A Study of Adjacent Level Anterior Treatments in a Randomized, Prospective Clinical Trial of the SECURE®-C Cervical Artificial Disc

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Purpose: Adjacent level disc disease is an important consideration in the treatment of Symptomatic Cervical Disc Disease. The rate of incidence of adjacent level treatment utilizing an anterior approach to the cervical spine was compared between the investigational (SECURE®-C) and control groups (ACDF). Results are presented from patients who participated in the IDE study who have reached 24 months post-operative.

Methods: A prospective, randomized pivotal IDE study of the SECURE®-C device (Globus Medical, Audubon, PA) 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 anterior cervical discectomy and fusion (ACDF), with the exception of the first five non-randomized patients from each site who received the investigational treatment. The U.S. 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, and other conditions as specified in the study protocol. All Study 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. Data from all participating IDE sites having received appropriate approval by their respective Institutional Review Boards are presented.

Results Summary: Three hundred eighty (380) patients were treated in the approved IDE Study (the first five patients at each site were non-randomized to the SECURE®-C implant). Data is presented from randomized patients only: 151 patients were treated with the investigational SECURE®-C device and 140 received the control ACDF. Two of the patients treated with the SECURE®-C device received additional anterior surgery at adjacent levels; one patient underwent a two-level fusion at 16.9 months post-op; the other received another cervical disc replacement at an adjacent level at 17.3 months post-op. Seven of the patients in the control ACDF cohort experienced adjacent level treatments, six of these patients received a two-level anterior fusion between 7 weeks post-op and 35 months post-op; one underwent a three level anterior fusion at 20.8 months post-op. Adjacent levels requiring treatment occurred at both above and below the index level, with no evident trends in the data. The rate of anterior adjacent level surgery was 4.9% for the control group, and 1.3% for the cervical disc arthroplasty group.

Conclusion: The incidence of anterior surgical treatment for adjacent level disc disease was higher in the control ACDF group as compared to the incidence among those patients who were treated with the investigational SECURE®-C device. These results suggest that devices such as SECURE®-C that utilize motion preservation technology may help reduce the risk of developing adjacent level disease in the cervical spine.