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Prospective, Controlled Results of Patients Treated with Expanded Indications for ProDisc®-C

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Background: Cervical total disc replacement (TDR) is intended to address discogenic pain and preserve physiologic motion between two vertebral bodies in patients with symptomatic cervical disc disease (SCDD). TDR may thus prevent long-term subsequent accelerated degeneration at adjacent disc levels. During the ProDisc®-C IDE trial, patients who did not meet the inclusion/exclusion criteria as defined by the study could be considered for compassionate use exemption. Each case was reviewed by the Food and Drug Administration (FDA) for approval. The objective of this study is to present the data from patients treated with expanded indications during the prospective, randomized, controlled ProDisc®-C (Synthes USA Products, LLC, West Chester, PA) Investigative Device Exemption (IDE) trial conducted in the USA between C3-C7.

Methods: The study was conducted at 14 sites. A total of 55 patients were treated under compassionate use. The expanded indications included: 2 level TDR (25); 2 non-contiguous level TDR (1); 3 level TDR (11); single level TDR adjacent to a fusion (12); and 2-level TDR adjacent to a fusion (6). Patients were assessed pre-operatively, and post-operatively at 6 weeks, 3, 6, 12, 18 and 24 months. Patients were evaluated by Visual Analog Scale (VAS) Pain and Intensity (Neck and Arm), Surgery Again, Neck Disability Index (NDI), and SF-36 standardized questionnaires.

Results: Pre-operatively, the average age was 44.6 years old with 72.7% of patients on narcotics and 83.6% reporting greater than 1 year of neck/arm pain. NDI and SF-36 scores were significantly less compared to pre-surgery scores at all follow-up visits for all indications ($p < 0.0001$). Overall neurological success was achieved by about 90% of patients at all time points. VAS neck pain intensity and frequency as well as VAS arm pain intensity and frequency were statistically lower at all follow-up time points compared to pre-operative levels ($p < 0.0001$) for all indication treatments. Radiological evaluation showed no evidence of device migration, device subsidence, or decrease in disc height. Results show that at 24 months post-operatively, greater than 80% of ProDisc®-C patients achieved ≥ 4 degrees of motion or maintained motion relative to pre-operative baseline at each operated level. 82% of patients at each time point responded "yes" to having the same surgery again.

Conclusions: Currently ProDisc®-C is approved for a single level surgery between C3-C7. This paper of Class I data shows that expanded indications in well chosen patients can result in positive clinical outcomes. These outcomes are similar to single level surgery. However, previously published reports have shown that multi-level ACDF procedures are not as successful as single level procedures. As more clinical experience is reported, these expanded indications could lead to greater options for difficult multi-level cervical cases.