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**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 2 Year Follow-up**

J.J. Yue<sup>1</sup>, R. Garcia<sup>2</sup>, R. Ramachandran<sup>1</sup>

<sup>1</sup>Yale University School of Medicine, Orthopaedic Surgery, New Haven, CT, USA, <sup>2</sup>Aventura Hospital, Orthopaedic Surgery, Aventura, FL, USA

**Background content:** Total disc prostheses created for motion have different mechanisms and levels of constraint. These inherent properties 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 two different sites by two separate surgeons.

**Patient sample:** One of 3 ADRs were implanted into each patient as part of a FDA clinical trial. Charite-16 Prodisc-14, and Activ-L-65.

**Outcome measures:** Patients were evaluated using ODI, VAS, and SF-36 3.

**Methods:** Patients undergoing a single-level ADR were randomized to receive either a Charite, Prodisc or Activ-L implant. ODI, VAS and SF-36 baseline, 1 yr and 2yr data were evaluated in this study.

**Results:** Overall mean ODI across all groups decreased from 59.3 to 26.2. Individually, the mean ODI for the Activ-L patients decreased from average 59.8 at baseline to 13.9 at 24 month follow up, Prodisc fell from 64.8 to 28.7 and Charite from 53.4 to 36.0 (Table 1). The VAS back score across all groups decreased from a mean of 78.5 to 32.8 at 24 months post-operatively. For the Activ-L patients the mean baseline VAS for back pain was 81.8 and fell to 14.5 at 24 months. Prodisc fell from 84.0 to 44.7 and the Charite patients fell from 69.9 to 39.3 (Table 2). Physical health score from SF-36 rose from baseline of 30.4 to 50.2 in the Activ-L pts, 29.2 to 36.3 in Prodisc and 32.3 to 41.4 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 intra-operative left iliac vein tear. One Activ-L patient required a posterior foraminotomy. Two Prodisc patients required removal of the Prodisc implant and conversion to a fusion as a result of bilateral pedicle fractures.

**Conclusions:** The controlled translation device (Activ-L) had the greatest improvement in VAS, ODI, and SF-36. The controlled translation device was the only implant to show an increase in ROM as compared to baseline. All three implants appear efficacious in reducing ODI and VAS as well as an increase in physical and mental parameters of the SF-36.

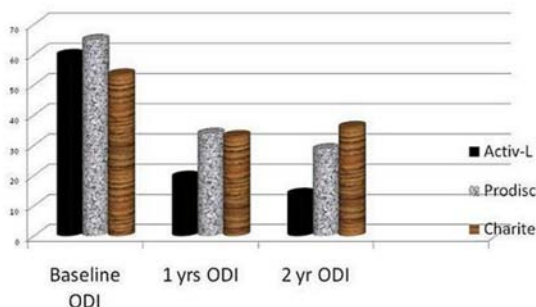


Table 1. ODI Data

[Table 1]

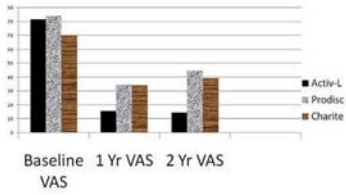


Table 2. VAS Back Data

[Table 2]