**Long-term Clinical Experience with SECURE®-C Cervical Disc Arthroplasty**

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**Purpose:** Long-term follow-up is essential to understanding the effects of cervical arthroplasty. This study compares clinical results of semi-constrained cervical arthroplasty using the SECURE®-C Cervical Artificial Disc (Globus Medical, Audubon, PA) with that of traditional anterior cervical disectomy and fusion in a prospective, randomized, Investigational Device Exemption (IDE) clinical trial, at the top enrolling site. Data from post-operative visits up to three years are presented.

**Methods:** An IDE clinical trial was conducted, with 57 patients enrolled at this site. The first five patients were treated with the artificial disc, and all patients thereafter were randomized 1:1 to either SECURE®-C or control ACDF with the ASSURE cervical plate and an allograft spacer. Patients with single-level symptomatic cervical disc disease (SCDD) between C3 and C7 defined by neck and/or arm pain, herniated nucleus pulposus, radiculopathy or myelopathy were enrolled. All patients were between 18 and 60 years of age, had 6 weeks of conservative therapy, and had a Neck Disability Index (NDI) of at least 30/100. Neck Disability Index (NDI), Visual Analog Scale (VAS) neck and arm pain, SF-36 Health Status Survey, and patient satisfaction are collected pre-operatively and at 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively and annually thereafter. Data from one center is presented; of the 57 patients treated at this site, 31 were treated with SECURE®-C (first 5 non-randomized plus 26 randomized) and 26 received ACDF. Outcome data from these patients are analyzed.

**Results summary:** Both treatment groups demonstrated significant improvement in NDI. Average NDI for SECURE®-C patients was 46.0 (±12.3) preoperatively, reduced to 7.4 (±11.5) at 6 months, 4.3 (±10.2) at 1 year, 3.6 (±8.4) at 2 years and 6.0 (±11.9) at 3 years. Average NDI for ACDF patients was 56.2 (±13.1) preoperatively, reduced to 7.6 (±8.9) at 6 months, 3.8 (±6.7) at 1 year, 5.7 (±10.4) at 2 years and 2.3 (±2.5) at 3 years. The first five non-randomized patients improved from 44.4 (±15.5) preoperatively to 2.4 (±2.6) at 6 months, zero at 1, 2 and 3 years. Average VAS neck pain scores decreased significantly from 50 (±31.7) preop to 13.1 (±24.4) at 1 year and 7 (±15.7) at 2 years and 13 (±21.2) at 3 years for the SEC group, and from 67 (±26.4) preop to 10.5 (±18.2) at 1 year and 14 (±23.1) at 2 years and 7 (±15.1) at 3 years for the ACDF group. Similarly, SF-36 PCS improved for both groups at all time points. No implants required removal, and no complications or device-related events occurred in either treatment group at this top enrolling site.

**Conclusion:** SECURE®-C cervical arthroplasty and ACDF patients experienced significant postoperative improvement in pain and function. There was no apparent learning curve for these procedures; the first five arthroplasty patients experienced 100% improvement in pain and function (NDI) by one year that has been maintained through three years thus far. Continued follow-up data is needed to determine long-term safety and efficacy beyond three years.