AO DIALOGUE CONTROVERSIES

FUSION x DISC REPLACEMENT FOR DISCOGENIC PAIN

"The ultimate treatment for symptomatic disc degeneration should be disc arthroplasty instead of arthrodesis"

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Degenerative disease of the disc is one of the most frequently treated spinal conditions. Symptoms created by a degenerative cascade of the disc are related to the residual segmental mobility and the elimination of motion often resulting in pain relief, but at the cost of impaired function. The demand from both the clinicians and society for a better solution in the treatment of symptomatic degenerative disc disease beyond arthrodesis is universally increasing.

Spinal fusion became, very early, the gold standard of treatment for severe intervertebral disc pathologies. Although arthrodesis cages, implants, prepared allograft tissue/spacers, and other advances in spinal fixation and fusion biology have resulted in increased fusion rates, this technology fails to address the predictable pitfalls of segmental fusion itself. Interbody arthrodesis alters the normal disc structure, function, and can result in long term complications related to the biomechanical changes.

Spinal arthroplasty is quickly becoming a logical step in the treatment of severe degenerative disc disease [Figure 1]. The clear advantage of spine arthroplasty is its ability to restore and maintain the motion segmental anatomy and function, while successfully treating the patient's axial symptoms. The disc structure has multiple functional components, and therefore, the artificial disc must completely replace the original diseased tissue [Figure 4]. This will permit the technology to be applied to any stage of disc degeneration if the adjacent tissues are not involved. It can be assumed that the indications for usage of disc arthroplasty will be similar to current interbody arthrodesis techniques. If spine arthroplasty produces clear benefits, similar clinical outcomes, and acceptable risks, it will be an ideal adjunctive device to replace segmental arthrodesis in the management of symptomatic degenerative disc disease.

Functional disc replacement is not a new idea. The initial steps of implantation dates back to the late 1950's performed by Fernstrom using a SKF ball bearing to produce a "ball joint" mechanism of the disc [Figure 2]. The unique demands on spine arthroplasty implants necessitate that the intervertebral disc is not a true joint (with a center of rotation that is mobile) and serves a double function of mobility and damping with load repartition properties. The acceptance of arthroplasty to replace techniques of lumbar arthrodesis in disc disease will require a thorough analysis of the cost-benefit and risk assessment. Patient safety, efficacy, and value compared to current fusion techniques will need to be similar with this new and exciting technology.

Compared to the medical advances in knee and hip arthroplasty, the progress in the last 30 years has been slow for the development of spinal arthroplasty. Over a decade ago, three mechanical disc prostheses were presented at the North American Spine Society (NASS) with optimistic insight to new methods for the treatment of degenerative disc

disease. Although significant research has been conducted, knowledge, and expertise has been accumulated, there has yet to be a specific disc implant available in the United States for routine usage. Additional experience and research to evaluate the mechanical design, stability, and subsequent FDA regulatory pathways may result in an additional 3-5 years before this technology is universally available to clinicians globally.

The biomechanics of the lumbar motion segment have been well documented and studied in the past 2 decades. It may not be currently possible to mimic and reproduce all the mechanical properties and longevity of a natural disc without multi-components and materials. Contact stresses on an intervertebral arthroplasty will have to be minimized by having design characteristics of a significant cross-sectional surface area to distribute the load over the vertebral endplate. Unlike hip & knee arthroplasty, such large biomechanically stable implants will create specific surgical insertion problems. Disc arthroplasty implants need to have secure fixation methods to prevent catastrophic migration complications. Because of the complex structural and functional properties of the ankle, elbow, and wrist, arthroplasties in these joints have not been as successful as reconstructions of the hip and knee.

The treatment of symptomatic spinal diseases is fundamentally different than peripheral joints. The function of the peripheral joint is to allow a wide range of movements with cartilaginous surfaces. On the hand, intervertebral motion segments do not involve simple cartilaginous joints, but rather a highly complex structure consisting of peripheral collagenous bands, mucopolysacharide gels, and proteoglycans. The average spine motion segment undergoes approximately 100,000,000 cycles in a lifetime, and about 6 million each year. This highly complex structure of the disc allows small, precise

movements around all three axise, and the center of rotation is mobile and not static. These unique structural, functional, and pathogenic factors create obstacles in the development of an efficient, predictable, and reliable artificial disc for the human spine. The average implant survivorship is estimated to be 30 million cycles (5 years of clinical usage), and therefore the demands on spine arthroplasty implants will be challenged.

In symptomatic degenerative disc disease, the origin of nociception is multi-factorial, and pain can originate at any of the components of the three-joint complex. When a patient undergoes a spinal arthrodesis, all the structures capable of nociceptions are rigid in contrary to motion preserving techniques. The literature is suggestive that the clinical outcome is not directly related to the occurrence of a biological osseous incorporation, and that a non-union of the spine does not preclude to a good outcome. The current published data on spine arthroplasty success is comparable to that of fusions.

There is a complex nature of back pain in its relationship to surgery and less than ideal outcomes are often related to poor indications, rather than the technology or techniques themselves. There are many designs and concepts for spine arthroplasty, but most of the current world experience is with the Link SB III Charité (Link Inc.) and the ProDisc Modular Total Disc (Spine Solutions Inc.) [Figure 3]. From a biomechanical point of view, preservation of motion is considered to be more important than load distribution and damping effect. Each of these implants is characterized by a three-component modular design consisting of two metallic endplates and a polyethylene insert. Both of the implants have a primary goal of obtaining and maintaining distraction of the motion segment. An estimated 3,000 implantations have been described in the two

designs. The reported clinical results have been promising and future prospective clinical trials will be available in the near future.

Further scientific research will be needed to assist in many areas to include:

- Morphological Factors influencing outcome?
- Disease of the posterior column of the motion segment?
- Behavior of the implants at 5, 10, and 20 years?
- Adjacent level disease with motion preserving implants?
- Influence of the center of rotation?
- Revision Strategies of Arthroplasty?
- Contraindications for Arthroplasty?

SUMMARY:

There will always be a role for spinal arthrodesis in deformities or unstable conditions. However, spinal fusion for the management of degenerative disc disease in the absence of instability and deformity, though performed quite frequently, is not universally accepted by our patients or society. Despite extensive research, engineering, and pre-clinical testing, the ultimate safety and efficacy in spine arthroplasty can only be determined by performing clinical studies. Strict regulations and the unfortunate litigious environment of the United States creating increased costs will slow the development of this technology and its ability to treat many suffering patients.

Indeed, many unanswered questions about the precise indications, techniques, survivorship, and revision strategies of spinal arthroplasty need to be further clarified. But, this is a result of general deficiencies in understanding the axial/discogenic pain

mechanisms and precise methods of diagnosing pain generators. Progress in implant development, the acceptance of, and clinical routine in less invasive surgical approaches, as well as the result of lumbar spinal procedures have initiated a willingness for scientific discussion, and clinical acceptance of new ideas and technology.

We are at the beginning of another period of technology explosion in the field of spine surgery, which can be compared to the "Charnley era" in the development of hip arthroplasty. There are many obstacles to overcome, but the clinical need is compelling and the potential for spine arthroplasty is great. It is therefore, reasonable to apply this advancing technology to the spine pathologies and create a new gold standard, allowing our patients to preserve motion and function with symptomatic degenerative diseases.

FIGURES

Figure 1

The advantages of Arthroplasty compared to Arthrodesis includes:

- Preserving Motion
- Immediate Pain Relief
- Frequency of Failed Fusion
- Adjacent Level Degeneration

Figure 2

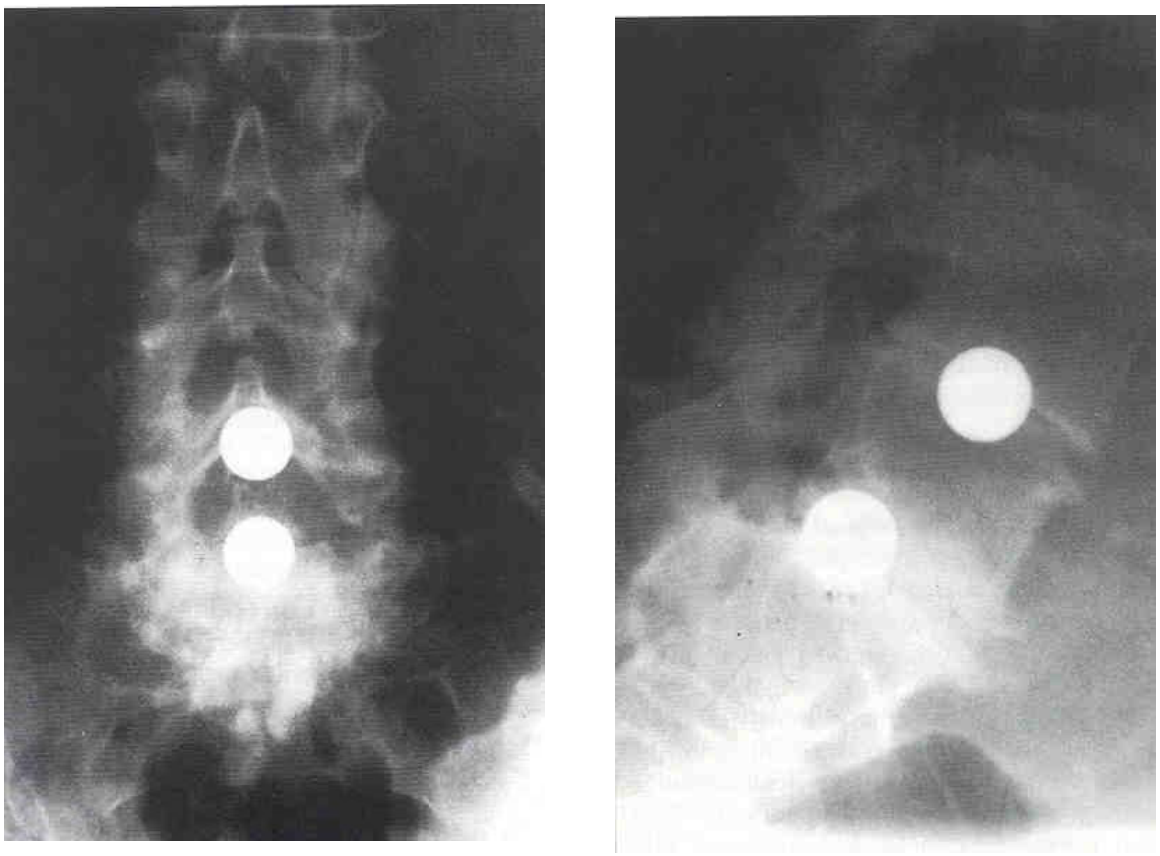

Figure 3

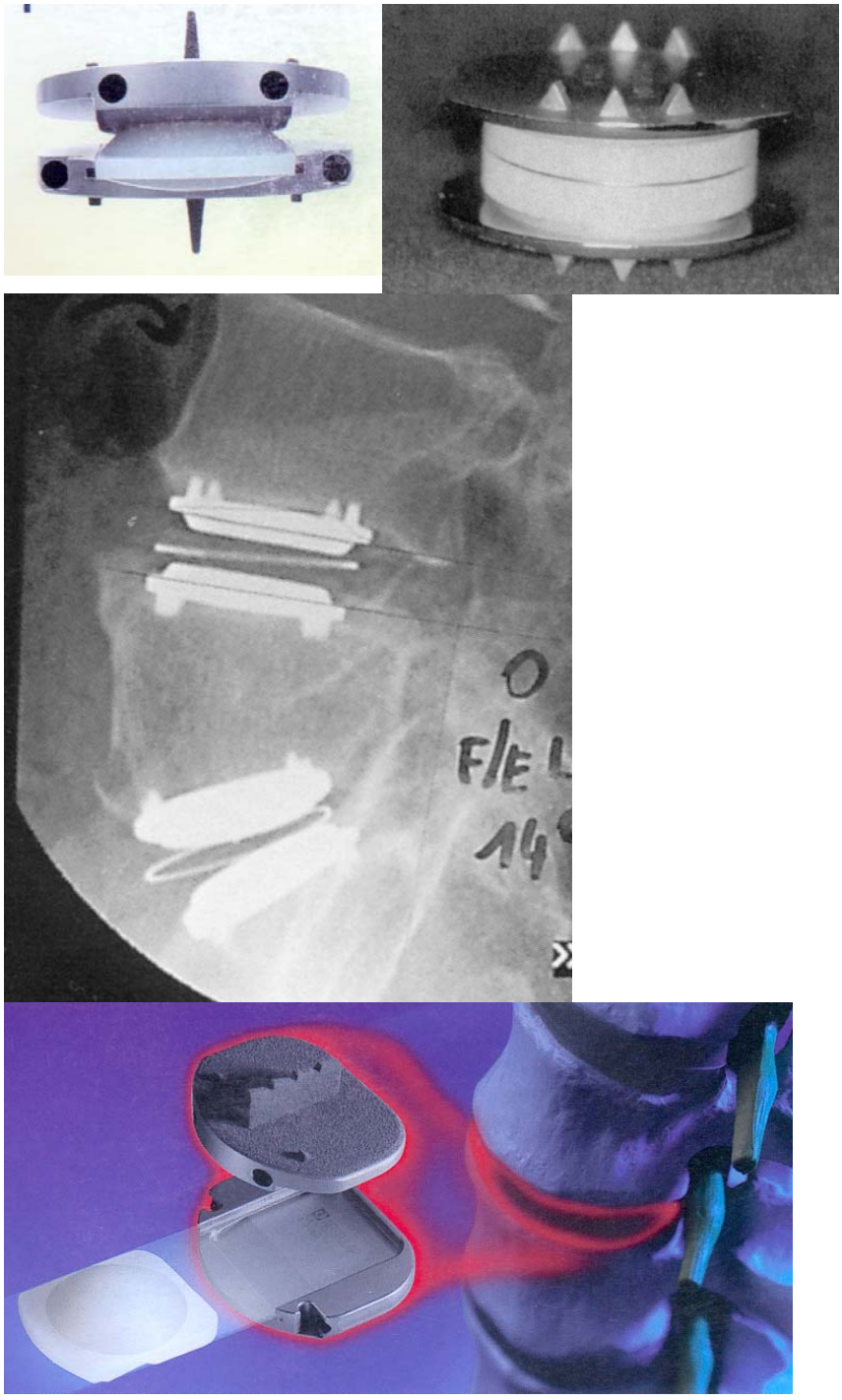

Figure 4