Radiographic Outcomes Following Cervical Disc Arthroplasty Compared to Anterior Cervical Discectomy and Fusion in a Prospective Randomized Study

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Purpose: The intent of cervical disc arthroplasty is to maintain normal physiologic motion of the cervical spine rather than traditional fusion which immobilizes the diseased segment. Radiographic outcomes of cervical arthroplasty as compared to anterior discectomy and fusion were assessed in a prospective, randomized clinical trial of the SECURE®-C Cervical Artificial Disc (Globus Medical, Audubon, PA).

Methods: A prospective randomized IDE study of the SECURE®-C device compared to control fusion was conducted at eighteen participating sites in the United States. Enrolled patients were randomized 1:1 to either the investigational SECURE®-C disc or the control ACDF, with the exception of the first five non-randomized patients from each site who received the investigational treatment. The dual articulating device allows for a range of motion of up to 30° (±15°) in flexion-extension, 20° (±10°) lateral bending, unlimited axial rotation, and 1.25mm of translation in the sagittal plane. 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. Anterior-posterior and lateral films were obtained pre-operatively and at 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively. Flexion/extension radiographs were obtained preoperatively and at 6, 12 and 24 months post-op. Measurement of disc height and range of motion (flexion-extension and AP translation) on flexion/extension films was conducted by Medical Metrics, Houston, TX. Data from IDE sites having received approval by their respective Institutional Review Boards are presented.

Results summary: Three hundred eighty (380) patients were treated in this IDE. Data is presented from randomized patients only: 151 patients received the investigational SECURE®-C device and 140 received the control ACDF. Flexion-extension range of motion increased for SECURE®-C patients, with 8.5° (±4.80) at preop and 9.3° (±5.91) at 2 years, as compared to ACDF patients who had 7.2° (±4.31) of motion preop, that decreased to 0.70° (±0.72). AP translation during flexion-extension also increased for SECURE®-C patients, with 0.9mm (±0.62) at preop and 1.2mm (±0.81) at 2 years, which compares to ACDF patients who had 0.8mm (±0.59) of motion preop that decreased to 0.1mm (±0.08). Disc height increased significantly for patients treated in the SECURE®-C cohort; the pre-op average was 3.8mm (±0.75) and increased to 5.7mm (±0.99) at 2 years. In the ACDF group the average pre-op disc height was measured at 3.7mm (±0.71) and grew to 4.3mm (±1.24) for those reaching 2 years. No device migrations or displacements, including superior and inferior subsidence, were observed in any patients treated with the SECURE®-C device. Radiolucencies of more than 25% were evaluated; none of the SEC patients and 3.8% of the control demonstrated radiolucencies at 24 months post-operative.

Conclusion: The SECURE®-C group had greater range of motion and increased disc heights as compared to the ACDF group, as expected. The unique dual articulating design of the SECURE®-C implant also allows for AP translation during motion. The SECURE®-C device may help restore and maintain normal physiologic motion and increase disc height in the cervical spine.