

# **Lumbar Arthroplasty vs. Anterior Interbody Fusion at One-Level: Clinical Results at 5-Year Follow-up from the IDE Study of the CHARITÉ Artificial Disc**

Richard D. Guyer, MD, Paul C. McAfee, MD, Robert J. Banco, MD,  
Fabien D. Bitan, MD, Andrew Cappuccino, MD,  
Fred H. Geisler, MD, PhD, Stephen H. Hochschuler, MD,  
Richard T. Holt, MD, Louis G. Jenis, MD, Mohammed E. Majd, MD,  
John J. Regan MD, Noam Y. Stadlan MD,  
Scott G. Tromanhauser, MD, Douglas C. Wong, MD,  
Scott L. Blumenthal, MD, Donna Ohnmeiss, PhD

Texas Back Institute, Plano, TX, USA

## **BACKGROUND CONTEXT:**

---

Previous presenters and authors have described follow-up of various lengths for patients having had lumbar arthroplasty for the treatment of degenerative disc disease. Follow-up in these patients has been reported from 6 months to 17 years. Though long-term follow-up of large single-center patient cohorts is important, only long-term follow-up of patients enrolled in prospective, randomized, controlled studies represents Level I data. The IDE study of the CHARITÉ Artificial Disc was the first prospective, randomized, controlled trial studying lumbar arthroplasty at one level from L4 to S1 compared to fusion.

## **PURPOSE**

---

The purpose of the study was to determine clinical outcomes in patients with a lumbar total disc replacement (TDR) vs. patients with lumbar fusion, at one level, with follow-up to 5 years.

## **STUDY DESIGN/SETTING**

---

This study is a prospective 5-year follow-up of patients originally enrolled in the prospective, randomized FDA-regulated IDE trial comparing lumbar arthroplasty with the CHARITÉ Artificial Disc to anterior lumbar interbody fusion (ALIF) with fusion cages. Inclusion/Exclusion criteria and all study methodology were previously described by Blumenthal et al.<sup>1</sup>

## **PATIENT SAMPLE**

---

Of the 304 patients enrolled in the randomized trial, 133 (90 CHARITÉ Disc, 43 fusion) were evaluated clinically and radiographically at 5-year follow-up.

All patients were treated for single-level symptomatic disc degeneration unresponsive to non-operative management.

## **OUTCOME MEASURES**

---

Oswestry Disability Index (ODI), Visual Analog Scale (VAS) assessing pain, SF-36 health questionnaires, and work status. Flexion/extension radiographs were used to assess range of motion.

## METHODS

---

The pre- to post-operative outcome scores were compared to baseline and between the two groups.

## RESULTS

---

Mean percent changes at 5 years compared to baseline for ODI (**Figure 1**, CHARITÉ: -49.5% points vs. Fusion: -52.7% points); mean absolute change for VAS pain scores (**Figure 2**, CHARITÉ: -38.7 vs. Fusion: -40.0); and SF-36 PCS questionnaires (**Figure 3**, CHARITÉ: +12.6 points vs. Fusion: +12.3 points) were similar between groups.

In patient satisfaction surveys, 78% of CHARITÉ patients were satisfied vs. 72% of fusion patients. As shown in **Figure 4**, Patients employed full-time included 66% of CHARITÉ patients vs. 46.5% of fusion patients ( $p=0.0403$ ). Long-term disability was recorded for 8.0% of CHARITÉ patients and 20.9% of fusion patients, ( $p=0.0441$ ). Additional index-level surgery was performed in 7.7% in the CHARITÉ group and 13.9% in the fusion group. The mean index-level ROM at 5 years was  $6.0^\circ$  for CHARITÉ patients and  $1.0^\circ$  for fusion patients.

## CONCLUSIONS

---

The results of this 5-year, prospective, randomized multi-center study are consistent with the 2-year reports of non-inferiority of the CHARITÉ Artificial Disc vs. ALIF with fusion and iliac crest autograft. No statistical differences were found in clinical outcomes between groups. CHARITÉ patients reached a statistically greater rate of full-time employment and a statistically lower rate of long-term disability, as compared to fusion patients. The mean ROM at the index-levels were not statistically different from those observed at 2-years post-operative. This Level I data is the only randomized, controlled data for lumbar arthroplasty with 5-year follow-up.

Figure 1

# ODI: Percent Change From Baseline

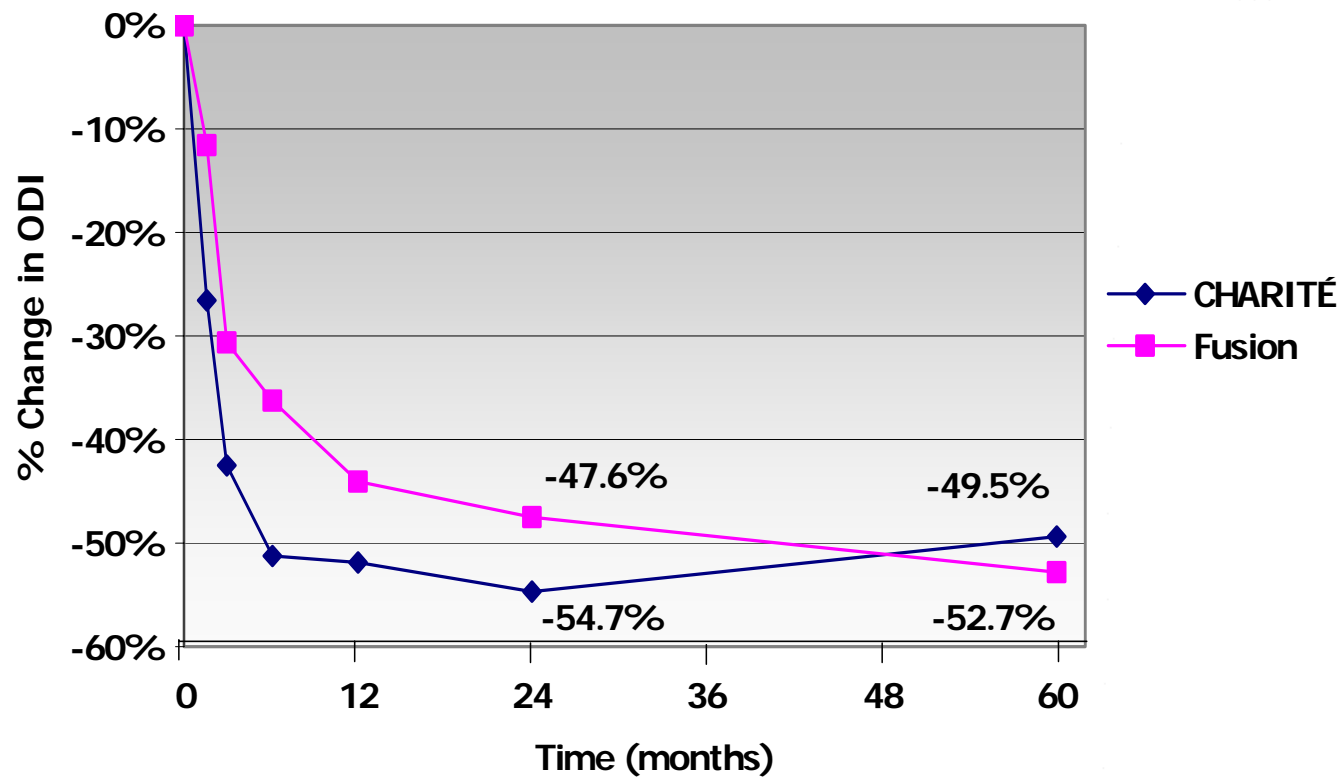
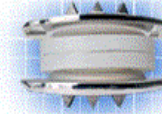


Figure 2

## Mean VAS Change From Baseline

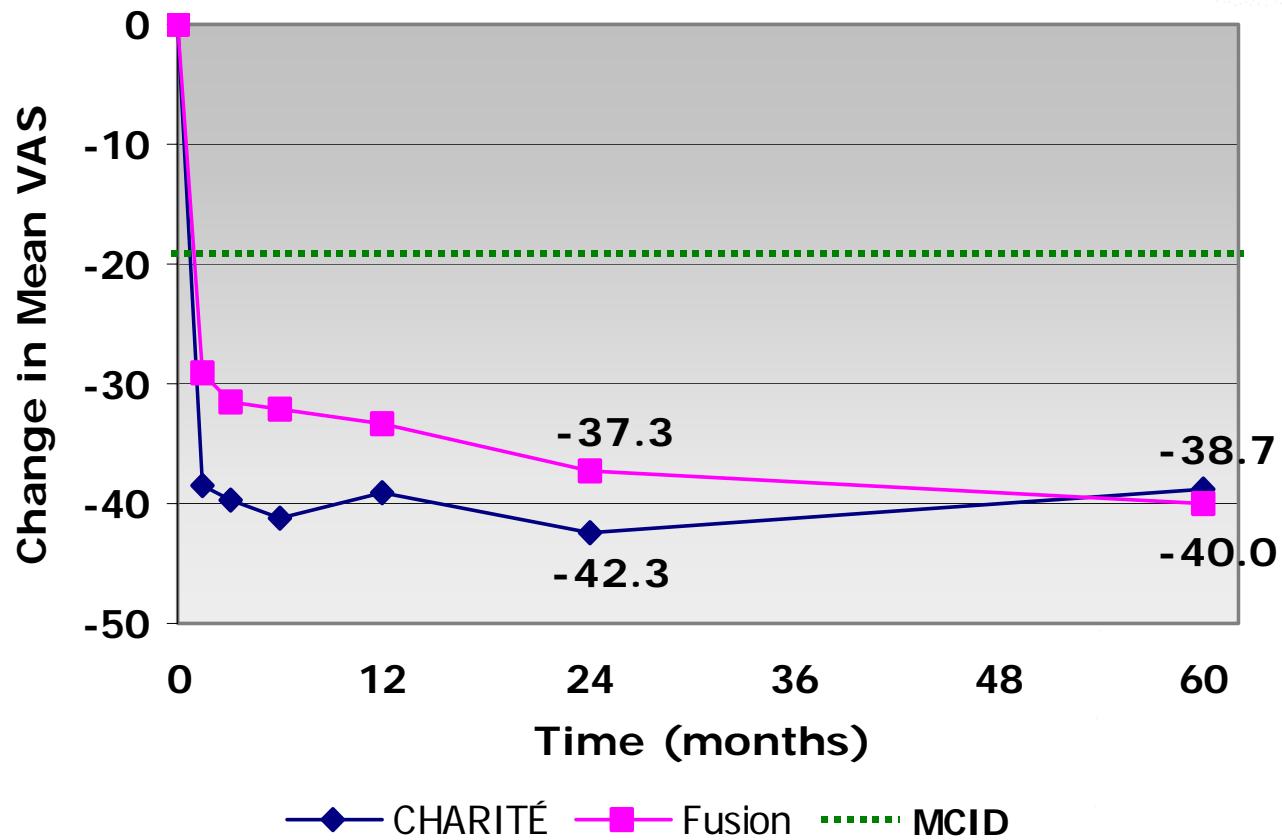


Figure 3

## Mean PCS (SF-36) Change

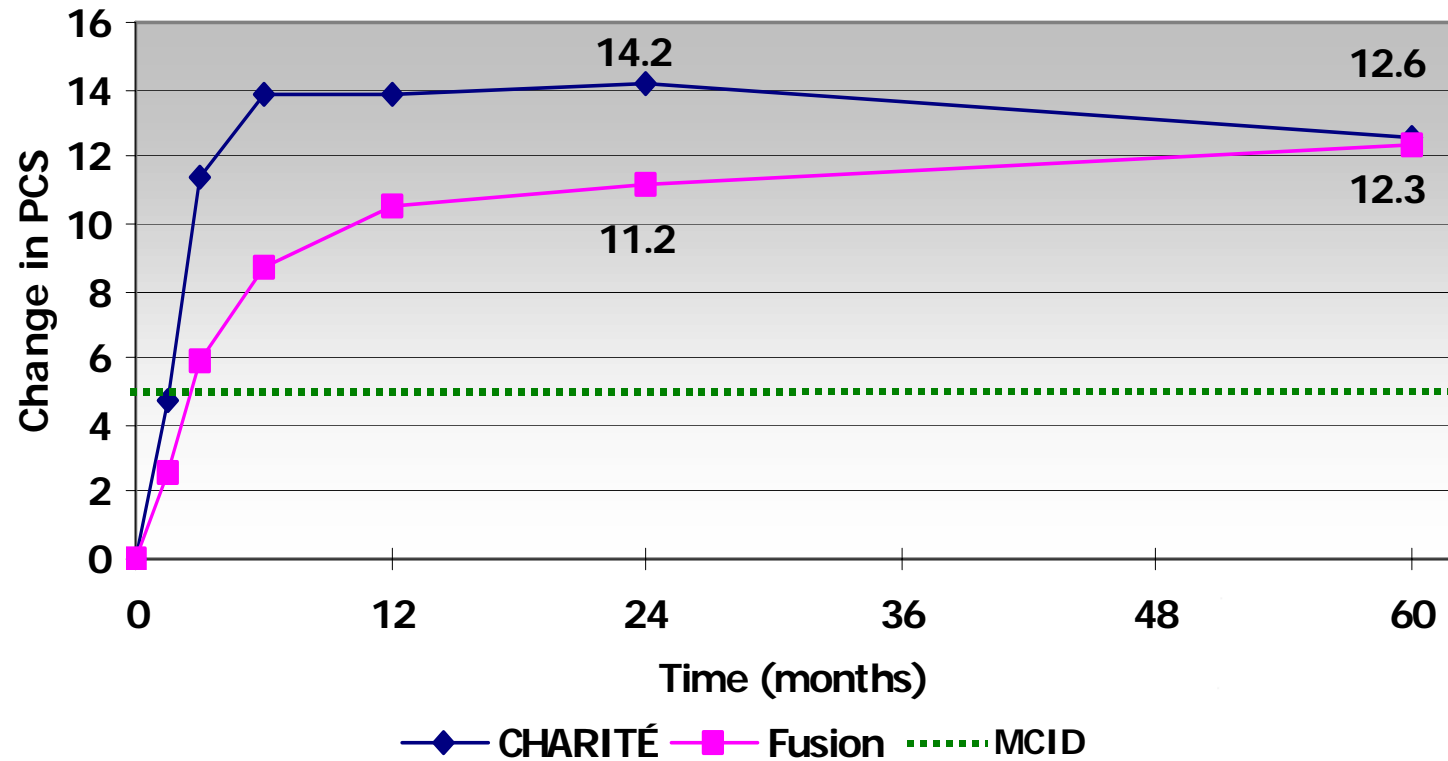


Figure 4

## Work Status at 5-year Follow-up

