

**Abstract: 352**

**SECURE<sup>®</sup>-C Cervical Artificial Disc IDE: Two Year Clinical Outcomes**

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**Purpose:** Results from 188 patients enrolled at five sites participating in a U.S. IDE clinical trial for the SECURE<sup>®</sup>-C Cervical Artificial Disc are presented.

**Methods:** The SECURE<sup>®</sup>-C device (Globus Medical, Audubon, PA) is the subject of an Investigational Device Exemption (IDE) study that is being conducted at multiple centers across the U.S. This IDE is a randomized prospective pivotal study of the SECURE<sup>®</sup>-C device. Enrolled patients are randomized 1:1 to either the investigational SECURE<sup>®</sup>-C disc or the control anterior cervical discectomy and fusion (ACDF), with the exception of the first five non-randomized patients from each site who received the investigational treatment. Indications include symptomatic cervical disc disease (SCDD) in one vertebral level between C3 and C7 defined by neck and/or arm pain, herniated nucleus pulposus, radiculopathy or myelopathy, and other conditions as specified in the study. All patients have completed at least 6 weeks of conservative therapy, have a Neck Disability Index (NDI) of at least 30 (as a percentage of the 50 point total) and are between 18 and 60 years of age. Outcome measures and radiographic evaluations are collected pre-operatively and at 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively. Outcome measurements include NDI, Visual Analog Scale (VAS) measurements of neck and arm pain, SF-36 Health Status Survey, and patient satisfaction. Data from five centers having received appropriate approval by their respective Institutional Review Boards are presented.

**Results summary:** One hundred eighty eight (188) patients were treated at these five sites: 108 patients received the investigational SECURE<sup>®</sup>-C device and 80 received the control ACDF. The average age was 43.0 years for SECURE<sup>®</sup>-C and 44.7 years for ACDF patients. One hundred forty three patients (143) have reached 2 year follow-up: 87 SECURE<sup>®</sup>-C and 56 ACDF. SECURE<sup>®</sup>-C patients demonstrated significant improvement in average NDI from 51.9 preoperatively to 10.6 at 2yrs, as compared to control patients improving from 54.5 pre-op to 14.9 at 2 years. Both groups also demonstrated statistically significant improvement in VAS neck and arm pain at 2 years compared to preoperative values. Differences between NDI and VAS outcomes for SECURE<sup>®</sup>-C and ACDF treatment groups are not statistically significant. At 24 months post-op, patient satisfaction was 92% for the SECURE<sup>®</sup>-C group and 86% for the ACDF group. One SECURE<sup>®</sup>-C and four ACDF patients had revision surgery due to continued pain. An additional SECURE<sup>®</sup>-C patient received another cervical disc at an adjacent level. No further complications or device-related adverse events occurred to date in any study patients at these sites.

**Conclusion:** The data suggests that the SECURE<sup>®</sup>-C Cervical Artificial Disc may be used to treat symptomatic cervical disc disease and may help reduce pain and improve function. Continued follow-up is needed to determine the safety and efficacy of this treatment.