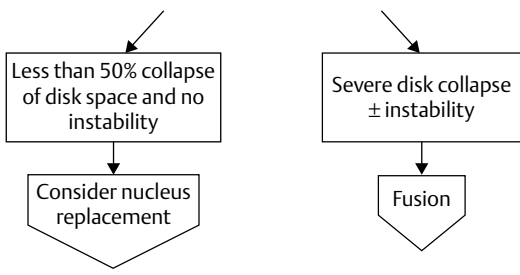


Severe Discogenic Low Back Pain



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Nucleus Replacements

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Nucleus replacement technologies are designed to replace the nucleus and restore annular fiber length and tension to replicate physiologic disk function and maintain motion to minimize the propagation of the degenerative cascade. Since the 1990s, numerous devices have been trialed consisting of plastics, ceramics, hydrogels, elastic coils, inflatable devices, and injectable fluids and polymers. Ideally, a nucleus replacement should be capable of restoring normal disk load distributions as well as restore the hydraulic pumping mechanism needed for nutrient delivery to the inner annulus. The device also needs to be stable enough to minimize the excessive motion that can lead to extrusion. Surgeon acceptance has been slow, due in part to the fact that nucleus replacements are an early-stage treatment for discogenic low back pain, indicated at a point in the disease process that is traditionally treated with nonoperative modalities. Nucleus replacement is currently very experimental. The PDN device (Raymedica, Minneapolis, MN), first developed in 1988 and modified twice, is currently involved in a three-center pilot Investigational Device Exemption (IDE) study in the United States and is commercially available outside of North America and Japan. Numerous other devices are currently involved in cadaveric, animal, and human clinical studies outside of North America.

◆ Indications and Contraindications

The ideal indications are early single-level disk degeneration or herniation with or without radiculopathy that has failed aggressive conservative management for at least 4 to 6 months. Conservative management includes oral steroids, nonsteroidal antiinflammatories, careful judicious use of narcotic medications or muscle relaxants, bracing, short-term rest with early progressive return to normal activities, and observation. Contraindications to nucleus replacement include severe symptomatic

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spinal stenosis, spondylolisthesis greater than grade I or isthmic spondylolisthesis of any grade, significant facet degeneration, severe end-plate irregularities or Schmorl's nodes, incompetent annulus, disk height less than 5 mm, severe osteoporosis, infection, and ankylosing spondylitis.

◆ Workup

History and Physical Examination

The history and physical exam should focus on location and pattern of back or leg pain (referred versus radicular patterns). Muscular spasm, deformity, tenderness to palpation, and range of motion are assessed. A thorough neurologic exam including evaluation of reflexes and motor and sensory function is performed. Given the significant confounding psychosocial factors that accompany discogenic back pain, it is important to try to identify secondary gain issues as well as other issues such as substance abuse, history of mental or physical abuse, or psychological factors that may significantly decrease the likelihood of a positive outcome with surgical treatment.

Spinal Imaging

Plain radiographs are helpful in assessing disk space height and end-plate morphology. Flexion-extension radiographs can help identify spondylolysis and spondylolisthesis. Magnetic resonance imaging (MRI) is useful in diagnosing disk herniations and disk degeneration. Changes consistent with disk degeneration include desiccation (black disk), end-plate reactive marrow changes, and high-intensity zone (HIZ) lesions (annular tear). End-plate reactive changes can be assessed to help distinguish between earlier stage disease with internal disk derangement and little end-plate reaction (better for nucleus replacement) and later stage disease with more advanced collapse and end-plate reaction (better for fusion or disk replacement). MRI is also useful in identifying contraindications to nucleus replacement such as severe stenosis, facet arthritis, infection, and Schmorl's nodes. Computed tomography (CT) scans are less useful than MRI scans, but are able to evaluate end-plate morphology, facet degeneration, stenosis, and bony trauma.

Provocative diskography is used to prognostically identify disk pathology. The provocative portion of the exam is subjective, and interpretation of data can vary among physicians. Disk derangement is identified by fissuring within the disk, whereas annular integrity can be assessed by the presence or lack of dye extravasation on pressurization. Concordant reproduction of pain on disk pressurization is generally required for a positive test. Negative controls should be present as well before considering surgical intervention.

◆ Devices

The PDN device (Raymedica, Minneapolis, MN) was developed by Dr. Charles Ray in 1988 and has undergone several design modifications. Currently it is composed of a hydrogel core within a polyethylene jacket (**Fig. 64-1**). The hydrogel absorbs 80% of

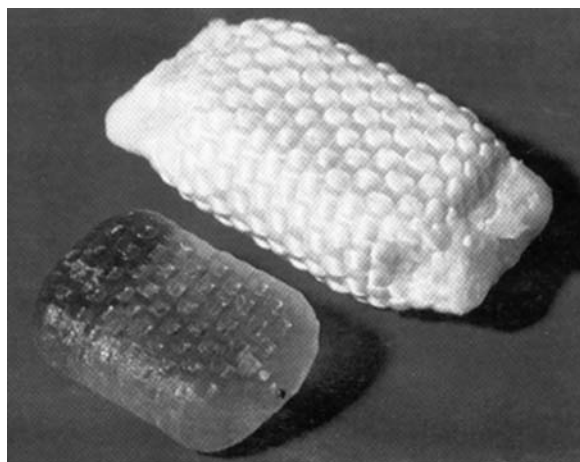


Figure 64-1 The PDN device has a hydrogel core surrounded by a polyethylene jacket that limits its vertical expansion. (Courtesy of Raymedica, Inc., Bloomington, MN.)

its weight in water. Initially, two PDN devices were placed side by side posteriorly utilizing a trephine. High extrusion rates and a 38% reoperation rate led to a change in surgical protocol in which two devices are placed side by side transversely. The anterior tapered unit is sutured to the posterior rectangular unit. In this protocol, the anteroposterior diameter of the disk must be at least 37 mm. Bertagnoli and Vazquez described the anterior lumbar transspsoatic approach in an attempt to avoid compromising posterior structures and minimize the chance of extrusion. The PDN-SOLO (Raymedica, Minneapolis, MN, USA) is a thinner single unit that may replace the two-unit design. Clinical trials of the PDN began in 1996, with little clinical data reported. Presented, but unpublished, data have shown an improvement of mean Oswestry scores and visual analog pain scores. Over 2000 patients, mainly in Europe, have received the PDN device. In December 2003, a three-center IDE pilot study with 20 patients was started in the United States.

Although the PDN device is the prototypical nucleus replacement, there are several different device designs in various stages of development. The DASCOR (Disc Dynamics, Minneapolis, MN, USA) implant is a polyurethane polymer injected under controlled pressure from an injection pump that cures in situ (**Fig. 64-2**). The pressurized liquid polymer fills the nucleus void minimizing migration and extrusion. Bench and animal studies are completed but unpublished. A multicenter European clinical human trial is underway.

The Aquarelle device (Stryker/Howmedica, Rutherford, NJ) is made of polyvinyl alcohol hydrogel. It is inserted in a dehydrated state through a 5-mm cannula. Water is absorbed from adjacent tissue, filling the device to a 70% water content, doubling the device size and providing an interference fit. The water content of the device changes in response to applied loads. A small human pilot study was completed in 2001, but Stryker has currently placed the project on hold.

The Newcleus (Zimmer, Warsaw, IN) is a preformed, curled, elastic-coiling spiral polycarbonate urethane device. After implantation, it absorbs 3 to 5% of its weight in

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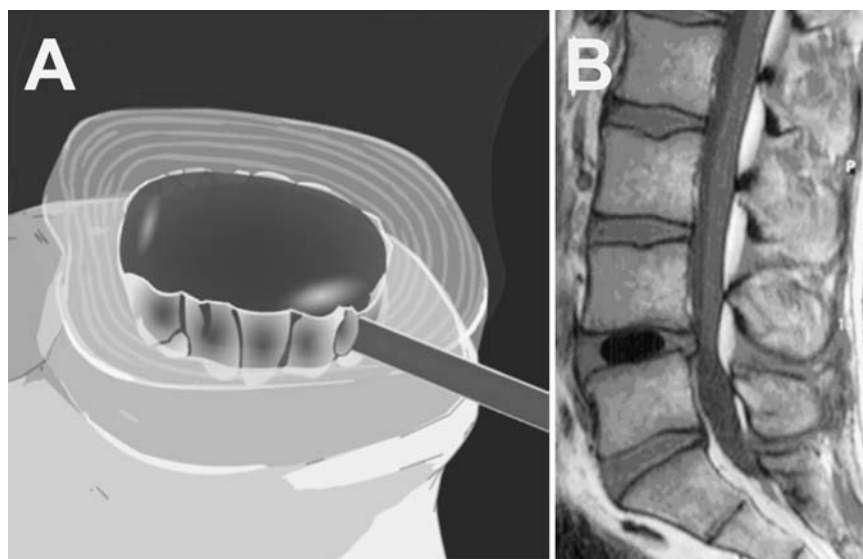


Figure 64-2 The DASCOR™ disk arthroplasty device is injected as a liquid under pressure through the catheter (A). A sagittal MRI (B) demonstrates the cured injectate in situ. (Courtesy of Disk Dynamics, Inc., Eden Prairie, MN.)

water. It acts as a spacer with shock absorbing properties, but does not provide the osmotic nutrient pumping action that a hydrogel theoretically does. The device is inserted as an open procedure through a posterolateral annulotomy similar to a microdiscectomy. Once placed, the device uncoils to fill the nuclear void. Unpublished bench and animal studies have been completed. This device has been implanted in ten patients to date.

◆ Conclusion

Motion preservation technology, of which nucleus replacement is a part, for spinal reconstruction is slowly becoming a reality. Many questions need to be answered through thorough scientific evaluation to identify the appropriate use of these devices. Nucleus replacement is very experimental and will likely work best when utilized within a well-defined clinical window. Questions that need to be answered include patient selection criteria, device longevity, wear-debris characteristics, device containment, and annular healing.

Suggested Readings

Bao Q, Yuan H. New technologies in Spine: nucleus replacement. *Spine* 2002;27:1245-1247

Review of essential concepts of nucleus replacement and device designs.

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Bertagnoli R, Vazquez RJ. The anterolateral transpoatic approach (ALPA): a new technique for implanting prosthetic disc-nucleus devices. *J Spinal Disord Tech* 2003;16:398-404

Review of a new surgical approach for nucleus replacement implantation.

Husson JL, Korge A, Polard JL, et al. A memory coiling spiral as nucleus pulposus prosthesis: concept, specifications, bench testing, and first clinical results. *J Spinal Disord Tech* 2003;16:405-411

Review of the development and early bench and clinical testing of the Newcucleus device.

Jin D, Qu D, Zhao L, et al. Prosthetic disc nucleus (PDN) replacement for lumbar disc herniation: preliminary report with six months follow-up. *J Spinal Disord Tech* 2003;16:331-337

Clinical review of short-term follow-up for the PDN device.

Klara PM, Ray CD. Artificial nucleus replacement: clinical experience. *Spine* 2002;27:1374-1377

Essential review of the PDN device.

Shim CS, Sang HO, Park CW, et al. Partial disc replacement with the PDN prosthetic nucleus device: early clinical results. *J Spinal Disord Tech* 2003;16:324-330

A clinical review of the PDN device. A steep learning curve was reported, with four of the first ten patients experiencing device extrusion.