Prospective Randomized Multi-center Trial Comparing 3 Lumbar Disc Prosthesis

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Introduction: All lumbar total disc replacements have the potential to maintain motion. However, they may differ in design and function, and these differences may affect their clinical performance. Although there have been several large multi-center studies comparing clinical outcomes of lumbar TDR to lumbar fusion, there are few reports of prospective randomized studies comparing different lumbar disc implant types.

Purpose: The purpose of this study was to determine the clinical outcome of patients undergoing lumbar disc replacement, and to compare the clinical outcomes between 3 different implant types.

Methods: All patients enrolled at 3 sites in a FDA IDE trial were included in this study. All patients had single level symptomatic pain at either L4/5 or L5/S1. All patients had a retroperitoneal approach. The first 3 patients at each site were non-randomized training cases (Activ L), while all other patients were randomized 2:1 to either the investigational group (Activ L), or the control group (Charite or Prodisc).

Results: 162 patients are included in this study (23 Charite, 27 Prodisc, and 112 Activ L). 94 patients were males, and 68 were females. L4/5 was involved in 53 patients, and L5/S1 in 109 patients. The mean operative time for Charite was 109 minutes, for Prodisc 101 minutes, and for Activ L 95 minutes. The mean blood loss for Charite was 257cc, for Prodisc 83cc, and for Activ L 107cc. The length of hospital stay was 2.6 days for Charite, 1.8 days for Prodisc, and 2.0 days for Activ L. There were statistically significant improvements in ODI and VAS in all 3 groups (p< 0.05). Overall mean ODI across all groups decreased from 59.3 to 26.2. The VAS back score across all groups decreased from a mean of 78.5 to 32.8 at 24 months post-operatively.

Individually, the mean ODI for the Activ-L patients decreased from an average of 57.4 at baseline to 18.1 at 24 month follow up, Prodisc fell from 58.4 to 22.0 and Charite from 54.4 to 34.0. For the Activ-L patients the mean baseline VAS for back pain was 80.8 and fell to 18.5 at 24 months. Prodisc fell from 80.7 to 22.7 and the Charite patients fell from 75.1 to 35.1.

Conclusions: The results of this prospective randomized study support previous prospective studies which report favorable clinical results for lumbar TDR. In addition, the results of this study demonstrate significant improvement in ODI and VAS in patients undergoing lumbar TDR, regardless of implant type.