Intermediate Follow-up after Treatment of Degenerative Disc Disease with Bryan Cervical Disc Prosthesis: Single-level and Bi-level

Jan Goffin, MD, PhD (Leuven, Belgium), Adrian T.H. Casey, MD (London, UK), Pierre H. Kehr, MD (Illkirch, France), Klaus Liebig, MD, PhD (Erlangen, Germany), Bengt Lind, MD, PhD (Gothenburg, Sweden), Carlo Logroscino, MD (Rome, Italy), Vincent M. Pointillart, MD, PhD (Bordeaux, France), Frank Van Calenbergh, MD, Johannes van Loon, MD (Leuven, Belgium)

INTRODUCTION: Can a new, functional intervertebral cervical disc prosthesis provide relief from objective neurological symptoms and signs, improve patient functionality, decrease pain, and provide long-term stability and normal range of motion? Dynamic fluoroscopy studies were conducted to establish the ability of the device to maintain motion at the implanted and adjacent levels. In addition, normal, degenerate, and fused patients were studied for comparison. Results of this additional fluoroscopic study will be presented.

METHODS: A multicenter clinical trial was initiated in January 2000 to assess the safety and effectiveness of the Bryan Cervical Disc prosthesis in treating single-level cervical degenerative disc disease compared to Anterior Cervical Discectomy and Fusion (ACDF). Patient inclusion criteria for the study were single-level disc herniation or spondylotic changes at the C3-C4 to C6-C7 levels with radiculopathy and/or myelopathy that had not responded to conservative treatment. Patients with symptomatic cervical radiculopathy and/or myelopathy were implanted with the Bryan prosthesis after a standard anterior cervical discectomy (ACD). The Bryan Cervical Disc prosthesis was implanted in 97 single-level patients utilizing a specialized instrumentation system designed to provide accurate, precise intervertebral placement of the prosthesis. The investigational team included 9 surgeons in 7 centers in Belgium, France, Sweden, Germany, Great Britain, and Italy. A multicenter trial studying the results of implanting disc at two adjacent levels was initiated in January 2001. Patient inclusion/exclusion criteria were similar. The study enrolled 39 patients. At scheduled follow-up periods the effectiveness of the device was characterized by evaluating each patient's pain, neurological function, and range of motion at the implanted level. Follow-up assessments included neurological assessment by an investigator, pain and function self-assessment by the patient, and range of motion and device stability assessment by an independent radiologist. The results of the neurological and patient assessments were combined into an overall clinical outcome and the patient assigned a score of excellent, good, fair, or poor based on the following modified Odom's criteria: * Excellent:
improvement in most (80%) of the pre-operative signs and symptoms, with little deterioration (not more than 10%) * Good: improvement in some (70%) of the pre-operative signs and symptoms, with some deterioration (not more than 15%) * Fair: improvement in half (50%) of the pre-operative signs and symptoms, with some deterioration (not more than 20%) * Poor: improvement in few (less than 50%) of the pre-operative signs and symptoms, or significant deterioration (more than 20%) Long-term stability was assessed as the absence of device migration and/or subsidence. Range of motion was assessed using standard radiographic techniques. In addition, dynamic fluoroscopy follow-up data was obtained on a subset of patients from one center.

RESULTS: Single-level clinical analysis includes data from 46 patients at one year, and 9 patients at two years. Patients scored as excellent, good, or fair at one year and two years following implantation were 87% and 89%, respectively. These results compare favorably with the short-term clinical outcomes associated with ACDF, as reported in the literature. At two years there was no measurable subsidence of the devices (based on a measurement detection threshold of 2 mm). Evidence of initial and temporary anterior/posterior device migration was detected in one patient and suspected in another. No devices have been explanted or surgically revised. At one year, 38 patients (86%) demonstrated flexion/extension range of motion equal to or greater than two degrees. The range of motion for patients at one year averages just over 8 degrees with a standard deviation of 5 degrees. At two years, 10 out of 10 patients (100%) demonstrated flexion/extension range of motion equal to or greater than two degrees; the average was 11 degrees with a standard deviation of 5 degrees. Complications are generally limited to unresolved pain (often not associated with the neck and/or the treated level) and one hematoma requiring re-operations. Bi-level results include data from 17 patients at six months, and 4 patients at one year. Patients scored as excellent, good, or fair at six months and one year following implantation were 82% and 100%. At six months 32 levels (in 17 patients), and at one year 7 levels (in 4 patients) demonstrated flexion/extension range of motion equal to or greater than two degrees. The range of motion for patients at six months averages 7 degrees with a standard deviation of 3 degrees, at one year averages 9 degrees with a standard deviation of 6 degrees. Complications include a pharyngeal/esophageal wound, an vertebral hematoma/esophageal wound, a cerebral spinal fluid leak, and an epidural hematoma. The pharyngeal wound and esophageal wounds were due to intubation occurring during post-operative re-interventions. The CSF leak occurred during removal of a posterior osteophyte with a freehand burr and was therefore unrelated to the instrumentation.

CONCLUSIONS: While these results are still somewhat preliminary and the number of patients is limited, the Bryan® Cervical Disc prosthesis shows
promise as an alternative to fusion and its associated complications and morbidities for the treatment of degenerative cervical disc disease.

- If noted, the author indicates something of value received. The codes are identified as: a - research or institutional support, b - miscellaneous funding, c - royalties, d - stock option, e - consultant or employee. For full information, refer to inside back cover.

- The FDA has not cleared the drug and/or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an “off label” use). For full information, refer to the disclaimer information at the back of the book.