

Abstract: 120**Prospective Evaluation of the Charite™ Lumbar Artificial Disc Replacement with Minimum Three-year Follow up***K.A. Pettine¹*¹The Spine Institute, Loveland, CO, USA

Purpose: To evaluate the clinical results of Charite A.D.R. from a completely independent F.D.A. I.D.E. study site. The surgeon has no financial ties to Depuy and was not involved in the Charite study.

Methods: Sixty-six patients at one I.D.E. site. The Charite data will be presented. All surgeries were single level L4-L5 or L5-S1. Inclusion/Exclusion criteria included: DDD at either L4-L5 or L5-S1, six months of conservative therapy, ODI of 40 % pre-operatively and VAS of 40mm out of 100mm pre-operatively, previous spinal surgery or fusion at treatment level, back or leg pain of unknown origin, degenerative spondylolesthesis at treatment level, spondylitis at treatment level, significant stenosis at treatment level, fibromyalgia/autoimmune disease, active systemic infection, cancer. Demographics were similar between groups. Average patient age 42; Average B.M.I. 27; Male/female ratio (C) 13/18. Ratio of L4-5 to L5-S1 was (C) 19:12. Oswestry Disability Index (ODI), Visual Analogue Scale (VAS), patient satisfaction, and flexion/extension radiographs on every patient were evaluated pre-op and at 6 weeks, 3 months, 6 months, 12 months, 24 months and 36 months post-op utilizing audited F.D.A. I.D.E study forms.

Results: Operating time average: 104 minutes at L4-L5 and 79 minutes at L5-S1. Average blood loss: 45 cc at both levels. Hospitalization average: 22 hours.

ODI results: Pre-op = (C) 63.8; twelve months = (C) 27.25; twenty-four months = (C) 20.5 ($p < 0.001$). 36 months= (C) 2.6 ($p < 0.001$). VAS results: pre-op = (C) 85.1; twelve months = (C) 31.4; twenty-four months = (C) 33.8 ($p < 0.001$). 36 months= (C) 19.8 ($p < 0.001$).

At twelve month follow up 32% of (C) patients had an ODI less than 10. At twenty-four months the percentage increased to (C) 33% . At thirty-six months 38% had an ODI of less than 10. Also at twelve months 39% of (C) patients had a VAS of less than two. At twenty-four months the percentage changed, (C) 29%. These patients were considered basically „pain free „with „normal“ function.

The F.D.A. I.D.E. definition of clinical success was met in

84 % of (C) patients. Clinical success was defined by at least 25% improvement in ODI at 24-month follow up. Patient satisfaction based on strict criteria at two-year follow up was (C) 88% and at three year follow-up 92%.

Complications - Three patients required re-operation: one to reposition implant midline; two patients were posteriorly instrumented and fused due to implant invagination into the L4 vertebral body; and a second patient developed bilateral L4 pedicle fractures. Both of occurred within eight weeks after the initial A.D.R.

Conclusion: Charite patients demonstrated clinical efficacy with significant decrease in ODI and VAS ($p < 0.001$) from pre-op to three-year follow up. FDA Clinical success was met in 84% of the patients. Satisfaction was 92% at three years. These results are better than reported in the Charite IDE study. These results represent the only class one data from a completely independent study site without financial disclosures with Depuy.