Chapter 13

Integration of Nucleus Arthroplasty™ Technology into the Continuum of Care

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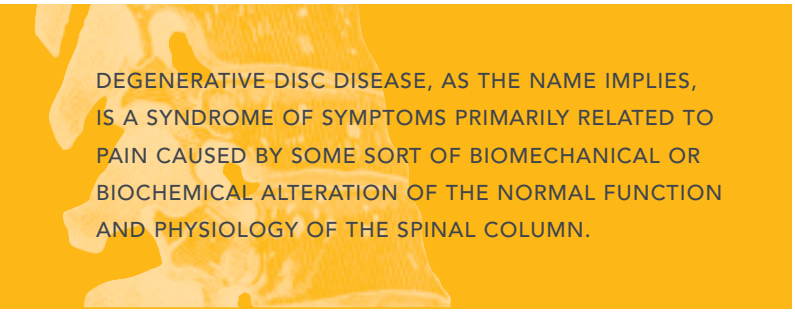
INTRODUCTION

There is a fine line between what is called degenerative disc disease (DDD) and simply the normal aging process of individuals. In the near future, with the assistance of gene expression and molecular markers, this line may be able to be drawn more accurately.

Degenerative disc disease, as the name implies, is a syndrome of symptoms primarily related to pain caused by some sort of bio-mechanical or biochemical alteration of the normal function and physiology of the spinal column. It can cause an abnormal interaction between the soft tissues (e.g. ligaments, capsules) and the bony elements. This abnormal interaction might result in

loss of function and/or normal loading-motion coupling of the spinal unit.

There have been several classifications and attempts, both radiographically and clinically, to describe the degenerative process. Unfortunately, radiographic classification does not necessarily correlate with a patients' clinical symptoms nor does it correlate a patients' clinical outcomes with an attempted treatment. However, over the last few years, more research has been done to try to better understand the natural course of this disease, as well as the physical, emotional, social and economical impact of this process which could be self-limited or, on the contrary, continue to affect the patient's quality of life. Health generic and disease specific outcome instruments have been utilized more often to understand the starting and end points of this complex disease and its different treatments.



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RADIOGRAPHIC ASSESSMENT

Findings seen on plain radiographs can be helpful in determining the stage of the disease and possible treatment options. These include: endplate shapes (concave, convex, flat, or irregular); endplate irregularities (presence of Schmörl nodes or cysts); motion quantity and quality (with fluoroscopic views); alignment and sagittal profiles. However, it is also paramount to rule-out other associated pathologies that could confuse the diagnosis, such as the presence of spondylolysis, spondylolisthesis or coronal deformities. Bone scans or nuclear medicine, can be useful to rule-out these pathologies, as well as to identify particular endplate problems or occult, benign or malignant tumors. A CT scan, alone or used in conjunction with discography, can provide a fairly good description of the anulus, endplates, facets, and pars interarticularis. Sagittal and coronal reformats can provide a more detail evaluation. An MR scan can be complementary by helping to better assess the disc height, nucleus hydration, anular tears, endplate inflammation and subchondral bony changes.[1]

In the past, we looked at the radiographic differences between patients with degenerative disc disease and herniated nucleus pulposus. Using MRI, patients diagnosed with earlier stage degenerative disc disease had primarily concave endplates. Similarily, patients with a herniated nucleus pulposus and concave endplates demonstrated less degeneration. Conversely, patients with a diagnosis of herniated nucleus pulposus and flat endplates had more disc degeneration. In addition, differences in endplate concavity were noted in patients when comparing degenerated and non-degenerated levels on both MRIs and plain radiographs. Therefore, endplate concavity seems to be a good predictor of the level of disc degeneration.[1]

CLINICAL SCENARIO

When patients present to clinicians, the main underlying symptoms are generally low back pain with possible associated leg and neurologic complaints, and disability caused by these symptoms. By a combination of the radiographic imaging techniques discussed above, physical examination, as well as the patient history, the diagnosis of chronic low back pain secondary to degenerative disc disease can be made. However, in addition, there could be associated pathologies, such as psychological, social or emotional with significant socio-economical impacts that can affect the presentation and possible outcome of any attempted treatment.

TREATMENT OPTIONS

The majority of patients presenting with low back pain secondary to degenerative disc disease, without any progressive or significant neurologic findings, should first be treated by non-surgical options. This attempt should be tried for a significant amount of time, (three to twelve months) and could combine strategies that involve, but are not limited to, physical therapy, pain management, physiatry, rehabilitation, medications, acupuncture and other modalities. The majority of such patients will benefit from these therapies and may never require surgical intervention. However, there is a small percentage that will not be helped with these techniques. Therefore, once all these conservative modalities have been tried and there has been no improvement in quality of life due to pain, surgical intervention becomes an option.

Until recently, spinal fusion was the only option for the treatment of this population, regardless of disease stage. However, this surgery has several associated factors. Many patients will try to avoid this "fearful" surgical procedure and try to live with the pain for several years. This may entail the need for significant narcotic medication that, as we know, can affect their pain perception. This chronic pain syndrome at some point could become an irreversible situation. In addition, when a patient is excluded from their obligations and responsibilities for a long period of time, their likelihood of returning to their previous level is not high. This creates a significant social and economical impact that becomes a major public health issue in many countries. However, the newer options now available to the patient mean that less invasive surgery could come sooner, thus negating the need for a fusion.[2,3]

Over the last ten years, there have been numerous ideas presented to obviate the need for a fusion. These ideas involve restoring motion when it is lost, stabilizing motion when it is unstable, or limiting motion in situations where motion is excessive or abnormal. All these techniques and technologies have an intrinsic major goal of decreasing the associated surgical morbidity and allowing a faster patient recovery.[2,4-6,8-13]

One such technology emerging as a treatment option for patients with mild to moderate degenerative disc disease is the use of Nucleus Arthroplasty™ systems. These systems might be an excellent treatment option for patients with primary discogenic back pain, with or without leg pain. Currently, most devices in this field are typically contraindicationed for patients with excessive body mass index, irregular endplates, incompetent anulus, or significant collapse of more than 50% of the disc space. Furthermore, patients with spinal instability or deformity might not be a good candidate for stand-alone nucleus replacement.

As discussed in Chapter 8, Nucleus Arthroplasty systems can be described as mechanical (e.g. non-load sharing motion devices), polymer (e.g. load-sharing motion devices) or tissue engineered implants (e.g. non-structural tissue scaffolds). Each may play a vital role in the treatment algorithm. For the initial stages of DDD, where there are no significant anular tears, no segment instability, no significant nucleus removal and no significant collapse, *in situ* formed void filling technology and tissue engineered implants might be an option. For mild to moderate stages of DDD, with more noteable anular disruption and disc space collapse, load-bearing devices that can provide structural support and help stabilize segment motion, such as pre-formed polymer and structural *in situ* formed devices, might be an option. For later-stage DDD, with more significant collapse and significantly altered load-sharing, mechanical devices may serve as an alternative to fusion.[2,4,6,7,11] These are general recommendations based on what is known today. Understanding the expected *in situ* biomechanical performance of a nucleus replacement implant, combined with clinical data, will be essential to selecting technologies that match the patients' need.

NUCLEUS ARTHROPLASTY SYSTEMS CAN BE DESCRIBED AS MECHANICAL, POLYMER OR TISSUE ENGINEERED IMPLANTS.

The need for Nucleus Arthroplasty sytems is supported by data presented in Chapter 5. When we looked at patients treated in our office in the past, 40% of the surgical group that underwent a fusion procedure or a total disc replacement for back pain secondary to degenerative disc disease, could, potentially, have benefited from Nucleus Arthroplasty treatment. Therefore, this technology would seem marked for success provided we can match the proper patient with the appropriate implant, approach, and postoperative rehabilitation program. All these factors are believed to be of equal importance and integral to a successful outcome.

WHEN WE LOOKED AT OUR PATIENTS TREATED IN OUR OFFICE IN THE PAST, 40% OF THE PATIENTS THAT UNDERWENT A FUSION PROCEDURE OR A TOTAL DISC REPLACEMENT FOR BACK PAIN SECONDARY TO DEGENERATIVE DISC DISEASE, COULD, POTENTIALLY, HAVE BENEFITED FROM NUCLEUS ARTHROPLASTY TREATMENT.

THE NUCLEUS REPLACEMENT DEVICES CURRENTLY BEING DEVELOPED VARY GREATLY IN DESIGN AND FUNCTION. UNDERSTANDING THEIR BIOMECHANICAL AND CLINICAL PERFORMANCE IS KEY TO ENSURING PROPER DEVICE UTILIZATION.

CONCLUSION

Nucleus replacement will most likely become a major option for patients with mild to moderate degenerative disc disease. Ideal candidates will be patients with discogenic back pain that present without significant anular tears or endplate irregularities, preservation of disc height, good bone quality, and normal body mass index (BMI).

The nucleus replacement devices currently being developed vary greatly in design and function. Understanding their biomechanical and clinical performance is key to ensuring proper device utilization.

Nucleus Arthroplasty technologies provide the opportunity to intervene sooner in the degenerative cascade and could prolong or obviate the need for the next step (e.g. posterior dynamic stabilization or a total disc replacement). This extension of the algorithm should hopefully delay or obviate the need for radical procedures, such as fusion, in the future.

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