Chapter 2 Nucleus Arthroplasty™ Motion Preservation Technology versus Nucleus Replacement

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The purpose of this chapter is to help clinicians understand the difference between Nucleus Arthroplasty motion preservation technology and nucleus replacement. While the discussion may seem subjective, the difference between the two terms is vast and can have a significant impact on a clinical practice.

Nucleus replacement is much like any other joint replacement within the body. It is meant to replace one biologic component with another that mimics normal biological function. However, simply replacing the disc nucleus with a prosthetic device may not address the problems incurred by patients suffering from degenerative disc disease (DDD). Unfortunately, DDD is a problem that is not limited to one portion of the vertebral disc or a single spinal level. Rather, it is a complex disease that must be addressed comprehensively.

NUCLEUS ARTHROPLASTY MOTION PRESERVATION TECHNOLOGY GOES BEYOND NUCLEUS REPLACEMENT AND INVOLVES A COMPREHENSIVE SYSTEMATIC APPROACH TO DDD.

Nucleus Arthroplasty motion preservation technology goes beyond nucleus replacement and involves a comprehensive systematic approach to DDD. It is not only the implant that is important in Nucleus Arthroplasty technology, but the consideration of many factors including proper patient selection, indications, surgical technique/approach, and post-operative rehabilitation. Nucleus Arthroplasty technology involves a complete spectrum of treatment starting with the initial consultation in the surgeon's office and ending with follow-up and monitoring six months post-surgery. The systematic approach of Nucleus Arthroplasty technology is better suited to providing predictable and successful outcomes than the device-only approach of nucleus replacement.

A discussion of the evolution of hip replacement surgery can set the stage for the discussion of changes currently occurring in Nucleus Arthroplasty technology. In the 1970s, a degenerated hip joint was treated with a hip replacement device. One of the biggest problems with early hip replacements was that the cement used to attach the device to the femur and acetabulum loosened, resulting in performance problems. The clinical issues were not simply related to the product but also involved post-operative patient care. These problems were addressed with a systematic approach to hip replacement. Uncemented hip replacement devices with a porous coating that allowed bone ingrowth were developed and replaced devices that were cemented into place. The new generation implant was designed to function with the patient and was not merely a device within the body. In addition to improving the implant-to-patient match, specific post-operative rehabilitation protocols were developed and optimized. The surgeon provided specific and detailed instructions on when the patient should put weight on the leg and when he or she should start walking.

Nucleus replacement therapy is currently in an analogous state to hip replacement surgery in the 1970s. A systematic approach involving the whole continuum of care is required to achieve optimum clinical outcomes with Nucleus Arthroplasty technology. Nucleus Arthroplasty system technology is much more complex than hip replacement given the intricacies of the spine. It is therefore necessary to address all variables that can affect the outcome of the treatment. For example, optimal patient selection and surgical technique without proper rehabilitation will lead to minimal success. Similarly, thorough post-operative rehabilitation without appropriate patient selection will also result in a poor outcome.

While this may seem like common sense, most companies developing Nucleus Arthroplasty devices have not reached such a conclusion. Most products are simply nucleus replacement devices and not arthroplasty systems. Given that each implant may treat a slightly different indication and require a different surgical technique means that a unique system involving extensive clinical experience must be developed for each product. Most disc replacement technologies are not ready for transformation into Nucleus Arthroplasty systems. While companies can refine their devices, instruments and surgical techniques through pre-clinical testing, the indications, patient selection criteria, and post-operative protocol can only be discerned through actual clinical experience.

Several issues must be addressed in order to advance the field of Nucleus Arthroplasty motion preservation system. First, the process of disc degeneration must be better understood. Not all DDD is the same, just as not all cases of spondylolisthesis and herniation are the same. Variations in the process of DDD make it difficult to treat the condition and to achieve predictable outcomes. Second, nucleus replacement devices currently being developed have crossover indications and applications that make it difficult for the clinician to determine which device is best suited for a particular patient at a given stage of the disease process. Additionally, how a patient's DDD is classified can impact patient selection criteria for Nucleus Arthroplasty therapy. There is a large difference between what is called mild DDD and what is called early stage DDD. Some clinicians believe severe disc collapse must be present before a patient is considered to be in the early stages of DDD. However, in many cases, a patient may experience pain for an extended period of time, even though radiographic evidence of DDD is lacking. These patients may still be good candidates for Nucleus Arthroplasty non-fusion technology.

THE FUTURE FOR THE NUCLEUS ARTHROPLASTY MARKET WILL BE MORE INDIVIDUALIZED AS THE YEARS GO BY.

Due to the need to develop specific patient selection and indication criteria for specific devices, the future for the Nucleus Arthroplasty market will be more individualized as the years pass. The goal is for a company to have a multitude of device sizes that can be implanted using a variety of approaches and implantation techniques. In this way, the implant and surgical approach can be tailored to address specific patient requirements. Once again, clinical data is imperative to develop the requisite patient and product selection criteria. Without valid evidence, it is more difficult to develop a Nucleus Arthroplasty system that provides reproducible and successful clinical results. After these issues are addressed, it is expected that the indications for Nucleus Arthroplasty systems will be wider than those for total disc replacements. As more technologies attain long-term clinical history, the evolution from nucleus replacement to Nucleus Arthroplasty motion preservation technology will become clearer to the orthopedic industry, as other arthroplasty technologies have in the past.