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Two Year Follow-up Results of NUBAC, a Peek on Peek Nucleus Replacement Device: A Prospective Worldwide Multi-center Clinical Study

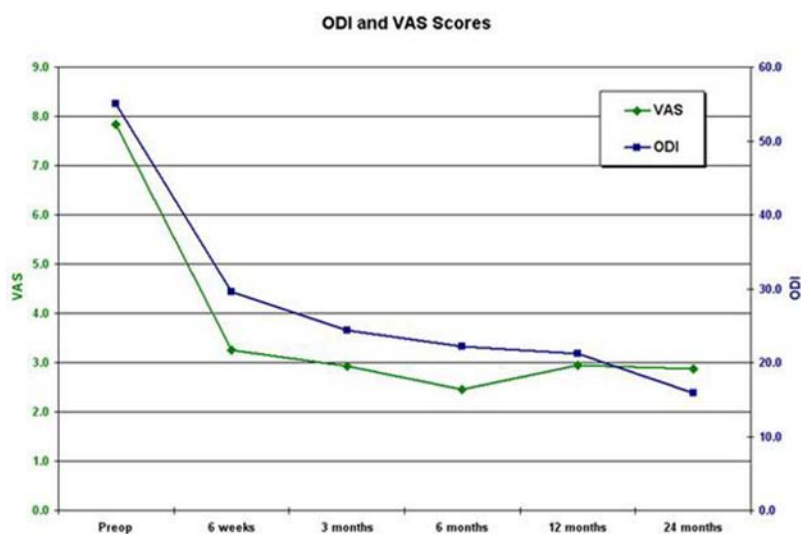
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Introduction: NUBAC is a nucleus replacement device being utilized as an alternative in treating low back pain caused by early to moderate degenerative disc disease (DDD). The device is manufactured from PEEK-OPTIMA, and consists of two plates and an inner ball/socket articulation, a feature widely used in total disc replacements, but unique among nucleus replacement devices. Worldwide, about 300 patients have been implanted with the device since 2004. A U.S. feasibility study has been completed and the U.S. pivotal trial is currently underway. The worldwide clinical performance is assessed of this nucleus replacement device using traditional outcome parameters.

Methods: An ongoing non-randomized, prospective, multicenter clinical study which includes patients with discogenic back pain secondary to mild or moderate degenerative disc disease enrolled in the US feasibility study and outside of the US. Intra-operative and post-operative vascular and neurological complications, ODI and VAS scores at pre-op, 6 weeks and 3, 6, 12 and 24 months were assessed, along with radiographic imaging to assess disc height and range of motion (ROM). Operative time and length of hospital stay were recorded to gain preliminary knowledge on the economic benefits. The average age was 41 years with 49% male and 51% female patients. The anterolateral (11.6%), lateral (28.5%) and posterior (59.9%) approaches were all utilized for device implantation. Seven patients had two-level implantations (one L3/L4-L4/L5, all others L4/L5-L5/S1). Device implantations were at the L2/3 (1.4%), L3/4 (4.6%), L4/5 (49.4%) and L5/S1 (43.8%) levels. Of the 300 patients implanted, 124, 122, 106, 65 and 24 patients were followed for 6 weeks and 3, 6, 12 and 24 months, respectively.

Results: The average operating time was 101 minutes, with an average estimated blood loss of 76 cc. No major intra-operative or post-operative vascular and neurological complications occurred. Most patients were discharged from the hospital in 1-2 days. The mean preoperative VAS and ODI scores improved significantly at six weeks and were sustained through 2 years (Figure 1). Radiographic results demonstrated preservation of disc height, with segment mobility maintained.



[Figure 1. ODI and VAS scores.]

Discussion: The clinical experience gained so far has demonstrated that NUBAC performs as intended. These results are thought to be due to the design of the device with its articulation and large contact area, which allows for the ability to use all three surgical approaches (anterior retroperitoneal, lateral transpsoas and posterior) and provides even load

transmission throughout the ROM resulting in maintenance of disc height. In addition, these worldwide clinical results has allowed for IDE pivotal approval.

Conclusions: The pain relief, improvement in function, lack of major intra-operative and postoperative neurological complications along with maintenance of disc height and ROM, suggests that NUBAC can be a viable and less invasive surgical treatment option than total disc replacement or fusion for patients with lumbar discogenic back pain secondary to mild to moderate DDD.