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Biomechanical Testing of Charité Disc Replacements versus Fusion Using Hybrid Testing Protocol and Follower Load

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Biomechanical Testing of Charité Disc Replacements versus
Fusion Using Hybrid Testing Protocol and Follower Load

A Thesis Submitted to the
Yale University School of Medicine
in Partial Fulfillment of the Requirements for the
Degree of Doctor of Medicine

By

Edward Teng
2007

ABSTRACT

Statement of Purpose: To quantify adjacent level effects following Charité disc replacement compared to fusion, using the follower load and the new standard hybrid testing method in flexion, extension, and torsion.

Summary of Background Data: As opposed to fusion, artificial discs not only preserve motion, but may diminish adjacent level effects and thus slow adjacent disc degeneration. This study aims to use hybrid test protocol and follower load to perform *in vitro* multidirectional testing and quantify adjacent- and other- level (AOL) effects following one- and two-level disc implants compared to fusion.

Methods: Five intact human cadaveric lumbar specimens underwent multidirectional testing in flexion, extension, and bilateral torsion loading with $\pm 10\text{Nm}$ unconstrained pure moments under 400N follower load. Intact specimen (T12-S1) total ranges of motion were first determined for each loading direction and then used as input for the 5 subsequent hybrid tests: 1) one-level Charité disc implant at L5-S1; 2) one-level simulated 360° fusion at L5-S1; 3) two-level Charité disc implants at levels L4-L5 and L5-S1; 4) combined one-level Charité disc implant at L4-L5 and one-level simulated 360° fusion at L5-S1; and 5) two-level simulated 360° fusion at L4-S1. Using repeated measures single factor ANOVA and Bonferroni statistical tests ($p < 0.05$), intersegmental motion redistribution was compared between intact and testing conditions.

Results: One- and two- level Charité disc preserved physiological motion, whereas one-level L5-S1 fusion increased intersegmental motions at proximal levels. Two-level fusion at L4-L5-S1 produced markedly increased motions at proximal levels, but converting the L4-L5 fusion to a Charité produced results equivalent to a one-level L5-S1 fusion. In axial torsion, both one- and two-level disc implants preserved motions at all levels. Although the one-level fusion did not produce significant changes, the two-level fusion did result in significant increases in motion at proximal levels.

Conclusions: The fusion simulations did not only affect motion re-distribution at adjacent-levels, but also at other-levels cephalic to the fusion. A prosthetic disc placed above a fusion could not buffer the proximal levels from increased motion from the fusion.

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Introduction:

Low back pain is the fifth leading reason for medical office visits¹, occurs in roughly 25 percent of the working population each year, and cost 90.7 billion dollars in health care expenses in 1998². Other epidemiological studies indicate similar prevalence of low back pain in other industrialized nations. In the UK, low back pain was the single largest cause of absence from work in 1988-89 and in Sweden 14.8 million work days were lost due to back pain in 1987³. The recurrence rate of low back pain is estimated at 85% and is the third most common cause of surgical procedures.⁴⁻⁶ One of the primary suspects in the underlying pathology of low back pain is disc degeneration. Degenerative disc disease (DDD) results in decreased intervertebral disc height, facet joint arthropathy or spondylosis, vertebral slip or spondylolithesis, and spinal stenosis with narrowing of the neural foramen. The process is suspected to have a multi-factorial patho-etiology involving genetics, along with occupational and environmental exposures.⁷

Arthrodesis is the established gold standard for the treatment of DDD in the lower back.⁸ The treatment for DDD starts with non-operative conservative management including physical therapy, therapeutic injections, and analgesic management. While fusion has been demonstrated to reduce pain and improve disability scores, there are concerns over the consequences of a rigid fusion on remaining adjacent levels. These consequences, termed adjacent level effects, include facet joint osteophytes, spinal stenosis, and accelerated disc degeneration with spondylolithesis. There is controversy, however, whether these changes are the upshot of arthrodesis or whether they represent the natural history.⁹⁻¹² In addition, there is disconnect between radiological evidence of

adjacent level changes and clinical symptoms.^{12,13} Despite these concerns, rates of fusion in the United States have continued to increase over the past two decades.¹⁴

Artificial discs for treatment of DDD aim to preserve motion at the affected level and avoid strain on adjacent levels by preserving physiological motion throughout the spine. The Charité artificial disc (DePuy Spine, Raynham, MA) is the most widely available artificial disc and has been implanted more than 7,000 times worldwide.¹⁵ The Charité IV disc features a bi-convex sliding core made of ultra high molecular weight polyurethane articulating with two Co-Cr endplates with ventral and dorsal teeth coated with titanium and hydroxyapatite. Favorable clinical results have been reported on the Charité disc,¹⁵⁻¹⁹ with the best evidence presented from an FDA randomized controlled trial that showed significantly improved pain and disability scores compared to BAK cage fusion at 24 months follow up.²⁰ In addition to preserving motion, the Charité prosthesis also showed better disc height maintenance and less subsidence compared to BAK cage fusion.²¹

Comment: Charite III has no coating
Charite IV has coating.

Despite the promising clinical results, knowledge about the biomechanical function of implanted discs and the effects on adjacent levels has been limited. Hitchon, et. al., examined the biomechanics of the Maverick disc (Medtronic Sofamor-Daneck, Memphis, TN) but did not examine adjacent level effects.²² Cunningham, et. al., performed *in vitro* cadaveric studies showing increased motion at the superior and inferior levels when Charité disc implantation at L4-L5 was compared to fusion.²³ It is necessary to compare the effects of prosthesis versus fusion at multiple adjacent levels. In addition, neither of these studies used follower load, as developed by Patwardhan,²⁴⁻²⁶ to simulate the effect of spinal muscles and truncal load. It is believed that follower load

simulates in vivo conditions and should be used for in vitro testing.²⁷⁻²⁹ Finally, prior tests did not use the hybrid testing method, as established by Panjabi^{30,31} to examine adjacent level effects in a standard repeatable laboratory independent fashion. The purpose of our study was to examine the biomechanical effects of the Charité disc prosthesis on all spinal levels, including adjacent, using a multisegmented spine while applying follower load under the hybrid testing method.

▪ **Statement of Purpose**

To quantify adjacent level effects following Charité disc replacement compared to fusion, using the follower load and the new standard hybrid testing method in flexion, extension, and torsion.

▪ **Hypothesis**

Using an artificial disc replacement not only helps to preserve physiologic motion of the specific implants level, but also protects adjacent levels from experiencing pathologic hypermobility as compared to fusion.

▪ **Specific Aims**

1. Characterize degree of physiological motion preservation by artificial disc replacements compared to fusion in flexion extension and axial rotation
2. Characterize degree and pattern of adjacent level effects in artificial disc replacements compared to fusion in flexion extension and axial rotation.
3. Determine whether an artificial disc placed near a fusion could buffer adjacent levels from pathological hypermobility.
4. To propose hybrid testing protocol as the new standard for testing artificial discs on cadaver models
5. To establish our pure moment machine with frictionless design as standard for testing specimens.
6. To establish follower load mechanism as method for simulating physiological truncal load and compressive effects of spinal muscle.

▪ **Materials and Methods**

Specimen Preparation: Five fresh human cadaveric lumbar spines from T12 to S1 were harvested en bloc for this study (mean age, 68, standard deviation, 14). Upon receipt, specimens were screened in the anteroposterior and lateral view using fluoroscopy: any specimens with evidence of disc space narrowing, osteophytes, facet malformation, fractures, metastatic processes, and bone spurs unsuitable for testing were

returned. Specimens were stored in double bags at -20°C until dissection. After thawing overnight at 4°C , soft tissues were removed, taking care to preserve all osteoligamentous structures. Specimens were mounted in parallel quick setting epoxy mounts (Body Filler, Bondo Corporation, Atlanta, GA) at the T12 and S1 levels such that the spine was in neutral posture and the L3-4 segment remained horizontal. To improve fixation, screws were placed cranially into T12 and caudally into S1 segments. Next, follower load rods were implanted laterally into vertebral bodies, and were approximated such that the line connecting two adjacent rods would pass through the center of rotation. Ball bearings were attached bilaterally on the rods. Five flag shoes were then attached to the anterior surface of vertebral levels L1 to L5. Flags with three non-collinear light emitting diodes mounted on plexiglass were affixed to the shoes at levels L1 through L5 and directly to the upper (T12) and lower mounts (S1). To prevent desiccation of osteoligamentous structures during testing, the specimen was kept moist with 0.9% saline during all points of testing.

Three Dimensional Flexibility and Hybrid Testing: Testing was performed on a custom built machine capable of applying pure moments in x-, y-, and z- axes by a pneumatic motor. (Figure 1) Also attached to upper mount are two pneumatic pistons that apply the follower load. A rotating acentric mass was affixed to the lower mount to help reduce friction of the overall system. Motion was monitored using an Optotrak model 3020 motion analysis system (Northern Digital Inc., Waterloo, Canada).

Non-destructive, unconstrained, three dimensional testing was carried out first on intact specimens in room temperature (22⁰C) by applying a maximum of ± 10 Nm using flexibility protocol³² in the flexion, extension, and bilateral axial torsion in the presence of 400N follower load. After two preconditioning cycles (0.5Nm increments every 3 seconds) readings were taken on the third cycle (0.2Nm increments every 3 second). Three-dimensional rotational data (degrees) were collected to give total range of motion (tROM) of the whole spine, and ROM at each intersegmental level. The tROM from intact condition was then used as input for the subsequent testing under the hybrid testing method^{10,30,33,34}: pure moment is applied to match the tROM established during intact testing. (Figure 2) The underlying philosophy behind the hybrid method is that patients will attempt to move their bodies in the same way after surgery as they did before surgery. When patients attempt to achieve the same ROM after fusion or disc implantation, the result is motion redistribution at other levels.

The six test conditions are as follows:

1. Intact Specimen
2. One-level SB Link Charité III disc at L5-S1 (DePuy Spine, Raynham, MA)
3. One-level Simulated 360⁰ Interbody Fusion at L5-S1
4. Two-level SB Link Charité III disc at L4-L5 and L5-S1
5. Two-level Combined Simulated 360⁰ Interbody Fusion at L5-S1 and SB Link Charité III disc at L4-L5
6. Two-level Simulated 360⁰ Interbody Fusion at L4-L5 and L5-S1

Surgery

Disc Implantation

The Charité artificial discs were implanted according to manufacturer's guidelines. A vertical midline incision was made through the anterior longitudinal ligament after confirmation by fluoroscopy. The incision was extended bilaterally to accommodate the implant, and a discectomy was performed through this opening. Care was taken to curettage all of the cartilaginous endplates without disturbing the osseous endplates. The [the anterior and posterior edges of the endplates were exposed](#) and the posterior longitudinal ligament was cut to enlarge the posterior height. The incision was extended as necessary insert and size the matching metal endplate. Angles of endplates were checked under fluoroscopy and selected as to enable the polyethylene core to sit horizontally. After appropriate endplates were loaded into the insertion instrument, they were tapped into place and underwent parallel distraction using paint paddle-type instrument taking care not to scratch the cupped endplates. Proper disc height was selected such that the remainder of the annulus was pulled sufficiently taut after removal of insertion instrument. [The placement of the artificial discs were checked under fluoroscopy in the lateral view for proper placement of the polyethylene core just posterior to the midline, and AP view for coronal midline placement.](#) The same [implantation](#) procedure was used for L4-L5 and L5-S1 discs.

Fusion Simulation

The pedicle screws for 360⁰ interbody fusion were placed at the same time as disc implantation to reduce variability between testing conditions with and without fixation. Pedicle screws were advanced through to the anterior surface of the L4 and L5 vertebral bodies, crossing over inside the vertebral body (Figure 3). Simulated fusion was achieved on the posterior side using standard Schanz pedicle screw system (6.0mm) and on the anterior side using custom fitted metal spacers that were tied tightly together using 50lb fishing wire. This technique was used for one-level (L5-S1) and two-level (L4-L5 and L5-S1) fusions by rigidly anchoring each level to the base mount.

Data Analysis and Statistics

Repeated measures analysis of variance (ANOVA) and Bonferroni post-hoc analysis were performed on the intervertebral motion in degrees to assess statistical significance between the five testing conditions compared to intact. Statistical significance was set at $P < 0.05$ and trends were set at $P < 0.1$.

Methodology Work Credit

All aspects of the present study involve medical student candidate Edward Teng. Cadaver dissections were conducted by Edward Teng, implant and fusion procedures on the specimens, including all aspects of taking care of the human spines. George Malcolmson designed the testing machine and did a large part of the programming involved in testing the specimens. George performed the initial testing runs of the first 2 specimens. Gwen Henderson and Edward Teng carried out the rest of the study including testing, collection

of data from optotrak machines, processing data to give euler angles, and analyzing the data to produce the plots and charts that are used as figures in the manuscript.

▪ Results

The intersegmental ranges of motion (ROM's) are presented in degrees and as a percent change in a normalized score. The normalized score was calculated by dividing the ROM at each level by the total ROM of the whole spine under each testing condition. This gives a normalized percentage of each level's contribution to the total ROM of the whole spine. In this fashion, we obtain a better representation of intersegmental ROM within each testing condition, and also aids in visualizing the change in motion redistribution.

The results indicated preservation of [the overall range of](#) motion at target and adjacent levels with prosthetic disc implantation versus fusion (Figure [4, 5](#)). Statistically significant changes from intact conditions are reported in Table 1. The Charité disc prosthesis at L5-S1 contributed 6.4° of overall motion in flexion and -4.0° in extension at the L5-S1 level, without significant changes in motion at intact proximal levels. Successful fusion was achieved at L5-S1 and resulted in significant increases in motion at L1-L2 thru L3-L4 (17.6% to 22.9%) and trend towards increased motion at T12-L1 (26.1%). The two-level Charité discs at L4-L5-S1 surprisingly resulted in a significant decrease in contributed motion (-35.0%) at the superior instrumented L4-L5 level. In contrast, the combined fusion at L5-S1 with Charité disc at L4-L5 had results similar to the 1-level fusion and produced 6.5° overall motion in flexion and -4.8° in extension at

the L4-L5 level. Finally, the two-level fusion at L4-S1 was successful with very small motions at the fused sites and significant increases in motion at T12-L1 thru L3-L4 (48.5% to 74.3%).

The pattern of adjacent level effects was similar in axial-torsion, however, prosthetic discs were found to produce increased motion compared to intact (Figure 6, 7). Statistically significant changes were not found, except in the two-level fusion condition (Table 2). Left rotation is represented as positive, and right rotation as negative. The one-level disc implant at L5-S1 contributed 2.2° overall motion to the left and -2.1° to the right for a total of 29.0% increase in contributed motion at L5-S1 compared to intact L5-S1 disc. In contrast, the one-level fusion at L5-S1 had a total decrease in motion of -38.1% at L5-S1 and produced slightly increased motions at proximal levels (3.9% to 10.0%). The two-level Charité discs at L4-L5-S1 produced increased motions at implant levels L4-L5 with 1.9° left rotation and -2.1° right rotation, and implant level L5-S1 with 2.1° left rotation and -1.6° right rotation. In contrast, the fusion at L5-S1 with Charité disc at L4-L5 was compensated for by an increase in overall contributed motion of 32.5% at the L4-L5 disc implant compared to intact. The proximal levels were buffered by the L4-L5 disc prosthesis and experienced minor changes (-2.2% to 8.3%). Finally, the two-level fusion resulted in significant increases in contributed motion at all intact proximal levels (20.2% to 26.1%).

▪ Discussion

An important goal of motion-preserving artificial disc technology is to reduce or eliminate adjacent level effects. There are only a few biomechanical studies examining the motion of artificial discs,^{22,23,35} and even fewer have compared adjacent level effects in artificial discs using standardized tests. Our study aimed to investigate intervertebral motion at target and adjacent levels using the standardized hybrid method approach^{30,31} while applying follower load. The results indicate that the prosthetic discs are able to [produce intact levels in overall range of](#) motion at the target level, [and](#) also minimize alterations in motion at proximal segments. In comparison, fusion resulted [in](#) a direct relationship between number of levels fused and increase in motion at all proximal levels. The results are encouraging for the development of artificial discs.

This *in vitro* study had limitations in its inability to simulate specific aspects of *in vivo* conditions. It has been suggested that follower load axial compression be used during *in vitro* testing to more accurately simulate *in vivo* spinal forces. While our follower load path was set to travel through the center of rotation in neutral position, the true instantaneous center of rotation is not a fixed point. Previous studies demonstrate that position of the follower load does affect the total ROM, if set in a neutral versus flexed position.²⁴ In our study, however, the follower load path was set according to the neutral posture for all spines for every testing condition, and therefore the results are comparable to each other. Exact truncal loads during physiological motion are not known but previous studies have found no change in overall motion under 400N of compressive preload.³⁶ Inflammation and the development of scar tissue around the annulus and remaining structures may affect the long-term *in vivo* motion of discs. The early clinical

results of Charité trials, however, reported *in vivo* ROM of 10.3° at 51-month follow-up¹⁸, which match our ROM's between 7.5° and 12° .

Aside from *in vitro* conditions, there were limitations based on testing procedure and selection of specimens received for testing. The duration of testing was extended for a number of days during which the specimen could not be frozen. As the spine decayed, the overall motion tended to increase [which then data relative to the testing order. In other words, the overall condition of the spine would degrade as testing proceeded from the intact condition through to the 2-level fusion condition.](#) This [degradation process and testing order bias](#) was accounted for by normalizing the intersegmental ROM's to determine the percent each level contributed to the total ROM for the whole spine under each testing condition. The percentage change in these normalized ratios was then presented to give a better representation of how each testing condition affected each level. Due to limitations in cadaveric spine selection, the average age of our sample was 68. The prosthetic discs, however, are more often implanted in a younger population. Ideally, a larger sample size and younger population would be used for testing. Error calculations are small compared to the overall motion of the spine and intersegmental motions. Stress and loading of the posterior facet joints could not be examined in this study, but were analyzed using finite element analysis.³⁴

The placement of the Charité prosthesis was pivotal to obtaining good range of motion at the level of the disc and thus decreasing adjacent level effects. During testing trials, it became evident that the ideal placement of the prosthesis was slightly posterior to the sagittal midline. Flexion and extension motion of the segment above the prosthesis was significantly restricted when placed anteriorly, but when the posterior longitudinal

ligament was cut and prosthesis moved posteriorly, the overall range of motion resembled intact conditions. This experience corroborates with the findings of clinical investigators that have also reiterated the importance of accurate surgical placement. Clinical trials have reported that flexion-extension range of motion and clinical disability score improvements were correlated with surgical technical accuracy of Charité disc placement.²¹ According to McAfee et al., if the implant is placed in the ideal location, the center of rotation would be located in posterior third of the implant. In terms of adjacent level effects, when good range of motion was obtained in the present study from the prosthetic disc, the proximal levels experienced minimal change in motion. When the range of motion of the prosthetic disc was low, thus trending towards a fusion, proximal levels experienced increased motion. This supports previous reports associating sagittal malalignment and low range of motion of prosthetic discs with development of junctional degeneration.³⁷

The results from the present study indicate single-level implants preserve the same [overall total range of](#) motion as the intact disc at the L5-S1 level in flexion and extension. The goal of artificial discs is to preserve motion, and in doing so to prevent adjacent segment degeneration. First and foremost, it is then important to establish the viability of motion of the disc and its capacity to preserve motion. Huang et al³⁸ reported at 8.6 year follow up that patients who retained over 5⁰ of motion at the disc implantation level had better outcomes as measured by the Oswestry Disability Index and modified Stauffer-Coventry scores. The Charité FDA trial²¹ reported that flexion-extension ROM improved with surgical accuracy, which was correlated with good clinical outcomes. The authors reported a mean ROM of 7.5⁰ in flexion-extension at 24 months follow up. In

comparison, Lemaire et al¹⁷ reported a mean ROM of 10.3° in flexion-extension among 100 patients at 10 year follow up with 90% having good or excellent clinical outcomes and 91.5% return to work rate. Although follower load was not applied, Cunningham et al²³ performed in vitro studies on the Charité disc and showed a minor 3% increase in ROM compared to intact. The study also found that the center of rotation for the prosthetic disc closely resembled that of the intact disc for L5-S1 in flexion-extension on radiograph. The present study confirms the biomechanical preservation of motion of the Charité artificial disc. The intact ROM for the L5-S1 level was found to be 4.2° in flexion and 6.5° in extension, for a total ROM of 10.7°. After Charité disc implantation at L5-S1, there was a shift of motion towards flexion to give 6.4° in flexion and 4.0° in extension, for a total ROM of 10.4°. There was no significant difference in the overall total ROM for L5-S1 level between the intact condition and the artificial disc condition.

While, the overall range of motion in the two conditions does not differ, the distribution in motion towards flexion made be partially explained by the posterior placement of the prosthesis which may produce more motion in the flexion direction— and help to unload the posterior facet joints. Some studies, however, have also suggested that TDR may increase posterior facet loads by 2.5 fold. A previous finite element analysis³⁴ reported increased motion in extension (40%) which resulted in a 25% increase in facet loads. While the present study did not show increased motion in extension, the issue of stress and strain on the posterior elements has been raised before. Posterior facet arthritis or any other posterior element pathology is a known contraindication for total disc replacement. The design of the Charité disc allows for translation in the AP plane which may help to reduce excessive facet joint stress and capsuloligamentous loads. The

relationship between the degenerative process that affects discs and the posterior facet joints is unclear, and it is possible that individuals who have developed degenerative disc disease may have a natural history for posterior element degeneration. Controlled trials with careful patient selection are necessary to elucidate the relationship between degenerative disease of the anterior and posterior columns and its clinical outcomes.

In addition to preserving [overall ROM](#) at the operative level, the present study found that a single level implant at L5-S1 did not affect the biomechanics at adjacent proximal levels in flexion and extension compared to the intact condition. The crucial advantage of artificial discs over the gold standard arthrodesis is in preventing excessive motion at the adjacent level. Few *in vitro* biomechanical studies have looked specifically at this topic. Cunningham et al²³ reported unaltered pattern of motion distribution at adjacent levels compared to intact. The results were normalized in a similar fashion to the present study, by dividing the motion at each level by the total motion. In this case, the specimens used were L3-S1, with a reconstruction performed at L4-L5: therefore, adjacent motion could be measured at the immediately adjacent proximal (L3-L4) and distal (L5-S1) segments. The authors of this study reported 0% change at the proximal segment, and 3% increase at the distal segment compared to intact in flexion and extension with disc prosthesis. By comparison, there was an 11% increase at the proximal level and 20% increase at the distal level with fusion using the BAK with posterior pedicle screw and rod fixation. This trend is similar to the findings of the present study which examined the change in distribution of motion at the five proximal segments. In the one-disc (L5-S1) condition, the change in contributed motion at the five proximal levels was insignificant with a range of -4.2% to 5.4%. By comparison, the five proximal

levels in the one-fusion (L5-S1) condition produced an equally distributed and significant increase in motion from 15.9% to 26.1%. An explanation for the discrepancy in magnitude between the present study and the previous study is the number of intervertebral discs that were available to compensate for the loss of motion. In the prior study, the motion lost at one level was redistributed to two levels whereas in the present study five levels were available for motion redistribution. It can be concluded, however, that the artificial discs maintain physiological motion at adjacent levels whereas fusion results in a pattern of increased adjacent motion.

An interesting phenomenon was noted in the two-level (L4-L5-S1) disc implant where there was increased motion in flexion extension at the inferior L5-S1 disc implant, but decreased motion at the superior L4-L5 disc implant. The overall contributed motion by the L4-L5 prosthetic disc was 35.0% less compared to intact, whereas the L5-S1 prosthetic disc increased by 15.1% compared to intact. When examining the divided motion in flexion and extension, the effect is still pronounced but less dramatic. The superior L4-L5 disc implant produced 4.2° motion in flexion, and 3.2° in extension, whereas the intact L4-L5 disc produced 5.4° in flexion and 6.2° in extension. The inferior L5-S1 disc implant produced 7.1° in flexion and 5.0° in extension, whereas the intact L5-S1 disc produced 4.2° in flexion and 6.5° in extension. These results are interesting as pure moment is being applied to the specimen, therefore all levels should experience the same moment. The increased motion at the L5-S1 disc in the two-disc condition compared to the single-level L5-S1 disc implies that the L4-L5 disc is stiffer than the intact, thus resulting in compensation of motion at the L5-S1 level. This effect is then essentially adjacent level hypermobility caused by increased stiffness of L4-L5 disc

which is absorbed by the L5-S1 disc. Hence, there are slightly increased motions at the T12-L4 discs (1.3% - 15.5%), reflecting this adjacent level effect-like process. The cause of the increased stiffness for the L4-L5 disc is uncertain but may be due to friction and entrapment of the sliding core, which has been documented in previous studies.³⁶ This information must be kept in light of clinical studies that have indicated better outcomes in 1-level implants than in 2-level implants.¹⁵ In addition, the FDA clinical trials for the Charité disc only accepted candidates for 1-level implantation.^{20,21} More clinical trials must be performed in order to accurately compare the clinical outcomes of 1- versus 2-level implants.

Furthermore interesting was that fusing the L5-S1 level while keeping the L4-L5 prosthetic disc resulted in restored [overall](#) motion of the L4-L5 prosthetic disc. In other words, when the L5-S1 disc was fused and became relatively stiffer than the L4-L5 disc, the situation was reversed and the L4-L5 disc compensated for lost motion in the L5-S1 fusion. The L4-L5 disc produced 6.5^0 in flexion and 4.8^0 in extension, which again mirrors the previous shift towards flexion, while maintaining the same overall range of motion as the intact disc. An accurate comparison in regards to adjacent level effects should then be made to the 1-level fusion at L5-S1. The proximal levels in the 1-level fusion had 15.9% to 26.1% increases in contributed motion at T12-L5 (5 FSU's/intact intervertebral levels), whereas the proximal levels in the disc-fusion condition produced 20.8% to 30.3% increases in motion (4 FSU's/intact intervertebral levels). In other words, the disc-fusion condition and 1-level fusion condition produce similar patterns in terms of adjacent level effects. The minor difference in these patterns can be accounted for by two reasons: The first is that there are fewer intervertebral levels to distribute the motion, and

the second is that the increased stiffness of the L4-L5 disc implant, although achieved intact [overall](#) motion, did not have [enough](#) increased motion to have protective buffering of the superior adjacent levels. It has been suggested that 5° of motion is necessary to prevent the development of adjacent segment degeneration with 1-disc implants^{38,39}. Although the clinical results may differ, the biomechanical results of the present study indicate that in order to buffer the intact discs from a fused level, it must compensate for the amount of lost motion.

The overall biomechanical pattern in axial torsion was similar to flexion and extension except that prosthetic discs produced increased ROM compared to intact. Previous studies have also shown increased motion in axial rotation with the Charité disc²³, possibly due to the unconstrained design of the disc in axial rotation. Intervertebral disc height may be more distracted in prosthetic disc conditions compared to intact condition, resulting in increased motion. It has been suggested that sufficient tensioning of the annulus during surgery may help to prevent excessive rotation. As mentioned prior, it was not possible to simulate *in vivo* healing and inflammatory processes to study its effects on axial rotation. Because of the increased motion of the disc, there was decreased motion at proximal levels in axial torsion, as seen in the 1- and 2-level implant conditions (-2.1% to -9.7%, and -4.3% to -13.8%). As per the discussion above, when a fusion was implemented at the L5-S1 level, the L4-L5 prosthesis was capable of compensating for lost motion in the axial rotation plane, and thus produced little effect on proximal levels (-2.2% to 8.3%). In this scenario, due to the unconstrained axial rotation, the disc was capable of buffering the effects of the fusion at L5-S1 to prevent adjacent level effects at proximal levels. Although significant differences in adjacent segment motion were only

found in the 2-level fusion condition, there is still increased motion at proximal segments due to 1- and 2- level fusions.

An interesting phenomenon that was revealed in our study is that motion redistribution at multiple proximal levels occurs equally. Previous *in vitro* studies examining adjacent level effects have only looked at the immediately adjacent level or two levels away. These experimental trials and clinical studies have suggested that adjacent level effects are not only seen in the adjacent level, but also in the subsequent level. Weinhoffer et. al., described increases at both L3-L4 and L4-L5 levels in a L5-S1 fusion. They showed a greater increase in the L4-L5 (Proximal 1) level compared to the L3-L4 (Proximal 2).⁴⁰ Hambly et. al., on the other hand, performed a radiological review of 42 patients after lumbosacral fusion and documented that degenerative changes occurred at the more distal P2 level with equal frequency as the P1 level.⁴¹ Schlegel et al⁹ performed a review of patients who had previously undergone fusion who presented with recurrence of back pain. This study also revealed that the P2 level was just as likely as the P1 level to show degenerative changes. The present study lends support to the notion that motion lost due to a fused segment is redistributed to multiple adjacent levels, not just the immediately adjacent level. Although it is common to evaluate the immediately adjacent P1 level for adjacent level effects, the results point toward the importance of examining more distal adjacent levels. It is possible that with smaller stresses, we see preferential increase at the P1 level, but as the strain increases with lengthier fusions, the increase in motion becomes equally distributed among all proximal levels. Using a complete C1-S1 spine with all intervertebral discs would perhaps distinguish between an equal or graded distribution pattern. Whether the pattern of motion distribution correlates with the clinical

adjacent segment disease remains to be clarified. Further long-term prospective follow up studies are necessary to elucidate the cause-effect relationship among fusion, motion redistribution, and clinical symptomatology.

Despite our hopes, it is possible that adjacent segment degeneration may still occur with prosthetic discs. We must acknowledge that the etiology of adjacent segment degeneration is unknown, and that it may be part of natural history. Previous studies examining the relationship between fusion and adjacent segment disease have elicited this point.⁹ In a previous clinical study examining the Prodisc prosthetic disc implant,³⁹ 24% of patients who had undergone implantation had radiological evidence of adjacent level effects on long term flexion-extension. The authors found a significant relationship between decreased range of motion of the prosthetic disc and the development of adjacent segment degeneration. Whether the radiological development of adjacent segment disease was due to loss of motion, or because of natural causes is difficult to determine. Mayer et al⁴² reported results from a non-randomized prospective study and found 8.8% of patients who received Prodisc implants had developed adjacent segment degeneration. While the results from the present study indicate greatly reduced adjacent level effects, it may still be possible to see development of adjacent segment degeneration from natural history. Ultimately, long term prospective trials comparing the incidence of adjacent segment disease in fusion versus artificial disc are needed to validate the benefit of prosthetic discs.

▪ Conclusion

In conclusion, this study aimed to test the biomechanics of artificial disc implants compared to simulated fusion using hybrid testing method and follower load axial compression. While prosthetic discs are capable of preserving [overall range of](#) motion at the implanted level, they can also diminish adjacent level effects as demonstrated by [comparison with](#) the results from a one-level fusion. It is possible that two-level disc implantation may result in increased stiffness of the superior prosthesis, but after fusing the inferior implant the superior disc [regains some range of motion](#). Axial rotation tended to have a similar profile to flexion-extension, but with greater range of motion most likely due to increased height distraction. The two other phenomena that were noted were a shift towards flexion of the total ROM after disc implantation and an equal redistribution of lost motion at multiple proximal levels.

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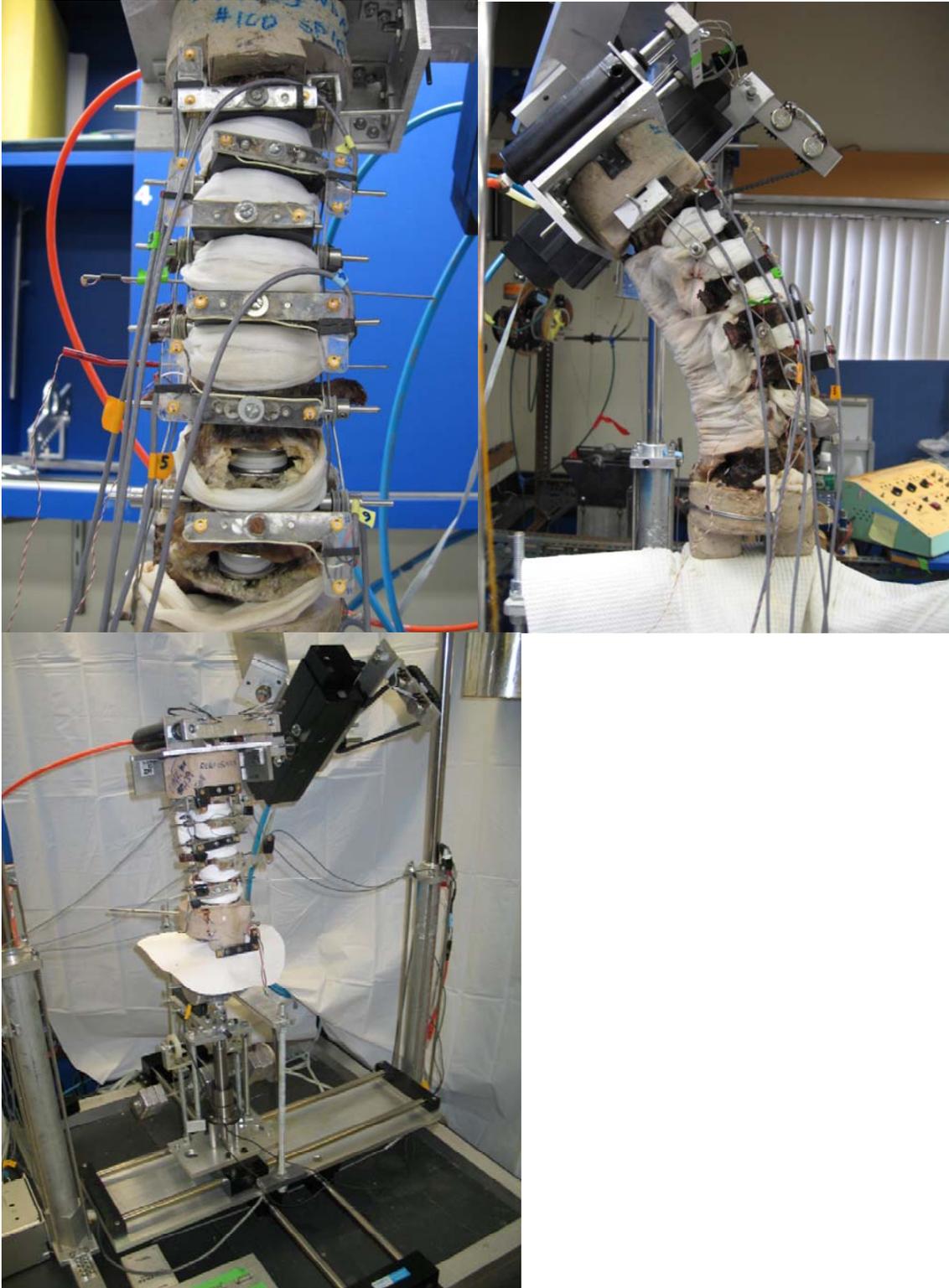


Figure 1: Photographs of the experiment setup in AP, lateral, and oblique views. The sample spine, with artificial discs implanted at L4-L5 and L5-S1, is loaded into the custom designed machine with LED sensors at each level, and follower load cables applied bilaterally along the sides of the specimen.

Hybrid Test Method

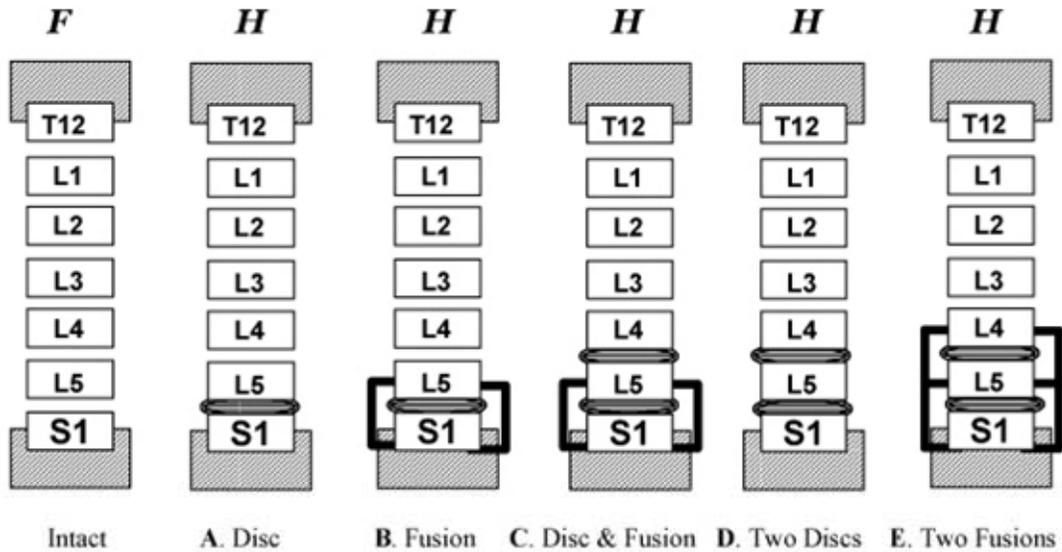


Figure 2: Figure showing all six testing conditions: Intact, 1 Disc at L5-S1, 1 Fusion at L5-S1, 1 Disc at L4-L5 with 1 Fusion at L5-S1, 2 Discs at L4-L5 and L5-S1, and 2 fusions at L4-L5-S1. The intact condition is tested in represents the flexibility protocol (F) in which 10Nm of moment are applied to the spine specimen and the total range of motion (ROM_T) is determined. The remaining five conditions (A-E) are tested in hybrid protocol in which just enough moment is applied to the specimen in order to reach the (ROM_T).

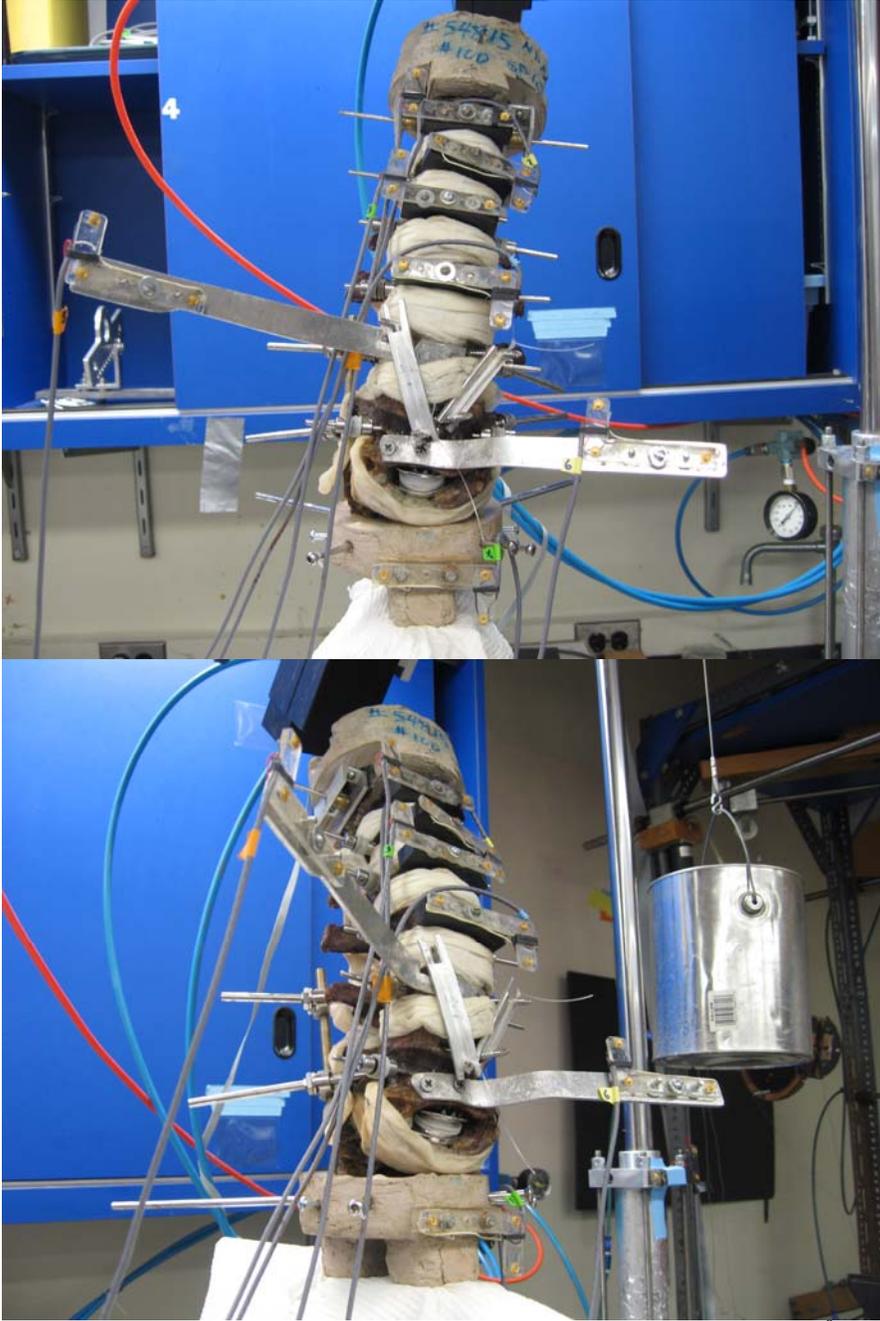


Figure 3: Photograph in AP and oblique views of simulated 360⁰ interbody fusion construct at L4-L5 showing pedicle screws were crossed inside the vertebral body with threaded portion extending anteriorly. Custom fitted metal spaced are seen placed between the screws at the L4 and L5 segments for anterior fusion and Schanz pedicle screw system is applied on the posterior side. Since the anterior side of the vertebral bodies then had pedicle screws extending from them, the LED flags could not be applied directly onto the surface of the body. Instead, custom metal extensions were made to rigidly attach the flags to the vertebral bodies without interfering with the fusion construct. The above photographs show a fusion applied at L4-L5, but actual testing took place with either a 1-level (L5-S1) or a 2-level (L4-L5-S1) fusion.

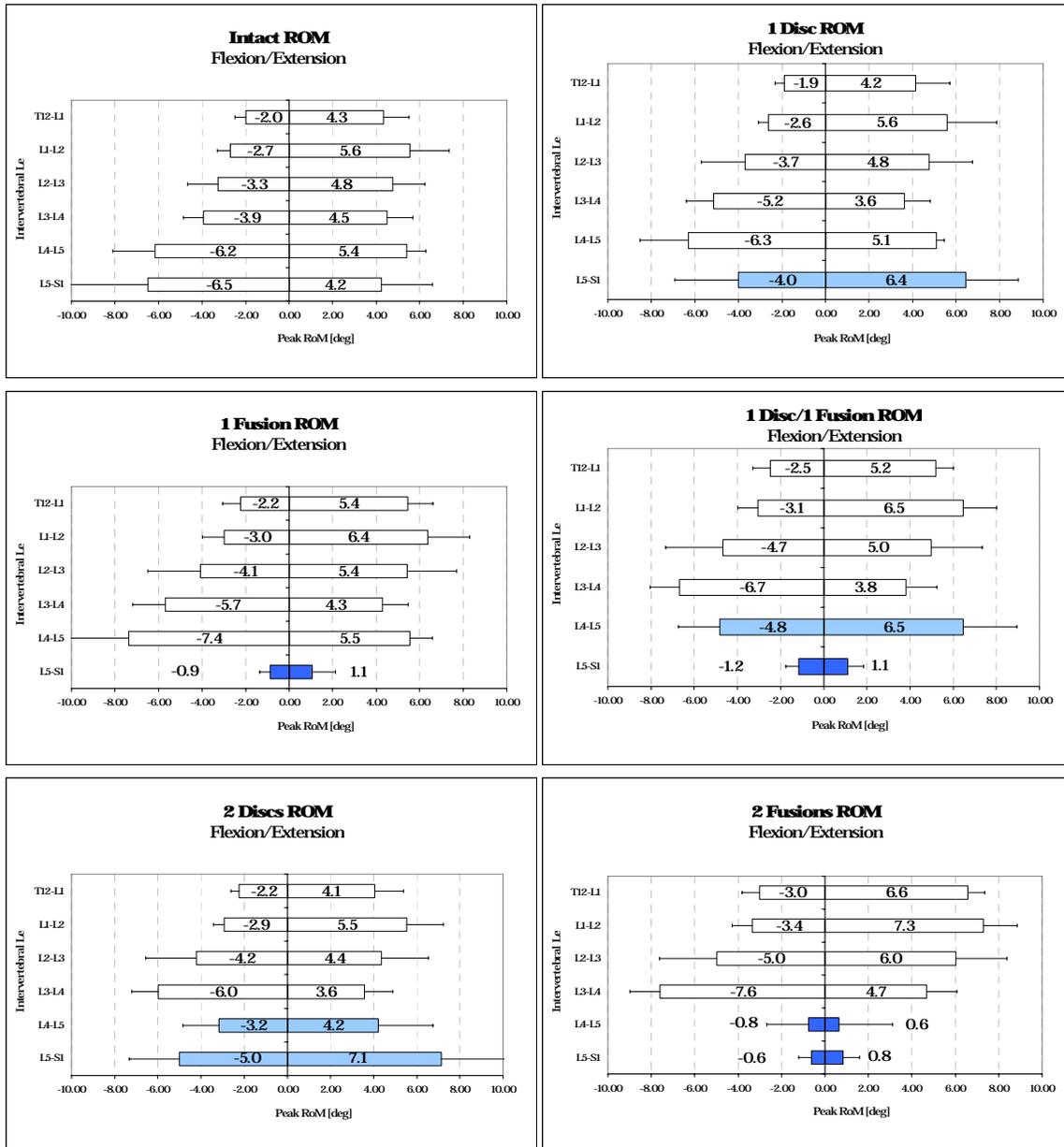


Figure 4: Flexion-Extension range of motion (ROM) at each intervertebral level for all six testing conditions (Intact, 1Disc, 1Fusion, 1Disc & 1Fusion, 2Discs, 2Fusions). Each sub-plot is presented with the intervertebral level on the Y-axis (L5-S1) and ROM in degrees on the X-axis. Light blue represents artificial discs, Dark Blue represents fusions.

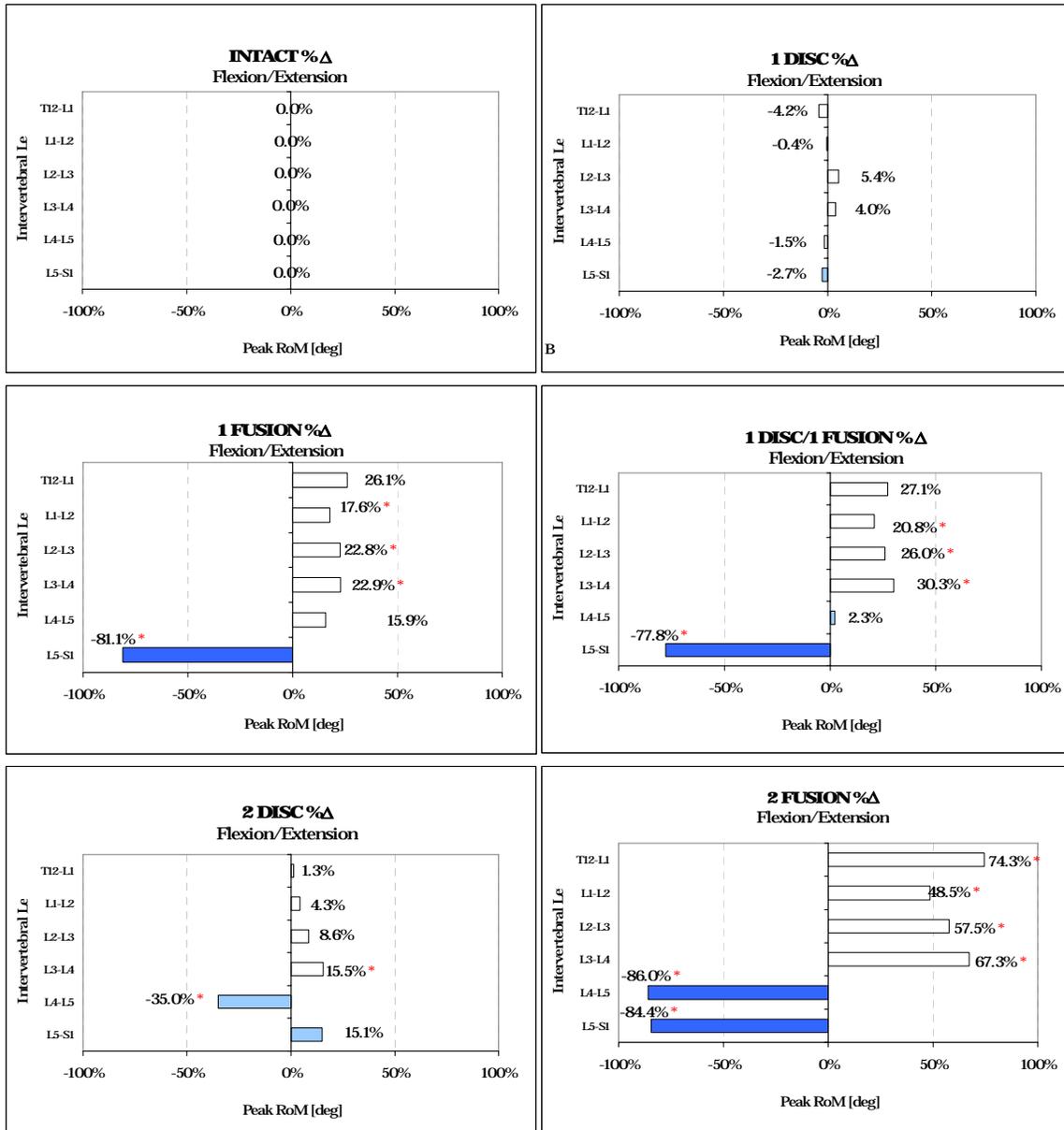


Figure 5: Change in distribution at each level in flexion-extension for all six testing conditions (Intact, 1Disc, 1Fusion, 1Disc & 1Fusion, 2Discs, 2Fusions). Each sub-plot is presented with the intervertebral level on the Y-axis (L5-S1) and change in percent distribution at each level. The percent contribution at each intervertebral level for all six test conditions were calculated (all 6 level should add up to 100% in each condition). The percent contribution at each level in the intact condition was then subtracted from each level in each testing condition to give the change in percent contribution ($\% \Delta = \%_{\text{level}} \times \text{test condition A} - \%_{\text{level}} \times \text{test intact} / \%_{\text{level}} \times \text{test intact}$). Light blue represents levels with artificial discs, Dark Blue represents levels with fusions. Red asterisks represent significant changes ($p < 0.05$) from intact condition.

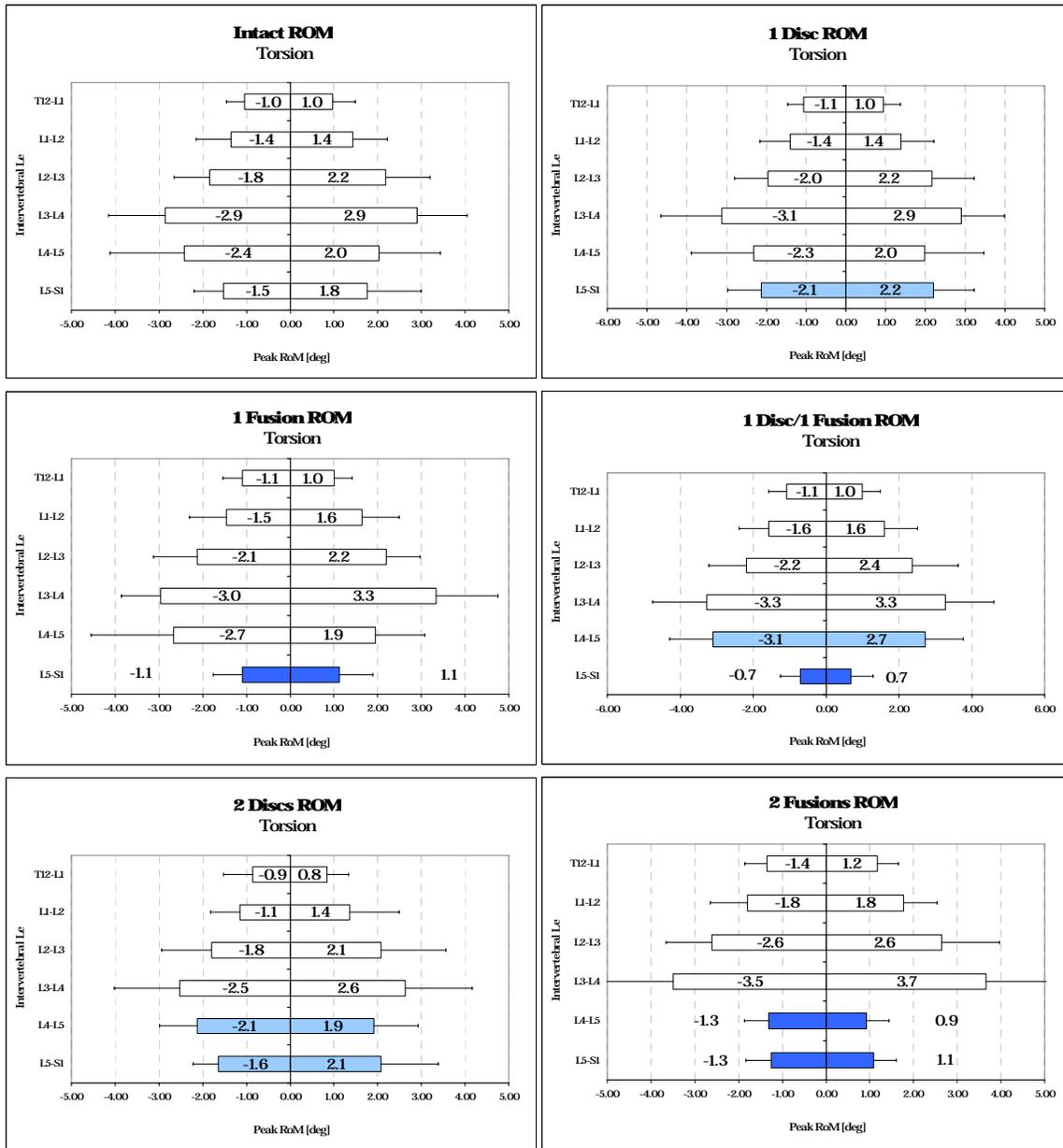


Figure 6: Axial torsion range of motion (ROM) at each intervertebral level for all six testing conditions (Intact, 1Disc, 1Fusion, 1Disc & 1Fusion, 2Discs, 2Fusions). Each sub-plot is presented with the intervertebral level on the Y-axis (L5-S1) and ROM in degrees on the X-axis. Light blue represents artificial discs, Dark Blue represents fusions.

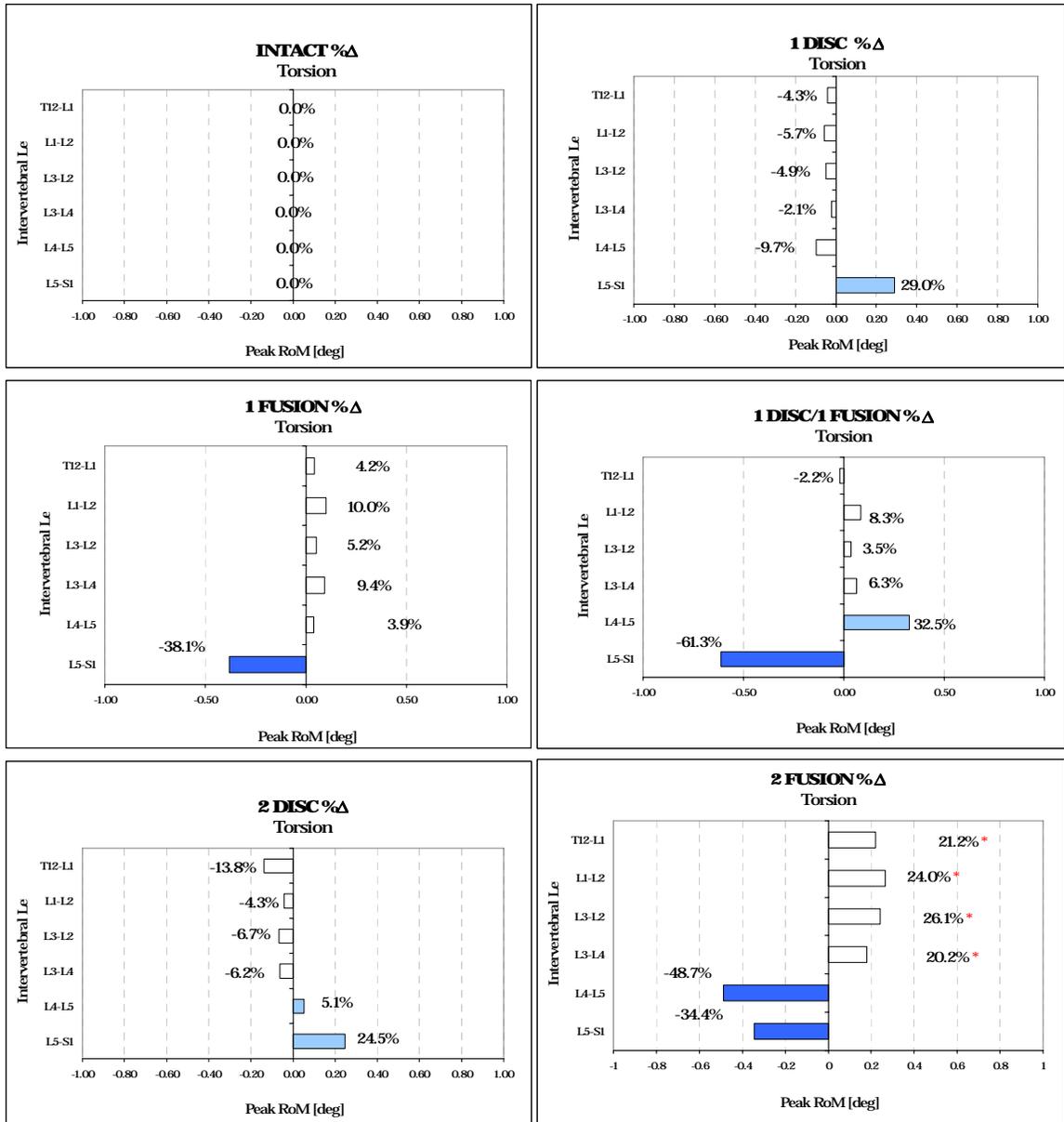


Figure 7: Change in distribution at each level in axial torsion for all six testing conditions (Intact, 1Disc, 1Fusion, 1Disc & 1Fusion, 2Discs, 2Fusions). Each sub-plot is presented with the intervertebral level on the Y-axis (L5-S1) and change in percent distribution at each level. The percent contribution at each intervertebral level for all six test conditions were calculated (all 6 level should add up to 100% in each condition). The percent contribution at each level in the intact condition was then subtracted from each level in each testing condition to give the change in percent contribution ($\% \Delta = \%_{\text{level X test condition A}} - \%_{\text{level X test intact}} / \%_{\text{level X test intact}}$). Light blue represents levels with artificial discs, Dark Blue represents levels with fusions. Red asterisks represent significant changes ($p < 0.05$) from intact condition.

Statistical comparison of ROM at each level compared to Intact in Flex-Ext

Flexion Extension ROM \pm SD

| | T12-L1 | L1-L2 | L2-L3 | L3-L4 | L4-L5 | L5-S1 |
|------------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Intact | 6.33 \pm 1.10 | 8.25 \pm 1.90 | 8.04 \pm 1.44 | 8.44 \pm 1.35 | 11.57 \pm 2.44 | 10.73 \pm 4.65 |
| 1 Disc | 6.06 \pm 1.32 | 8.22 \pm 2.07 | 8.47 \pm 1.11 | 8.77 \pm 1.88 | 11.39 \pm 1.97 | 10.44 \pm 3.93 |
| 1 Fusion | 7.98 \pm 1.08 | 9.70 \pm 1.73 | 9.87 \pm 1.80 | 10.37 \pm 1.52 | 13.40 \pm 3.11 | 2.02 \pm 1.54 |
| 1 Disc/1 Fusion | 8.04 \pm 1.20 | 9.97 \pm 1.42 | 10.13 \pm 1.53 | 10.99 \pm 1.67 | 11.84 \pm 3.65 | 2.38 \pm 1.7 |
| 2 Discs | 6.41 \pm 1.27 | 8.61 \pm 1.73 | 8.73 \pm 1.07 | 9.74 \pm 1.73 | 7.52 \pm 3.83 | 12.34 \pm 3.22 |
| 2 Fusions | 11.03 \pm 2.02 | 12.26 \pm 1.34 | 12.60 \pm 2.11 | 14.11 \pm 1.64 | 1.62 \pm 0.91 | 1.67 \pm 1.95 |

| | |
|--------------|-------------|
| significance | $p < 0.05$ |
| trend | $p < 0.065$ |

repeated measures ANOVA with Bonferroni post-hoc analysis

Table 1

Range of motion (ROM) in the flexion extension axis presented in degrees \pm standard deviation. The range of motion at each intervertebral level (T12-L1 thru L5-S1) is presented on the X axis and the 6 testing conditions on the Y axis. Results from statistical tests (repeated measures ANOVA with Bonferroni post-hoc analysis) is presented in color with significant differences ($p < 0.05$) in pink, and trends toward significance ($p < 0.065$) in yellow.

Statistical comparison of ROM at each level compared to Intact in Axial Rotation

Torsion ROM ± SD

| | T12-L1 | L1-L2 | L2-L3 | L3-L4 | L4-L5 | L5-S1 |
|------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Intact | 2.02 ± 0.92 | 2.79 ± 1.57 | 4.03 ± 1.82 | 5.76 ± 2.42 | 4.46 ± 3.09 | 3.29 ± 1.88 |
| 1 Disc | 1.91 ± 0.81 | 2.64 ± 1.58 | 3.91 ± 1.86 | 5.71 ± 2.60 | 4.07 ± 3.03 | 4.10 ± 1.82 |
| 1 Fusion | 2.06 ± 0.85 | 3.06 ± 1.68 | 4.27 ± 1.78 | 6.22 ± 2.27 | 4.55 ± 2.99 | 2.18 ± 1.41 |
| 1 Disc/1 Fusion | 1.97 ± 0.96 | 3.02 ± 1.67 | 4.32 ± 2.26 | 6.20 ± 2.78 | 5.52 ± 2.17 | 1.31 ± 1.11 |
| 2 Discs | 1.81 ± 1.14 | 2.67 ± 1.76 | 4.13 ± 2.52 | 5.48 ± 3.03 | 4.29 ± 1.84 | 3.96 ± 1.76 |
| 2 Fusions | 2.44 ± 0.98 | 3.46 ± 1.60 | 5.09 ± 2.29 | 6.92 ± 3.17 | 2.16 ± 0.95 | 2.27 ± 1.05 |

| | |
|--------------|-----------|
| significance | p < 0.05 |
| trend | p < 0.065 |

repeated measures ANOVA with Bonferroni post-hoc analysis

Table 2

Range of motion (ROM) in the axial torsion axis presented in degrees ± standard deviation. The range of motion at each intervertebral level (T12-L1 thru L5-S1) is presented on the X axis and the 6 testing conditions on the Y axis. Results from statistical tests (repeated measures ANOVA with Bonferroni post-hoc analysis) is presented in color with significant differences (p < 0.05) in pink, and trends toward significance (p < 0.065) in yellow.

