Prospective Study of NUBAC Nucleus Replacement: Combined Data from 2 IDE Sites

D. Coric1, M. Songer2
1Carolina Neurosurgery and Spine Associates, Charlotte, NC, United States, 2Marquette Medical Center, Marquette, MI, United States

Introduction: In the continuum of treatment for DDD that is unresponsive to conservative care, a more minimally invasive treatment option, such as nucleus replacement, is preferred for patients with early to moderate DDD. NUBAC is a nucleus replacement device manufactured from PEEK-OPTIMA, and consists of two plates and an inner ball/socket articulation, a design unique among nucleus replacement devices. After successful completion of an IDE feasibility study, NUBAC was the first nucleus replacement device to gain IDE pivotal study approval in the U.S. The clinical and radiographical results from two sites participating in this ongoing pivotal study is reported.

Methods: Thirty-two NUBAC patients patients with discogenic back pain secondary to mild to moderate degenerative disc disease at L4/L5 who had failed conservative care for at least 6 months are included. A lateral retroperitoneal approach at the L4/L5 level was used in all patients for nucleus removal and device implantation. ODI and VAS scores at pre-op, 6 weeks and 3, 6, 12, 24 and 36 months were assessed, along with neurological status. Radiographic imaging was used to assess disc height and range of motion (ROM), with qualitative radiographic imaging to assess subsidence and endplate sclerosis. The control arm for this study is Prodisc with a randomization of 1:1.

Results: Four cases were training cases. For the overall cohort, the average age was 43.8 years with 44% male and 56% female. The average operating time was 108.0 minutes with an average estimated blood loss of 48.3 mL. The average length of hospital stay was 1.5 days. There were no major intra-operative complications. The average follow-up was 24 months (3-36 months). Average ODI scores improved preoperatively from 55.6 to 35.4 at 6 weeks, and were maintained to 7.5 at 36 months. Average VAS scores improved preoperatively from 7.2 to 3.4 at 6 weeks, and were maintained to 1.1 at 36 months. Average disc height was 8.5 mm preoperatively and at 24 months was 7.9 mm. Preoperative flexion-extension ROM was 6.9° and at 36 months was 6.5°. There was no subsidence or endplate sclerosis reported. The operative, clinical and radiographic results for the control arm were similar to prior PMA data.

Conclusions: This is the first report from the U.S. on data from two sites participating in an ongoing IDE pivotal study evaluating the safety and efficacy of NUBAC. The preliminary analysis of data from these two sites show significant improvements in pain and disability, and that range of motion and disc height were maintained, similar to the control arm. NUBAC patients had shorter operative times and shorter hospital stays as well as less intraoperative blood loss.