



## Chapter 20

# Nucleus Replacement Complications and Salvage Procedures

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### **KEYPOINTS**

- The surgical approach selected for implantation of nucleus replacement technologies can influence initial placement and performance.
- Important aspects of the surgical technique include disc space preparation and subsequent sizing of the selected implant to the available space.
- An additional complication associated with the use of nucleus replacement technologies is the potential for allergic reaction.
- Nucleus replacement is less invasive than fusion or TDR technologies that tend to be more destructive to the surrounding tissues and bone.
- Revision surgery for nucleus replacement devices offers many advantages over other non-fusion alternatives that are utilized later in the continuum of care.

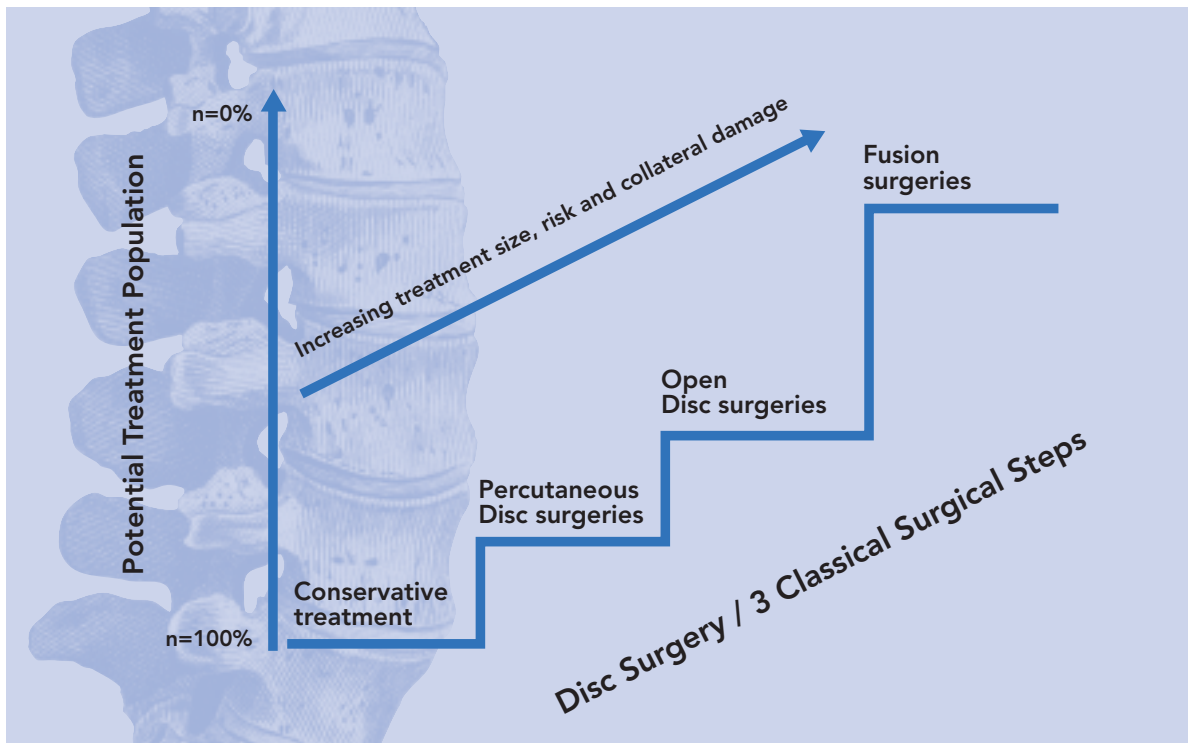


Figure 1  
Bertagnoli<sup>10</sup>

## INTRODUCTION

Degenerative disc disease (DDD) is one of the most common etiologies associated with low back pain (LBP). Currently, low back pain is addressed using treatment modalities that incorporate the use of non-operative or operative care. In general, surgical treatment for low back pain occurring as a result of DDD is considered only after prolonged failure of non-surgical treatment options. Often in such instances, the patient's quality of life is so profoundly affected, that surgery is the only viable treatment.

The main goals in treating lumbar DDD are to identify the pain generator(s) and restore function. For many years, this goal has been accomplished using spinal fusion with interbody devices and/or rigid posterior instrumentation. More recently, the use of motion preserving alternatives, such as total disc replacement (TDR), are now being employed. In addition, the use of Nucleus Arthroplasty™ or nucleus replacement therapies has moved to the forefront. These technologies are very promising as the intent is to replace only the damaged or diseased nucleus, while seeking to restore function, maintain disc height, and preserve motion. Thus, nucleus replacement is less invasive than fusion or TDR technologies that tend to be more destructive to the surrounding tissues and bone.

Currently, there are a number of different design concepts in development and evaluation.<sup>1,2</sup> In general, nucleus replacement can be simply classified as preformed devices, which include hydrogels or mechanical solutions, and *in situ* devices, which involve component mixing and *in situ* cure. The ability to successfully implement nuclear replacement technologies is exciting as such solutions seek to expand the available surgical treatment options and potentially redefine the current continuum of care.

Paramount to the success of any surgical procedure is the proper identification of the treatment indications and selection of the corresponding patient population. Obviously, each surgical procedure has its own associated risks, complications, and potential benefits that must be assessed prior to treatment. One of the most common problems with nucleus replacement technologies is their use in patients with advanced degenerative disc disease, where the window of opportunity for this type of treatment is far gone. Thus, prerequisites for positive and predictable surgical outcomes involve adequate surgeon training in combination with the application of strict inclusion and exclusion criteria.<sup>3</sup>

For the purposes of this chapter, the discussion associated with complications will be divided into specific areas including biomechanical, surgical approach, surgical technique, patient selection, and other concerns. This will be followed by a brief discussion of salvage procedures related specifically to nucleus replacement technologies.

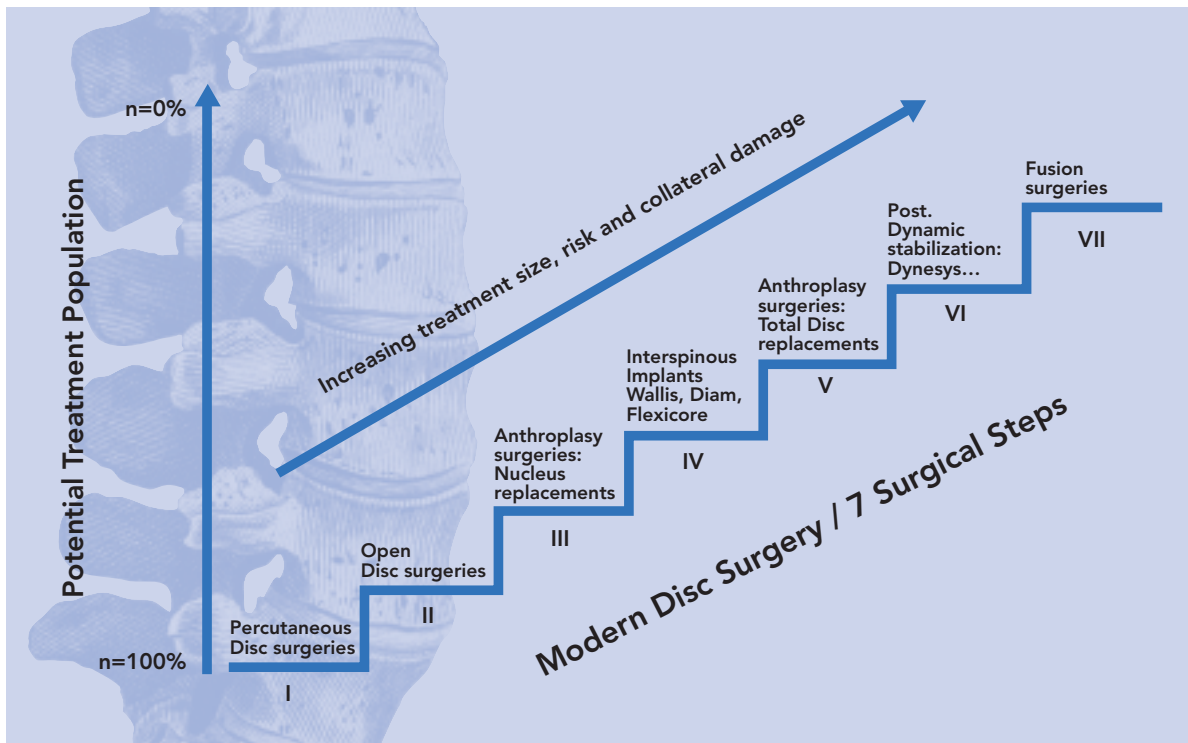


Figure 2  
Bertagnoli<sup>®</sup>

## BIOMECHANICAL ISSUES

Biomechanical performance issues associated with nucleus replacement devices are similar to those of other non-fusion, motion preserving devices and include wear, fracture/failure, dislocation, migration, subsidence, and loss of motion. Based on the existing clinical information, the majority of these complications are rare with the exception of device migration and subsidence. While migration tends to be related to the surgical approach and device configuration, subsidence, and resulting endplate damage, is more directly related to device design. The ability to determine the appropriate device stiffness has proved to be a challenging endeavor as it represents a balance between the load carrying capacity of the device and the structural integrity of the vertebral endplates. If the device load carrying capacity is too low, disc height may not be maintained, while a load carrying capacity that is too high may result in endplate remodeling and/or fracture. Extensive testing has been performed to further investigate the effects of implant stiffness, sizing and conformity in an effort to strike an appropriate balance.

## APPROACH RELATED ISSUES

Until recently, the most common surgical approach used in conjunction with the placement of spinal devices has been an open posterior hemilaminotomy. This approach has the advantage of

allowing the surgeon to address posterior pathologies, such as herniations. However, depending on the extent of the pathology, access to the disc space requires significant dissection of the posterior musculature and associated osteoligamentous structures, and may require a partial facetectomy, leading to spinal instability. Spinal instability is more problematic with nucleus replacements devices, primarily due to the lack of attachment to bony structures, making device migration an issue.

The use of a posterior approach also poses challenges to the nucleus removal process. The limited surgical window coupled with the anatomy of the spine make it difficult to adequately remove nucleus from the contralateral regions within the disc. Inadequate nucleus removal can inhibit proper device placement and subsequently influence implant motion. Intraoperatively, the use of contrast medium can be helpful to assess the extent of the nucleus evacuation prior to device placement.

Bertagnoli, et al,<sup>4</sup> have described the use of an anterior lateral transpoasotic approach (ALPA) for nucleus replacement. In this procedure, the disc space is accessed laterally by way of the retroperitoneum, and involves longitudinal splitting of the psoas muscle. The approach utilizes a safe anatomical zone that allows for sparing of the posterior osteoligamentous structures. With ALPA, a larger section of the annulus can be exposed, simplifying the nucleus evacuation and implant insertion processes.

The most commonly reported complications with the ALPA approach were transient (< 3 months) psoas neurapraxia that presented as numbness of the left anterior thigh<sup>5</sup>, particularly at L4-L5, due to the location of the nerve root. Experience in combination with the use of neural surveillance monitoring can help to minimize this risk. In addition to neurapraxia, minor asymptomatic issues with anterior device migration (within the disc space) were also noted. Obviously, the major limitation to ALPA is that, due to iliac crest location in most patients, the procedure can not be used for implantation at L5-S1.<sup>4</sup>

The use of an anterolateral or anterolateral retroperitoneal approach (ARPA) allows complete access to the lumbar region including L5-S1, via an oblique pathway to the spine. Ideally, it is intended that the disc space be accessed without disruption of the anterior longitudinal ligament and minimal mobilization of the greater vessels. Proper training and the assistance of a vascular surgeon can be of great benefit in performing this procedure. Complications related to this approach are similar to other anterior surgeries and include potential injuries to the muscles, nerves and major vessels, but to a lesser degree when compared to a direct anterior approach.

Lastly, the transcoccygeal axial approach is a novel concept that can be used to access the lower lumbar spine through the sacrum.<sup>6</sup> This approach can be performed without damaging the annulus, but requires penetration of the endplate in order to obtain access to the disc space and remove the nucleus. Clinical complications associated with this procedure are not yet known.

## **SURGICAL TECHNIQUE/ PROCEDURE RELATED COMPLICATIONS**

As mentioned earlier, device migration and subsidence have been noted in the literature.<sup>5,7</sup> Shim, et al, reported on extrusions with the PDN<sup>®</sup> prosthetic disc nucleus device. In this study, the authors noted that extrusion issues were closely related to surgical technique and patient selection. All extrusions in this series occurred in the early surgical cases. The authors indicated that there is a learning curve associated with disc space preparation and implant sizing techniques for nucleus replacement devices that is different from other spinal procedures.

Disc space preparation is a key element as inadequate removal of the nucleus material can influence the ability to properly position the implant. Any remaining nucleus can also produce increased intradiscal forces that act to move the device out of the nuclear cavity. In addition, during the preparation of the disc cavity, the

use of sharp instruments is discouraged due to the possibility of damaging the cartilaginous endplates as damage may impact the biomechanical strength and characteristics.

Coupled with the importance of nucleus removal is the ability to appropriately size the implant to the evacuated space as improper implant sizing can have a significant impact on long-term implant performance. If the implant is too small for the disc space, the likelihood of migration is increased. In contrast, if the implant is too large for the disc space, the intradiscal forces will be much higher than the normal loading state resulting in endplate remodeling, subsidence and, to a lesser degree, potential migration of the implant. Additionally, the use of an ALPA or ARPA surgical approach offers the ability to suture or reapproximate the annulus after implant insertion helping to prevent implant migration.

## **DEVICE-RELATED COMPLICATIONS**

In general, device-related complications with nuclear replacement technologies are less serious than others, such as total disc replacement.<sup>8</sup> One of the more challenging complications with nucleus replacement technologies is vertebral endplate remodeling. The general consensus is that endplate remodeling indicates an altered load environment in which the nuclear replacement device is much stiffer than the native disc material. Based on a review of the literature, it is not uncommon to have some changes in the endplate morphology that resolve over time. In addition, despite the somewhat ominous radiographic appearance of endplate remodeling, in many cases it is not associated with a bad clinical outcome.<sup>9</sup>

## **PATIENT SELECTION AND CONTRAINDICATIONS**

Appropriate patient selection is integral to obtaining good clinical outcomes. Nuclear replacement technologies are currently targeted for use in mild to moderate DDD. The intent of the procedure is to replace the diseased nucleus and maintain disc height, while preserving segmental motion. Thus, patients with significant facet arthropathy, spinal deformity or instability would not be appropriate for this technology.

Ideal patients would have a reasonable preservation of disc height (< 50% loss in height as compared to a healthy adjacent segment), with vertebral endplates that are slightly concave and free of irregularities. In addition, good bone quality and competent annular tissue are also desirable. In contrast, patients that are significantly overweight (expressed by body mass index (BMI)), osteoporotic or

present with significant disc herniations would be undesirable candidates. Currently, the ability to extend or broaden the use of this technology for such applications is still not clear.

## OTHER MISCELLANEOUS COMPLICATIONS

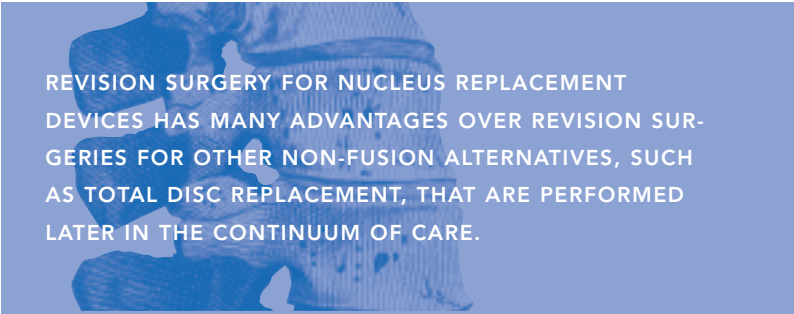
The goal of a nucleus replacement device is to replace the native nucleus material. Technologies developed to achieve this goal are utilizing a host of new materials in comparison to those used in standard orthopedic implants. Thus, additional complications include the potential for allergic reaction to the implant materials or contrast media used during the implant sizing process. In addition, depending on the implant technology, the ability to adequately view the implant or surrounding tissues post-operatively may be problematic using standard imaging modalities, (X-ray, MRI, CT).

Based on existing clinical data, the risk of heterotopic ossification has not been shown to be a significant problem with nucleus replacements. This can be a problem in more invasive procedures that require more involved dissections and/or preparation of the endplates, such as in total disc replacement procedures.

## SALVAGE

The removal of failed nucleus replacement devices will largely be accomplished via mechanical means. Consequently, the difficulties associated with removal will be closely related to the device type. Preformed and mechanical devices may be easier to revise as their inherent design facilitates removal *en bloc*. In addition, such technologies possess a known shape quality allowing visual inspection to be utilized to ensure complete device removal. Revision of *in situ* curable designs may pose more of a challenge as the implant size and shape will vary for each application. In addition, some implants of this type are not contained within a barrier, and may potentially integrate with the surrounding disc tissue. In such instances, the ability to ensure complete removal may be challenging as the devices may not be viewable using imaging modalities. Regardless of the device type, the tissue destruction required to complete the removal process may limit the surgeon's revision options.

In general, revision surgery for nucleus replacement devices has many advantages over revision surgeries for other non-fusion alternatives, such as total disc replacement, that are performed later in the continuum of care. This is largely due to the fact that the initial surgery to place a nuclear implant is much less destructive to the



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vertebral bodies and surrounding tissue. This preservation of the annulus and posterior anatomy, enables the use of surgical revision strategies that utilize additional motion preservation technologies (interspinous spacers, TDR, dynamic stabilization).

In essence, the successful introduction of nucleus replacements and other motion sparing technologies will significantly expand the treatment options currently utilized today<sup>10</sup> (Figures 1 & 2). This potential shift in the continuum of spinal care will provide the surgeon flexibility in selecting an appropriate initial or salvage procedure that is focused on maintaining spinal motion and slowing the progression of the degenerative cascade.

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