

Cervical Disc Replacement: Interim five year follow-up results from the United States prospective randomized Bryan Clinical Trial

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INTRODUCTION:

The published two-year results of the pivotal FDA IDE trial of cervical arthroplasty compared to ACDF for treating single-level degenerative cervical disc disease revealed a statistically superior overall success rate in the arthroplasty group. The purpose of this study is to evaluate the currently available data at half of a decade to determine their consistency over time and to assess complications and revision surgeries.

METHODS:

463 patients were enrolled in a prospective, randomized, controlled, multi-center study with a 1:1 randomization scheme; 242 in the arthroplasty group and 221 in the control group. No statistical differences were seen between the groups for demographics and preoperative measures. As of May 28, 2010, 5-year follow-up data were available for 193/242 (79.8%) of the arthroplasty patients and 159/221 (71.9%) of the control patients. The study's primary outcome measure, overall success, as well as secondary functional outcome measures (NDI, SF-36, arm and neck pain scores), were collected at pre-defined time points out to 60 months postoperatively.

RESULTS:

At 60 months postoperatively:

Overall success rate: 160/193 (82.9%) for the arthroplasty group, 119/159 (74.8%) for the control group, $p=0.043$;

NDI score: 15.9 arthroplasty, 19.1 control, $p=0.020$;

Neck pain score: 23.8 arthroplasty, 28.8 control, $p=0.031$ (Change from preop: -51.3 arthroplasty, -45.2 control, $p=0.031$); and

SF-36 PCS: 47.3 arthroplasty, 44.0 control, $p=0.006$ (Change from preop: 14.4 arthroplasty, 11.8 control, $p=0.006$);

Cumulatively up to 60 months: Second surgery at index level: 11 (4.5%) arthroplasty, 11 (5.0%) control;

Possibly related AEs: 9 (3.7%) arthroplasty, 14 (6.3%) control;

Possibly device-related and serious (grade 3 or 4) AEs: 4 (1.7%) arthroplasty, 9 (4.1%) control.

CONCLUSIONS:

Based on currently available data, excellent results continue out to 5 years postoperatively in both the arthroplasty and ACDF groups. Continued statistically significant differences are present for overall success that favor the arthroplasty cohort at 60 months, as was seen at 24 months postoperatively. The NDI, SF-36 PCS and neck pain scores also showed improvement in the arthroplasty group that was statistically significant at 60 months compared to the control group. Second surgery and adverse events were very low in both groups with no

statistically significant differences between groups at half a decade postoperatively.