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Prospective Randomized Study of Interpedicular Motion Pre and Post Lumbar TDR: Comparison of Unconstrained, Semi-constrained, and Constrained TDR Designs

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Introduction: Lumbar disc degeneration can alter normal segmental motion. Abnormal segmental motion may lead to low back pain. The goal of lumbar TDR is to alleviate pain by restoring physiologic motion. A common source of persistent pain following lumbar TDR is facetogenic pain. As the popularity of lumbar TDR increases, so will there be an increasing potential role for posterior dynamic stabilization devices to salvage patients with pain following lumbar TDR. Previous studies have documented significant changes in interpedicular distance between maximum flexion and extension in asymptomatic volunteers. There have been, however, no studies on lumbar disc arthroplasty patients.

Purpose: The purpose of this study is to determine the changes in interpedicular distance (IPD) between flexion and extension in patients undergoing lumbar TDR, and to compare IPD among 3 different lumbar implant designs.

Methods: Patients from 2 centers enrolled in an FDA IDE trial were included in this study. All patients had single level TDR at either L4/5 or L5/S1. Patients were randomized to either an unconstrained (Charite), semi-constrained (Activ L), or constrained (Prodisc) implant. All data were collected prospectively. All radiographs were digitized and analyzed by an independent core laboratory (Medical Metrics, Inc.) using validated, computer-assisted methods. IPD was measured between the mid-pedicular axes of adjacent vertebrae using points slightly posterior to the superior articular process of each vertebra, representing the typical location of the junction between the posterior rod and pedicle screw in dynamic systems. Interpedicular motion (IPM) was calculated as the difference in the IPD in flexion minus the IPD in extension.

Results: IPD in extension was 35+/-7.8mm preoperatively with no difference between treatment groups (p=0.77), and increased an average of 2.4+/-5.9mm between pre and post-op, with no significant difference between TDR designs (p=0.87). The mean pre-operative IPM was 4.4+/-3.5mm with no difference between treatment groups (p=0.27). Pre-operatively, there was a non-significant trend (p=0.089) for greater IPM at L5/S1 (5.0+/-3.5mm) versus L4/5 (3.7+/-3.4mm). The mean post-operative change in IPM for all patients, relative to the pre-operative IPM was 0.05+/-3.5mm. The mean change in IPM from pre to post-operative lumbar TDR by implant design was +0.08+/-3.5mm for Activ L patients, -0.91+/-3.6mm for Charite patients, and +0.19+/-3.2mm for the Prodisc patients(p=0.65).

Discussion/conclusions: Interpedicular motion is a measure of segmental motion in the region of the facet joints and where dynamic stabilization systems are typically implanted. In order to recreate normal segmental kinematics lumbar TDR designs must allow for physiologic IPM. Our data suggests that lumbar TDR maintains pre-operative IPM similarly among different implant design types. Although not reaching statistical significance there was a trend to suggest greater IPM at L5/S1 over L4/5, a finding which could affect implant selection depending on the operative level. These data also provide reference data that may help in optimizing posterior dynamic stabilization if required to salvage a failed TDR.