Cervical Disc Arthroplasty in Patients with Prior Fusions: Results from the PCM US IDE Prospective Randomized Clinical Trial

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Introduction: The efficacy of cervical disc arthroplasty in the treatment of symptomatic levels adjacent to prior fusions is largely unstudied due to prior fusion being an exclusionary factor in most cervical arthroplasty trials.

The US FDA investigational device exemption (IDE) trial of the porous coated motion (PCM) cervical disc arthroplasty device compared to anterior cervical discectomy and fusion (ACDF) was the first such trial to allow for treatment adjacent to prior fusion. The current analysis examined clinical and radiographic success of the subset of the IDE trial population where treatment was at levels adjacent to prior fusion.

Methods: A prospective, multi-center, randomized, controlled trial of PCM versus ACDF in the treatment of degenerative conditions of the cervical spine -- including adjacent segment disease -- was undertaken. The per protocol patient sample at 2 years included 395 patients (211 PCM, 184 ACDF control). 37 of these patients (23 PCM, 14 ACDF control) had undergone an adjacent fusion an average of 7.2 years (range 0.4-26.3 years) prior. Endpoints of the trial were determined by success across five categories: neck disability index (NDI) (≥20% improvement), maintenance or improvement of neurological status, no subsequent secondary surgical interventions (SSSI), absence of major adverse events, and absence of radiologic complication. Subgroup analyses were performed between PCM and ACDF patients with prior fusions, as well as between those with and without prior fusions within each the PCM and ACDF groups individually.
Results: Of those with prior fusions, NDI success was met in 76% (16/21) of PCM and 86% (12/14) of ACDF patients (2-side p-value=0.676). In patients without prior fusions, 84% (138/165) of PCM and 81% (109/135) of ACDF groups met NDI success. Neurological status success was met in 96% (21/22) of PCM and 100% (14/14) of ACDF patients with prior fusions; and 95% (156/165) of PCM and 88% (120/136) of ACDF patients without. SSSI success was met in 83% (19/23) of PCM and 100% (14/14) of ACDF patients with prior fusions and 96% (159/166) of PCM and 93% (127/137) of ACDF without. Radiographic success was met in 95% (18/19) of PCM patients and 77% (11/14) of ACDF patients with prior fusions, and in 99% (160/162) of PCM and 93% (127/136) of ACDF without. No comparisons were statistically significantly different between or within groups. Average range of motion (ROM) after PCM in patients with prior adjacent fusions was 9.7° at baseline and 6.2° at 2 years (p<0.001); similar to PCM in patients without prior fusions (7.7° to 5.6°; p<0.001).

Conclusions: This study suggests PCM to be a viable surgical reconstructive option adjacent to prior fusions with results at least equivalent to ACDF. The outcomes following the treatment of symptomatic degeneration at levels adjacent to prior fusions were equivalent to those in primary surgeries, suggesting that prior cervical fusion need not be a contraindication to cervical arthroplasty.