A Prospective Clinical Comparison of 3 Biomechanical Types of Lumbar Disc Replacements: A Semi-constrained Device, a Controlled Translation Device, and an Unconstrained Device Minimum 3 Year Follow-up

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Background content: Lumbar total disc replacements have different mechanisms and levels of constraint. These inherent properties of the implant may have biomechanical significance on the motion segment, adjacent segments and surrounding structures and may alter the patient's clinical course.

Purpose: To determine if there are differences in clinical outcomes based on type of ADR implant by evaluating data from a prospective randomized FDA clinical trial.

Study design/setting: Patients were evaluated from three different sites by three separate surgeons who had one of three different types of ADR.

Patient sample/methods: One of three ADRs were implanted into each patient as part of a FDA clinical trial. Charite (23), Prodisc (27) and Activ-L (112) were randomly selected for implantation into a group of people with similar demographics and inclusion/exclusion criteria.

Outcome measures: Patients were evaluated using ODI, VAS, and SF-36 3, 6, 12, 24, and 36 months post op. These patients also had a clinical evaluation.

Results: Overall mean ODI across all groups decreased from 56.7 to 21.7 at 3 yrs. Individually, the mean ODI for the Activ-L patients decreased from average 57.4 at baseline to 11 at 36 month follow up, Prodisc fell from 58.4 to 14 and Charite from 54.4 to 39.5. The VAS back score across all groups decreased from a mean of 78.9 to 29.4 at 36 months post-operatively. For the Activ-L patients the mean baseline VAS for back pain was 80.8 and fell to 10.7 at 36 months. Prodisc fell from 80.7 to 28.0 and the Charite patients fell from 75.1 to 49.6. Physical health score from SF-36 rose from baseline of 29.7 to 50.4 in the Activ-L pts, 28.3 to 48.6 in Prodisc and 30.7 to 39.9 in Charite pts. ROM for the Activ L implant increased from 7.4 to 9.9. ROM of the other 2 implants decreased as compared to baseline.

Complications: One patient undergoing the Charite procedure had an incisional hernia and another had an intra-operative left iliac vein tear. Two patients undergoing implantation Activ-L device had onset of new leg pain postoperatively that had resolved at 9 month follow-up. One Activ-L patient required a posterior foraminotomy. Another Activ-L patient had a proximal DVT. Two Prodisc patients required removal of the Prodisc implant and conversion to a fusion as a result of bilateral pedicle fractures with polyethylene subluxation that occurred greater than 6 months after index surgeries.

Conclusions: The controlled translation device (Activ-L) had the greatest improvement in VAS, ODI, and SF-36 as compared to the other 2 devices. The controlled translation device was the only implant to show an increase in ROM as compared to baseline. Statistical analysis was not possible due to FDA ongoing study status. All three implants appear efficacious in reducing ODI and VAS as well as an increase in physical and mental parameters of the SF-36. Overall operative time, blood loss, length of hospital stay and complications were comparable. Two bilateral pedicle fractures with polyethylene subluxation occurred in the Prodisc group at a delayed time requiring implant removal and fusion.