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**2-level Cervical Disc Arthroplasty: Clinical Results from 6 Centers in a Prospective Randomized IDE Trial**

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**Introduction:** With the introduction of cervical arthroplasty in the USA, appropriate indications for these devices must be carefully studied. We report early clinical outcomes from six centers participating in the ongoing prospective randomized Prestige LP investigational device exemption (IDE) clinical study comparing arthroplasty with anterior fusion in patients with two-level cervical disc disease.

**Methods:** To date at these six sites, 180 patients with two adjacent levels of cervical disc disease have undergone surgery and received either the Prestige LP devices (n = 97) or a two-level anterior cervical discectomy and fusion utilizing allograft spacers and the Atlantis anterior cervical plate (n = 83). At the time of this report, 29% of patients have been evaluated at the two-year follow up interval. Entrance criteria included symptomatic two-level cervical disc disease documented neurological deficit and confirmatory preoperative imaging studies. Demographic variables including age, sex, race, and work status are similar between the two study groups. Operative variables including operative time, blood loss and levels treated were also similar. All patients were evaluated according to the standardized IDE protocol preoperatively and at defined postoperative intervals: 6 weeks and 3, 6, 12, and 24 months. Outcomes measures include neck and arm pain visual analog scales (VAS), neck disability index (NDI), and the Short-Form 36 (SF-36). Cervical flexion/extension, A/P, and neutral lateral x-rays were obtained at all data points. Additionally, all adverse events are recorded.

**Results:** Preoperative values for the VAS, NDI and SF-36 scores were similar. There is a statistically significant postoperative improvement for both groups at the 12 month follow-up interval. At 24 months, there was a 40.8 point mean improvement in the NDI in the Prestige group as compared to a 30.1 point improvement in the fusion group. In the SF-36 PCS, a 17.8 point mean improvement is seen in the Prestige group as compared to a 14.6 point improvement in the fusion group. The Neck and arm pain VAS also showed greater mean improvement in the Prestige LP group at 24 months compared to the fusion group. These two-year differences are encouraging for multi-level cervical disc arthroplasty. Radiographic analysis shows the Prestige device to maintain segmental motion. Rates of adverse events are similar in both groups; however there have been six secondary surgical procedures in the fusion group and one in the Prestige group.

**Conclusion:** Analysis of two-year data from 6 sites participating in the Prestige LP 2-level IDE study suggest that cervical disc arthroplasty appears to achieve favorable outcomes at two-year postoperative for patients with 2-level cervical disc disease. Longer term-follow-up is required.