



Chapter 27

The Future of Nucleus Arthroplasty™ Technology

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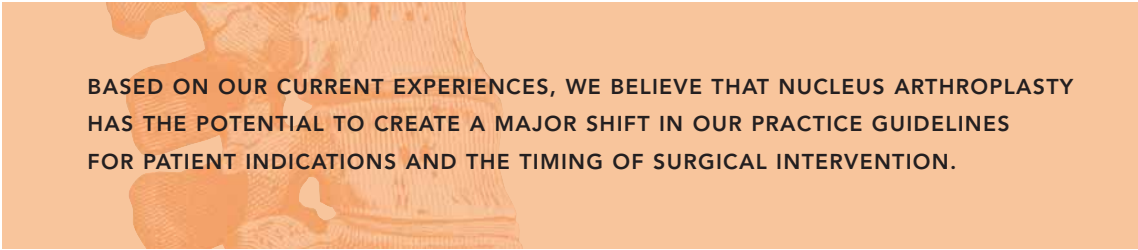
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Over the last few years, a significant amount of knowledge has been gained in regard to the stages of degenerative disc disease or degenerative cascade. Although our understanding of the process has improved, there is still a great deal of variability in terms of the patient's response to treatment. In some patients, the degeneration will continue to progress, while others will return to an asymptomatic state and remain so for long periods of time.

There is a significant clinical difference between the terms early degenerative disc disease and mild degenerative disc disease as it relates to deciding what is best for the patient. One term involves radiographic parameters, the other, clinical parameters and duration of symptomatology. It is quite possible to have disabling back pain for many months or years without significant disc collapse that is visible on imaging studies. Conversely, it is possible to have a two-week acute low back pain attack with imaging studies showing advanced disc deterioration with no prior history of back pain.



BASED ON OUR CURRENT EXPERIENCES, WE BELIEVE THAT NUCLEUS ARTHROPLASTY HAS THE POTENTIAL TO CREATE A MAJOR SHIFT IN OUR PRACTICE GUIDELINES FOR PATIENT INDICATIONS AND THE TIMING OF SURGICAL INTERVENTION.

Thus, historically, the surgical treatment of degenerative disc disease has only been pursued after the failure of established non-surgical alternatives. While some of these non-surgical options have shown reasonable evidence of success, most have not. Regardless, some patients have embarked on virtually unending, expensive, and unpredictable treatments. Many of these individuals declined into what is called "chronic pain syndrome."

We do know that patients that fall within this subset tend to respond poorly to surgical treatment and often have central disc protrusions that do not improve from decompressive surgeries alone. In fact, some surgeons claim that outcomes for this treatment group can be directly impacted by the fragile psycho-emotional status of the patient by the time surgery becomes an option.

At this time, the remaining surgical options include fusion or total disc replacement. Evidence-based medicine has shown in multiple, randomized, controlled clinical studies that such technologies can be effective for the treatment of disabling chronic low back pain secondary to degenerative disc disease in a select group of patients.^{1,2} However, due to the aggressive nature of these approaches, to treat patients with such devices could be considered a drastic over-treatment.

One of the more promising developments regarding the treatment of DDD is that early diagnosis can allow earlier treatment, recovery, and return to normal function. The intent then would be to hopefully avoid many late-stage surgeries and allow patients to return to their normal life without enduring many long years of suffering and prolonged recovery.

As this phenomenon has come to light, we have seen a definite increase in both the use and awareness of nucleus replacement devices to fill the treatment gap. Nucleus replacements represent a very attractive alternative to the more invasive surgical options noted above. Current concepts seek to address an existing disease state with the intention of slowing or stabilizing disease progression without sacrificing the disc or other surrounding tissues. As a next stage, we will most likely see nucleus replacements used in hybrid configurations that provide the opportunity to combine

the mechanical load-sharing aspects of a device with physiologic tissue engineering solutions (growth factors, gene therapies). The use of hybrid treatments is an important concept as it represents one in a series of steps to restore function of the nucleus pulposus.

Based on our current experiences, we believe that nucleus arthroplasty has the potential to create a major shift in our practice guidelines for patient indications and the timing of surgical intervention.

As we look toward the future, we would expect this technology to advance towards earlier intervention that is more focused on repair and regeneration of the native nucleus. In fact, such transformations are already underway. Although in its infancy today, advancements in gene expression analysis techniques and markers will hopefully identify patients that are unlikely to benefit from conservative measures. This rapid recognition will provide surgeons with the opportunity to pursue an appropriate surgical treatment at an earlier stage when surgery may be a relatively "minor" procedure.

Obviously, to reach this endpoint a great deal of additional research will be required. However, one thing is clear: As our knowledge of the degenerative cascade and its treatment continues to grow, we will constantly be re-evaluating our definition of the perfect candidate within this emerging sector in spinal surgery termed "Nucleus Arthroplasty™."

REFERENCES

1. Zigler, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. *Spine* 2007 May 15;32(11):1155-62.
2. McAfee P. A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part II: evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. *Spine* 2005 Jul 15;30(14):1576-83.