SELECTED ABSTRACTS DELIVERED AT THE 10TH ANNUAL AOSPINE NORTH AMERICA FELLOWS FORUM

Consistent with EBSJ's commitment to fostering quality research, we are pleased to feature some of the most highly rated abstracts from the 10th Annual AOSpine North America Fellows Forum in Banff, Canada. Enhancing the quality of evidence in spine care means acknowledging and supporting the efforts of young researchers within our AOSpine North America network. We look forward to seeing more from these promising researchers in the future.

61–62

Single-center results at 7 years of prospective, randomized ProDisc-C total disc arthroplasty versus anterior cervical discectomy and fusion for treatment of one level symptomatic cervical disc disease

Authors Thomas Kesman, Daniel Murrey, Bruce Darden
Institution OrthoCarolina, Charlotte, NC, USA

ABSTRACT

Study design: Prospective randomized controlled study.

Introduction: Symptomatic cervical disc disease (SCDD) causing radiculopathy is a common diagnosis traditionally treated surgically with anterior cervical discectomy and fusion (ACDF).

Objective: The purpose of this trial is to compare the safety and efficacy of total disc arthroplasty (TDA) using the ProDisc-C (Synthes Spine Company, LP, West Chester, PA, USA) implant to ACDF in patients with single-level SCDD between C3 and C7.

Methods: This study is a report of the single-site results from a trial of 13 sites in a multicenter trial. Patients for this study were enrolled and treated in accordance with the approved US Food and Drug Administration protocol, using a non-inferiority design. The trial used a prospective, randomized controlled methodology. Patients were randomized to either TDA using the ProDisc-C device or ACDF in a one-to-one method. All enrollees were evaluated preoperatively and postoperatively at 6 weeks, 3, 6, 12, 18, 24, 36, 48, 60, 72, and 84 months. Data was collected using the Visual Analog Scale (VAS) for neck and arm pain/intensity, and satisfaction. Neck Disability Index (NDI) and Short-Form 36 (SF-36) questionnaires were also completed. Adverse events were recorded.

This study is part of a multicenter US Food and Drug Administration investigational device exemption study funded by Synthes Spine, West Chester, PA, USA.

Results: Twenty-two patients were randomized to each arm of the study at this site. All operations occurred between C4 and C7 with most being at C5–6 and C6–7 and only two at C4–5. Operative time was similar (ProDisc-C 98 ± 16 min; ACDF 95 ± 23 min; P =.59). The NDI improved in the ProDisc-C group more than in the ACDF group (ProDisc-C preoperative 54.2 ± 12.8 to 7 years 14.1 ± 18.1 vs ACDF preoperative 53.6 ± 14.1 to 7 years 26.9 ± 23.8) (P =.11). Total range of motion was maintained in the ProDisc-C while it diminished as expected in the ACDF group. The VAS scores and SF-36 scores all showed at minimum non-inferiority of the Prodisc-C group and trended toward superiority of the TDA group in some metrics including neck pain. Seven additional operations were carried out among the entire study group, all in the ACDF group with three reoperations at the same level and four operations at an adjacent level. Four of 44 patients died within 7 years of the index operation, all from unrelated causes [1].

Conclusions: The Prodisc-C implant appears to be safe and effective for the treatment of SCDD. Patients with the implant generally retained more motion at the involved segment than those with an ACDF and had a lower reoperation rate.

REFERENCE

1. **Murrey D, Janssen M, Delamarter R, et al** (2009) Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. *Spine J;* 9(4):275–286.

AUTHOR DISCLOSURE INFORMATION

Kesman TJ: Direct Research/Institutional Support; AOSpine North America.

Murrey D: Royalties; Stryker Spine. Speaker's Bureau/Paid Presentation; Synthes Spine. Paid Consultant; Synthes Spine, Stryker Spine. Stock; Amedica Corp /US Spine, Pioneer Surgical Technology. Direct Research/Institutional Support; AOSpine North America. Res/Inst Support thru dept/div/practice; Synthes Spine.

Darden BV: Royalties; Stryker Spine. Speaker's Bureau/Paid Presentation; Stryker Spine. Unpaid Consultant; BioMedFlex. Stock; BioMedFlex, Pioneer Surgical Technology. Direct Research/Institutional Support; AOSpine North America. BOD/owner/officer/committee h/c org; CSRS, LSRS. Editorial/gov board med/ortho pubs; JAAOS, JSDT, Journal of Spinal Cord Medicine, Spine.