

# Clinical and Radiological Mid-Term Outcomes of Lumbar Single-Level Total Disc Replacement

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## Abstract Author Information

**Study Design.** Prospective single-center case cohort study.

**Objective.** Evaluation of clinical and radiographic outcomes of a consecutive 122-patient cohort with discogenic back pain, at 2- to 10-year follow-up periods, treated by a single surgeon, with CHARITÉ Artificial Disc (DePuy Spine, Raynham, MA).

**Summary of Background Data.** Minimum 2-year clinical and radiographic level 1 data for the first lumbar artificial disc, the CHARITÉ Artificial Disc (DePuy Spine), have recently been published, demonstrating sustained clinical benefit of the device for the treatment of degenerative disc disease.

**Methods.** Patients were assessed preoperatively using clinical outcome measures, including visual analog scale (VAS) score back and leg, Oswestry Disability Index (ODI), 36-Item Short Form Health Survey (SF-36), and Roland-Morris Questionnaires (RMDQ), and further assessed postoperatively, 3-, 6-, 12-months, and yearly thereafter.

**Results.** Average follow-up was  $44.9 \pm 23.3$  months ( $n = 122$ ). The median age at surgery was  $43.0 \pm 9.0$  years. Preoperative diagnosis included degenerative disc disease in 118 (96.7%) and internal disc disruption in 4 (3.3%). Surgery was performed at L5–S1 in 96 (77.9%) patients and at L4–L5 in 27 (22.1%). Statistically significant clinical improvements from baseline were observed on VAS (back and leg), ODI, SF-36 PCS, SF-36 MCS, and RMDQ 3 months onward. Back VAS scores decreased from  $78.2 \pm 21.3$  preoperatively to  $21.9 \pm 27.8$  by final follow-up. ODI scores decreased from  $51.1 \pm 17.3$  to  $16.2 \pm 17.9$  at last follow-up. The RMDQ scores also decreased from  $16.7 \pm 4.7$  to  $4.2 \pm 5.8$ . SF-36 PCS and MCS increased from  $25.7 \pm 11.0$  to  $46.4 \pm 10.3$  for PCS and from  $35.5 \pm 17.4$  to  $51.6 \pm 10.8$  for MCS. Patient satisfaction surveys indicated that 90.56% patients rated their satisfaction with the surgery as “excellent” or “good” at 2 years. Range of motion averaged  $8.6 \pm 3.5$  (median =  $8.0^\circ$ ) at the last follow-up time point.

**Conclusion.** Outcomes verify the clinical efficacy of total disc replacement for treatment of discogenic back pain with or without radiculopathy. The outcomes instruments demonstrated statistically significant improvements 3 months onward.

**Level of Evidence:** N/A

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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