

Nubac Intradiscal Arthroplasty: Preclinical Studies and Preliminary Safety and Efficacy Evaluations

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ABSTRACT

BACKGROUND

Disc arthroplasty is gaining popularity for treatment of low-back pain caused by degenerative disc disease (DDD). It can involve total disc replacement or partial disc or nucleus replacement (or augmentation). Compared with total disc replacement, nucleus replacement is less invasive, has less surgical risk, has faster postoperative recovery, and doesn't "burn bridges" should further surgery be required. However, nucleus replacement has a high risk of implant expulsion because the device is not fixed to the vertebrae. Nubac is the first polyetheretherketone (PEEK)-on-PEEK articulated disc arthroplasty device designed to optimally restore the lumbar anatomy and biomechanics.

METHODS

ISO 10993 standards were used to evaluate the biocompatibility of the PEEK material. Chemical and thermal-mechanical tests and in vivo study assessed PEEK's biostability after exposure to high g irradiation and harsh oxidative conditions. Biomechanical tests to evaluate kinematic properties and anatomical restoration of the implanted lumbar motion segments and implant expulsion risk assessments were performed with a human cadaveric model. Because of the novelty of PEEK-on-PEEK as a self-mating articulating material, extensive wear tests were conducted with unidirectional and coupled motions. Static and fatigue strength also were tested. Animal study with a baboon model was conducted with gross, radiographic, biomechanical, and histological evaluations at 6 and 12 months postoperatively. Preliminary clinical data were collected through a prospective multicenter cohort study.

RESULTS

PEEK demonstrated exceptional biocompatibility and biodurability. Nubac restored disc height and motion segment range of motion. The unique articulating design of the Nubac demonstrated low risk of implant expulsion in a human cadaveric model. Wear tests showed that the Nubac has minimal wear and compares favorably to other disc arthroplasty materials. The Nubac also had excellent static and fatigue properties for the intended application. The animal study showed that the Nubac caused no adverse local or systematic tissue reaction and there was no detectable wear debris. The preliminary clinical data showed no major intraoperative vascular and neurological complications. There was significant Visual Analog Scale and Oswestry Disability Index score improvement.

CONCLUSIONS

The preclinical data supported the design rationale, and the preliminary clinical data (level II evidence) on safety and efficacy were encouraging.

CLINICAL RELEVANCE

The Nubac could be a viable first surgical option for patients with back pain caused by DDD.

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