

## In Vitro Testing of Lumbar Disc Arthroplasty Devices

Denis J. DiAngelo<sup>a,b,\*</sup>, Kevin T. Foley<sup>a,b</sup>, Brian P. Morrow<sup>a</sup>, Peter Wong<sup>a</sup>, Kelly Kiehm<sup>b</sup>, Anthony Sin<sup>b</sup>, Rudolf Bertagnoli<sup>c</sup>, Celeste Abjornson<sup>s</sup> and Brian P. Kelly<sup>a</sup>

<sup>a</sup>Department of Orthopedic Surgery and Biomedical Engineering, University of Tennessee Health Science Center, Memphis, TN, USA

<sup>b</sup>Department of Neurosurgery, University of Tennessee Health Science Center, Memphis, TN, USA

<sup>c</sup>Spine Center, St. Elizabeth Klinikum, Straubing, Germany

<sup>s</sup>Synthes Spine, West Chester, PA Research support from Synthes Spine, West Chester, PA and use of the surgical facilities at the Medical Education and Research Institute, Memphis, TN, USA

**Abstract:** *Background Context:* Interest in lumbar disc arthroplasty as an alternative to fusion surgery continues to grow. The goal of disc arthroplasty is to replace the diseased disc while preserving and/or restoring motion at the operated spinal level. Different paradigms exist in the design of total disc arthroplasty devices. *Purpose:* The purpose of this study was to compare the *in vitro* biomechanics of a more constrained ball-and-socket design (Prodisc-L, Synthes Spine and Maverick, Medtronic) and a less constrained mobile-bearing design (Charité, DePuy). The biomechanical performance of the disc prostheses was compared to harvested and fused spine conditions. The fused model was simulated using single-level posterior pedicle screw fixation instrumentation. *Study Design/Setting:* *In vitro* test to compare the biomechanical properties of three different lumbar disc replacement devices in a human cadaveric model. *Methods:* Twenty human cadaveric lumbar spines (L1-sacrum) were tested in flexion, extension, lateral bending, and axial rotation under displacement control to a target bending moment of 8Nm. The spine conditions tested were: harvested spine (n=19); L5-S lumbar disc replacement using Prodisc-L (n=13); Maverick (n=7); Charité (n=6); and L5-S pedicle screw fixation (PSF) (n=19). The first 12 spines were split into 2 groups: 6 were instrumented with the Charité and 6 with the ProDisc-L. The next 7 spines tested were split into 2 groups: 4 instrumented with ProDisc-L and 3 with the Maverick. After completing all tests on the second group of 7, the Maverick and ProDisc-L discs were swapped between spines and retested. The Click'X pedicle screw system (Synthes Spine) was used to simulate the fusion model in all spines tested. For axial rotation tests, a 100N compressive load was applied. Measurements included vertebral motions, total spine rotation, and applied loads. The percent contribution of rotation at the instrumented (L5-S) level relative to total rotation (L1-S), as well as at the remaining adjacent levels relative to total rotation, was determined a common load limit (8Nm) and compared using a one-way ANOVA and SNK test (P<0.05). *Results:* A significant reduction in motion occurred at the operated level of PSF condition compared to the three disc arthroplasty conditions for all loading modes. No differences occurred between the 3 disc conditions for all modes tested, except at the instrumented level of the ProDiscL (93% of H) and Maverick (128% of H) spine conditions during combined flexion+extension. The reduced motion at the operative level of the PSF condition was transferred to the adjacent levels and caused a significant increase in motion during combined flexion+extension at all adjacent levels for the 3 disc arthroplasty conditions, during combined right+left lateral bending at L1-L2 for all disc conditions and at L3-L4 for the Charité, and during combined right+left axial rotation at L3-L4 for all three disc conditions. *Conclusions:* Issues pertaining to adjacent segment disease (ASD) with pedicle screw fixation were supported by increased motion contributions at multiple sub-adjacent segments. However, disc arthroplasty eliminated any significant increase and may prevent ASD. Compared to pedicle screw fixation, the three differently designed disc prostheses (Prodisc-L, Maverick, and Charité) remained stable and provided improved lumbar mobility. The only notable difference between the disc designs was the increased combined flexion+extension motion at the operative level of the Maverick disc compared to the ProDisc-L device.

**Keywords:** Lumbar spine, biomechanical testing, spinal instrumentation, lumbar disc, arthroplasty, biomechanics.

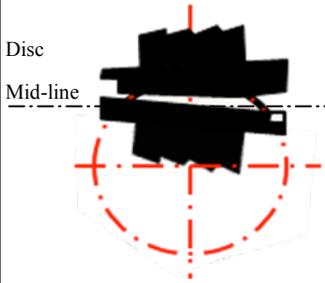
### INTRODUCTION

Back pain is one of the most common reasons to seek care and affects approximately one fourth of the adult

population in the United States [1]. When conservative treatments for this disease fail, surgery may be indicated. For lumbar spine structural pain, the gold standard surgical treatment has been vertebral body fusion. Reported drawbacks and complications associated with spinal fusion surgery have included the need for external orthosis, the development of pseudoarthrosis, which may be associated with continued symptoms of back pain, the degeneration of

\*Address correspondence to this author at the Department of Orthopedic Surgery and Biomedical Engineering, The University of Tennessee Health Science Center, 956 Court Ave., Suite E226, Memphis, TN 38163, USA; Tel: 901-448-7744; Fax: 901-448-7387; E-mail: [ddiangelo@uthsc.edu](mailto:ddiangelo@uthsc.edu)

**Table 1. Design features of lumbar total disc replacement devices.**

Design Features	ProDisc-L	Maverick	Charite
Side Profile of Disc Implant			
Classification	Constrained	Constrained	Semi-constrained
Initial Fixation	Keel	Keel	Teeth
Number of Components	2	2	3
Articulating Materials Theoretical	metal – UHMWPE*	metal - metal	metal - UHMWPE
Superior – Inferior Location of COR	Inferior Vertebra	Inferior Vertebra	Within Implant
Anterior – Posterior Location of COR	Center of Implant	~ 5mm Posterior	Center of Implant

\*UHMWPE: ultra high molecular weight polyethylene

levels adjacent to the fused region, or not work to help resolve the patient's symptoms [2-7]. Use of motion preservation devices, including total disc arthroplasty, has recently become a potential alternative to fusion that aims to overcome some of these limitations by replacement of the diseased disc, restoration of disc space height, and preservation of motion at the operated spinal level [8]. Disc arthroplasty offers the potential to not only treat the underlying disc mediated pain, but better control the advancement of degenerative disease at the adjacent segments.

Different constructs exist in the design of total disc arthroplasty (TDR) devices which vary by the type of motion constraint imposed by the device. One design allows the device to have rotation, similar to a ball and socket joint. The ProDisc-L (DePuy Synthes Spine, West Chester, PA) and the Maverick (Medtronic, Memphis, TN) utilize this feature, but have design differences that may contribute to varied kinematic responses. Another less constrained TDR, the Charité disc implant (Depuy Spine, Raynham, MA), involves a mobile polyethylene core that can translate between components in addition to unconstrained rotation. The core translations make the center of rotation (COR) mobile.

It remains of clinical interest to better understand the effects of these different TDR designs on the biomechanics, replacement level specificity, adjacent segment effects and comparison of function to a healthy lumbar disc and any improvements and/or differences when compared with traditional fusion surgery. The purpose of this study was to compare the *in vitro* biomechanics of a more constrained ball-and-socket design (Prodisc-L and Maverick) and a less constrained mobile-bearing design (Charité) in a human

multi-level cadaveric lumbar spine model. The biomechanical performance of the disc prostheses was compared to harvested and fixated spine conditions. The fixated model was simulated using single-level posterior pedicle screw fixation instrumentation.

## MATERIALS AND METHODS

### Spinal Instrumentation

Three different disc prostheses were studied: the ProDisc-L (DePuy Synthes Spine, West Chester, PA), Maverick (Medtronic, Memphis, TN), and Charité disc implant (DePuy Synthes Spine, Raynham, MA). A list of design features describing these three TDRs is given in Table 1. The ProDisc-L has an articulating surface with a 14.5mm (medium size) or 16.5mm (large size) radius of curvature, whereas the Maverick has a 10mm (nominal) radius of curvature. The COR for both of these constrained disc designs are located in the subjacent body. The COR of the Charite disc is located at the center of the disc along the anterior-posterior midline similar to the ProDisc-L. The COR location of the Maverick disc is approximately 5 mm posterior to that of the ProDisc-L. Variations in the COR placements are illustrated in Table 1.

### Specimen Preparation

Twenty fresh frozen human cadaveric lumbar spines with mean age of  $56.7 \pm 14.9$  years were procured. All spines were screened with anteroposterior and lateral radiographs to exclude any specimens with gross osteopenia or anatomic abnormality. Bone density measurements were not done.

### Flexion + Extension Motion Profiles for Levels L1-S

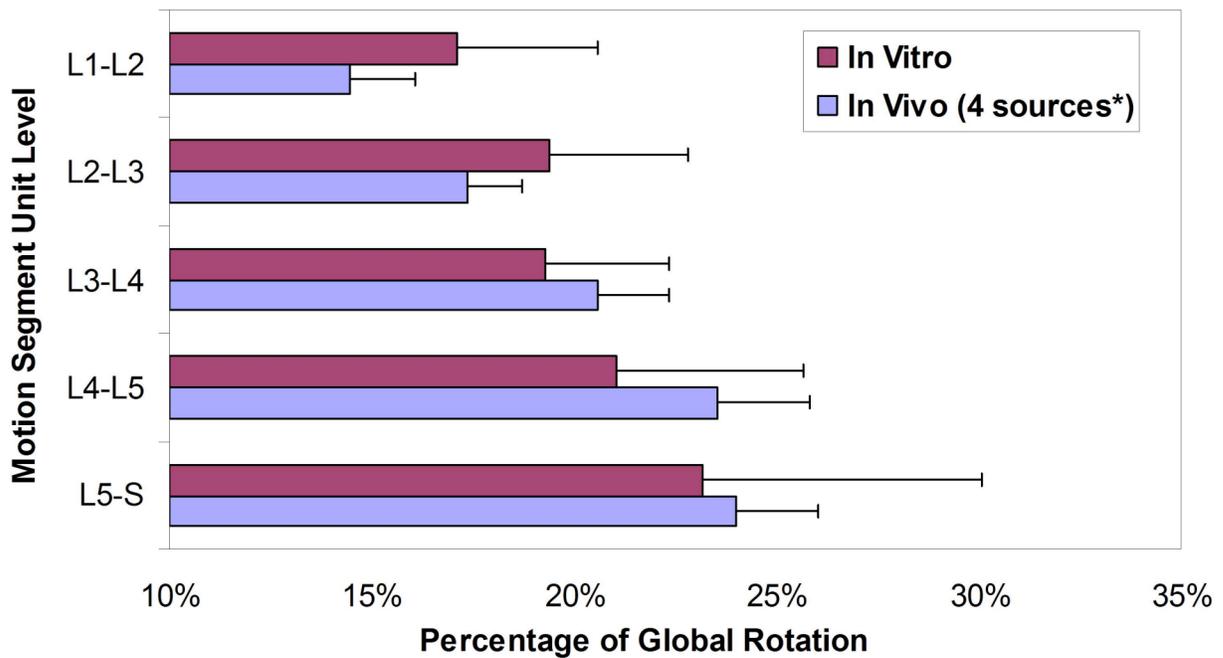


Fig. (1). Bar graph showing combined flexion/extension MSU rotations for *in vitro* testing method compared with published *in vivo*\* data [13-16].

However, any specimen that was unable to provide adequate end plate purchase to prevent subsidence, as determined by the spine surgeons, was not used. One specimen was discarded due to poor tissue quality for implant fixation reducing the total sample size to nineteen.

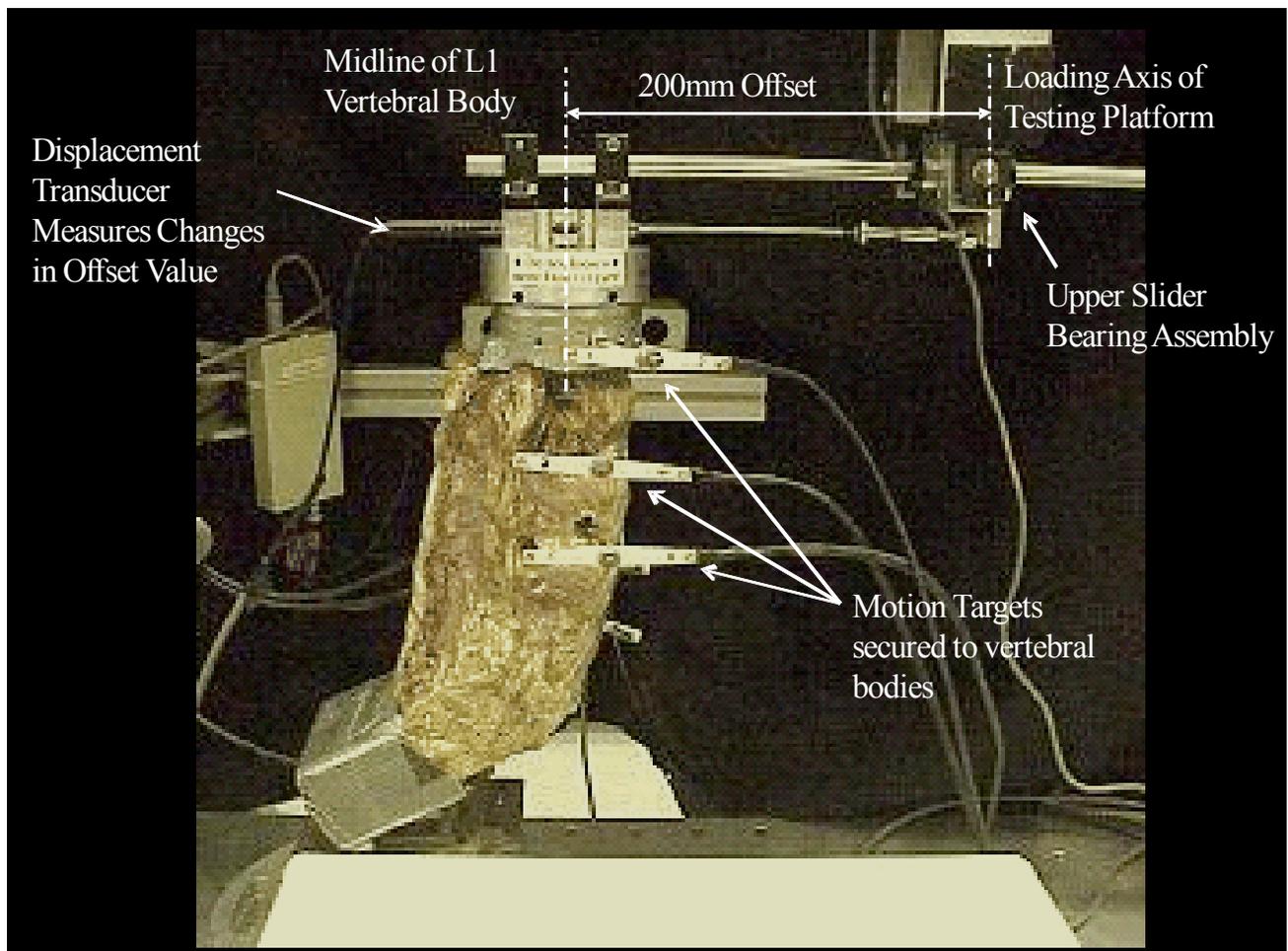
For each specimen surrounding paravertebral soft tissues were dissected while preserving spinal ligaments, discs, and bone. The posterior elements were not removed for testing. Specimens were potted in a neutral, upright orientation with low-melting-point, bismuth alloy (Small Parts, Miami Lakes, FL) applied to the L1 vertebral body and sacrum. Threaded rods were placed into the lateral aspects of the vertebral bodies to secure light emitting diode (LED) targets used with an optical motion tracking system. Target attachment did not interfere with the placement of lumbar disc prosthesis or pedicle screw instrumentation.

#### Nondestructive Testing Protocol

Although various *in vitro* testing methods have been employed to study the stability of lumbar spinal instrumentation, the pure moment loading method is the most common [9]. Pure moment methods are suitable for ranking different fixation systems. However, they are less appropriate for studying motion preservation or non-fusion instrumentation systems, as they do not replicate physiologic loading conditions nor do they induce physiologic motion responses at segments adjacent to an instrumented level. The same holds true for hybrid testing methods [10] that force an erroneous amount of motion compensation to occur at non-instrumented segments by forcing all instrumented spine conditions, including fixated conditions, to obtain the same global motion response of the intact spine condition.

As the lumbar spine flexes or extends *in vivo* from a neutral upright orientation, the weight of the upper body acts eccentric to the lumbar spine. When this body load is transferred to the top of the lumbar spine, a compressive load and bending moment occur. An eccentric load testing protocol [11, 12] was developed and used that applied a compressive load eccentric to the long axis of the spine which induced a bending moment distribution across the spinal construct that increased in the caudal direction. This protocol has been used to study other lumbar spinal instrumentation [11, 12]. Validation of the eccentric load testing protocol was provided by the close congruence of *in vitro* flexion/extension motion response shown in Fig. (1) to that of published *in vivo* data [13-16].

The experimental set up for flexion and extension is shown in Fig. (2). A single tension/compression load cell (Transducer Technologies, Temecula, CA) was positioned in-line with the actuator shaft. The other end of the load cell connected to an upper mounting fixture assembly that included a linear bearing and pinned assembly connected to slotted shaft that attached to the spine. The offset between the center of the upper potted spinal body and the actuator was 200mm. The linear bearing provided a nearly frictionless connection to the splined shaft to reduce applied shear forces during the movement of the actuator. With the load axis of the actuator eccentric to the spine, a compressive force (25N L1 pot + applied load) and flexion/extension bending moment were applied to the spine. The spine was rotated 90 degrees in the mounting fixtures to apply a lateral bending moment. A rotational displacement transducer (Data Instruments, Acton, MA) was attached to the upper pinned assembly and measured the global rotation of spine. The displacement transducer recorded changes in the moment



**Fig. (2).** Experimental Setup for Flexion/Extension Eccentric Load Testing Protocol.

arm length between the upper pot and load axis of the actuator during flexion/extension or lateral bending tests.

The spines were first tested in the Harvested condition in flexion, extension, lateral bending, and axial rotation. For flexion, extension and lateral bending tests, the spine was positioned at a 200mm offset from the actuator load axis. Since axial rotation is strongly coupled with lateral bending, the spines were unconstrained in axial rotation during lateral bending tests and unconstrained in lateral bending during axial rotation tests [17-19].

For axial rotational tests, the upper slider bearing assembly was replaced with a vertical linear bearing assembly that constrained the top of the spine from rotating but permitted free upward or downward translation. A turntable mounted on an x-y table was added to the base of the spinal construct. Upward movement of the actuator pulled a cable system that in turn rotated the turntable and applied an axial torque to the spine. A torque load cell inline in line with the vertical linear bearing assembly measured the torque transferred through the spinal construct. A compressive preload of 100N was continuously applied to the spine by placing 100N stationary weights on top of the L1 pot. This amount falls between the no load condition used with the pure moment test methods and a 400N load used with the follower load test protocol. A counterbalancing load of 45N was applied to the turntable to return the specimen to

the neutral position during the unloading phase. Right and left axial rotations were produced to simplify changing position of the cables that turned the rotary table.

Tests were performed under displacement control with a programmed triangular shaped displacement-time waveform of 6.4 mm/sec, corresponding to approximately 2.0 deg/sec overall spine motion. Specimens were nondestructively tested in flexion/extension and lateral bending to a target bending moment of 8Nm. This target moment of 8Nm falls within the typical load condition used by other spine researchers [10, 11, 20-23, 24-30]. Spines were preconditioned with five cycles before testing with each test trial comprised of three loading cycles. To avoid dehydration spines were moistened throughout the study with 0.9% saline solution.

### Spinal Test Conditions

Following completion of the harvested tests, a conventional anterior discectomy and end plates preparation were performed by a spine surgeon experienced with total disc replacements to prepare for disc implantation after which the spines were tested with the disc implant in place. The discectomy procedure included removal of the anterior longitudinal ligament, anterior annulus, and nucleus pulposus, and extended posteriorly to the posterior longitudinal ligament. All procedures were performed at the Medical

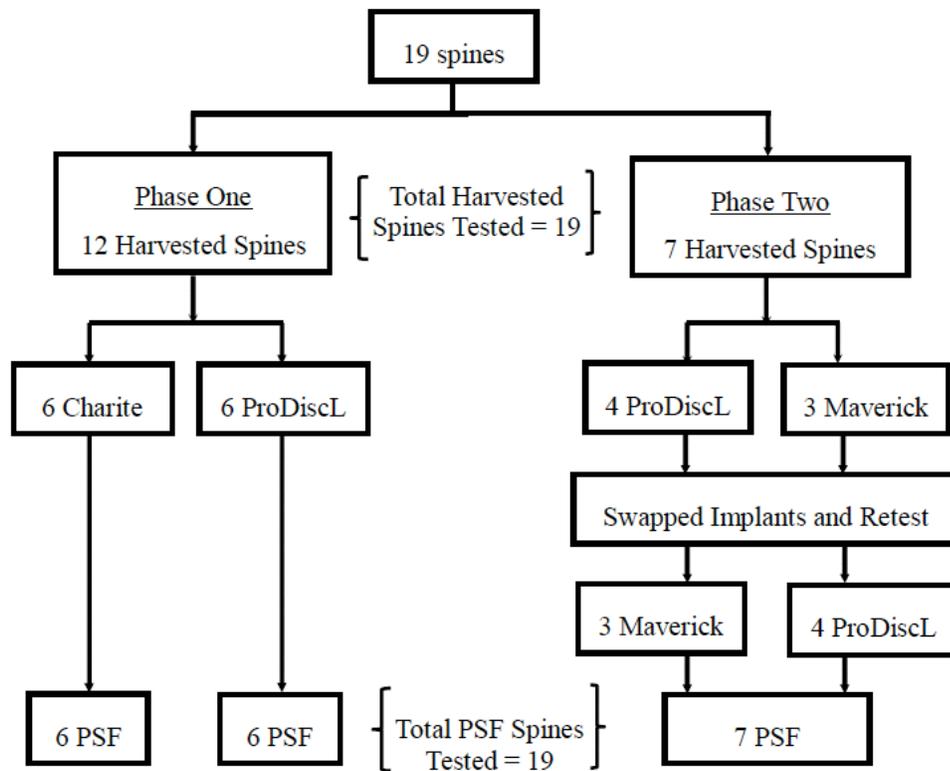


Fig. (3). Flowchart of Spine Test Conditions.

Education Research Institute, (Memphis, TN) as per manufacturer’s surgical guidelines.

A total of twenty specimens were procured and five different spine conditions were evaluated. They included the Harvested spine, L5-S1 lumbar disc replacement using ProDisc-L, Maverick, Charité, and L5-S1 pedicle screw fixation (PSF). This study was done in two phases as illustrated in Fig. (3). The first phase of the study compared the ProDisc-L and Charite discs to the intact and fixated models. In phase One, 12 spines were randomly split into 2 groups: 6 spines were instrumented with the Charité and 6 spines with the ProDisc-L. The second phase of the study compared the ProDisc-L and Maverick discs to the intact and fixated conditions. Eight spines were used in Phase two with four spines allocated per implant type. However, during the surgical placement of one of the maverick discs, one specimen was rejected due to poor tissue quality. This reduced the total specimen count for phase two to 7 specimen.

Unlike in the first phase where only one disc implant was tested per specimen, both discs were tested in each specimen during phase two. That is after the initial implanted spines were tested, all implants were removed. The ProDisc-L implants were then placed by the spine surgeon as per industry specifications into those specimens that previously had Maverick discs. In a similar way the maverick discs were implanted into the spines that previously been used for the ProDisc-L implants. After all of the re-instrumented spines were tested, the total number of specimens per implant was 7. As such the number of specimens per implant is not equal. However, this did not prevent a valid statistical

comparison of the data. The final spine condition to be tested was the instrumented PSF condition.

The 7 remaining harvested spines were split into 2 groups: 4 instrumented with the ProDisc-L and 3 with the Maverick. After completing tests on the second group of 7, the Maverick and ProDisc-L discs were swapped between spines and retested. The Click’X pedicle screw system (DePuy Synthes Spine) was used to simulate the fixated model in all spines tested with the disc replacement functioning as an inter-body graft (Fig. 4). The disc implants remained in place and the pedicle screw spinal instrumentation was inserted as per manufacturer’s specifications under fluoroscopic image guidance to ensure proper sizing and placement. In the end the fixated condition was representative of a typical salvage operation involving pedicle screw and rod instrumentation without disc implant removal. A similar spine condition was tested by Cunningham *et al.* [31] and found to be biomechanically equivalent to femoral ring allograft with posterior pedicle screw and rod instrumentation.

### Data Processing and Management

Measurements included vertebral body rotations, total spine rotation, and applied loads. The moment applied to the spine at mid-line of L1 vertebral body ( $M_a$ ) was calculated from the vertical force reported by the in-line load cell ( $F_a$ ), the total rotation of the upper pot reported by the rotational transducer ( $\theta_{rdt}$ ), and the displacement offset ( $d_a - d_{idt}$ ) between the upper pot and load axis:  $M_a = F_a(d_a - d_{idt})/\cos(\theta_{rdt})$ , where  $d_a$  is the initial offset distance between the load axis and the center of the upper pot. For each test trial, the vertebral rotation and applied moment data were

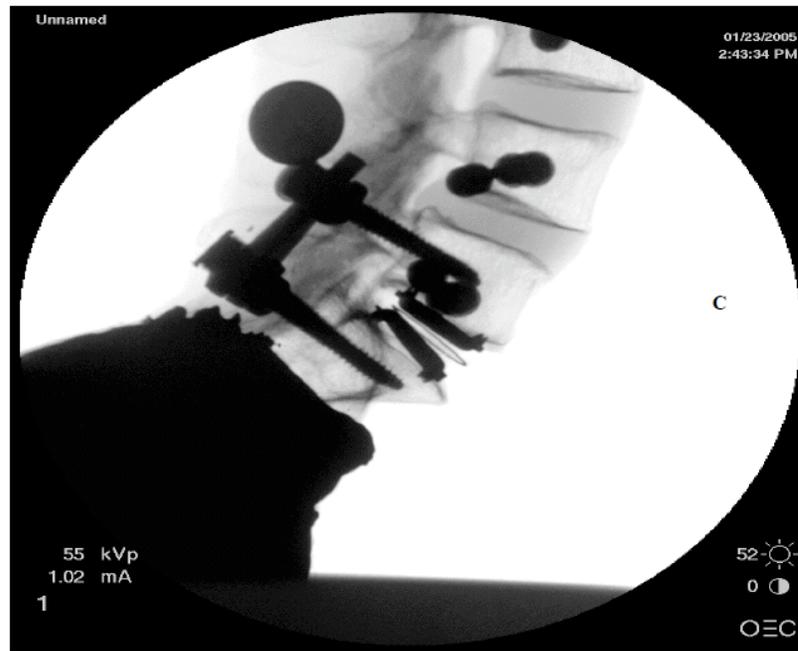


Fig. (4). Post-operative radiograph of the simulated fixated spine condition.

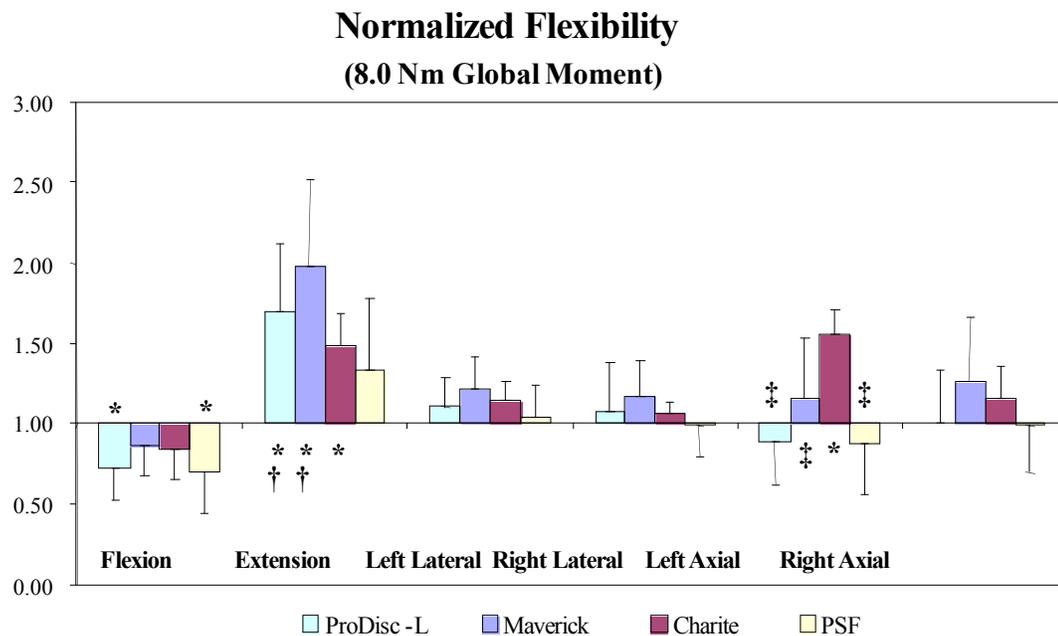


Fig. (5). Normalized flexibility of the altered spine conditions relative to the harvested condition. (\* Signifies significant difference between the harvested condition, † signifies significant difference from the fixated condition, ‡ signifies significant difference with respect to the Charité implanted condition).

combined to calculate global (L1-S1) spine flexibility which was normalized to the Harvested condition to account for intrinsic differences between specimens. The percent contribution of rotation at the instrumented (L5-S1) level relative to total rotation (L1-S1), as well as at the remaining adjacent levels relative to total rotation, were determined at a common load limit, normalized to corresponding values for the Harvested condition, and statistically compared between instrumented groups. All data analyses were performed at a load limit of 8Nm bending moment. Statistical tests were conducted using a one-way ANOVA and SNK test ( $P < 0.05$ ).

## RESULTS

### Normalized Flexibility

Mean normalized global flexibility charts for the four instrumented spine treatments are summarized in Fig. (5). In flexion the fixated spine condition significantly reduced global flexibility by 30% compared to the Harvested spine condition. All TDR interventions reduced the global flexibility, but only the ProDisc-L significantly reduced the flexibility of the Harvested condition by 28%. In extension

the Charité, ProDisc-L and Maverick spine conditions significantly increased global flexibility over the Harvested condition by 48%, 70% and 98%, respectively. No other significant differences occurred in all other modes of loading, with the exception of left axial rotation, where the Charité spine condition demonstrated a mean increased flexibility of 55% over the Harvested case that was significantly different from all other spine conditions.

### Relative Motion Segment Unit (MSU) Rotations

#### Flexion/Extension

Mean operated level (L5-S1) and global (L1-S1) spinal rotations are given in Table 2 for all spine conditions. The mean segmental rotations at each spinal level for all spine conditions are provided in Figs. (6 to 8). The percent contribution of each MSU rotation within each spine condition normalized to its contribution in the Harvested case is summarized in Figs. (9 to 11) with statistical differences indicated.

For the Fixated spine condition in flexion-extension, the contribution of operative L5-S1 level to overall spinal rotation was reduced by 72% compared to its contribution in the Harvested case. The MSU contributions relative to global spinal rotation at levels L1-L2, L2-L3, and L3-L4 for the Fixated condition significantly increased by 33%, 28%, and 21%, respectively over the Harvested condition. For the three different disc implants relative motion contributions at all levels were not different from those for the Harvested condition. Significant differences in percent motion contributions between all TDR conditions and the Fixated spine condition occurred at levels L2-L3 and L5-S1, and additionally at L3-L4 for the ProDisc-L and Maverick spine conditions. Between the different types of TDR implants a significant difference occurred between ProDisc-L and Maverick at the L5-S1 level with the Prodisc-L reducing motion contribution by 7%, and the Maverick increasing the contribution by 28% compared to the Harvested case.

#### Lateral Bending

In left-right lateral bending motion contribution at the L5-S1 treated level for the Fixated spine specimen was significantly reduced by 54% compared to the Harvested case, and significantly different from that of the ProDisc-L, Maverick and Charité implants which reduced the L5-S1 contribution by 14% and increased it by 17% and 32%, respectively. No significant differences were found in motion contribution when all levels were added together between TDR and Harvested conditions.

#### Axial Rotation

In left-right axial rotation motion contributions for the Fixated condition were significantly reduced by 60% at the L5-S1 and increased by 53% at L2-L3 levels compared to the Harvested condition. Motion contributions at the treated L5-S1 level for the ProDisc-L, Maverick and Charité conditions were all significantly different from the Fixated condition and increased relative to the Harvested condition by 9%, 51%, and unchanged, respectively.

## DISCUSSION

The ProDisc-L and Maverick implants represent a more constrained ball and socket design of total disc replacement as compared to the mobile core design of the Charité. As previously discussed by Huang *et al.* [23] more unconstrained designs may have a kinematic advantage via a mobile COR that can better compensate for variations in surgical placement and deviations between the implant and true physiologic location of a moving COR. Additional mobility may also prevent excessive capsuloligamentous and facet loads at extreme flexion or extension. In contrast more constrained ball and socket type designs may have the advantage of shielding the facet joints (posterior spinal elements) from considerable shear forces that occur during daily activities.

Limited biomechanical data are available that characterizes the different TDR design features. In this study, the biomechanical properties of the ProDisc-L, Charité, and Maverick TDR devices were studied using a multi-level lumbar spine model. Hitchon *et al.* [24] evaluated the Maverick disc implant at L4-L5 under pure moment loading to 6Nm. Their results for the implanted condition showed increased L4-L5 ROM as compared to the Harvested state for all modes of testing (16.3 vs. 10.9 degrees in flexion-extension, 10.8 vs. 8.1 degrees in bi-axial rotation, 18.8 vs. 8.9 degrees in left-right bending). Cunningham *et al.* [25] reported a significant increase in motion at the instrumented L4-L5 level for the Charité over the harvested condition of 44% for axial rotation under pure moment loading. Using pure moments with a 400N follower load, Goel *et al.* [26] reported different results of a 26% increase in flexion and a 98% increase in extension ROM. O'Leary *et al.* [27] reported increased segmental range of motion of 47% in combined flexion-extension over the harvested case, for the Charité at L5-S1.

Using a hybrid protocol with 400N follower load Panjabi *et al.* evaluated both the ProDisc-L and Charité disc implants in independent studies [28, 29]. For the single level Charité at L5-S1 no significant differences in motion at all levels in flexion-extension and bi-axial torsion occurred with a 2.7% reduction and 24.6 % increase in motion at the operated level respectively. For a single level ProDisc-L at L5-S1 no significant differences in motion at all levels were observed in flexion-extension with a 1.1% reduction in motion at the operated level as compared to the harvested spine. However, significant increases in L5-S1 segmental motion of 55.5% and 72.8% were observed for left-right lateral bending and bi-axial torsion respectively.

Given different *in-vitro* testing protocols, surgical procedures and variations thereof, it is difficult to speculate on the performance of different implant designs based on these studies. Results from load based investigations may indicate potential for increased ROM with the Maverick and Charité implants though the modes of loading in which increases were observed varied. Additionally, core entrapment with the Charité which locked the mobile core over a portion of the range of motion in 8 of 10 implants was also observed by O'Leary *et al.* [27] which indicated that total disc replacements may not always function as intended.

**Table 2. MSU rotations of all spine conditions for all modes of testing in degrees. (mean  $\pm$  standard deviation).**

		Flexion					
	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1	L1-S1 Total	
Harvested	-5.0 (1.8)	-4.3 (1.5)	-5.4 (1.9)	-5.7 (1.9)	-5.9 (2.3)	26.3 (5.2)	
Prodisc-L	-3.8 (2.3)	-2.9 (1.0)	-3.2 (1.1)	-3.7 (1.1)	-3.3 (1.6)	16.9 (4.8)	
Maverick	-4.7 (2.1)	-4.0 (1.7)	-5.0 (1.8)	-4.5 (1.7)	-5.2 (2.6)	23.4 (7.5)	
Charite	-4.5 (1.5)	-4.2 (1.9)	-5.2 (1.8)	-5.9 (2.7)	-4.9 (1.2)	24.8 (7.9)	
Fusion	-4.4 (2.0)	-3.7 (1.9)	-4.3 (2.0)	-4.6 (2.3)	-1.0 (0.5)	18.0 (7.4)	
		Extension					
	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1	L1-S1 Total	
Harvested	2.8 (1.2)	2.0 (0.9)	2.3 (0.8)	2.6 (1.2)	3.7 (1.6)	13.5 (4.5)	
Prodisc-L	5.0 (1.2)	3.7 (1.6)	3.7 (1.3)	4.7 (1.9)	4.8 (2.2)	22.0 (6.4)	
Maverick	4.5 (1.7)	3.5 (1.6)	3.9 (1.5)	3.8 (1.9)	7.1 (3.6)	22.8 (9.1)	
Charite	4.0 (1.2)	3.1 (0.9)	3.8 (0.9)	4.5 (2.0)	4.9 (2.8)	20.2 (6.7)	
Fusion	4.5 (1.9)	3.5 (1.9)	3.7 (1.4)	4.0 (2.2)	1.2 (0.6)	16.9 (6.3)	
		Left Lateral Bending					
	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1	L1-S1 Total	
Harvested	-4.0 (1.1)	-4.3 (1.6)	-5.1 (1.7)	-3.2 (0.8)	-2.4 (0.8)	19.0 (4.6)	
Prodisc-L	-4.6 (1.1)	-4.4 (1.3)	-5.8 (2.3)	-3.7 (1.3)	-2.2 (1.2)	20.7 (4.6)	
Maverick	-4.6 (1.2)	-4.5 (1.9)	-6.6 (2.2)	-4.2 (1.2)	-2.8 (0.7)	22.8 (4.4)	
Charite	-4.1 (1.7)	-5.1 (2.1)	-5.5 (1.1)	-3.6 (1.1)	-3.6 (0.5)	22.0 (4.5)	
Fusion	-4.6 (1.4)	-4.6 (1.8)	-5.3 (1.9)	-3.4 (1.4)	-0.7 (0.4)	18.5 (5.1)	
		Right Lateral Bending					
	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1	L1-S1 Total	
Harvested	4.1 (1.1)	3.7 (1.5)	5.2 (1.2)	3.4 (1.3)	2.2 (0.8)	18.5 (3.0)	
Prodisc-L	4.4 (1.7)	3.9 (1.8)	4.3 (1.4)	3.5 (1.5)	1.9 (1.1)	18.0 (5.2)	
Maverick	4.1 (0.7)	4.3 (2.1)	5.1 (1.3)	3.4 (1.3)	2.6 (0.8)	19.5 (4.9)	
Charite	4.3 (1.1)	4.7 (1.5)	5.6 (0.7)	4.2 (1.5)	3.7 (0.6)	22.5 (1.8)	
Fusion	4.6 (1.3)	4.2 (2.4)	5.2 (1.7)	3.4 (1.6)	0.7 (0.3)	18.0 (4.9)	
		Right Axial Rotation					
	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1	L1-S1 Total	
Harvested	1.0 (0.7)	1.2 (0.7)	1.7 (0.9)	2.0 (1.2)	1.8 (1.1)	7.7 (2.1)	
Prodisc-L	1.0 (0.5)	1.3 (0.7)	1.4 (0.8)	1.7 (0.5)	1.7 (1.0)	7.1 (2.5)	
Maverick	1.0 (0.3)	1.4 (1.2)	1.4 (0.5)	2.4 (0.8)	2.4 (1.1)	8.6 (3.0)	
Charite	1.7 (0.6)	1.7 (1.2)	2.1 (0.6)	2.1 (0.9)	2.5 (1.4)	10.1 (2.3)	
Fusion	0.9 (0.6)	1.7 (1.2)	2.2 (1.2)	2.1 (1.3)	0.5 (0.4)	7.4 (3.1)	
		Left Axial Rotation					
	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1	L1-S1 Total	
Harvested	-0.8 (0.5)	-1.2 (0.8)	-1.8 (0.9)	-1.9 (0.9)	-1.7 (0.6)	7.3 (1.9)	
Prodisc-L	-1.0 (0.3)	-1.0 (0.4)	-1.3 (0.7)	-1.8 (0.8)	-1.2 (1.0)	6.2 (1.4)	
Maverick	-1.0 (0.4)	-1.6 (1.2)	-1.6 (0.9)	-2.2 (1.0)	-2.0 (0.8)	8.4 (3.1)	
Charite	-1.6 (0.5)	-1.5 (1.6)	-2.9 (0.7)	-2.7 (1.8)	-3.2 (1.3)	11.8 (4.1)	
Fusion	-1.0 (0.5)	-1.5 (1.2)	-1.9 (0.9)	-1.8 (1.3)	-0.6 (0.7)	6.9 (2.8)	

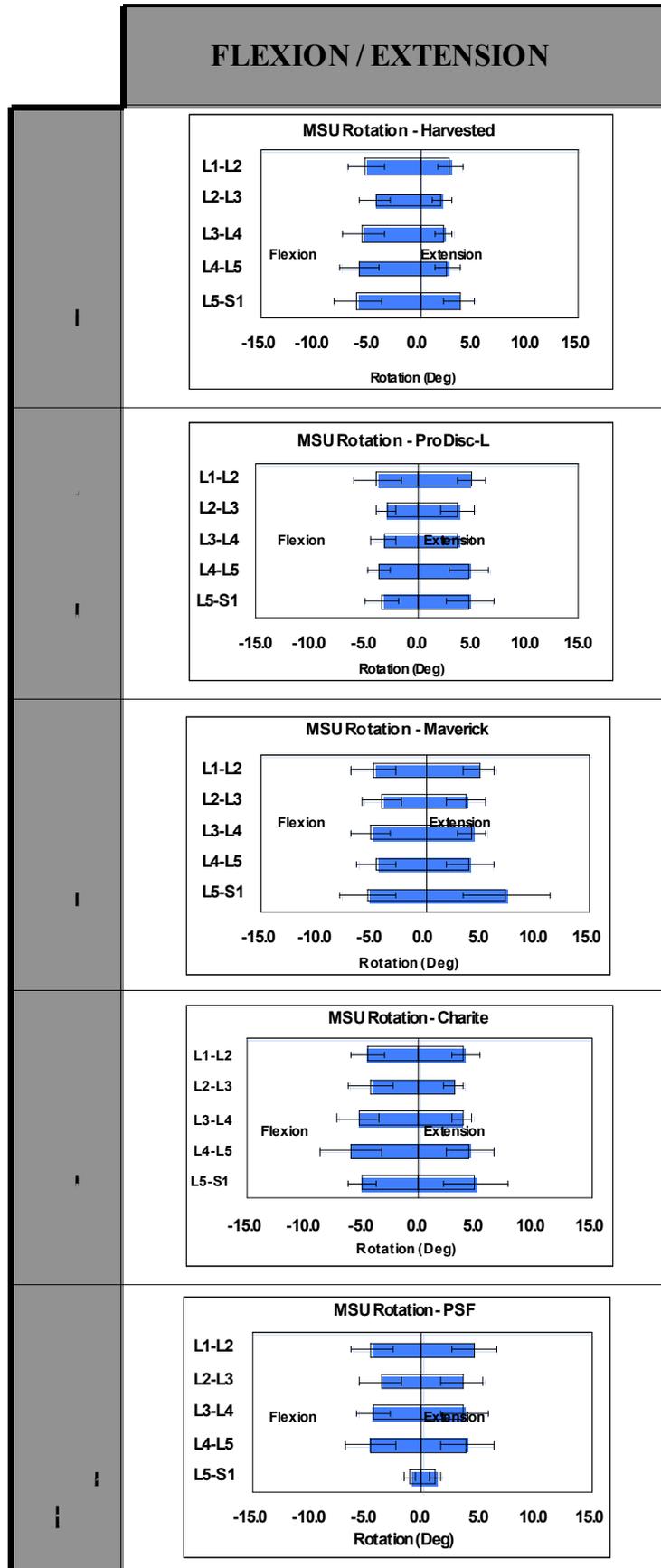


Fig. (6). Individual motion segment unit (MSU) rotations for each spine condition during flexion and extension.

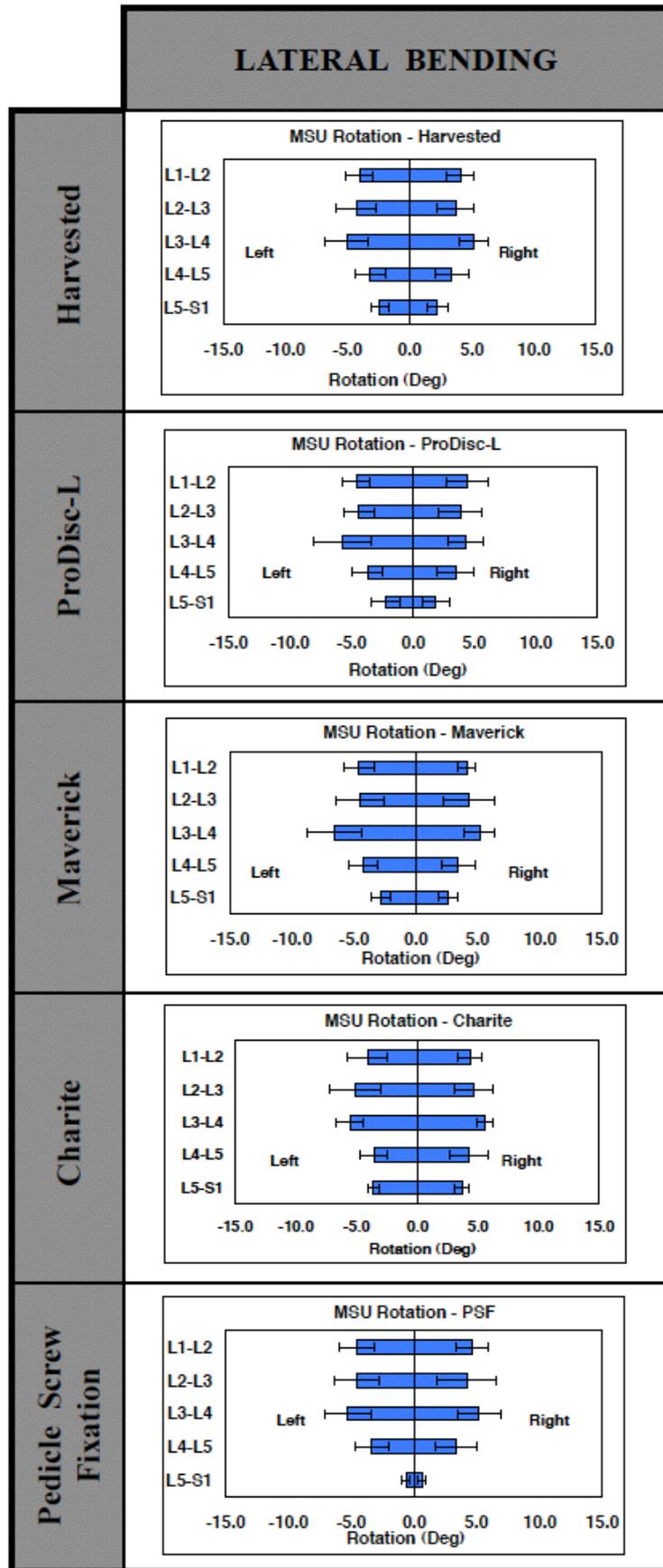


Fig. (7). Individual motion segment unit (MSU) rotations for each spine condition during lateral bending.

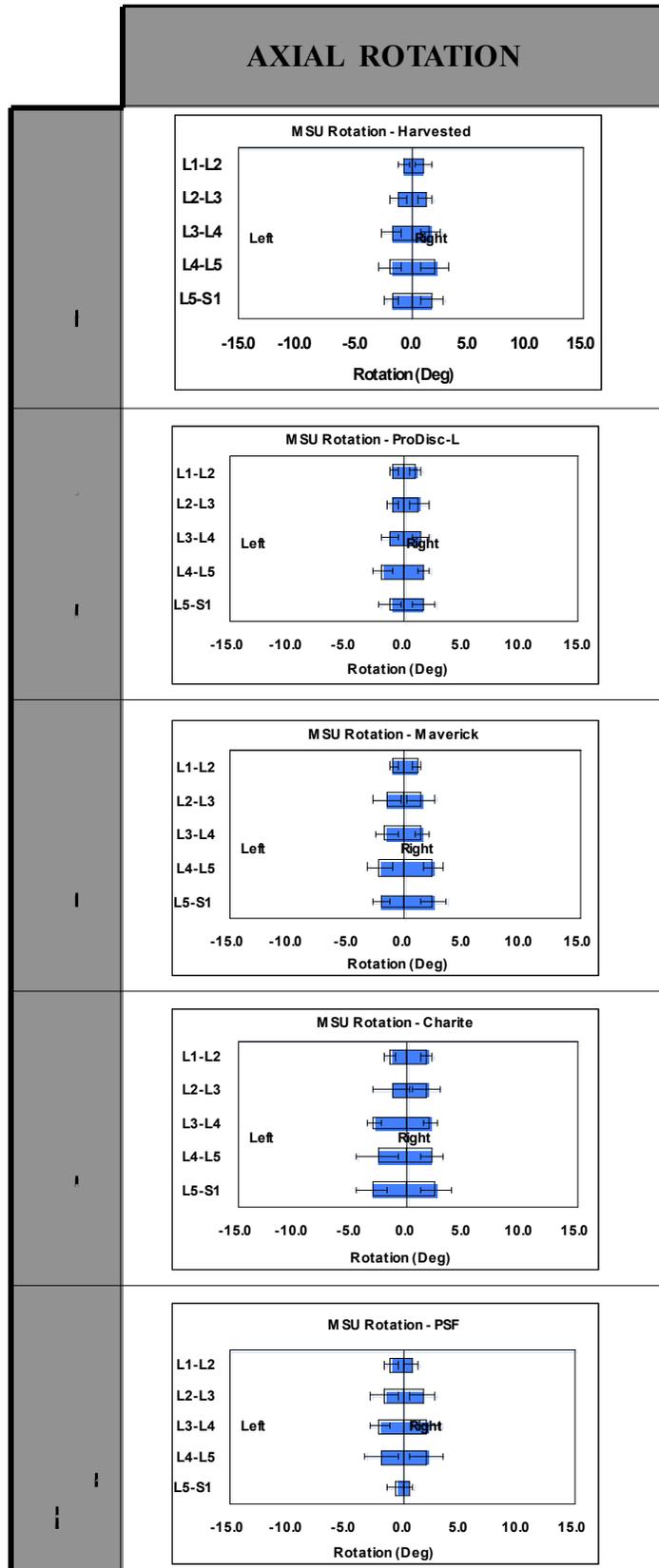
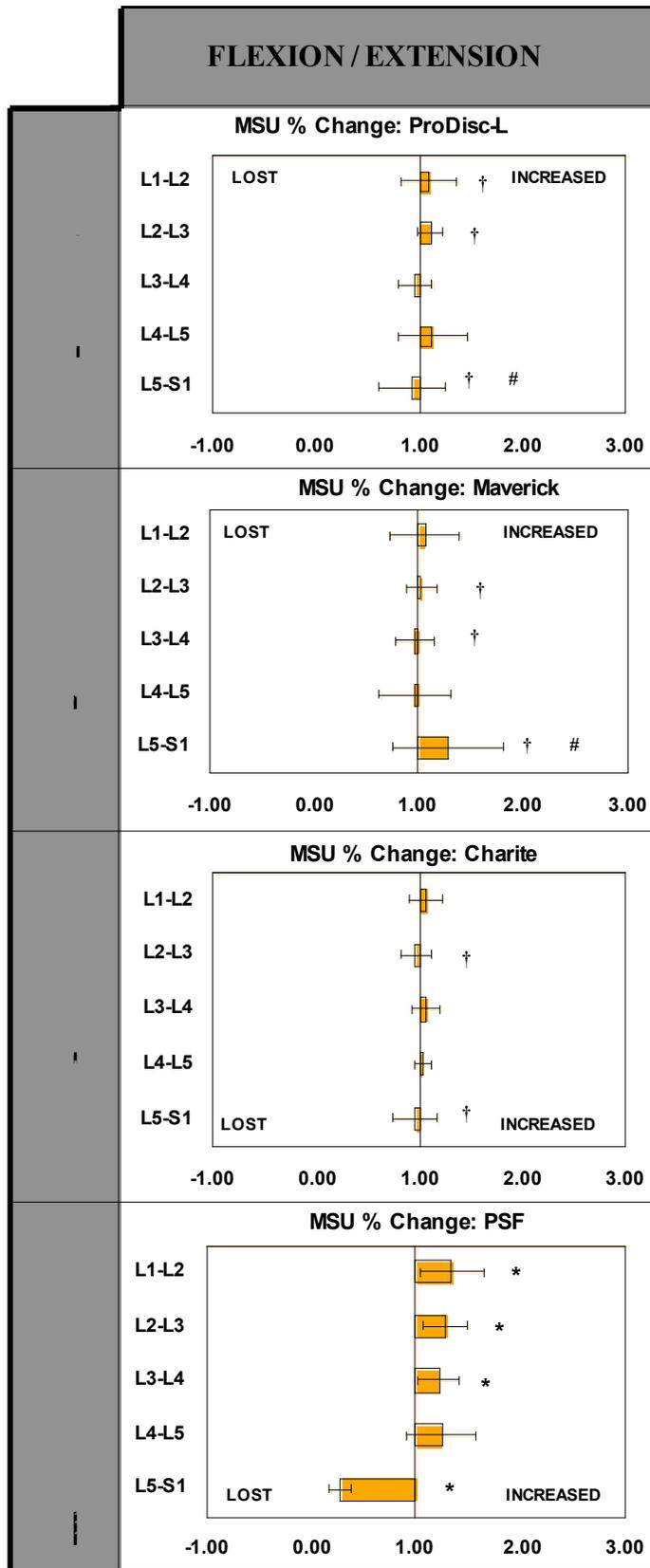
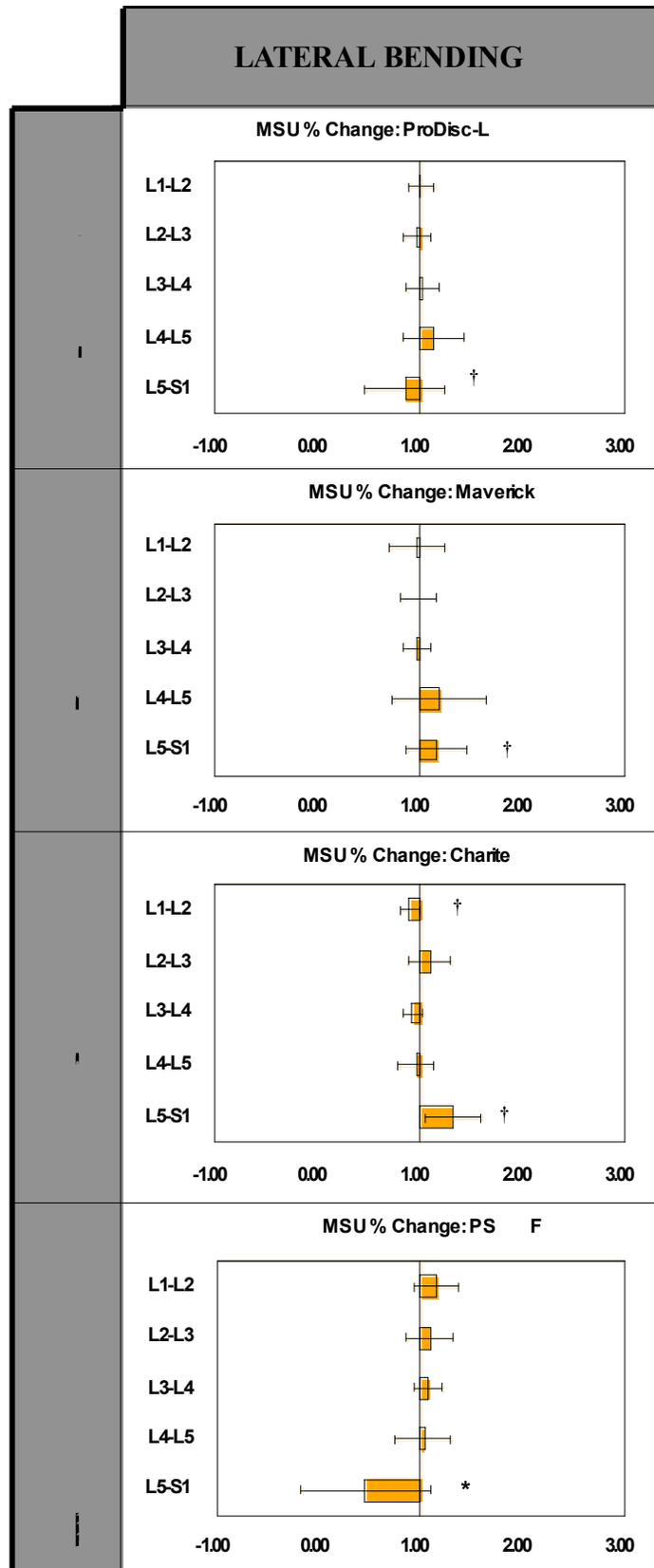


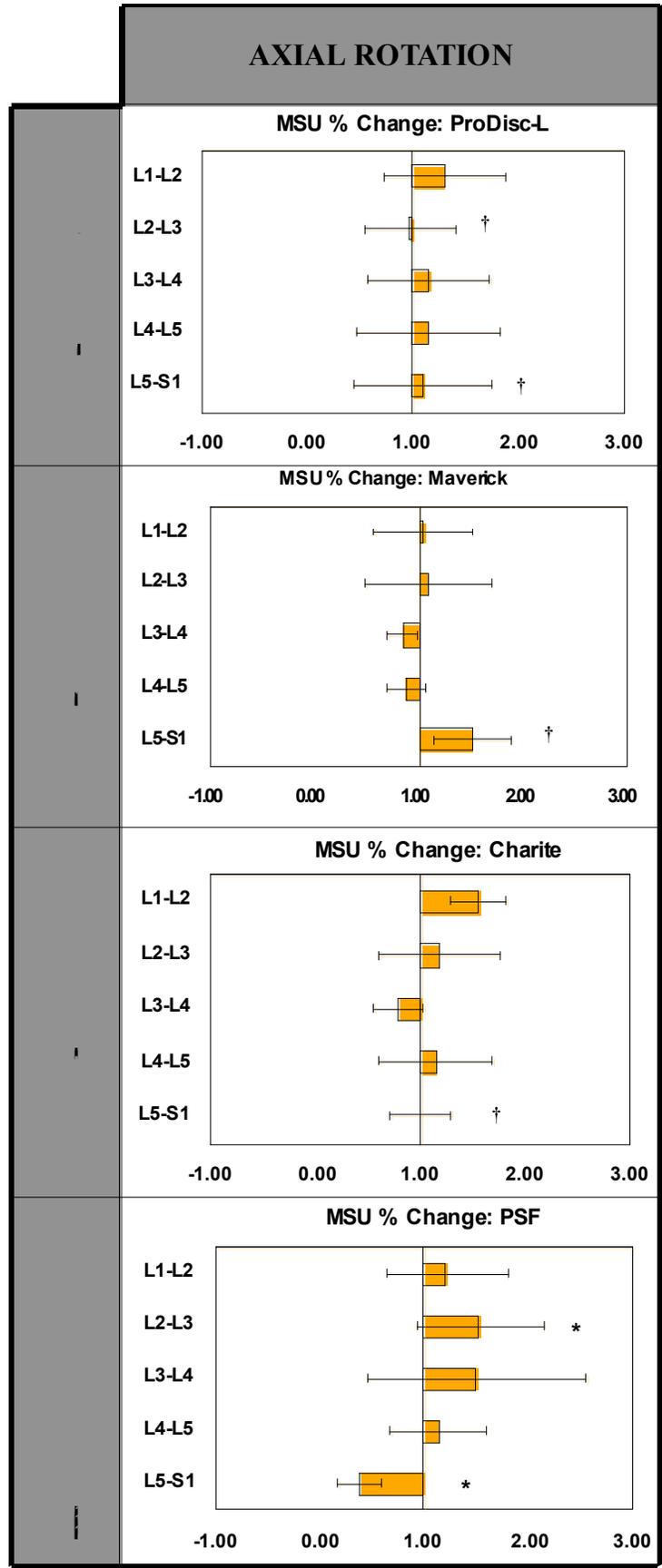
Fig. (8). Individual motion segment unit (MSU) rotations for each spine condition during axial rotation.



**Fig. (9).** Percent changes in MSU rotations for the altered spine conditions normalized to the harvested condition (\* Signifies significant difference between the harvested condition, † Signifies significant difference with respect to the fixated condition, # Signifies significant difference between the ProDisc-L and Maverick disc implanted conditions).



**Fig. (10).** Percent changes in MSU rotations for the altered spine conditions normalized to the harvested condition during lateral bending. (\* Signifies significant difference between the harvested condition, † Signifies significant difference with respect to the fixated condition, # Signifies significant difference between the ProDisc-L and Maverick disc implanted conditions).



**Fig. (11).** Percent changes in MSU rotations for the altered spine conditions normalized to the harvested condition during axial rotation. (\* Signifies significant difference between the harvested condition, † Signifies significant difference with respect to the fixated condition, # Signifies significant difference between the ProDisc-L and Maverick disc implanted conditions).

In the hybrid protocol [10] excessive movement beyond the harvested condition is less likely to be detected since specimens are never moved beyond the global harvested range of motion. Reported increases in segmental motion at the instrumented level may be the result of reduced stability due to the surgical procedure itself as opposed to implant design or function.

In the current study, the biomechanical stability and range of motion of the ProDisc-L, Maverick and Charité total disc prostheses and segmental pedicle fixation were compared directly in-vitro at a common end load limit. With respect to spinal flexibility significant changes occurred for the different spine motions, most notably during extension loading of the disc prostheses. These changes were attributed more to the nature of the surgical procedure itself; severing of the anterior longitudinal ligament and replacement of the disc with a mechanical device that cannot resist tension.

Posterior pedicle screw and rod instrumentation without disc implant removal simulated a salvage operation that caused a significant reduction in motion contribution at the treated level compared to the Harvested and all TDR conditions for all modes of testing. For this Fixated condition significant increases occurred across all of the un-instrumented adjacent MSU levels during flexion-extension and at L2-L3 during axial rotation. The increased motion response at these adjacent levels may contribute to the advancement of degenerative changes at these spinal levels.

All three TDR conditions maintained mobility at the treated level. None of the TDR spine conditions resulted in significantly increased or decreased spinal movement at all levels superior to the operated region (L1-L5).

Mean flexion-extension L5-S1 ROM for the Harvested, ProDisc-L, Charité, and Maverick conditions were 9.6, 8.1, 9.8, and 12.3 degrees, respectively. These data agree well with published clinical results from Ziegler *et al.* [32] reporting a mean flexion-extension ROM of 7.7 degrees in 286 patients at 24 months follow-up with ProDisc-L, and both Thierry [33] and Lemaire *et al.* [34] who reported flexion-extension ROM's of 10.1 and 10 degrees respectively after 10-year follow-ups of the Charité total disc. In the current study the Charité and Maverick discs demonstrated mean L5-S1 ROM's that were all greater than the Harvested ROM, the Charité producing the greatest ROM in combined lateral bending and torsion. The mean ROM for the ProDisc-L was less than that for the Harvested condition for all modes of testing. Other clinical studies have pointed towards a similar observation. For the ProDisc-L implant, Huang *et al.* [35] reported a mean in-vivo flexion-extension range of motion of 4 degrees at 8.7-years follow-up. In a 2-year follow-up, Leivseth *et al.* [36] reported that motion at the treated level with ProDisc-L was restored to 74% of the untreated ROM and to 45% of ROM for a 'normal' population data base. The authors pointed to soft tissue adaptation as well as factors not controlled in the study such as implant sizing, placement and surgical technique as possible reasons for the poor outcome. Siepe *et al.* [37] reported significantly reduced L5-S1 ROM from 8.1 degrees post operatively to 5.1 degrees following application of the ProDisc-L in 62 patients after 42 months follow-up. Lastly, Shim *et al.* [38] clinically compared the ProDisc-L and

Charité discs at 3-years follow-up. Facet degeneration and ROM at L4-L5 were not significantly different between the two implants however, ROM at L5-S1 was significantly greater for Charité (11.2 degrees) than ProDisc-L (5.6 degrees).

In the current study the ProDisc-L implant demonstrated only a 7% motion contribution reduction at the instrumented level in flexion-extension that was significantly different from that of the Maverick implanted condition, which demonstrated a 28% increase. Both devices represent a constrained ball and socket type of device with similar locations for the radii of curvature in the lower vertebral body, however the COR of the ProDisc-L is 5mm anterior to that of the Maverick when placed in the spine. We have previously investigated the effects of changing the location of a fixed COR on segmental mechanics and ROM in the intact human lumbar MSU [39]. Six lumbar MSU's were tested under kinematic input by varying fixed COR's to common end load limits using a multi-axis robotic testing frame. This study demonstrated that resulting segmental ROM was greater for a more posterior COR (10 degrees) versus an anterior COR (6.1 degrees). However, a more posterior placed CoR significantly increased the shear load across the disc plane. This data points toward the antero-posterior location of the fixed COR in a ball and socket type implant as being a significant factor (in addition to other mechanical and surgical variables) in determining segmental ROM.

Lastly, adjacent segment degeneration (ASD) following spinal fusion and the influence of total disc arthroplasty remains a controversial issue. Recent clinical evaluations support significant degenerative changes following fusion that are age related however, the clinical significance may be more limited since cases of symptomatic ASD are less in number with only the more severe cases affecting clinical outcome [5-7]. In the current study increased motion compensation attributed to ASD effects were observed following fusion, however, the increased MSU contribution did not only occur at spinal levels immediately adjacent to the treated level, but also at other non-adjacent spinal levels. A previous investigation on simulated fusion and ASD effects in the cervical spine conducted within our laboratory by Schwab *et al.* [40] yielded a similar result that is also consistent with the observations of Hoogendorn *et al.* [41]. In their study fusion of the L3-L4 vertebrae in an in-vivo goat model produced no adjacent level effects but severe degeneration one level removed from the fusion site.

### Study Limitations

The current testing protocol applied a compressive load and rotational bending moment to the spine without any external shear load. Additional tests are warranted to understand the influence of shear forces on the immediate fixation of TDR devices as well as the impact of shear loads on segmental motion patterns. The loading conditions were idealized with no modeling of muscle forces included. However, use of follower load concepts [30] that also apply coupled conditions of a bending moment and compressive load to simulate muscle activity bear a negative connotation when used to evaluate disc arthroplasty devices as they may

inadvertently stabilize the device beyond daily living conditions, where minimal muscle involvement occurs (i.e., upright stance, sitting, laying down). The results of the current study are indicative of the acute stability of the different spinal devices tested. Variations in surgical procedure, including sagittal alignment and disc angle, were not documented nor controlled. The ProDisc-L and Maverick prostheses employ a single keel for initial fixation that may have been compromised during the removal of one disc and reinsertion of the other one. However, none of the discs showed signs of loosening and all discs remained stable throughout the duration of the study. Measures of importance

## CONCLUSION

Issues pertaining to adjacent segment disease (ASD) with pedicle screw fixation surgery were supported by increased motion contributions at multiple sub-adjacent segments. However, disc arthroplasty eliminated any significant increase and may delay or prevent ASD. Compared to pedicle screw fixation, all three differently designed disc prostheses (ProDisc-L, Maverick, and Charité) remained stable and provided improved lumbar mobility. The only notable difference between the disc designs was the increased flexion-extension motion at the operative level of the Maverick disc compared to the ProDisc-L and may relate to A-P positioning of the device COR. The extent to which implant design affects long term survival and function remains unclear. Additional studies investigating coupled loading scenarios (flexion-extension or lateral bending with axial rotation) and/or measurement of the shear loads across the disc may help to further explain the influences of the different design features found in these mechanical disc prostheses.

## CONFLICT OF INTEREST

The authors confirm that this article content has no conflicts of interest.

## ACKNOWLEDGEMENTS

Research support from Synthes Spine, West Chester, PA. Use of the surgical facility at the Medical Education Research Institute, Memphis, TN.

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Received: November 23, 2013

Revised: February 15, 2014

Accepted: February 17, 2014

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