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Biomechanical assessment and fatigue characteristics of an articulating nucleus implant

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Abstract

Background: Extrusion is a known complication of lumbar nucleus replacement devices. Despite this fact, this complication has not been well studied in an in vitro cadaveric model under fatigue-loading conditions.

Methods: Lumbar constructs (with treated and control levels) were tested in intact, postdisectomy, and postnucleus implant conditions under compression, torsion, and bending for initial biomechanical assessment. Constructs were then tested for 100(k) cycles under fatigue loading to assess extrusion risk. Potential adverse effects to vertebral and endplate fractures were assessed using gross dissection and macroscopic and micro-computed tomography evaluation techniques.

Results: Based on the initial biomechanical assessment, implantation of the nucleus device significantly increased disc height compared with the discectomy condition, and there were no significant differences between the intact and implanted conditions for range of motion or stiffness. All constructs completed the 100(k) cycles with no extrusions. There was evidence of implant shift toward the right lateral annulus on postfatigue images. Postfatigue dissection and imaging showed no evidence of macroscopic endplate or trabecular fractures.

Conclusion: Using a 2-level lumbar in vitro construct, the biomechanical function of the treated level with an articulating nucleus implant was similar to intact. In vitro fatigue testing showed no implant extrusion and macroscopic changes to the bony structure or cartilaginous endplates when comparing treated and intact levels.

Keywords: Lumbar spine; Intervertebral disc; Nucleus replacement; Disc height; Lateral bending; Range of motion

Introduction

In industrialized nations, back pain is nearly ubiquitous with a prevalence of 60%–90%, which is second only to the common cold as a reason for a physician visit.[1] Although it is extremely difficult to accurately identify a pain generator, disc degeneration is postulated to be the common and often times the earliest precipitator of low-back pain. With regard to spinal mechanics, discs act to bear and distribute loads as well as dissipate energy.[2] The ability of the disc to perform these functions is primarily attributed to its unique composition of the soft proteoglycan-rich inner core (nucleus pulposus) and the tough collagen-rich outer shell (annulus fibrosus).[2–5]

Disc degeneration in general results from reduced proteoglycan content in the nucleus and reduced nuclear hydration. The resulting biomechanical changes in the disc lead to loss of disc height and increasing biomechanical demand on the annulus with imbalance in the stress distribution across the disc space.[5,6] As tension in the annulus is lost, an anterior or posterior instability of the motion segment can ensue. Increasing loads on the annulus may lead to annular tears with or without disc herniations. Continued loss of disc height can lead to osteophyte formation, facet arthrosis, and stiffness of the motion segment. Pain from degenerative disc disease (DDD) occurs at any stage of this degenerative cascade from very early disc degeneration to instability and deformity.

Traditional treatment modalities for symptoms resulting from disc degeneration are focused on decompression with or without fusion. These treatment modalities do not attempt to halt the degenerative cascade, and in many instances, lead to further progression of degeneration. Although short-term outcomes after lumbar discectomy have been shown to be superior to conservative care,

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long-term outcomes have been compromised by persistent back pain and a high risk of reoperations with a significant number of reherniations.[7–10] Arthrodesis of the motion segment is still the gold standard for treatment of chronic disabling back pain of discogenic origin. However, it is difficult to predict the clinical response to arthrodesis as it depends on multiple factors, such as, the diagnosis, previous surgeries, prior fusion attempts, and number of levels requiring fusion. Long-term studies have shown a fusion rate of 87% and clinical success rate of 76% for DDD.[11,12] There are several disadvantages inherent to arthrodesis; most importantly, it can change the biomechanical loading of the adjacent segment leading to accelerated degeneration.[13,14]

In this context, intradiscal replacement of the nucleus is one possible alternative to spinal fusion procedures and the procedure has a history.[15,16] While preserving the biomechanics of the annulus fibrosus and cartilaginous endplate, nucleus pulposus implants are designed to provide stable motion, increase disc space height, relieve or lessen transmission of shear forces on the remaining annulus (restoring their natural length), and stabilize spinal ligamentous structures.[3] Currently, the indication for a nucleus replacement is for symptomatic lumbar discogenic back pain not responding to active conservative treatment for a minimum of 6 months. An magnetic resonance imaging should demonstrate early-stage degenerative changes with disc height more than 5 mm and an absence of Schmorl nodes. Standing X-rays should also demonstrate spondylolisthesis less than grade I at the symptomatic level, with disc height loss less than 50%.[14,17]

Nucleus replacement with a variety of prosthetic materials has been described. The success of such devices has been limited.[18–21] Unfortunately, a commonly reported complication has been extrusion of the device from the intradiscal space.[21–24] Various reasons for device extrusion have been demonstrated. These range from failure of the annular injury to heal, to the use of undersized devices, to fragmentation of the device itself. Potential patients for a device like a nuclear replacement are typically in the second to fourth decade of life. Arthroplasty devices for such patients will need to reliably last 30–40 years. Both the history of device failure and the lengthy service life of a nuclear replacement mandate rigorous biomedical fatigue testing to ensure patient safety and satisfaction. Fatigue testing of individual devices under physiologic loads for millions of cycles is possible if the goal is to examine the wear and longevity of the device itself.[20,25,26] However, the commonly reported problem for these devices relates to extrusion from the intervertebral disc space and the best available model is an in vitro cadaveric model.[20,27,28]

The purpose of this study was to assess the biomechanical function of an articulating nucleus replacement device in an in vitro cadaveric model and assess any adverse effects on the intervertebral disc and vertebral endplate under fatigue-loading conditions. More specifically, this was a preclinical pilot study examining an unconstrained polyetheretherketone (PEEK) on PEEK nucleus replacement (Nubac, Pioneer Surgical Technology, Marquette, Michigan). This device was designed to have an internal articulation and 2 smooth endplates and therefore allows limited translation within the intervertebral disc space (Fig. 1).

Materials and methods

Specimen preparation

Three fresh-frozen human cadaver spines from the 12th thoracic vertebrae through the sacrum were harvested and stored at −20°C until testing. Each specimen underwent plain X-ray in anteroposterior (AP) and lateral views and a lumbar dual-energy X-ray absorptiometry scan to assess the disc height, osteophyte formation, and bone density. The lumbar dual-energy X-ray absorptiometry followed a standardized lumbar spine clinical protocol (GE Lunar DPX-IQ), and scanning was performed with rice bags surrounding each specimen to emulate the abdominal tissues. Exclusion criteria consisted of significant disc height loss (disc height less than 7 mm), significant osteophyte formation, or evidence of osteoporosis (T score less than −2.5 or for this age and gender bone density less than 0.76 g/cm^2). Table 1 lists the specimen information.

Test specimens consisted of a contiguous pair of functional spinal units (FSUs), which resulted in 2 specimens per spine (T12-L2 and L3-5). For each specimen, 1 intervertebral disc served as a control level (randomized) and the adjacent intervertebral disc served as a surgical level (treatment).

Nondestructive biomechanical tests

The top and bottom vertebral bodies of the specimen were potted into fixtures and attached to a servohydraulic materials testing machine (MTS Corp, Eden Praire,

Fig. 1. Articulating PEEK nucleus replacement used in this study.