



Chapter 21

Nucleus Arthroplasty™ Technology: Patient Demographics and Selection

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KEYPOINTS

- Based on estimates, nucleus arthroplasty technology may represent up to 28% of the spinal motion preservation market by the year 2015.
- Potential benefits of nucleus arthroplasty include maintaining disc height and improving function, while preserving the annulus fibrosus, cartilaginous endplate, and ligamentous structures.
- Nucleus arthroplasty is an attractive treatment method for degenerative disc disease as it either follows or accompanies discectomy; it may serve to fill the treatment gap between conservative therapies and more aggressive surgical measures.

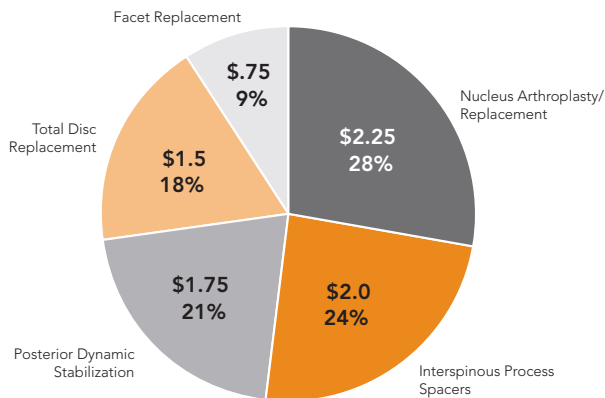
INTRODUCTION

Over the last 15 years, the global spine industry has grown from a market that was less than \$100 million in annual revenues to approximately \$6.5 billion in 2007. Current estimates show the spine market is growing by 15%–20% a year, with certain niches in distinct geographical markets growing by 40%–100%.

While the spinal device market has grown dramatically, it is still relatively small in comparison to the annual incidence of back pain and the availability of approved treatments with demonstrated clinical efficacy.

Recent trends in the surgical management are shifting toward techniques that attempt to minimize soft tissue dissection and preserve the spinal motion segment. The future market opportunity for such technologies is expected to be quite large (\$8.25 billion by 2015), with many applications being years away from commercialization.

2015 Motion Preservation Market



\$8.25 Billion

Source: Viscogliosi Bros., LLC

Based on this projection, in 2015 the nucleus arthroplasty/replacement market represents 28% of the total motion preservation market, or roughly \$2.25 billion dollars. The goal of nucleus arthroplasty is to address degenerative disc disease (DDD) by replacing the diseased nucleus with a prosthetic implant that mimics the behavior of the normal nucleus pulposus (NP). Potential benefits include maintaining disc height and improving function, while preserving the annulus fibrosus, cartilaginous endplate, and ligamentous structures. Ideally, such technologies can also be implemented to treat mechanical back pain, prevent post-discectomy degeneration, and reduce the rate of recurrent disc herniation.

PATIENTS SUFFERING FROM DDD NORMALLY PRESENT WITH SIGNIFICANT PAIN. THIS MANIFESTS MOST COMMONLY AS DEBILITATING LOW BACK PAIN, WITH OR WITHOUT LEG PAIN, OR, IN MANY CASES, DEBILITATING RADICULAR PAIN WITH A MILD BACK PAIN COMPONENT.

CURRENT TREATMENTS FOR DDD

Patients suffering from DDD normally present with significant pain. This manifests most commonly as debilitating low back pain, with or without leg pain, or, in many cases, debilitating radicular pain with a mild back pain component.

At this time, there are few treatment options to address DDD at its various stages. The current treatment continuum has been limited, consisting largely of conservative care, discectomy, and fusion. In some instances, total disc replacement may also be utilized; however, use of this application has been slower than expected, principally due to reimbursement issues.

- 1. Conservative Treatment:** Conservative therapy consists of bed rest, pain medication, and physiotherapy. If this process does not work, then surgery may be considered. The challenge remains: when to pursue surgical intervention or when to stay the course with conservative management. There is a lack of options for a surgeon who has a patient that is not responding well to pain medication and bed rest, but is not ready to go into the operating room.
- 2. Discectomy Surgery:** The most common surgery for herniated discs of the lumbar spine is a discectomy. This surgery is an early-stage treatment, where the patient with a bulging disc undergoes removal of the tissue which is causing nerve compression. This is the first surgical option because it is relatively less invasive than others and it directly treats the cause of the pain, namely the herniated disc. Unfortunately, there are many patients for whom a discectomy alone does not work and who require an additional treatment option, but are not degenerated to the point of being the perfect patient for fusion. These patients have to make the difficult decision of either having continued pain and/or discomfort without undergoing an additional surgical procedure, or possibly receiving a fusion, which is excessive surgery and may not solve their problem.

3. Fusion: Fusion was originally developed to assist those patients who were in unbearable clinical conditions, such as those suffering from a spinal deformity. Soon enough, the methods went outside of their intended patient population, and were used in non-deformity patients to fuse painful segments in the spine. While fusion immobilizes the painful area within the spine and can provide stability to the spinal column, it is in many cases not the ideal option. Although conservative therapy does not necessarily get to the root of the problem, fusion tends to “over-treat” patients. Fusing the affected levels may afford some temporary relief of pain, but it can also have a negative effect on the adjacent levels.¹ Some opinion leaders believe, and it has been corroborated by clinical evidence, that the adjacent levels can suffer from facet hypertrophy, facet arthropathy, spinal stenosis, osteophyte formation, and posterior muscular debilitation.

NUCLEUS ARTHROPLASTY™ TECHNOLOGY

Nucleus arthroplasty represents one of many opportunities to expand upon the current treatment continuum. The technology is primarily intended for early to mid-stage degenerative disc disease in a patient population that is non-responsive to extended conservative care. Should surgical intervention be pursued, nucleus arthroplasty represents an attractive treatment method as it either follows or accompanies discectomy and is less invasive than total disc replacement (TDR).

Currently, there are two general types of nucleus replacement implants: preformed implants that are inserted into the nucleus space and *in situ* formed implants that are injected into the nucleus space in a viscous state. Preformed implants have the advantage of providing more uniform implant polymer characteristics and superior biocompatibility. *In situ* polymers, on the other hand, are designed to be injected through a smaller annular window and cured within the nucleus cavity to improve implant conformity and stress distribution, while decreasing the risk of dislodgement. While the general indications between the two types are similar, they are likely to undergo further refinement as more clinical experience is gained.^{2,3}

The accompanying table provides an outline of the current nucleus replacements by device name, company, device type, and clinical stage.

NUCLEUS ARTHROPLASTY REPRESENTS ONE OF MANY OPPORTUNITIES TO EXPAND UPON THE CURRENT TREATMENT CONTINUUM.

DEVICE	COMPANY	TYPE	CLINICAL STAGE
BioDisc™	CryoLife	Injectable	CE Mark Trial
DASCOR™	Disc Dynamics	Injectable	Pilot IDE Trial
DiscCell™	Gentis	Injectable	European Pilot Study
Geliflex SP	Synthes	Injectable	Pre-Clinical Development
HydraFlex™	Raymedica	Preformed	Pilot IDE Trial
NeoDisc™	Nuvasive	Preformed	Pivotal IDE Trial
NeuDisc™	Replication Medical	Preformed	European Trial
NUBAC™	Pioneer Surgical	Preformed	Pilot IDE Trial
NuCore™	Spine Wave	Injectable	Pilot IDE Trial
PNR	TranS1	Injectable	Filed for Pilot IDE Trial
Regain™	Biomet	Preformed	Pilot IDE Trial

PATIENT SELECTION

As with any medical device, proper patient selection for the use of nucleus replacement technologies is crucial to clinical success. The underlying principle of nucleus arthroplasty is to replace only the diseased nucleus portion of the patient's intervertebral disc. The objective of the procedure is to restore or maintain disc height necessary to re-establish annular tension and ligamentous stability. The nucleus replacement device may also assist in shock absorption and load transmission, a critical component lacking in the design of total disc replacements.⁴

Ultimately, nucleus arthroplasty procedures are intended to preserve the bone and ligamentous structures that are integral to the patient's spinal segment motion. To that end, it is of great importance that the patient has annular, endplate, and posterior elements that are still capable of functioning properly. Significant compromise of these base components will directly affect the ability of a nucleus replacement device to perform as intended, potentially resulting in implant subsidence or migration.

A more detailed discussion of the indications/contraindications specific to nucleus arthroplasty procedures is provided below.

Indications

- Symptomatic degenerative disc disease (L2 to S1)
- Discogenic low back pain, with or without leg pain
- Failed conservative (non-operative) management
- No significant osteophyte formation
- Appropriate disc height at index level (device dependent)

Contraindications

- Severe symptomatic central spinal, foraminal, or lateral recess stenosis
- Spondylolisthesis (greater than Grade I)
- Segmental instability
- Fractured and/or degenerated facet joints (greater than Grade I)
- Disc collapse of greater than 50% as compared to a healthy adjacent level
- Schmorl's nodes or endplate irregularities
- Significant disc herniation (extrusions)
- Incompetent annulus (defect in annular contour)
- Osteoporosis

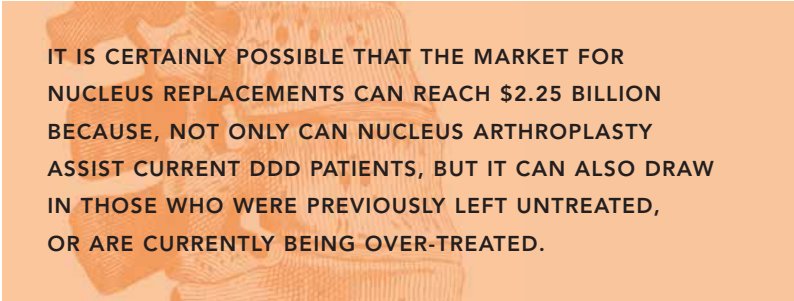
- Other
 - BMI >35
 - Malignant tumors
 - Systemic or localized infection

KEY FACTORS TO SUCCESS

For nucleus arthroplasty technologies to be successful, current concepts must show acceptable clinical outcomes in relation to alternative treatments. In addition, a shift in mindset will be required in regard to the importance of early surgical intervention.

Given that nucleus replacement is a nascent technology, the market must adapt to its benefits and learn its downfalls. It is certainly possible that the market for nucleus replacements can reach \$2.25 billion because, not only can nucleus arthroplasty assist current DDD patients, but it can also draw in those who were previously left untreated, or are currently being over-treated.

With new technologies being developed and moved through the commercialization pathways, surgeons will soon have a myriad of options to choose from. It is then the responsibility of industry to educate the surgeons and patients on the proper indications, contraindications, surgical technique, etc., so that these new minimally and less-invasive solutions can truly benefit patients.



IT IS CERTAINLY POSSIBLE THAT THE MARKET FOR NUCLEUS REPLACEMENTS CAN REACH \$2.25 BILLION BECAUSE, NOT ONLY CAN NUCLEUS ARTHROPLASTY ASSIST CURRENT DDD PATIENTS, BUT IT CAN ALSO DRAW IN THOSE WHO WERE PREVIOUSLY LEFT UNTREATED, OR ARE CURRENTLY BEING OVER-TREATED.

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