Lumbar Disc Nucleus Replacement for Refractory Back Pain: A Case Report
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Abstract
Back pain is one of the most common sources of pain and disability in the world. The value of surgically treating discogenic low back pain (dLBP) is controversial and currently limited to fusion or total disc replacement. The clinical case presented is a 25-year-old man with 5 years of spontaneous onset low back pain refractory to medical care. The patient was enrolled in a Phase 1 clinical trial designed to test the safety profile of a novel nucleus replacement device. He underwent a left-sided anterior retroperitoneal approach, nuclectomy and implantation of the PerQdisc. At the 2-year follow up period his pain scores had improved significantly. Dynamic radiographs demonstrated 23.4 degrees of segmental motion with no suggestion of inflammation on MRI.

This case demonstrates successful diagnosis of dLBP and surgical treatment using a novel motion-sparing and form-fitting nucleus replacement device, in the context of a clinical trial. While the diagnostic criteria used in this case report may be a useful guide to identify other patients with dLBP, the surgical treatment offered should be interpreted with caution until appropriate clinical trials are presented.

Keywords: Lumbar disc; discogenic low back pain (dLBP)

Introduction
Back pain is one of the most common sources of pain and disability in the world[1]. There are various types of pain commonly grouped into this broad pathological entity. Discogenic low back pain is a term generally applied when the affected disc is the actual source of pain. The cause of dLBP may be related to injury sustained by the nucleus pulposus (NP) or the annulus fibrosis (AF) by excessive wear and tear from poor biomechanics, significant accident, or injury [2]. The damage to the disc leads to inflammation within the NP and microtearing of the AF of the disc that contains the nucleus[3]. The nucleus tissue has poor blood supply and inflammation accumulates while abnormally sensitive nerve endings grow into microtears and render the disc hypersensitive to movements that would not otherwise cause pain[4].

The gold standard for surgical treatment of dLBP is controversial[5] but is currently limited to fusion and in some cases total disc replacement. Nucleus replacement alternatives have been tried in the past with varying success[6][7][8].

Case Report
The patient is a 25-year-old man with 5 years of spontaneous onset low back pain. He underwent extensive physical therapy, taken anti-inflammatory medication and low-grade opioids, as well as undergone facet-joint blocks
at L4-5 and injections to his bilateral Bertolotti’s joints all without lasting relief or improved function. The patient was unable to perform his semi-manual job as a pharmacist, standing 8-hours per day. On physical examination, he was 170 cm and 83 Kg, there were no neurological deficits found. In addition, the straight-leg test, femoral stretch test, and sacroiliac joint provocative maneuvers were all negative.

On MRI there was minimal degenerative disc changes (Pfirrmann Grade 2) and facet changes (Weishaupt grade 1) at L4-5 with minimal right-sided L4-5 partial-thickness annular tear (Figure 1).

A partial sacralization of the L5 vertebra and bilateral Bertolotti’s joints was also present. All other disc levels were very well preserved with Pfirrmann grade 1. On weight bearing radiographs, there was mild scoliosis with no signs of instability on dynamic views. At L4-5, there was segmental range of motion of 20.3 degrees, 11.8 mm of disc height, and 2.0 mm of antero-posterior translational motion.

On standard patient-reported questionnaires, the patient demonstrated severe disability (Table 1). He was identified by the treating surgeon as a potential candidate for enrollment into LOPAIN1 (Lumbar Operatively Inserted PerQdisc Artificial Implant following Nuclectomy), a Phase 1 prospective clinical trial designed to test the safety profile of a novel nucleus replacement device, based on the clinical presentation, annular disc defect on MRI, and the enrollment algorithm (Figure 2). The patient was approved by the Medical Advisory Board and underwent a left-sided anterior retroperitoneal approach, nuclectomy and implantation of the PerQdisc nucleus replacement device.

A standard PerQdisc procedure was performed on Apr 17, 2021 using an anterior retroperitoneal approach, in the supine position, to gain access to the L4/5 intervertebral disc. Dissection was straightforward to expose 1 cm² of the anterolateral surface area of the annulus. Exposure was maintained using the Phantom AL ™Retractor by TeDan Surgical Innovations. Sequential dilation was used to minimize trauma and access the nucleus pulposus. A nuclectomy was performed through the stoma using different rongeurs. Imaging balloon devices were used to confirm sufficient nuclectomy and disc space integrity before the final implant was positioned and filled with a room temperature vulcanizing silicone polymer. The instruments were removed after 10 minutes of curing time and a multilayered closure was performed.
The patient had a smooth postoperative recovery. He was discharged at POD 2 and progressively improved his overall function[4]. He returned to work on Jun 7, 2021. At the 2-year follow up period his pain scores had improved significantly. At 2-year follow up, dynamic radiographs demonstrated 23.4 degrees of segmental motion with no suggestion of inflammation on MRI (Figure 3).

**Discussion**

The biggest challenge of treating dLBP is making the correct diagnosis. Normal degenerative changes to the disc and other spinal elements are very common and differentiating such changes from pathological manifestations is radiologically difficult and unreliable making diagnosis of dLBP difficult. Additional diagnostic tools have been utilized in the past in making the correct diagnosis and physicians have mostly relied on provocative discography, intradiscal anesthetic blocks, and MR-spectroscopy[9][10][11] which are cause of significant debate and discord among experts[12]. As such, dLBP is largely diagnosed today by clinical suspicion and excluding other more tangible sources of pain, such as facet joint inflammation, nerve root compression, mechanical instability, and SI-joint dysfunction.

The treatment for dLBP includes physical therapy to improve biomechanics and pharmaceutical management to reduce pain and inflammation. Multiple types of intradiscal injection therapies have not had reliable results[8]. Some spinal societies recommend against the surgical treatment of dLBP[5] but nonetheless, some patients have convincing clinical presentations. Current surgical treatments target the total removal of disc material and/or the elimination of disc motion, through either various fusion techniques or total disc replacement. Multiple efforts have been made to develop selective nucleus disc replacement devices, but none are commercially available[8].

Spinal Stabilization Technologies™ developed the PerQdisc™ Nucleus Replacement System as a surgical alternative to fusion and total disc replacement in patients with dLBP. The PerQdisc replaces the physical space of the nucleus, in an attempt to recreate physiological motion, and redistribute the weight bearing forces and mechanical properties of the disc in a more natural fashion. It is presumed
to treat dLBP by removing the damaged nucleus tissue, while the nucleus replacement implant supports the annulus fibers and nearby tissues. It can be implanted anteriorly via a retroperitoneal approach or laterally via a transspsoas approach and a posterolateral access via a minimally invasive percutaneous approach through Kambin’s triangle is currently being evaluated in clinical studies. The PerQdisc is only available through clinical trial enrollment. Similar devices have demonstrated long-term efficacy[13] but have also been fraught by high failure rates, including subsidence, migration and expulsion[14][15][16]. Nonetheless, a true nucleus replacement device would represent a major engineering and medical feat as an ideal solution for many patients suffering from dLBP, as showcased in this clinical case report. While such results are encouraging, the challenge of reliability, clinical safety, and broad use of such devices will depend entirely on diagnostic accuracy and carefully designed clinical trials, which are underway.

Conclusion

This case demonstrates successful diagnosis of dLBP and surgical treatment using a novel motion-sparing and form-fitting nucleus replacement device, in the context of a clinical trial. While the diagnostic criteria used in this case report may be a useful guide to identify other patients with dLBP, the surgical treatment offered should be interpreted with caution until appropriate clinical trials are presented.

Conflict of Interest Statement

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References


