Superiority of Porous Coated Motion (PCM) Cervical Arthroplasty Compared to ACDF in a Prospective Randomized Clinical Trial

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Introduction: This is a prospective, randomized study of 264 consecutive one-level anterior cervical reconstructions to compare the clinical outcomes between cervical disk replacement and conventional anterior cervical fusion and instrumentation. This is a report of 264 patients from five investigational centers in the FDA prospective PCM trial using validated NDI, VAS, neurologic, and dysphagia outcomes instruments.

Methods: Patients between 18 and 65 years old with one-level symptomatic cervical radiculopathy and/or myelopathy for progressive neurological symptoms were randomized to undergo anterior decompression and PCM arthroplasty (n=146) or ACDF (control) (n=118). Subsequently, 143 patients underwent the arthroplasty procedure and 109 ACDF. At 24 months, complete follow-up data to calculate the primary endpoint was obtained for 128/143 (89.5%) investigational and 87/109 (79.8%) of control patients. Neurologic status was based on a composite outcome of muscle strength, intact sensation, reflexes and absence of pathologic reflexes at 24 to 60 months follow up. Patients self-reported dysphagia severity using the Bazaz scale preoperatively and at follow-up. The Bazaz scale has four classes of severity based upon the problems with swallowing that the patient has with both liquids and solids.

Results: PCM arthroplasty provided neurologic superior outcomes at 24 months post operatively, with 129/133 (97.0%) success versus ACDF controls 82/92 (89.1%) success (p = 0.016) (Figure 1). The maintenance of disk space height was significantly better in the PCM arthroplasty group compared to the control group (p < 0.0001). The incidence of reoperations was higher in the ACDF control group, 10% versus 6.8% in the PCM arthroplasty group. The composite per-protocol primary endpoint outcome was highly significant (p< 0.0001) showing superiority for PCM arthroplasty with 102/130 (78%) (90% confidence interval 72.5% to 84.4%) success versus ACDF controls 55/87, (63%) (90% confidence interval 54.7% to 71.7%) success. There was an observed trend towards improved outcome for patients treated with the PCM-V Teeth device 32/39, 82.1% (90% confidence interval from 71.9% to 91.2%) relative to those treated with the standard press-fit PCM 68/89, 76.4% (90% confidence interval from 69.0% to 83.8%). Though the trend was not statistically significant between PCM types, both groups demonstrated statistical superiority to the ACDF control group, as demonstrated by the confidence interval plots of figure 1. The Bazaz results demonstrate that while both the PCM and ACDF groups exhibited an initial postoperative problem with swallowing, the PCM group continued to improve with increasing time following implantation, while the ACDF only improved minimally. The PCM treatments indicated significantly lower incidence of dysphagia at three, twelve and 24 months post-operatively compared to ACDF controls (p< 0.05).

Conclusions: In a prospective randomized clinical study, the neurologic composite outcomes and the clinical outcomes proved superior for PCM cervical arthroplasty compared to ACDF controls at 24 months post-operatively.
Figure 1. Confidence Intervals of the Primary Endpoint