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The PDN[®] prosthetic disc-nucleus device

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Disclosure: The author initially conceived and patented the prosthetic disc nucleus and much of its associated instrumentation. He is a consultant to and owns shares in Raymedica, Inc., the manufacturer of the devices and instruments. The devices are not yet approved for implantation in the United States, although the CE mark has been obtained for worldwide application.

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Abstract The health of an intervertebral disc is based on a complicated interplay between physiology and biomechanics. The nucleus pulposus must remain well hydrated, and the surrounding annulus fibrosus must be competent in order for the disc to function properly. If either of these components fail, the disc will begin to degenerate, and clinically relevant symptoms may appear. Disc degeneration has traditionally been treated by either discectomy or immobilization of the affected vertebrae, and though these treatments can be effective, they also have their limitations. To help fill the therapy gap that exists for treating moderate degenerative disc disease, the PDN device has been developed. The device consists of a hydrogel core and a polyethylene jacket that are designed to assume the cushioning function of a healthy disc, while restoring/maintaining disc height and allowing normal range of motion. To receive the device, patients

must have a preoperative disc height of at least 5 mm and the vertebral endplates must be free of significant defects such as Schmorl's nodules or fractures. Two approaches can be used for implanting PDN devices: a hemilaminotomy approach, where the disc is accessed through the back, or an Anterior-Lateral transPsoatic Approach (ALPA), where the disc is accessed from the side. In either case, the nucleus material is removed from the disc, and the devices are placed transversely within the nucleus cavity. The amount of research and development currently taking place in the field of disc arthroplasty gives hope that the treatment of degenerative disc disease will soon become multifaceted, with numerous choices being available to surgeons and their patients.

Keywords Intervertebral disc · Disc arthroplasty · PDN device · Degenerative disc disease · Nucleus pulposus

Introduction

On 26 January 1996, in Wiesbaden, Germany, a 40-year-old man with disabling degenerative disc disease at the L5-S1 level was given three choices for treatment: (1) to continue with his problem, perhaps with additional conservative management, (2) to undergo a spinal fusion at the affected level, or (3) to have a new experimental device implanted with the intended purpose of restoring disc

function. He opted for the PDN prosthetic disc-nucleus device.

Six years later, over 550 patients have been implanted with this device [9], and the number of cases continues to increase as the advantages and efficacy of the device become more widely known and accepted. The PDN implant can be a valid choice – as opposed to fusion or pedicle screw fixation – due to the prospects of maintaining segmental flexibility, while requiring a less invasive surgical procedure. Based on these desirable goals, the device

is currently in use by selected clinicians in several countries all over the world, including the Middle East, Europe, and Latin America. Additionally, clinical trials are proceeding in Canada and the United States [10, 11].

In order to clarify the structure and function of the PDN device, it is important to review the basic biomechanical and physiological principles involved. Nearly 18 years of research and development have gone into realizing the implant, its surgical method, and associated instruments. Several of these details are reviewed below.

Disc mechanics and physiology

The primary functions of an intervertebral disc are to provide cushioning and allow the axial skeleton to remain flexible. The structures of the disc are the ligamentous anulus fibrosus and the hygroscopic nucleus pulposus. The anulus is constructed of multiple (up to 20) circumferential laminations or plies. The inelastic type 1 collagen fibers of each lamination attach to each adjacent vertebral body in a diagonal orientation [2]. Each lamination is composed of right- and left-handed patches of these angulated fibers, which tighten with torsion of the disc space in either direction. This orientation is important to maintain bi-directional torsional stability. At the same time, the fibers and their laminations permit bulging under load, thereby creating the cushioning effect. Interestingly, the organization of the right- and left-handed patches in each lamination creates small imperfections. Between each lamination is a thin layer of glycosaminoglycan gel that permits limited motion between the plies [1]. Scanning electron microscopy of the anular surface subjected to high pressure shows that, if the anular imperfections happen to overlap, microherniations of the gel may pass through. In all probability, these may represent the starting point for macroherniations at some later date.

The content of fibers within the outer anulus is perhaps 90% of the entire mass. Progressively towards the center of the disc, the component of gel increases with each layer until, at the central nucleus, the gel content is about 90% with only 5 or 10% fiber. These internal fibers are shorter collagen fibers that do not directly attach to the vertebrae, but provide some substance to the nucleus mass. Under load, the semisolid nucleus pushes radially out from the center of the disc, causing the anulus to bulge [3, 7]. Effectively, the anulus dissipates the compressive forces via tensioning of its collagen fibers. In much the same way that a pneumatic tire absorbs shock, the intervertebral disc acts as a cushion between the vertebral bodies.

Even when at rest, discs are constantly under load. The pressure within the confines of the anulus is normally several atmospheres, and therefore many times greater than arterial pressure, preventing the normal disc from having a vascular bed. In fact, only the outermost layers of the anulus are fed by capillaries, which are naturally accom-

panied by 0.5–2 μm polymodal, pain-transmitting free nerve endings. With the high standing and loaded pressure within the nucleus, and in the absence of vascularity, the nucleus and inner anulus are anaerobic. Even the low-level nutritional exchange of intradiscal metabolites cannot pass through the anular layers, instead passing through the intact cartilaginous endplate and its macroscopic channels. These channels contain villus-like connections to a microvascular bed, where there are microscopic clusters of arteriolar cells comprising effective microglomeruli. These microglomeruli act as filters of fluids and small molecular constituents, effectively isolating the hygroscopic nucleus gel from potential attack by blood-borne enzymes and globulins [6]. Although the exchange of metabolites is related to osmotic differential pressures across the filter membranes, the process of ridding the nucleus of byproducts to conversely bring in fluids and nutrients is augmented by a diurnal pumping action [10]. That is, during the daytime hours, under increased skeletal load, the vertical forces cause the byproducts to exit through the endplate and into the capillary bed. This mechanism reverses at night when the axial load is minimal. With the fall in intradiscal pressure, the hydrophilic nucleus gel pulls fluid and nutrients into the disc through the endplates [4, 5]. This exchange of wastes and nutrients has been found to be essential for the disc health [12, 13].

The intervertebral disc continues to function correctly as long as both the anulus and the nucleus are intact. However, as a result of the normal aging process, the composition of the nucleus changes: by the third decade of life the nucleus is more fibrous and shows a loss of some water-absorbing and binding ability [13]. With this natural progression, by the fifth decade the nucleus is usually significantly dehydrated and has lost its mucoid consistency. This stiffening of the nucleus restricts its ability to push the anulus from within the disc, causing the anulus to bear more of the load by direct compression rather than centripetal tensioning of its fibers. Meakin and co-workers demonstrated that, in a fully functional nucleus, loading causes both the inner and outer margins of the anulus to bulge outward. However, when the nucleus no longer functions properly, under similar loading the inner anulus bulges or folds inward as the outer margin bulges outward [8]. As the gel layers between the laminations also dry out, this folding of the anulus permits tearing and delamination, weakening the disc. In addition to destabilizing the disc, tears in the anulus may permit internal disc metabolites to escape and reach the outer belt of free nerve endings, transmitters of pain impulses. The metabolites may further escape into the vertebral canal or outward to bathe the nearby root ganglion. A number of these anaerobic metabolites, such as lactic acid, stromelysin, metaloproteinases, and phospholipase-A2, normally concentrated in the disc, reach higher concentrations within the non-functioning, non-pumping degenerated nucleus. If and when they leak onto the free nerve endings or the root ganglion, they may

precipitate acute or chronic back and/or leg pain. There may even be permanent changes in the ganglion under such chemical attack. This may be a common cause of severe, disabling discogenic back pain. Since only micromols of these metabolites can cause severe pain, a leakage sufficient to disable the patient can be provoked by very little motion of the segment. In the past, the most common method for removing the abnormal nucleus and stopping motion-induced discogenic back pain was to perform a fusion, discectomy alone often failing to stop the complex process.

Treating degenerative disc disease with a prosthetic nucleus

Fortunately, the clear majority of patients with natural disc degeneration never develop a clinically significant back problem, so no medical treatment is required. For others, however, the degeneration is accompanied by severe pain, and clinical intervention (conservative or surgical) may become necessary.

At present, the three standard options for treating degenerative disc disease are conservative treatment, discectomy, and immobilization. Conservative therapy largely consists of pain reduction by medication and various forms of applied therapy. The key indicators for surgical intervention are when the patient's lifestyle, work tolerance, emotional stability, or vocational activities are significantly altered due to debilitating pain. If the patient has psychiatric, legal, or social problems aggravating the condition, the indications become less clear and even confusing. Discectomy is primarily indicated in patients with direct nerve root compression, inflammation or vascular changes affecting the ganglion or root, but it is generally not indicated alone for the treatment of discogenic pain, due to the mechanical component of the problem that is inducing the back pain. Although the removal of most of the nucleus pulposus can relieve the nerve pressure and irritation, the segment is usually rendered less stable and less functional.

In many cases, the degeneration and pain may require some type of permanent immobilization of the segment. Numerous ways to stabilize degenerated vertebrae have been employed over the last 75 years, including bone grafting, plates, rods, pedicle screws, fusion cages, bone growth enhancing factors, or a combination of these. Although these methods usually succeed in relieving the motion-induced discogenic pain, they are highly invasive and permanently eliminate segmental function and mobility. Further, stiffening of a given segment may induce a more rapid degeneration of an adjacent segment.

The PDN disc-nucleus prosthesis has been developed to fill the therapy gap that exists between discectomy and fusion [10]. That is, the device offers a surgical solution to those patients whose discogenic back pain is sufficient to

Fig. 1 The hydrophilic nature of the PDN hydrogel allows the devices to absorb fluid and swell

indicate the need for surgical intervention, but whose segment(s) are not so degenerated that immobilization of the affected vertebrae is the only reasonable alternative. The PDN device is designed to assume the cushioning function of a normal disc and simultaneously maintain disc height and flexibility.

The PDN device is composed of a carefully formed hydrogel pellet that is encased in a polyethylene jacket (Fig. 1). The pellet is a copolymer of polyacrylonitrile (non-hydrophilic) and polyacrylamide (hydrophilic); the ratio of these two polymers determines the water absorbing and binding behavior of the finished hydrogel. The PDN pellets currently being used are designed to absorb 80% of their weight in water – this ability to absorb water and powerfully swell permits the device to restore or maintain disc height (Fig. 2). In order to limit the swelling, which unrestrained could potentially produce endplate fracturing, the pellet is surrounded by a very strong constraining jacket of high molecular weight and linear polyethylene fibers. The jacket also minimizes horizontal spreading, thus maintaining the implant shape so that it can retain the height of the disc even when subjected to heavy loading of the spine [11]. Each pellet (two are implanted in each enucleated disc space) has small platinum-iridium marker wires that are imbedded in the hydrogel in order to visualize the position and orientation of the implants by fluoroscopy during surgery and by ordinary X-ray imaging after surgery (Fig. 2).

It is very important to know that the PDN device and its component jacket have been subjected to mechanical and biological testing in order to ensure product safety and efficacy. Fatigue tests performed with loads of between 200 N and 800 N for 50 million cycles have shown that the device continues to function as designed, relative to load deflection, disc-height maintenance, and structural integrity. In addition, burst tests have been conducted using forces of up to 6000 N applied with no detrimental effects

Fig. 2 Pre- and postoperative radiographs of L4-L5 disc space. Disc height has noticeably increased following implantation of PDN devices. Wire markers within the hydrogel allow for better X-ray and magnetic resonance imaging visualization

on the hydrogel or the jacket. Biocompatibility tests for systemic toxicity, genotoxicity, and carcinogenicity have all been negative. Studies have also been done to test for polyethylene wear debris, a problem that has resulted in osteolysis with other total joint-replacement devices. However, the polyethylene used to manufacture the PDN jacket is of a higher molecular weight than that ordinarily used in artificial joints (hip and knee), and mechanical testing has consistently shown no wear debris production for the PDN device [11].

Appropriate patient selection

With any medical device, proper patient selection is crucial, and the PDN implant is no exception. Five years of research and over 550 cases have allowed us to correctly determine the patients who should receive devices. Important anatomical selection criteria include the lack of advanced disc degeneration, namely the height of the central disc cavity must be 5 mm or greater and the vertebral endplates must be free of significant defects such as Schmorl's nodules or fractures. Moreover, the patient's body mass index ($BMI = \text{weight in kg} / \text{height in m}^2$) must be less than 30, and total body weight must be less than 90 kg if the implant is to be inserted at the L5-S1 level, to reduce the potential for angular slippage.

Additionally, the anterior-posterior (AP) dimension of the affected disc (as indicated on magnetic resonance imaging films) must be large enough to accommodate the pair

of PDN devices. Data suggest that an AP diameter of at least 37 mm is necessary for two devices to fit properly – our studies have shown that when smaller disc spaces are implanted with the two devices, there is a greater rate of migration or dislodgment. When the disc diameter is less than 37 mm, a single implant may be used, or the case may be abandoned.

Implantation techniques

Two techniques are commonly used to implant PDN devices: a posterior hemilaminotomy approach or an Anterior-Lateral transPsoatic Approach (ALPA). In the posterior approach, the patient is placed in the usual prone-sitting position, with knees and hips flexed. The disc is approached as in a standard discectomy, with minimal removal of bone and ligament. The dura and nerve root are retracted, and a stab incision is made in the posterior annulus, after which an annulus dilator is used to provide wider access to the nucleus. The disc is enucleated thoroughly using straight and angled pituitary rongeurs. The goal is to completely evacuate the nucleus before the PDN devices are implanted. After the nucleus has been prepared, the jacket is grasped with an Allis clamp, and a smooth curving steel band is inserted into the disc cavity to act as a guide. Small impactors are then used to drive the PDN devices through the dilated annulus opening and properly align them transversely across the prepared disc space (Fig. 3).

Fig. 3 Anterior and posterior PDN devices implanted at the L4-L5 disc space. The devices are situated transversely within the vacated nucleus cavity

The ALPA technique, developed by Rudolf Bertagnoli, differs from the posterior approach in that the disc is accessed laterally. The patient is placed in a lateral-decubi-

tus position on an adjustable surgical table, and the table is flexed slightly to arch the upper flank, which will increase the distance between the iliac crest and the rib cage. The dissection passes through the external oblique, internal oblique, and transversus muscles. The retroperitoneal area is accessed and followed medially to the lumbar spine, where blunt dissection through the psoas muscle in a strict lateral direction is used to access the disc. A hinged flap is cut into the anulus and sufficient nucleus material is removed to accommodate the PDN devices. This approach is minimally traumatic, and the PDN devices are implanted directly into the disc space without having to be rotated 90° inside the nucleus cavity, as is the case in the posterior approach. As such, the implantation is faster and requires less surgical manipulation.

The future of the PDN device

The future of the PDN device and of artificial disc technology in general appears promising. The large number of patients requiring surgical relief from debilitating back pain, and the desire for more physiological methods of stabilizing the disc, are constant reminders of the need to find better solutions to this worldwide health condition. Presently there appear to be ten or more different types of prosthetic disc devices under development, with some currently in clinical trial. Those involving replacements of the nucleus, pioneered by the author, now include the Aquarelle, SINUX, and the PDN device. The total disc replacements include the Link SB Charité Artificial Disc, the ProDisc, and the Acroflex. Continued innovation and data from clinical outcomes will certainly advance disc arthroplasty technology over the next decade, greatly enhancing reasonable treatments for degenerative disc disease. It is also anticipated that cervical prostheses will arrive shortly. In this way, patients and surgeons will have additional, valid choices for care of various stages of symptomatic disc degeneration.

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