A Prospective, Randomized, Pivotal Study of the SECURE®-C Cervical Artificial Disc: Two Year Outcomes


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Purpose: Clinical outcomes from a pivotal 380 patient Investigational Device Exemption (IDE) study to evaluate the safety and effectiveness of the SECURE®-C Cervical Artificial Disc are presented.

Methods: A prospective, randomized pivotal study of the SECURE®-C device (Globus Medical, Audubon, PA) compared to control fusion was conducted at eighteen centers across the U.S. Enrolled patients were randomized 1:1 to either the investigational SECURE®-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 disc. Indications for study participation included 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. Outcome measures and radiographic evaluations were collected pre-operatively and at 6 weeks, 3 and 6 months, and 1 and 2 years post-operatively. An individual patient was considered to be a success by meeting the following criteria: pain/disability improvement of at least 25% in Neck Disability Index (NDI); no device failures requiring revision, re-operation or removal; absence of major complications; and radiographic fusion (control patients only). Alternative definitions of overall success included improvement of NDI in points rather than percentage, maintenance or improvement in neurologic status, absence of device-related events, and intraoperative changes in treatment as failures. Secondary outcome measurements included Visual Analog Scale (VAS) neck and arm pain, SF-36 Health Status survey, and patient satisfaction.

Results summary: Three hundred eighty (380) patients were treated in this study. Data is presented from randomized patients only: 151 patients received the investigational SECURE®-C device and 140 received the control ACDF. There were no differences in gender, age, race, height, weight or BMI between the two randomized groups. Eighty nine percent (89.2%) of SECURE®-C patients demonstrated NDI improvement vs. 84.3% of control patients. Ninety six percent (96.0%) of SECURE®-C and 94.9% of ACDF patients were neurological successes. Two percent (2.1%) of SECURE®-C patients required a removal, revision or reoperation at the index level as compared to 6.9% for the control group. There were no device-related adverse events reported in 96.6% of the investigational cohort vs. 91.6% of the control. Ninety eight percent (98.0%) of those treated with the investigational device experienced no intraoperative change in treatment and 89.1% of control patients demonstrated radiographic fusion. Both groups also showed statistically significant improvement in VAS neck and arm pain at 2 years compared to preoperative values. At 24 months post-op, patient satisfaction was 95.7% for the SECURE®-C group and 85.2% for the ACDF group. Overall success rates were 90.1% for the SECURE®-C group and 71.7% for the control group, using the original protocol definition. Superiority of the SECURE-C group to the control was established for overall success, with a posterior probability of 100% for the protocol-specified overall success and 98%-99% for alternative definitions of overall success.

Conclusion: Study results indicate that the SECURE®-C Cervical Artificial Disc is a safe and effective treatment for symptomatic cervical disc disease, as an alternative to anterior discectomy and fusion.