

Prospective, Randomized, Multi-Center FDA IDE
Study of CHARITÉ Artificial Disc
vs. Lumbar Fusion:
Index- and Adjacent-Level
Range of Motion at 5-Year Follow-Up

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Introduction

To evaluate the radiographic outcomes of all randomized patients from the 5-year CHARITÉ IDE study treated with CHARITÉ Artificial Disc vs. Lumbar fusion. Range of motion at baseline (pre-operative) and at the 5-year post-operative time point were compared.

Materials and Methods

Radiographs for all patients were available in anteroposterior, lateral and full flexion and extension views. All radiographs were scanned, digitized and analyzed using a computer-assisted method designed to measure differences between flexion/extension angles accurate to within 1°. Intervertebral angular range of motion was evaluated in patients with paired pre-operative and 5-year post-operative data. Motion was evaluated at the index and immediate adjacent levels. Change in motion from pre-op to 5-year post-op was used to evaluate the effect of each treatment on intervertebral motion over time.

Results

Patients were subdivided by operative level. The L4-L5 level included 25 arthroplasty vs. 10 fusion patients, while the L5-S1 level included 63 arthroplasty vs. 31 fusion patients. For patients operated at the L4-L5 level, pre-operative range of motion was $8.7^{\circ} \pm 5.9^{\circ}$ in the arthroplasty group, and $9.2^{\circ} \pm 5.0^{\circ}$ in the fusion group. There was no statistical difference between these two groups. At 5-year post-operative, range of motion was $6.1^{\circ} \pm 5.5^{\circ}$ for arthroplasty and $1.0^{\circ} \pm 2.3^{\circ}$ for fusion.

The change in index-level range of motion from pre-op to 5-year post-op was statistically significant for fusion patients ($p=0.0003$) but, while indicative of a trend, was not quite statistically significant for arthroplasty subjects ($p=0.0539$). In the arthroplasty cohort, adjacent-level range of motion at L3-L4 (preoperative: $7.4^{\circ} \pm 5.0^{\circ}$; 5-year: $7.3^{\circ} \pm 4.0^{\circ}$) and L5-S1 (preoperative: $7.9^{\circ} \pm 5.5^{\circ}$; 5-year: $8.2^{\circ} \pm 4.7^{\circ}$) were comparable from preoperative to 5-year post-operative. In the fusion cohort, adjacent-level range of motion at L3-L4 was mostly unchanged from pre-op ($8.0^{\circ} \pm 3.9^{\circ}$) to 5-year post-op ($8.9^{\circ} \pm 4.8^{\circ}$), while motion at L5-S1 showed a slight decreased ($8.1^{\circ} \pm 6.4^{\circ}$ vs. $7.2^{\circ} \pm 7.6^{\circ}$).

Results - continued

For patients operated at the L5-S1 level, index-level changes in ROM were not significant for arthroplasty patients (preoperative: $7.6^{\circ} \pm 5.6^{\circ}$; 5-year: $6.0^{\circ} \pm 5.2^{\circ}$, $p=0.2237$) but were significant for fusion patients (preoperative: $8.2^{\circ} \pm 6.3^{\circ}$; 5-year: $1.0^{\circ} \pm 1.1^{\circ}$, $p=0.0003$), as expected.

Adjacent-level changes at L4-L5 showed trends towards increased motion in arthroplasty patients (preoperative: $7.2^{\circ} \pm 5.5^{\circ}$; 5-year: $8.0^{\circ} \pm 5.4^{\circ}$) while there was no significant change in adjacent-level motion in fusion patients (pre-operative: $8.8^{\circ} \pm 4.8^{\circ}$; 5-year: $7.6^{\circ} \pm 5.5^{\circ}$).

Conclusions

In this study, there were no statistically significant changes in motion at the index and adjacent levels for arthroplasty patients after 5 years.

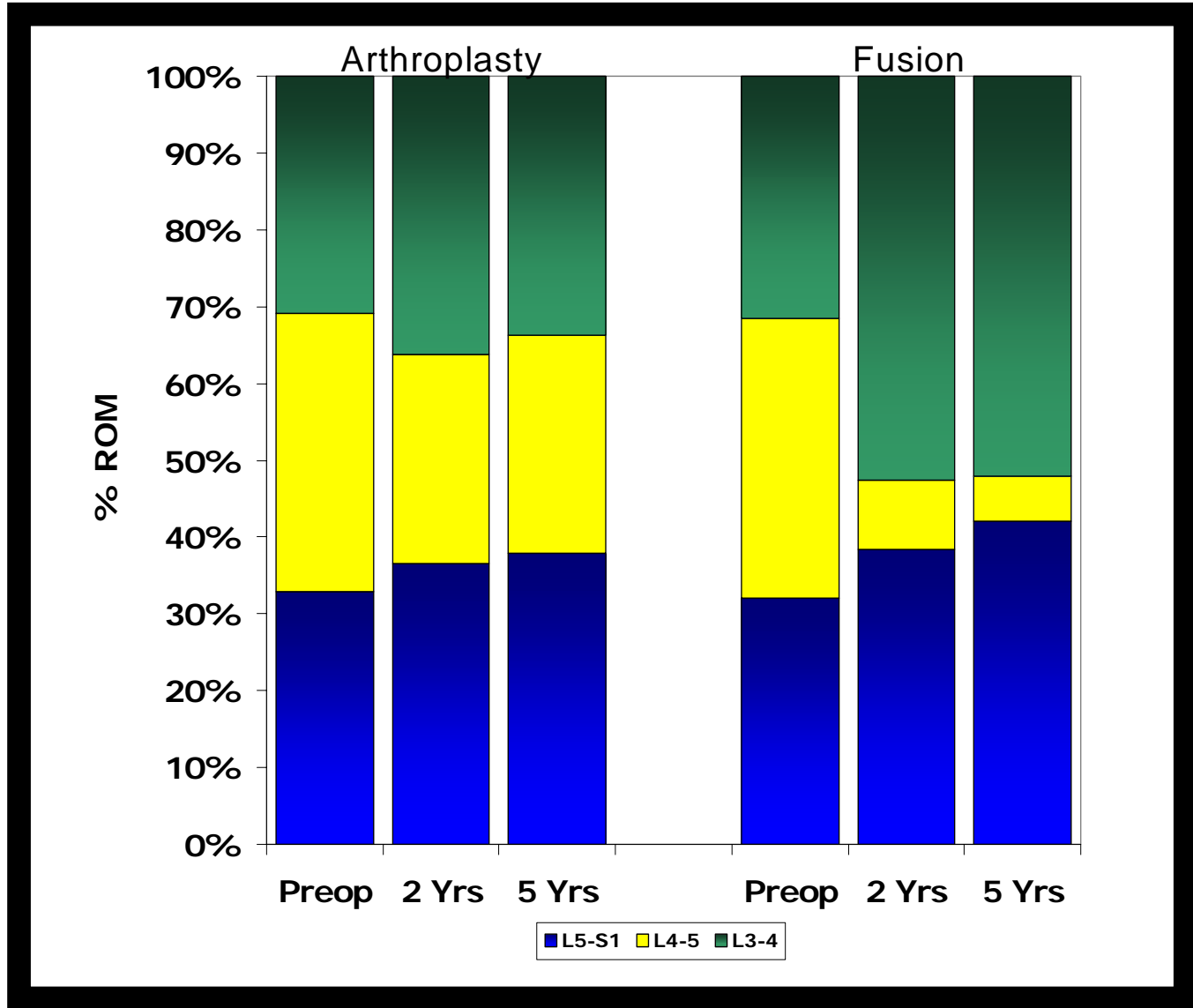


Figure 1

Graphic representation of the % of motion experienced from L3 to S1 for arthroplasty and fusion patients implanted at L4-L5 at the preoperative, 2- and 5-year post-operative time points.

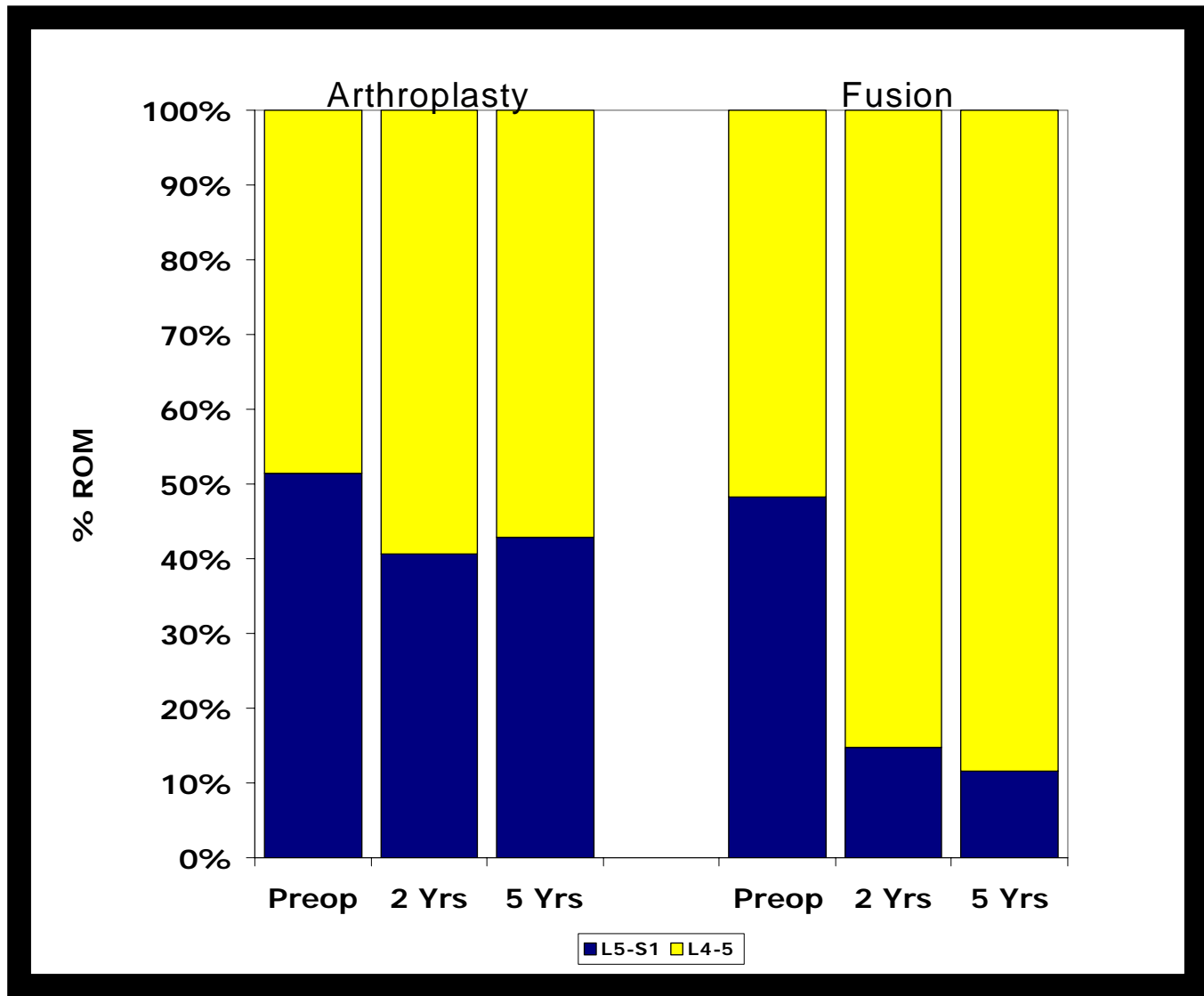


Figure 2

Graphic representation of the percentage of motion experienced from L4 to S1 for arthroplasty and fusion patients implanted at L5-S1, at the preoperative, 2- and 5-year post-operative time points.

Figure 3

ROM at the pre-operative, 2- and 5-yr post-operative time points. Pre-operatively, 36% patients had motion between 0° and 5°. This number increased to 47% at 2 yrs and 52% at 5 yrs. The percentage of patients with motion between 6° and 10° changed from 33% pre-operatively to 32% and 26% at 2 and 5 yr post-operative. Pre-operatively, 13 patients had motion greater and 15°. This ratio decreased to 5% at 2 and 5-yr post-operative.

