Introduction: With the introduction of cervical arthroplasty in the United States, appropriate indications for these devices must be carefully studied. We report clinical outcomes from six centers participating in the ongoing prospective randomized PRESTIGE® LP Disc 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, 51% of patients have been evaluated at the three-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, 24, and 36 months. Outcomes measures include neck and arm pain numerical rating scale (NRS) for both intensity and frequency, 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 NRS, NDI and SF-36 scores were similar. At 36 months, there was a 35.3 point mean improvement in the NDI in the PRESTIGE LP group as compared to a 30.0 point improvement in the fusion group. In the SF-36 PCS, a 15.9 point mean improvement is seen in the PRESTIGE LP group as compared to a 13.2 point improvement in the fusion group. The neck pain score improved 11.4 points in the PRESTIGE LP group at 36 months compared to 10.5 point in the fusion group. Radiographic analysis on average shows the PRESTIGE LP Disc to maintain segmental motion. Rates of adverse events are similar in both groups.

Conclusion: Analysis of three-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 three-year postoperative for patients with 2-level cervical disc disease. Longer term-follow-up is required.