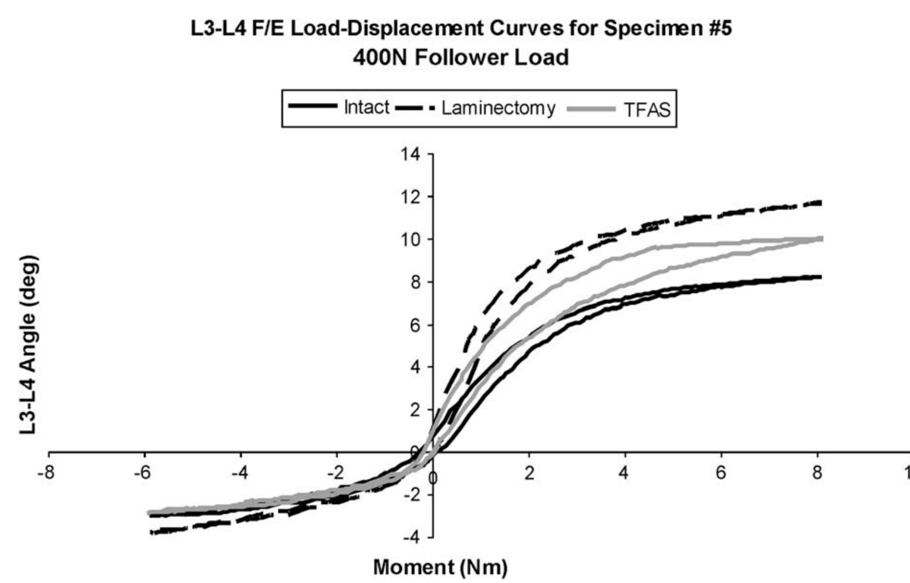

Fig. 4. Load-displacement curves for an L3–L4 segment in flexion-extension under 400 N preload. Intact, after complete L3 laminectomy and facetectomy, and after Total Facet Arthroplasty System implantation.

Table 1
Distribution of motion at all lumbar levels

Test Condition	L1–S1	L1–L2	L2–L3	L3–L4	L4–L5	L5–S1
Intact	43.0±9.4	6.9±2.3	7.6±2.4	8.7±2.0	10.2±2.9	9.6±4.5
Normalized (%)	100	16±3.2	18±3.8	21±3.5	24±4.3	23±9.5
Fusion	38.9±8.7	7.3±2.5	9.0±3.1	1.7±0.5	10.9±3.0	10.0±4.8
Normalized (%)	100	19±4.4*	23±5.5*	5.0±2.6*	28±5.4*	26±11*
TFAS	45.8±10.8	7.2±2.7	9.2±3.4	8.5±2.6	11.0±3.1	10.0±4.6
Normalized (%)	100	15±4.0	20±4.8*	19±5.2	24±3.7	22±9.8

*Denotes statistical significance when compared with the corresponding normalized value for the intact spine.
TFAS, Total Facet Arthroplasty System.

a destabilized L4–L5 segment after TFAS implantation were closer to the intact segment than the kinematics after posterior fixation. The current study validates the kinematics of TFAS at L3–L4 and in addition describes the effects of the implant on the neutral zone and stiffness, as well as the effect of the implantation on the adjacent levels. In addition, incorporating the complete lumbar spine provides a more representative model when considering the effect of an implant on adjacent-level biomechanics. The larger spine segment provides a more complete anatomic scenario through which both inter-level and intra-level interaction of the hard and soft tissues on motions can be considered.

The TFAS restored flexion-extension, lateral bending, and axial rotation ROM to the intact values at the implanted segment. The pattern of load-displacement curves of implanted segments approximated intact controls. Stiffness around the neutral posture is an important and clinically relevant measure of the stability of the spine. Panjabi [8,9] postulated that an increased laxity, as demonstrated by a substantially decreased stiffness or increased neutral zone, around the neutral posture of the spine after a destabilization procedure would put increased demand on the spinal musculature to provide the stability needed during activities of daily living. Increased muscle forces would, in turn, increase stresses in the spinal components and may contribute to pain. Prior studies of lumbar disc replacement have shown that although these implants are able to restore ROM, in many instances they do not adequately restore the neutral zone or the stiffness around the high-flexibility zone [6]. The results of this study confirmed that the TFAS preserved the neutral zone and restored stiffness (ie, stability) of the implanted segment in flexion and extension to intact values while allowing physiologic motion at the operated level.

Equally important to restoring dynamic stability, is the effect of any motion-restoring device on the adjacent segments. As shown in the current study, both absolute value (in degrees) and normalized (percent contribution to total) ROM at the adjacent levels was restored after TFAS implantation to near-normal values, in contrast to these parameters after fusion. Increased ROM at the level (L2–L3) above the treated level can likely be attributed to the complete L3 laminectomy which results in loss of the caudal attachment of the supraspinous/interspinous ligaments and ligamentum flavum between L2 and L3. Therefore, the tension band effect of posterior elements at the L2–L3 level was reduced. Preservation of the upper part of L3 lamina along with the attachment of L2–L3 ligamentous structures might have yielded different results.

In the present study, specimens were tested using a load-controlled test mode after each surgical procedure (destabilization, fusion, or TFAS reconstruction). This test mode simulated a clinical scenario wherein the moments applied to the spine are the same pre- and postoperatively. Panjabi and Goel [10] have described a so-called hybrid test protocol to assess the effects of fusion versus nonfusion procedures on the biomechanics of adjacent segments. The premise of the hybrid method is that the spine is forced to the same motion end points pre- and postoperatively (displacement-controlled test mode). With this testing method, after fusion increased motion at the mobile levels is required to achieve the predetermined global ROM end points. It is unclear whether this testing method is necessarily clinically applicable. In the present study, we analyzed the motion data obtained from a load-controlled experiment to yield adjacent segment motions as a percent of total lumbar motion. This normalization procedure has been used in previous studies to analyze the contribution of adjacent segments to the total lumbar motion in situations where the total lumbar motion differed in patients undergoing fusion versus arthroplasty procedures [11]. Although there is evidence that the patient's posture adapts over time in the postoperative period, the coping strategies for ROM (load-controlled or displacement-controlled) used by a patient postoperatively are poorly understood.

Because of the technical limitation of the current experimental set-up, a physiologic compressive preload was applied only while assessing the kinematics in flexion-extension, and was not applied in lateral bending or axial rotation. The preload resulting from muscle activity has a stabilizing effect on a motion segment; therefore, the results pertaining to lateral bending and axial rotation may be viewed as a worst-case scenario. Theoretically, lower ROM values than those reported here for lateral bending and axial rotation may be anticipated in vivo under a physiologic preload.

The sample size of nine specimens yielded a statistical power of greater than 80% in detecting a difference between intact and implanted segments of at least 2 degrees (with a standard deviation of the difference of 1.5 degrees). The above power analysis was based on observed motion responses of intact and implanted segments in flexion-extension and lateral bending. The statistical power was somewhat lower, 67%, in detecting a difference in axial rotation between intact and implanted segments of at least 2 degrees (with a standard deviation of the difference of 1.8 degrees).

In addition to restoring flexion-extension and lateral bending to the intact state after laminectomy-facetectomy, the TFAS was able to restore axial rotation. This is in contradistinction to other posteriorly applied so-called "dynamic devices." A prior study showed that after discectomy-facetectomy, the DIAM, a widely used interspinous process motion-preserving device, did not restore the rotational ROM to the intact level [12]. Similarly, the Dynesys, a pedicle-based dynamic device, showed increased axial ROM compared with the intact spine after destabilization [13]. Recreation of the intimate contact between the articular processes of the facet joint seems to be critical for controlling rotational motion.

The results of this study suggest that after wide decompression of the neural elements, TFAS may avoid the need for fusion by virtue of its ability to stabilize the surgically modified spine in a manner similar to intact, while restoring physiologic kinematics (range and pattern of motion) at the operated level. Furthermore, TFAS might result in more natural kinematics at the adjacent levels when compared with fusion. The present study results provide an insight into the spinal response to two distinctly different loading modes in the immediate postoperative period. These results may prove useful in developing guidelines for postoperative activities.

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