• A Prospective, Randomized Clinical Investigation of the Porous Coated Motion (PCM) Artificial Cervical Disc: 2 Year Results Comparing Outcomes of Compensated and Non-Compensated Patients

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Introduction: Historically, workers compensation (WC) has been shown to be a confounding factor for successful outcomes in spinal surgery. This analysis compares the clinical outcomes of WC and non-compensated (NC) patient from the US FDA IDE clinical trial of the Porous Coated Motion (PCM) artificial cervical disc versus anterior cervical discectomy and fusion (ACDF) with allograft and plate.

Methods: This study was a prospective, randomized, multicenter, IRB-approved IDE clinical trial evaluating longitudinal outcomes over 2 years comparatively between arthroplasty and fusion groups and, for the current subgroup analyses, between WC and NC groups. Patients 18-65 years of age with degenerative disc disease at one level between C3 and T1 with neurologic symptoms unresponsive to conservative care were included. The per protocol patient sample at 2 years included 395 patients. 340 patients had available data for subgroup analyses, including 45 WC (26 PCM, 19 ACDF) and 295 NC (163 PCM, 132 ACDF).

Clinical outcome measures, including the validated patient-reported neck disability index (NDI), maintenance or improvement of neurological status, and complications and adverse events were evaluated. Overall success was defined as a ≥20% improvement in NDI, maintenance or improvement in neurological status, no subsequent secondary surgery or intervention (SSSI), absence of major adverse events, and absence of radiologic complications. Where appropriate, measures were tested for differences between arthroplasty and fusion groups and between WC and NC groups at 2 years postoperatively.
Results: Demographic and baseline characteristics were well matched between WC and NC patients except on presence of litigation related to spinal disorder, which was notably higher in WC patients. At 2 years, regardless of treatment group, WC patients compared to NC patients had a significantly lower rate of NDI success (67% vs. 84%, p=0.011), absence of SSSI (87% vs. 95%, p=0.044), and overall success (53% vs. 73%, p=0.008), respectively. Success of WC patients compared to NC patients on absence of major complication (98% vs. 99.7%), neurological success (86% vs. 93%), and radiographic success (98% vs. 95%), were similar.

Comparing PCM patient outcomes by compensation status, overall success was met in 58% of WC and 78% of NC patients (p=0.048) and NDI success was met in 65% and 86% (p=0.021), respectively. Other outcomes were similar: SSSI success was met in 88% of WC and 95% of NC patients, neurological success was met in 92% and 95%, radiographic success was met in 100% and 99%, and major complications success was met in 100% and 100%, respectively (Figure 1).

Conclusion: Confirming the results of other studies, the pursuit of workers compensation claims negatively affects patient success, as demonstrated in both the current PCM and control groups. Lack of success was primarily seen in patient-reported subjective measures (PCM NDI success: 65% WC vs. 86% NC), where objective measures (SSSI, neurologic, radiographic, and major complications) were largely equivalent.

Figure 1. Percent success of workers compensation and non-workers compensation PCM patients.

See Disclosure Index pages 40–73/or legend on inside back cover.