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

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Abstract

Study Design. Prospective single-center case cohort study.


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 ± 23.3 months (n = 122). The median age at surgery was 43.0 ± 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 ± 21.3 preoperatively to 21.9 ± 27.8 by final follow-up. ODI scores decreased from 51.1 ± 17.3 to 16.2 ± 17.9 at last follow-up. The RMDQ scores also decreased from 16.7 ± 4.7 to 4.2 ± 5.8. SF-36 PCS and MCS increased from 25.7 ± 11.0 to 46.4 ± 10.3 for PCS and from 35.5 ± 17.4 to 51.6 ± 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 ± 3.5 (median = 8.0°) 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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