An Anatomic Approach to Minimally Invasive Spine Surgery
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Chapter _____Lumbar Artificial Disc Nucleus (in progress)

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Introduction

Chronic disabling spinal pain with or without sciatica is a common condition that is a major medical and economic problem world wide. It can be precipitated by normal physiologic loading, may be multi-factorial, and not well understood. The spinal disc, however, is suspected to be the major cause of pain and the focus of most spine surgeries. The two most common surgical procedures, discectomy and fusion, are currently the standard for treating lumbar disc herniations and for painful spinal disc degenerative disease believed by surgeons to be due to instability. Although discectomy, with proper patient selection, may have a reasonably good short term effect in relieving radicular pain, long term surgical morbidity may result in instability of the treated disc and may consequently speed the degenerative cascade and the resultant back pain. Discectomy may lead to secondary sequella such as facet arthrosis and spinal stenosis by altering the biomechanical properties of the intervertebral disc. Fusion, likewise, is a non physiologic solution that may cause adjacent level problems. Although further decompression and/or fusion is the current "gold standard" for relieving this back pain and sciatica, its long term clinical success leaves much to be desired as a surgical procedure, prompting investigators to develop alternatives to fusion. There is a great need for more effective

and longer lasting treatments for low back and radicular pain from a scientific as well as an economic point of view.

Wolfgang Rauschning's work illustrating the patho-anatomy of degenerative conditions of the lumbar, thoracic and cervical spine serves as a guide for surgeons wishing to treat spinal pathology with tissue sparing, minimally invasive spine surgery. (1) Rauschning emphasizes avoiding stripping the dorsal muscle column, a major trunk stabilizer and a common cause of failed back surgery syndrome. Hadjipavlou has explained the clinical sequence of events that may start the degenerative process through acute and repetitive injury. (2) While we have a good understanding of the degenerative process, there has not been any surgical intervention that can address and slow the degenerative process. Even if we could, the challenge is to understand why some degenerative conditions are painful and debilitating and in others, the degenerative process is well tolerated. When back pain is the problem, Bogduk has implicated the intervertebral disc using discography and other diagnostic injection techniques. The surgical focus of this chapter, therefore, is on the feasilibility of surgical replacement of the intervertebral disc nucleus as a treatment modality and as a means to slow the painful consequences of the degenerative process.

The Clinical Challenges of Nucleus Replacement as a treatment Modality.

While it is assumed that replacement of the nucleus pulposus is desirable after nuclectomy, we must understand the natural history of discectomy for disc herniation and when it is desirable to replace the nucleus as an appropriate procedure. Currently there is no consensus among surgeons on how much disc to remove in a discectomy for disc

herniation, and which discectomies are at risk for recurrence and subsequent segmental instability or symptomatic stenosis. The best we can assume is that the goals of disc replacement are to maintain or restore the normal height of the disc, to keep the annulus properly tensioned, and to provide shock and vibration absorption to the spinal segment. The patient's goal, however, is to reduce or eliminate their pain for as long as possible. It may be more realistic to just require the implant to maintain disc height, maintain motion, and preserve kinematics, in so far a satisfaction of these requirements is sufficient to ensure pain relief.

Biomechanical Considerations of an Implant Design

The original concept of nucleus replacement centers on the destabilizing effects of nuclectomy on the segmental stability of the spinal unit. Nucleus replacement aims to reduce discogenic pain by restoring the function of a normal nucleus. Much of the biomechanical and biochemical studies studies have centered on various bio-materials to provide support against compression, and still have some of the physiologic properties of the nucleus pulposus. Hydrogel, with its biocompatibility properties and ability to resist deformation when jacketed or supported by a Dacron or fabric mesh is one of the leading materials being investigated. The size of the implant and the surface area needed to supply the support is the second consideration. The third consideration is prevention of migration and extrusion, factoring in the condition of the annulus to contain the nucleus replacement implant. Studies by Ray Medica on their PDN® device has demonstrated that a single prosthetic device offering 50% less gel volume, but only 15% less surface contact area when compared to a dual implant, was sufficient to provide adequate motion

segment support and reduce surgical time. (3) Extrusion, where the highest risk is with flexion and extension, has been the greatest in vivo concern. Preservation of the annulus is therefore a factor, thus emphasizing on minimally invasive approaches for implantation. If the implant is too soft, there is a greater chance of extrusion if the implant is able to move or migrate within the disc with axial loading. The size of the annulotomy or herniation defect may also affect the stability of the annulus and risk of recurrence. The size of the PDN® device has limited its use in minimally invasive foraminal endoscopic implantation, but various implantation techniques using far lateral retroperitoneal and dorsal configurations are being tested to facilitate its clinical use.

Considerations for an Anisotropic Synthetic Hydrogel for Nucleus Replacement

The nucleus pulposus is a natural hydrogel, and replacement of some of its functions, such as osmotic pressure generation require a hydrogel implant. (4) Non-hydrogel Nucleus Replacements may not provide these functions and act as mechanical spacers only. A Nucleus Replacement Implant, therefore, ideally should replace or supplement as many physiological functions of the nucleus pulposus as possible. It should:

1. Generate osmotic intradiscal pressure to re-establish the disc height
2. Provide shock absorption capability
3. Decrease the long term surgical morbidity of discectomy

Of the various designs of implants under the development, they attempt to replicate the natural nucleus pulposus properties with various degrees of the success. The main problem from the surgical point of view is usually the demonstrated or potential extrusion

of the implant, sometimes soon after surgery. Replication Medical Inc. (4) has a Nucleus Replacement Implant under development that is designed to address the physiologic function of the nucleus pulposus. Its layered hydrogel structure is designed to distribute axial loads in the disc and its hydrogels mimic osmotic properties of the nucleus pulposus. (figure 1)

Anisotropic deformability of NeuDisc™ is achieved by its proprietary design. It alternates hydrogel layers reinforced by Dacron knitted mesh. The vertically layered structure alternate soft hydrogel layers to attain the proper stiffness required, but should be sufficiently soft to avoid damage to the endplate. The acrylic copolymer hydrogel mimics nucleus pulposus properties, and allows osmotic intradiscal swelling to provide lift and shock absorbing support. (4) NeuDisc™ is also designed to resist extrusions due to its anisotropic swelling design. Anisotropic swelling resists bulging as it swells, providing mostly lift support without creating undesired pressure radially. The Dacron net stabilizes the soft implant to resist extrusion. This assures that NeuDisc™ can be implanted through a small incision, avoid pressure on a weakened annulus, and quickly resume a shape which is much larger than the annular incision. (figure 2.)
Unloaded, the NeuDisc implant expands in thickness from its desiccated state of 2 mm to 15 mm in its hydrated state. Anisotropic expansion restricts lateral expansion to enlarge the footprint. Biomechanical bench testing of the Neudisc™ hydrogel implant tested the capability of the implant to provide axial lift force under various pressures ranging from 150 Newton to 3000 Newton. Lift force builds up to maximum lift in about two days, then stays constant over time, responding only to variations in temperature. When lift force is plotted for various hydration levels, at 60-65% hydration, it provides lift

parameters similar to young nucleus pulposus at 400 N. If exposed to compression in a fully hydrated state, NeuDisc™ resists compression beyond the physiologic limits in the disc. Moreover, when anisotropic expansion limits radial bulging, it decreases the danger of radial expansion pushing residual disc tissue out through an annular defect created either by a surgical annulotomy incision or herniation defect. (figure 4.)

The NeuDisc implant also remained physically intact and as functional as controls after 10 million compression cycles at 150% of maximum physiologic displacement. Initial fatigue testing also included cycling the hydrogel implants in unconfined compression between load levels of 200N and 800N. Throughout this testing it was demonstrated that lateral expansion and deformation of the implants resulted, but the Dacron fibers function to prevent creep and restrain the device laterally. This implant is designed to serve as a nuclear replacement with an intact annlus but not as a free standing implant. The implant fatigue samples completed the 10 million loading cycles intact with only minor surface cracking and no loss of function or change in water uptake. Initial in vitro results of testing suggest that the NeuDisc™ hydrogel implant may be a suitable nucleus pulposus substitute. (4)

Relevance to the Anatomic Approach and Minimally Invasive Spine Surgery

The ability and ease of insertion of the **NeuDisc™** implant through a 6mm fenestration in the annulus makes this a viable implant for endoscopic as well as open use. Endoscopic techniques, while not being utilized widely because of its steep learning curve, may gain more interest and acceptance as the procedure is further standardized and demonstrated to be as effective, but with less morbidity in patients requiring discectomy

for radiculopathy. Current endoscopic systems utilize a 6mm inner diameter / 7mm outer diameter cannula. The Y.E.S.S. system by Richard Wolf for endoscopic spine surgery has endoscopic cannulas, discectomy instrumentation, and an introducer that is ideally suited specifically for the **NeuDisc™** implantation.(5) Discectomy may be accomplished through the foraminal portal from T-10 to L-5, with plenty of room for instrumentation.(6) A uniportal or biportal technique may be utilized for nucleus implantation. Other advantages of this approach is in the endoscopic discectomy technique. Selective Endoscopic Discectomy™ is accomplished by chromo-discography™. (7) Experience with over 2000 patients undergoing endoscopic discectomy using the YESS technique has demonstrated that the surgeon has the flexibility to remove as much or as little disc as desired under direct visual control. With an endoscopic technique that has evolved over the past few years, evidence is being gathered for a longitudinal study to follow the long term results of the volume of disc removed by wet weight, guided by nuclear staining with indigocarmine dye, with subsequent degenerative sequella. Follow up surgery on these and new patients has also to allowed the author to visually evaluate degenerative conditions in a conscious patient. The evolution of the endoscopic technique has allowed for endoscopic surgery on many degenerative conditions of the lumbar spine. (7, 8,9,10,11,12,13) This technique is ideal for the implantation of the **NeuDisc™.** The size of the nucleus implant can then be measured or estimated by visualizing and measuring the cavity left in the nucleus pulposus after discectomy. The position and size of implant can further be determined by intraoperative imaging. (figure 5)

The implant is inserted through a standard beveled 6mm inner diameter cannula and visualized endoscopically as the implant is seated in place. (figure 6.) The implant unfolds after it is rotated to the proper position in the disc space. After waiting 48 hours, the implant is shown to have fully hydrated (figure 7) and is also demonstrated to provide vertical lift to the disc space in an unloaded cadaver trunk.(figure 8)

Nucleus prosthesis replacement has obvious advantages over total disc replacement. By replacing only the nucleus, it preserves the remaining disc tissues and therefore preserves their functions. Because the nucleus has a more uniform structure and function than the annulus and endplate, the design of the nucleus prosthesis is simpler and it can be designed to be implanted by minimally invasive means. Depending on the design and choice of material, it can be implanted using an endocopic technique with only a small incision in the annulus. Because the implant is not designed to be fixed to the vertebrae, no fixation component is required, and the surgical time should be comparable or only slightly longer to that required for a discectomy. Although implant extrusion remains a primary concern, it is less likely to cause permanent nerve injury because of its relatively small size and modulous of elasticity. In case of prosthesis failure, it is relatively easy to remove the implant anteriorly and convert to a total disc replacement procedure or a fusion.

The major limitation of the nucleus prosthesis is that it may only be for patients with early or intermediate stage degeneration because it requires a relatively competent natural annulus. In a disc with severe annular delamination or loss of height, the disc may adapt to their new structural characteristics and would hence be difficult to stretch significantly at surgery to accept the prosthesis. Restoring disc height may have its own

concerns if the spinal nerve and facet articulation has already adapted to its shortened state. Due to this concern, work is being considered for a less tall implant that is designed for narrowed, more degenerative discs. It is growing more and more clear that artificial disc or nucleus implantation may become the treatment of choice for lumbar and cervical disc disease, especially if implanted in patients to mitigate the degenerative process..

Artificial Nucleus Implants under Development

Currently, in addition to Replication Medical's hydrogel, there are various elastomers being tested as a nucleus replacement. The ones most theoretically suited for endoscopic insertion are the hydrogel material pioneered by Bao and Higham. Extensive testing has shown that the material is biocompatible and has the ability to absorb and release water under cyclic loading. The nucleus implant by Ray Medica (Bloomington, Mn) is a relatively rigid, semi-fluid hydrogel core in a flexible but inelastic woven polyethylene-fiber jacket. It has also undergone extensive testing and clinical trials. However, due to the size of the implant, and the potential for extrusion, various implant techniques and configurations are still being tested. Disc Dynamics, with Hansen Yuan as the lead clinical investigator, is developing a polyurethane polymer that is cured in vivo inside a balloon inserted through the annulotomy incision. (figure 9) This device has been shown to completely fill the void left by nuclectomy and restore disc height and disc modulus. (14) Christopher Yeung, M.D. a clinical investigator for Disc Dynamics, has demonstrated its feasibility for endoscopic implantation. After the balloon is filled with the polyurethane polymer, the balloon flattens at the endplates, and cures in situ,

leaving a footprint on the surface of the endplate without nucleus support. The advantage of the balloon is its ability to provide maximum end plate support.

J. Husson has reported on the use of a polycarbonate polyurethane (SULENE-PCU (SULZER®) implant **(Newcleus disc prosthesis)** in the form of a memory coil that is introduced through the annulotomy defect used for surgical discectomy. It is cut in situ and adapts to the void created by removal of the nucleus. Clinical evaluation with 1-4 year follow-up demonstrated no implant migration and maintenance of disc height. (15) Protein polymers, crosslinked with glutaraldehyde (Cryolife) have also been presented at the International Intradiscal Therapy Society Annual Meeting as a substitute for the nucleus. (16) Other protein polymers (Protein Polymer Technology, San Diego), an injectable disc nucleus that is injected as a liquid, but solidifies in about 90 seconds are also being tested. There are other companies with artificial spinal nucleus projects underway who have not revealed their progress in scientific meetings, but as work on nucleus replacement progresses, it has been estimated that this technology has the potential to be part of up to 50% of future spine surgeries.(17) The potential of disc replacement may parallel that of joint replacement for the near future.

Figures

Figure 1 The NeuDisc™ Design

Figure 2. The sequence of expansion: The originally flat, oval shaped, thin NeuDisc™ is rolled and implanted; then it unfolds and gradually swells due to hydration to its final large size.

Figure 3. Anisotropic expansion from 2mm to 15mm after hydration

Figure 4. Anisotropic Deformation of NeuDisc™ .
Radial Deformity is limited compared to the radial bulging of isotropic hydrogel.

Figure 5. Intraoperative insertion of NeuDisc™ in a cadaver. Isovue -300, a non-ionic radiologic contrast material, outlines the implant in a biportal endoscopic technique with the YESS system.

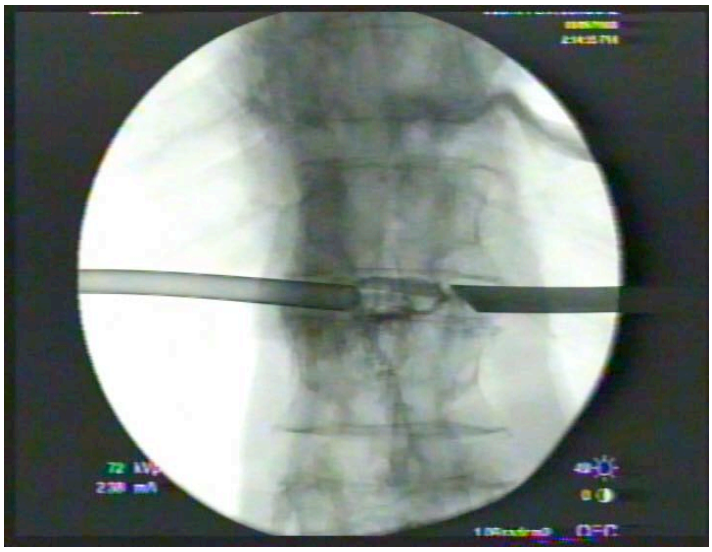


Figure 6. NeuDisc™ after endoscopic implantation

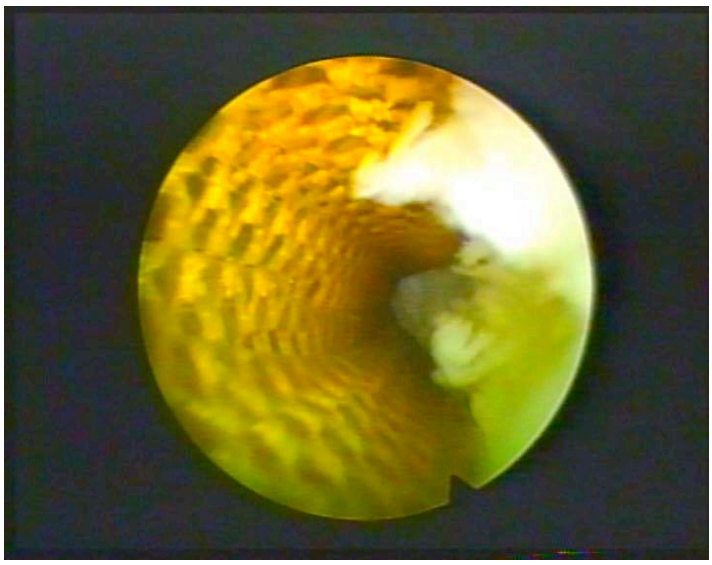


Figure 7. Hydrated NeuDisc™ after 48 hours

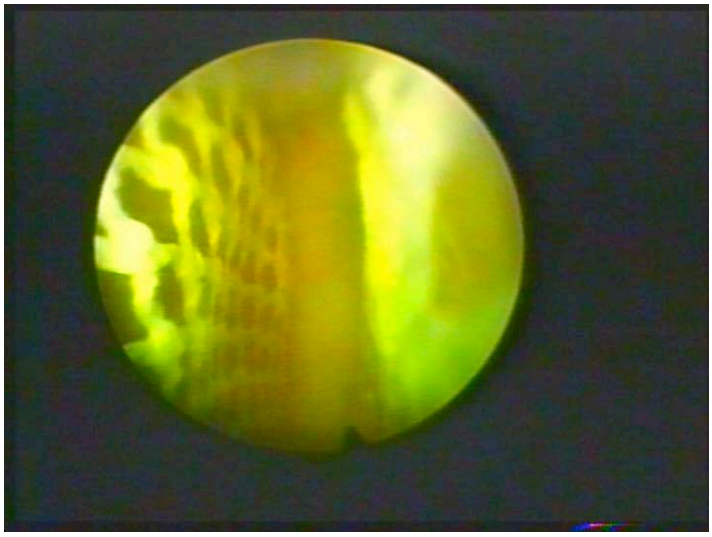


Figure 8. Disc height increased 2-3mm after hydration in an unloaded cadaver disc

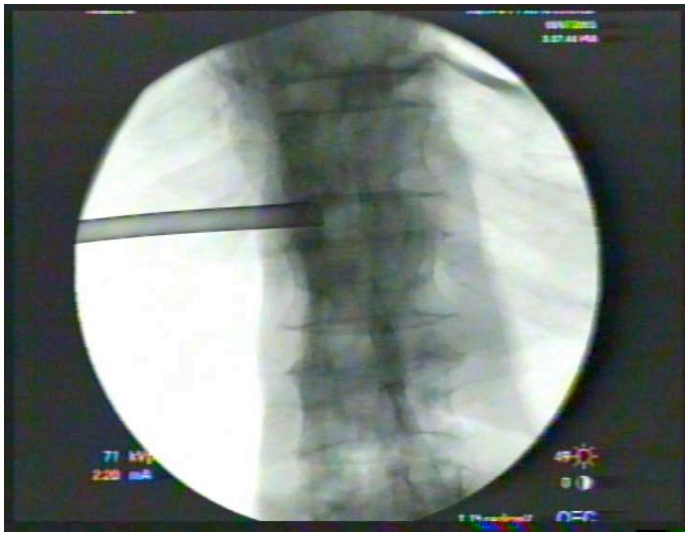
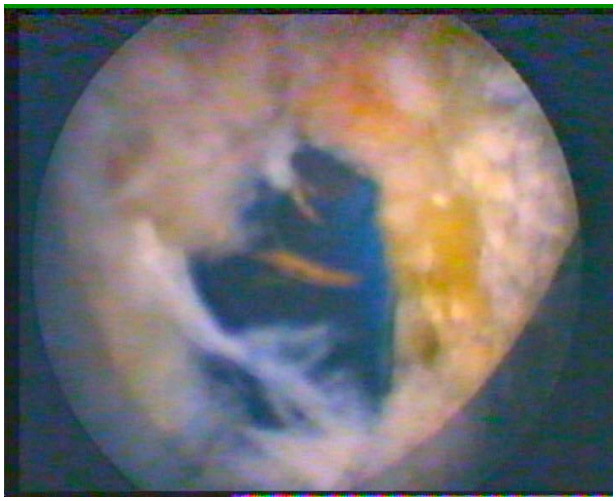


Figure 9. Endoscopic view of a balloon filled with Isovue-300 and indigocarmine dye, pressurized to fill the void created by endoscopic nuclectomy in a cadaver lumbar disc. This study was performed to study the ease of endoscopic implantation with a balloon and to visualize the filling of the balloon endoscopically and indirectly with fluoroscopy. (courtesy of Christopher Alan Yeung, M.D.)



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