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Two Year Follow-up Results from the US IDE Feasibility of NUBAC, an Articulating PEEK on PEEK Nucleus Replacement Device

D. Coric¹, J. Regan², M.N. Songer³,⁴,⁵
¹Charlotte Spine Center, Charlotte, NC, USA, ²Cedars Sinai Institute for Spinal Disorders, Los Angeles, CA, USA, ³Michigan Technological University, Mechanical Engineering, Houghton, MI, USA, ⁴Michigan State College of Human Medicine, Surgery, Lansing, MI, USA, ⁵Orthopaedic Surgery Associates of Marquette, Orthopedics, Marquette, MI, USA

Introduction: Nucleus replacement is gaining clinical acceptance as an alternative treatment option for patients with mild to moderate degenerative disc disease (DDD). NUBAC is a nucleus replacement device manufactured from PEEK-OPTIMA (PEEK), and consists of two plates and an inner ball/socket articulation, which is unique among nucleus replacement devices. After successful completion of pre-clinical design verification and validation, an IDE feasibility study was initiated to assess the clinical outcomes of this PEEK on PEEK nucleus replacement device. The results from the IDE feasibility study utilizing this device using traditional outcome parameters is reported.

Methods: This was a prospective, nonrandomized Investigation Device Exemption (IDE) feasibility study. Patients with discogenic back pain secondary to mild to moderate degenerative disc disease (DDD) at L4/L5 were included. Twenty patients enrolled at three centers participated in the study. A lateral transpsoas approach at the L4/L5 level with intraop neuromonitoring was used in all patients for nucleus removal and device implantation. Oswestry Disability Index (ODI), Visual Analog Scale (VAS) and SF-36 scores at pre-op, 6 weeks and 3, 6, 12 and 24 months were assessed, along with neurological status and patient satisfaction. Radiographic imaging was used to assess disc height and range of motion (ROM), with qualitative radiographic imaging to assess subsidence and endplate sclerosis.

Results: Eight of 20 patients were available for 2 year follow-up, eighteen of twenty patients were available for one year follow up. Average age was 41.7 years with M:F ratio 50:50. There were no major intra-operative or post-operative vascular and/or neurological complications. The average hospital stay was 1.4 days. The average blood loss was 47 cc. Analgesic usage pre-operatively was 65%. The mean preoperative VAS (7.1) and ODI (53.9) scores improved significantly at six weeks (3.4 and 30.7, respectively) and were maintained through 2 years (2.5 and 10.2, respectively) (Figure 1). All components of the SF-36 showed similar improvement. Neurological status was either maintained or improved on all patients. Radiographic results demonstrated preservation of disc height (Figure 2) and ROM, with no subsidence. Analgesic usage decreased significantly. At 24 months, ODI success was 87.5%, with neurological and total success 100% and 87.5%, respectively. There were no device failures throughout the 24 months follow up and more importantly, there were no device expulsions.

Conclusions: The results from this feasibility study are encouraging as demonstrated by the significant reduction in post operative pain, increase in function and patient satisfaction, along with maintenance of disc height and ROM. These results along with the data on hospital discharge time and analgesic usage suggest this procedure may provide patients and hospitals the benefits of better economic outcomes than fusion or total disc replacement. On the strength of the positive results of this pilot feasibility study, NUBAC has become the first nucleus replacement device to enter into IDE pivotal study.