Biomechanical Evaluation of a Novel Lumbosacral Axial Fixation Device

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Background: Interbody arthrodesis is employed in the lumbar spine to eliminate painful motion and achieve stability through bony fusion. Bone grafts, metal cages, composite spacers, and growth factors are available and can be placed through traditional open techniques or minimally invasively. Whether placed anteriorly, posteriorly, or laterally, insertion of these implants necessitates compromise of the anulus—an inherently destabilizing procedure. A new axial percutaneous approach to the lumbosacral spine has been described. Using this technique, vertical access to the lumbosacral spine is achieved percutaneously via the presacral space. An implant that can be placed across a motion segment without compromise to the anulus avoids surgical destabilization and may be advantageous for interbody arthrodesis. The purpose of this study was to evaluate the in vitro biomechanical performance of the axial fixation rod, an anulus sparing, centrally placed interbody fusion implant for motion segment stabilization. Method of Approach: Twenty-four bovine lumbar motion segments were mechanically tested using an unconstrained flexibility protocol in sagittal and lateral bending, and torsion. Motion segments were also tested in axial compression. Each specimen was tested in an intact state, then drilled (simulating a transaxial approach to the lumbosacral spine), then with one of two axial fixation rods placed in the spine for stabilization. The range of motion, bending stiffness, and axial compressive stiffness were determined for each test condition. Results were compared to those previously reported for femoral ring allografts, bone dowels, BAK and BAK Proximity cages, Ray TFC, Brantigan ALIF and TLIF implants, the InFix Device, Danek TIBFD, single and double Harms cages, and Kaneda, Isola, and University plating systems. Results: While axial drilling of specimens had little effect on stiffness and range of motion, specimens implanted with the axial fixation rod exhibited significant increases in stiffness and decreases in range of motion relative to intact state. When compared to existing anterior, posterior, and interbody instrumentation, lateral and sagittal bending stiffness of the axial fixation rod exceeded that of all other interbody devices, while stiffness in extension and axial compression were comparable to plate and rod constructs. Torsional stiffness was comparable to other interbody constructs and slightly lower than plate and rod constructs. Conclusions: For stabilization of the L_5-S_1 motion segment, axial placement of implants offers potential benefits relative to traditional exposures. The preliminary biomechanical data from this study indicate that the axial fixation rod compares favorably to other devices and may be suitable to reduce pathologic motion at L_5-S_1, thus promoting bony fusion. [DOI: 10.1115/1.2049334]

Keywords: Lumbosacral Fusion, Transaxial, Axial Fixation Device

Introduction

Interbody arthrodesis is commonly employed in the lumbar spine to eliminate painful motion and achieve stability by way of a bridging bony fusion. Interbody implants, hook and rod instrumentation, and plate systems have been developed for anterior, posterior, and lateral surgical approaches to facilitate fixation of the lumbosacral spine and promote long term interbody fusion.

Interbody implants may be advantageous biomechanically when compared to other types of fixation because of their proximity to the instantaneous axis of rotation (IAR) where they are loaded primarily in axial compression with little bending [1]. However, placement of interbody implants through an open approach can be associated with significant morbidity. To reduce morbidity, minimally invasive surgical approaches have been employed to access the interbody space [2,3]. Nonetheless, placement of interbody implants through an anterior, posterior, or lateral approach necessitates compromise of the anulus, an inherently destabilizing procedure. The current minimally invasive techniques may reduce morbidity, but do not eliminate iatrogenic destabilization.

Biomechanical testing has shown that a large box anulotomy will significantly reduce motion segment stiffness, a microdiscectomy has lesser effects, while piercing the anulus to make a 2 mm slit has no significant effect on mechanical properties [4,5]. These data are well recognized, yet interbody fixation methods have universally necessitated large anulotomies and disruption of inherent stabilizing tissues [6]. These approaches can reduce the intrinsic stability of the motion segment, particularly in extension [7].

Anterior and posterior instrumentation including hook and rod and plate systems avoid compromise of the disk, by adding stability without sacrifice of the anulus. However, when placed at a distance from the IAR, there may be a mechanical disadvantage because they are loaded greatly both axially and in bending [8].

To minimize disruption of the native stabilizing structures of a motion segment while capitalizing on mechanical advantages of interbody fixation, transdiscal fixation of the L_5-S_1 space has been suggested [9]. Using this technique, pedicle screws are placed into the vertebral body, through the disk space, to span the instrumented motion segment. Spanning the disk space axially has me-

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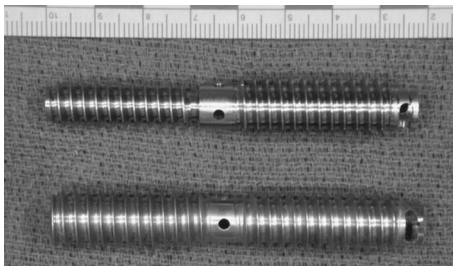

Fig. 1 The axial fixation rod is a cannulated, threaded, titanium rod with two distinct threaded sections—one superior, one inferior

chanical advantages, but to date, surgical approaches for placement of axial instrumentation in the intervertebral space have necessitated wide exposure and associated morbidity [10].

MacMillan et al. provided an early description of a minimally invasive technique for fixation of the L_5-S_1 segment via a transiliac-sacral pathway [11]. Through this minimally invasive approach, headless screws were placed obliquely across the disk space for fixation with good preliminary results.

A new axial percutaneous approach to the lumbosacral spine has recently been described by Cragg [12]. Using this technique, vertical access to the lumbosacral spine is achieved percutaneously via the presacral space. This approach allows for a novel means of access and fixation of the L_5-S_1 space axially.

The midline presacral entry is paracoccygeal using specialized instrumentation and bony landmarks of the ventral sacrum. With fluoroscopic guidance, serial dilators are used to access the inferior aspect of S_1 percutaneously. A transosseous tunnel is drilled through S_1 into the L_5-S_1 disk space. The tunnel is either continued through the disk into L_5 with the same drill, or a smaller concentric hole is drilled into L_5. Radial disk cutters are inserted through the axial tunnel and are used to remove the nucleus and abrade the endplate. A bone graft inserter is then passed through the osseous tunnel and autograft, demineralized bone matrix, bone morphogenic protein, or other osteoinductive material is inserted into the disk space. If the tunnel in L_5 is of the same diameter as S_1, a "nontapered" threaded fixation rod (with the same inferior and superior thread diameter and pitch) is inserted. If the tunnel diameter in L_5 is reduced, a "tapered" threaded fixation rod (with reduced superior diameter and different thread pitch) is inserted. The tapered rod can facilitate distraction of the motion segment if the superior thread is a more fine pitch than the proximal thread. Tapered and nontapered rods are shown in Fig. 1. After rod insertion, additional flowable osteoinductive material can be inserted through the cannulated rod via the radial ports in the central unthreaded portion of the rod. Bony fusion is facilitated by the graft material contained within the margins of the uncompromised anulus.

The axial approach to the lumbosacral junction spares all muscle, bony, and anular soft tissue and preserves all other surgical options. Early clinical results have shown minimal morbidity and excellent mechanical stability.

The purpose of this study was to conduct a preliminary biomechanical evaluation of two configurations of the novel axial fixation rod (TranS1 Inc., Wilmington, NC) as a means of stabilizing a motion segment to promote interbody fusion at the L_5-S_1 motion segment.

Method of Approach

The axial fixation rod is a cannulated, threaded, titanium rod with two distinct threaded sections—one superior, one inferior. As shown in Fig. 1, the central portion of the rod is unthreaded and contains radial holes through the walls. The inferior aspect of the rod mates with the insertion instrumentation for percutaneous transsacral placement. In this study, two variations of the axial fixation rod were evaluated: The nontapered rod with a major diameter of 12 mm along its full length; and the tapered rod with inferior-half major diameter of 12 mm and superior-half major diameter of 9 mm. The tapered rod has a smaller threaded area that the nontapered at the superior end, and thus has less surface contact area with the bone. However, the tapered rod has the advantage that can be used to distract the disk space.

Twelve 20 week old calf lumbar spines were obtained fresh and stored frozen below $-20\,^{\circ}$C until the time of use. Twenty-four motion segments, $L_{1\text{-}2}$, $L_{3\text{-}4}$, or $L_{5\text{-}6}$ were isolated for testing and all extraneous soft tissue was removed leaving the bony-ligamentous spine for testing.

After being thawed to room temperature, each motion segment was potted in low melting temperature alloy (LMA) and placed in a multi-degree of freedom mechanical testing machine to facilitate mechanical testing using an unconstrained flexibility testing protocol [13]. For testing, the potting fixture was bolted to the testing machine such that the specimen was rigidly attached to the machine. The inferior fixture rested on an x-y table which allowed the specimen unconstrained free motion during testing. A six axis load cell (AMTI, Inc., Watertown, MA) was used to measure the forces and torques being applied to the specimen during testing. The testing machine allows an axial compressive load to be applied continuously through the center of rotation of the single motion segment, as previously described by Patwardhan, while pure bending moments in flexion/extension, left/right lateral bending, and left/right torsion were applied to the specimen [14]. Relative changes in position and angulation were measured with high resolution optical encoders (Gurley Precision Instruments, Troy, NY) during testing.

Specimens were preconditioned by loading them cyclically in sagittal bending, lateral bending, and torsion for ten cycles at a rate of $2\,^{\circ}$/s. Applied force, applied moment, and displacement data were collected at a rate of at least ten samples per second using a portable data acquisition system (i/oTech, Cleveland, OH) during testing. Specimens were kept moist with 0.9% NaCl soaked gauze during testing.

Following the completion of ten preconditioning cycles, specimens were randomly assigned to either the low load group (500 N axial, 5 N m flexion/extension, 3 N m left/right lateral bending, 3 N m and clockwise/counter clockwise torsion with a 50 N axial preload) or high load group (10 N m flexion/extension, 10 N m lateral bending, 10 N m torsion with no axial preload) for testing. To establish base line properties, each specimen was first tested mechanically in its intact state for three cycles each in axial compression, lateral bending, sagittal bending, and torsion.

Following intact testing, motion segments were further divided into two treatment groups to receive either a single centrally located nontapered axial fixation rod (nontaper group), or a single centrally located tapered axial fixation rod (taper group). A sample size of six specimens was assigned to each combination of testing condition and treatment: high load taper, high load nontaper, low load taper, low load nontaper.

After intact testing, specimens were removed from the mechanical testing machine and the inferior vertebral body was unpotted from the LMA. Using a drill press with an 11 mm diameter bit, motion segments designated to the nontaper groups were drilled axially through the inferior endplate of the inferior body to the superior endplate of the superior body with care taken not to penetrate the superior endplate. Motion segments designated to the taper groups were drilled using the 11 mm drill from the inferior body to the center of the disk space in the same manner. A bushing was then placed into the existing hole and a smaller 6.4 mm diameter hole was drilled from the disk space to the superior endplate of the superior body using a power hand drill. The specimens were then repotted in LMA with gauze placed in the hole to prevent LMA from entering the axial channel. The potted specimens were placed in the mechanical testing machine and

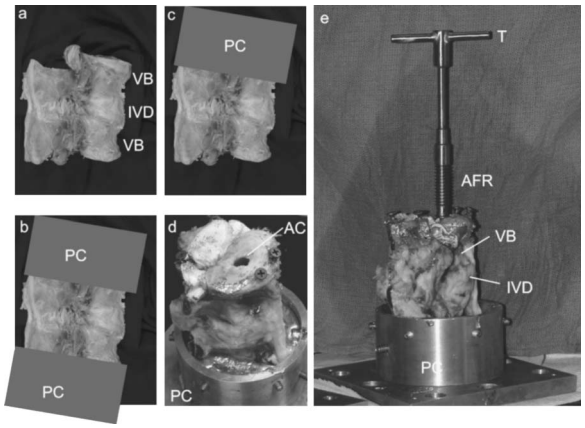

Fig. 2 (*a*) A calf motion segment with intact vertebral bodies (VB) and intervertebral disk (IVD) is shown. (*b*) The motion segment was potted in a potting cup (PC) in low melting temperature alloy and tested in its intact state. (*c*) The inferior vertebral body was unpotted. (*d*) The segment was then inverted and the axial channel (AC) was drilled and repotted. (*e*) After drilled-only testing, the inferior vertebral body was again unpotted and an axial fixation rod (AFR) was inserted (shown partially inserted). A T-handle wrench (*T*) was used to place the rod through the vertebral body and intervertebral disk into the adjacent vertebral body, which remained potted in the potting cup.

tested through the same three sets of range of motion cycles to determine the effects of drilling an axial channel through the motion segment.

After completion of drilled-only testing, specimens were removed from the mechanical testing machine and the inferior body unpotted from the LMA. The appropriate axial fixation rod was placed in the prepared motion segment, as shown in Fig. 2. The segment, with gauze covering the open end of the implant to prevent penetration of LMA, was again potted, followed by mechanical testing of the implanted specimen.

Implanted specimens in the low load groups were then subjected to additional cycles of testing (6.4 N m flexion/extension, 6.4 N m left/right lateral bending, 6.4 N m clockwise/counter clockwise torsion with no axial preload). After completion of mechanical testing, all specimens were removed from the mechanical testing machine and examined grossly.

Data from each third set of test cycles were used to determine the range of motion and stiffness for each specimen. Data from drilled specimens and implanted specimens were normalized and expressed as a ratio of their intact values. A repeated measures ANOVA and multiple t tests with the Bonferroni correction were used to determine significant differences between intact, drilled, and implanted values with $\alpha=0.05$.

Results

There were no failures or fractures of implants or motion segments during testing. All implants were placed centrally through the disk space. During drilling, there was a distinct "pop" when the drill penetrated through the endplate into the disk space. A substantial amount of torque was necessary to drive the threaded rods through the motion segments using the hand held instrumentation for both the tapered and nontapered rods. By direct visualization, the disk space in many specimens was distracted several millimeters during placement of the rods. Although not measured, this distraction appeared to be maintained during mechanical testing.

Drilling of the axial tunnel through the motion segment had little effect on the stability of the segment. The effects of drilling alone were only significant in axial compression, where the stiffness was reduced to 88% of intact, and torsion, where range of motion was increased by up to 50% of intact.

Results in the low load group, as shown in Table 1, indicate that specimens tested with the axial fixation rod (tapered or nontapered) exhibited an increase in axial compressive stiffness to 131.7% and 143.8% of their intact values, respectively. An increase in angular stiffness of the nontaper group was indicated by the marked reduction in ROM in flexion to 14.7%, extension to 32.5%, right lateral bending to 11.1%, and left lateral bending to 18.9% when compared to intact specimens. Similar reductions in ROM were observed in the taper group, with the greatest reduction in motion observed in flexion (20.8% of intact). A decrease in torsional ROM was observed with both implants but not to the extent of the other motions.

In the high load groups, there were increases in the stiffness of the tapered and nontapered groups, resulting in a reduced range of motion in all loading directions. As shown in Table 2, range of motion was reduced to 39% of intact flexion in the tapered group and 29% in the nontapered group, with similar reductions in other ranges of motion.

Discussion

Painful degenerative pathologies of the lumbosacral spine have historically been treated with arthrodesis and bony fusion. Stabilization with posterior instrumentation alone can be insufficient to eliminate pathologic motion, particularly when the segment is spondylolytic [15]. Posterior and 360° fusion procedures at the L_5-S_1 interspace have necessitated open exposures for adequate access to the wedge-shaped disk. Complications associated with

Table 1 Mean range of motion (ROM) and axial compressive stiffness data for specimens in the low load groups. LB=lateral bending, CW=clockwise, CCW=counter clockwise.

	Mean data (% of intact)	ROM at 5 N m flexion (°)	ROM at 5 N m extension (°)	ROM at 3 N m right LB (°)	ROM at 3 N m left LB (°)	ROM at 3 N m CW (°)	ROM at 3 N m CCW (°)	Axial stiffness (N/mm)
Taper	Intact specimen	4.5 (100%)	1.8 (100%)	2.9 (100%)	3.0 (100%)	0.4 (100%)	0.3 (100%)	2708.5 (100%)
	Drilled specimen	4.3 (91.7%)	2.3 (137.6%)	2.9 (104.1%)	2.9 (95.1%)	0.3 (107.8%)	0.4[a] (147.3%)	2409.3[a] (88.6%)
	Implant placed	0.9[a] (20.8%)	0.4[a] (40.1%)	0.8[a,b] (34.3%)	0.9[a] (29.1%)	0.2 (72.6%)	0.2[a] (77.7%)	3537.0[a] (131.7%)
Nontaper	Intact specimen	4.3 (100%)	1.8 (100%)	3.9 (100%)	4.1 (100%)	0.4 (100%)	0.4 (100%)	2489.8 (100%)
	Drilled specimen	4.6 (105.6%)	2.2 (124.7%)	4.0 (101.0%)	3.5 (91.1%)	0.4 (96.4%)	0.5[a] (151.2%)	2146.3[a] (87.6%)
	Implant placed	0.6[a] (14.7%)	0.5 (32.5%)	0.4[a,b] (11.1%)	0.5[a] (18.9%)	0.2 (51.7%)	0.3[a] (98.8%)	3442.5[a] (143.8%)

[a]Statistically significant difference ($p<0.05$) relative to intact condition.
[b]Statistically significant difference between tapered and nontapered treatments.

Table 2 Mean ROM data for specimens in the high load groups. LB=lateral bending, CW=clockwise, CCW=counter clockwise.

	Mean data (% of intact)	ROM at 10 N m flexion (°)	ROM at 10 N m extension (°)	ROM at 10 N m right LB (°)	ROM at 10 N m left LB (°)	ROM at 10 N m CW (°)	ROM at 10 N m CCW (°)
Taper	Intact specimen	5.1 (100%)	2.5 (100%)	7.1 (100%)	7.1 (100%)	1.2 (100%)	1.3 (100%)
	Drilled specimen	5.5 (107.0%)	2.8 (111.5%)	7.2 (100.6%)	7.1 (98.8%)	1.3 (100.9%)	1.3 (102.6%)
	Implant placed	1.9[a] (39.0%)	1.4[a,b] (56.6%)	3.7[a] (53.6%)	3.3[a] (47.3%)	1.0[a] (82.5%)	1.0[a] (76.8%)
Nontaper	Intact specimen	4.5 (100%)	2.9 (100%)	5.2 (100%)	5.5 (100%)	1.0 (100%)	1.0 (100%)
	Drilled specimen	4.9 (107.4%)	2.9 (101.7%)	4.9 (97.0%)	5.7 (103.9%)	1.0 (101.4%)	1.0 (93.6%)
	Implant placed	1.2[a] (29.3%)	1.2[a,b] (41.1%)	1.9[a] (40.2%)	2.0[a] (38.9%)	1.0 (96.0%)	0.9 (83.9%)

[a]Statistically significant difference $p<0.05$ relative to intact condition.
[b]Statistically significant difference between tapered and nontapered treatments.

these procedures such as nerve, vascular, and bowel injury, muscle denervation, arachnoiditis, and retrograde ejaculation have been reported with rates ranging from 5% to 35% [16–18].

Minimally invasive procedures for treatment of the lumbar spine have been described including miniopen, MIP PLIF, percutaneous pedicle screw placement, and laproscopic procedures [19–21]. The advantage of minimally invasive access to the lumbar spine, like other surgical procedures, includes reduced morbidity, diminished blood loss, and shorter hospital stay. Minimally invasive interbody cage placement has diminished morbidity relative to open procedures, but interbody cage placement through an anterior, posterior, or lateral approach necessitates compromise of the anulus, an inherently destabilizing procedure [22].

For stabilization and fusion of the L_5-S_1 motion segment, axial placement of implants offers potential benefits relative to traditional exposures for placement of interbody cages or posterior instrumentation. Biomechanically, it allows placement of stabilizing hardware in the interbody space without disruption of the anulus. The vertebral endplates and vertebral body bone can be used to anchor stabilizing implants or bone grafts. Thus, bending moments and axial forces developed not only during lateral bending and flexion, but also extension are stabilized by the implant.

Transdiscal placement of pedicle screws verified the feasibility of oblique axial fixation of L_5-S_1 [23]. Biomechanical testing indicated that motion segment stability was enhanced using oblique transdiscal fixation. Specimens fixed with transdiscal screws were stiffer in flexion than those fixed with pedicle screws and interbody devices, while transdiscal fixed specimens had similar stiffness in all other modes of testing.

Data from the current study indicate that axial placement of a single tapered or nontapered axial fixation rod as a stand-alone device significantly increased the stiffness of motion segments in all testing modes in comparison to the intact specimen. Data also indicate that the effects of drilling for placement of the axial fixation rod were minimal. Stiffness was significantly diminished only in counterclockwise torsion and axial compression due to drilling. The minimal changes resulting from axial drilling are unique relative to other procedures which necessitate large anulotomies and compromise of ligamentous structures. Thus there appears to be minimal iatrogenic destabilization from the transsacral axial approach to the L_5-S_1 disk space.

The use of interbody cages as a stand-alone treatment remains controversial, particularly in the challenging biomechanical environment of the L_5-S_1 motion segment [21,24,25]. Interbody cages alone may not provide sufficient stability, particularly in extension [26]. Clinically, interbody cages are commonly used in conjunction with posterior instrumentation. This offloads the interbody space, reduces range of motion, and reduces stresses at the bone-implant interface [27,28]. Subsequently, the likelihood of subsidence is diminished. Although interbody cages are seldom used as stand-alone devices, their relative contribution to motion segment stability as a stand-alone device has been well characterized.

The low load testing protocol used in the current study was selected so that mean stiffness values obtained for the axial fixation rod could be compared to those previously reported using the same protocol for stand-alone interbody cages. The BAK Device, BAK Proximity, Ray TFC, Danek TIBFD, Harms cage, Brantigan PLIF cage, Brantigan ALIF cage, femoral ring allograft, bone dowel, and InFix device were tested using the identical parameters utilized in the low load protocol of the current study [29]. The high load testing protocol used in the current study was selected so that mean range of motion values could be compared to those previously reported using the same protocol for the University Plate, Kaneda, and ISOLA systems [30]. As a basis of comparison, the range of motion of intact specimens from the current study is similar to those of the previously reported studies [30].

As shown in Tables 3 and 4, data indicate that of interbody devices, the nontapered and tapered axial fixation rods had the highest stiffnesses in flexion and lateral bending, while only the femoral ring allograft was more stiff in axial compression than the nontapered axial fixation rod. Stiffness data for extension were not reported for other interbody devices, presumably due to the inherent lack of resistance to extension motion.

Axial placement of a single axial fixation rod does not provide as high a resistance to axial rotation as it does in other testing

Table 3 Mean stiffness in flexion, lateral bending, torsion, and axial compression represented as a percentage of intact values (see Ref. [29])

	Stiffness (% intact)			
Device	Flexion	Lateral bending	Torsion	Axial compression
Nontapered axial fixation rod	169	562	134	144
Tapered axial fixation rod	131	288	116	132
BAK	115	120	115	135
Femoral ring	115	125	155	150
Bone dowel	105	130	115	115
Brantigan ALIF	100	90	65	90
Ray TFC	95	130	145	135
Brantigan PLIF	95	155	95	110
InFix device	95	200	110	100
Danek TIBFD	90	150	135	105
Single harms	90	80	105	110
BAK proximity	85	110	110	95
Double harms	70	115	100	95

Table 4 Mean range of motion in flexion, extension, lateral bending, and torsion at 6.4 N m (see Ref. [30])

Device	Range of motion (°)			
	Flexion	Extension	Lateral bending	Torsion
Nontapered axial fixation rod	0.81	0.89	1.29	0.71
Kaneda	0.85	0.93	1.95	0.42
Tapered axial fixation rod	1.13	1.04	2.10	0.54
Isola	1.46	1.71	0.70	0.56
University	1.51	1.56	1.36	0.48

modes because of its cylindrical shape and axial placement. However, mean torsional stiffness of specimens implanted with the axial fixation rods were comparable to other interbody devices. This may be attributed to the slightly oblique positioning of the device relative to the vertical axis, the high contact surface area of engagement at the bone-thread interface, and the contribution of the intact anulus.

In comparison to anterior and posterior instrumentation, the nontapered axial fixation rod resulted in the highest decrease in range of motion in flexion and extension. The nontapered axial fixation rod also resulted in substantial reduction in lateral bending range of motion with only the Isola system having a higher reduction. In axial rotation, the Kaneda and University systems reduced the range of motion more substantially than the nontapered axial fixation rod only by 0.12° and 0.06°, respectively.

The current study characterizes the contribution of the axial fixation rod to motion segment stabilization as a stand-alone device. Data from the current study do not indicate how well the rod will resist subsidence with chronic cyclic loading. The axial fixation rod is designed to have a high contact surface area with the vertebral body bone, thus reducing stresses at the bone-implant interface. Like interbody cages, the axial fixation rod can be used in conjunction with posterior instrumentation which further reduces the stresses at the bone-implant interface. Subsequently, the chances of bone resorption or implant loosening are likely diminished.

These preliminary biomechanical data indicate that the axial fixation rod compares favorably to other devices and may be suitable to reduce pathologic motion at the L_5-S_1 motion segment, thus promoting bony fusion. The results from this study provide a means for comparison of the stiffness and range of motion relative to other commonly used fusion devices. The data from this study, like the data to which they are compared, are collected from calf motion segments. The calf spine is a well documented model of the human lumbar spine, however, there are limitations to the clinical conclusion that can be gleaned from studies utilizing this model. The bone mineral density and strength of calf vertebral bone is superior to human, thus the response of the bone-implant interface may be different in healthy human bone, which may in turn be different from osteopenic bone. Relative to other fusion implants, the axial fixation rod stabilized the motion segment superiorly, but further research is necessary to fully understand the long term efficacy of transdiscal fixation with the axial fixation rod.

The percutaneous axial approach may be advantageous clinically to open procedures at L_5-S_1 because it requires minimal dissection and leaves the anulus intact. The axial approach may have advantages for access to the L_5-S_1 disk space for single level fusion and may be utilized for two-level fusions involving L_4-L_5 and L_5-S_1 using the same access.

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