

Introduction to Non-fusion Technologies in the Lumbar and Cervical Spine

Introduction

The term “motion-sparing technology” has been used to describe newer surgical techniques designed to preserve spinal motion while eliminating spinal pathology. Currently, the greatest amount of attention in this field has been given to total disc arthroplasty, although many other technologies are being developed for motion preservation, especially in the posterior lumbar spine. The principle behind motion-sparing technology is to allow the surgeon to treat the patient’s spinal condition that usually arises from the consequences of aging and disc degeneration, by a means that does not require spinal fusion or alteration of normal spinal biomechanics. This concept is not new.

This chapter summarizes the current knowledge regarding available technology in the field of motion preservation. Although the materials and designs of cervical and lumbar disc prostheses are similar, their indications and rationale differ. Cervical disc arthroplasty has been promoted as an alternative to the fusion that accompanies almost all anterior cervical decompressive procedures. Ideally, these implants would be indicated for many patients undergoing anterior cervical fusion for the treatment of radiculopathy and/or myelopathy. On the other hand, most decompressive procedures for lumbar radiculopathy are performed through a posterior approach, which does not provide adequate access to the anterior disc space to allow placement of any of the current lumbar disc arthroplasty designs. Consequently, the indications for lumbar disc arthroplasty in current Investigational Device Exemption (IDE) trials have focused on symptoms of axial back pain caused by primary lumbar disc degeneration. Other forms of motion-sparing technologies are being developed to preserve motion after posterior lumbar decompressive procedures.

Many of the products and technologies discussed in this chapter are currently undergone IDE trials conducted by the United States Food and Drug Administration (FDA). Outcomes data are being reported from centers involved in these trials, and comprehensive data from multi-center trials are likely to be presented within the next year and published within 18 to 24 months.

Lumbar Spine

Devices are being developed for the lumbar spine to replace or augment the function of all or part of the disc, the posterior ligaments or other portions of the spinal motion segment. Devices also are being developed to aid in decompression of lumbar stenosis. The rationale for these devices is reviewed with each specific device. These devices are at various stages of available in the United State, from recent FDA approval to preclinical development. Many of these devices are using proprietary technology with data not yet published, which prevents detailed description at this time.

Disc Arthroplasty

The general philosophy of disc replacement is similar to that of lumbar fusion for low back pain, but is considered the next generation in the surgical care of degenerative disc disease. This concept is similar to the progression of treatments for arthritis of diarthrodial joints, with historical surgical management consisting of fusion being superseded by total joint arthroplasty more than 25 years ago. Disc arthroplasty aims to replace the “pain generator” degenerative disc with a mobile implant instead of performing a fusion, thus allowing continued motion and in theory preventing adjacent segment degeneration, which is presumed to be the cause of long-term failure of fusions. As the principle of fusion for low back pain remains somewhat controversial, so should the concept of disc arthroplasty. The multi-directional nature of spinal motion and stability, including the contribution of the facet joints and posterior structures, complicates the replication of anatomic motion with simple devices. The complex nature and poorly understood causes of spinal pain also introduce challenges to improving clinical outcomes using disc arthroplasty.

The restoration of the mechanical integrity of the lumbar spinal motion segment involves consideration of kinematics, geometry and mechanics of the disc prosthesis. Normal kinematics of the disc involves motion in flexion/extension, lateral bending, axial rotation and translation with a variable instantaneous axis of rotation. With current disc prosthesis designs, the trend is to use mobile bearing to reproduce such complex motions. The use of such mobile bearings leads to some concern over the production of wear debris and the longevity of the prosthesis. Disc prosthesis geometry must approximate the geometry of the disc height and axial plane dimension to provide appropriate stability, fit within the intended level and preserve normal motion and load on the facet joints. The mechanics of the disc prosthesis must allow for normal load transmission through the disc without failure, load transfer or shifting to other structures such as the facet. Ideally, the key goal of disc arthroplasty, the prevention of adjacent segment degeneration, must be achieved without producing abnormal motion or stress on adjacent segments. In vitro test methods are being used in an attempt to predict the in vivo mechanical behavior wear properties of disc prostheses.

The first lumbar disc prosthesis to gain FDA approval (2004) is the Charité prosthesis (DePuy Spine). Clinical results of the disc replacement (n+182) were compared with those of anterior lumbar fusion with a cage implant (n+85) for the treatment of single level degenerative disc disease at L4-5 (approximately 30% of patients) or L5-S1 (approximately 70% of patients). Success was defined as 25% improvement in the Oswestry Disability Index, absence of device failure, absence of major complications and maintenance of or improvement in neurologic status. Follow-up was maintained at 24 months in 86% of patients who received disc replacement and 79% of patients who underwent fusion. The percentage of patients who had successful results at 6, 12 and 24 months were 44%, 51% and 63%, respectively, for the Charité group and 35%, 41% and 53%, respectively, for the fusion group.

The review panel raised the issue that 2 years of follow-up was inadequate to demonstrate proof that disc replacement prevented adjacent segment degeneration. There were also concerns regarding the potential for altered stresses on the facets that could lead to degeneration of the articulation and persistent pain. A postapproval study generating longer-term follow-up data is in progress. Other designs are currently undergoing clinical trials in the United States with the expectation that regulatory applications will be filed in the next few years.

Although the formal complete clinical trials are not yet published, some data are available from individual centers and from the FDA website. A patient satisfaction measure of those who received the lumbar disc arthroplasty device showed 74% were satisfied and 14% were "somewhat satisfied." Satisfaction among patients in the fusion group was 53% and 26%, respectively.

Other total disc prostheses remain at various stages of development and clinical use. Other metal-on-polyethylene or metal-on-metal designs include the ProDisc Artificial Total Lumbar Disc Replacement (Synthes, Inc, Paoli, PA), the MPD Motion Preservation Devices (Vertebron, Inc, Stratford, CT), Maverick (Medtronic Sofamor Danek, Memphis, TN) and the FlexiCore Lumbar Prosthesis (Stryker, Allendale, NJ), which are in specific clinical trials under IDE in the United States (see information on Charité and ProDisc lumbar artificial disc replacement).

Biologic "Devices" for Disc Replacement

Tissue engineering techniques are being developed to provide more biologic solutions to address disc replacement and degeneration. The capability to engineer a composite disc using a scaffold made of polyglycolic and polylactic acid was described in a recent study. Annular cells from sheep were seeded on the device and incubated for 1 day, with nucleus pulposus cells (also from sheep) in alginate gel suspension added 1 day later. The implants were then placed subcutaneously into athymic mice and harvested at 4, 8 and 12 weeks. Gross morphology, histology, collagen typing and proteoglycan,

hydroxyproline and DNA analysis all showed a strong similarity to native disc. Although challenges remain in optimizing scaffolds, cell sources, implantation techniques, fixation and long-term function, tissue engineering may offer viable solutions in the future.

Biologic regeneration and gene therapy techniques are also being applied to address disc degeneration. Initial findings in vitro and in limited in vivo studies suggest the potential of growth factors to help regenerate or repair degenerated disc. The effects of various growth factors on cells derived from the nucleus pulposus and annulus fibrosus in both animals and humans are being identified. Animal models are being used to determine the effects of the administration of growth factors on the normal disc and some injury models. Although the complexity of growth factor effects has slowed progress in this area of study, the potential remains that administration of one or more growth factors can promote regeneration or repair of disc tissues. The continuing development of gene therapy techniques has led to the application of these techniques to disc degeneration. Efficient transductions of genes into the cells of the nucleus can be done using adenovirus vectors, and several promising transduction factors have been identified. It has been suggested that gene therapy may have the potential to favorably alter the course of the disc degeneration process.

Motion-Sparing Posterior Devices

Posterior nonfusion devices are being developed to address instability and spinal stenosis. The Dynesys spinal system (Centerpulse Orthopaedics, Switzerland; now Zimmer, Warsaw, IN) is being developed to provide spinal alignment and dynamic stabilization while preserving the facets and disc. This system is a combination of polyethylene-terephthalate cords with polycarbonate urethane spacers as load-sharing members between metallic pedicle screws. In a biomechanical study, the Dynesys device restored stability to a destabilized spine to a level between that of the intact spine and fixation with an internal fixator. The device is believed to improve back pain by reducing the painful motion resulting from degenerative disc disease while retaining some motion to minimize adjacent segment problems.

Some devices are being developed to provide some stabilizing support to the posterior elements by being applied to the spinous processes of the degenerative segments. These devices are believed to improve back pain caused by degenerative instability, to preserve mobility and to be reversible. The concept behind these devices is to provide an intermediate step between the degenerative unstable spine and a fused motion segment in hopes of reducing back pain. The Wallis device (SpineNext, Bordeaux, France), the Interspinous U (Fixan, Peronnas, France) and the DIAM (Medtronic, Memphis, TN) are examples of devices being developed with this philosophy.

Cervical Spine

Rationale for Motion-Sparing Technologies

In the cervical spine, the primary rationale for motion-sparing technology (cervical disc arthroplasty) is to avoid any adverse biomechanical effects on adjacent motion segments that may result from current procedures. By doing so, it is hoped that the subsequent radiographic degeneration of those adjacent segments and the development of new clinical disease related to degeneration of those segments might be minimized or avoided. However, when the degeneration of adjacent motion segments is attributed to a prior surgical procedure, the natural history of degenerative disease at motion segments adjacent to unoperated cervical spondylosis is unknown. For example, it is unknown how frequently a patient with a C6-7 spondylosis causing C7 radiculopathy who does not undergo surgical treatment will experience progression of spondylosis at C5-6 that causes C6 radiculopathy. It has been hypothesized that the elimination of segmental motion after anterior interbody fusion of the cervical spine may have deleterious effects on adjacent motion segments over time, possibly accelerating the degenerative process at these levels. Biomechanical studies have shown in vitro that interbody fusion constructs can increase adjacent segment motion and adjacent disc strain.

The degenerative process at adjacent levels as seen radiographically may be best described as adjacent segment degeneration. This phenomenon has been observed among many patients undergoing anterior cervical decompression and fusion procedures who are assessed many years after surgical treatment.

When patients develop new symptoms of cervical radiculopathy and/or myelopathy that correlate with the development of degenerative changes at adjacent levels, the process is called adjacent segment disease. It has been reported that approximately 3% of patients undergoing anterior cervical decompression and fusion for radiculopathy and/or myelopathy will develop adjacent segment disease each year after the index operation, and the likelihood that a patient undergoing such a procedure will develop adjacent segment disease within 10 years is greater than 25%. The motion segments of C5-6 and C6-7 were found to be at highest risk of developing adjacent segment disease when not incorporated into the surgical procedure.

The primary method of motion preservation proposed for the cervical spine has been total disc arthroplasty. One of the benefits of this procedure in the cervical spine is that it allows the same interbody decompressive procedure through an anterior approach that is already routinely performed for cervical radiculopathy and myelopathy caused by either a herniated disc or spondylosis. In patients undergoing cervical disc arthroplasty, an articulating prosthesis is placed into the decompressed disc space instead of a bone graft and anterior cervical plate. Theoretically, such a procedure would not only allow decompression of the neural elements but also potentially decreases or even eliminates the deleterious effects of fusion on adjacent levels by preserving motion at the decompressed level.

Fundamental to the benefits of a cervical disc replacement is its ability to “spare” motion at the segment undergoing surgery. Range of motion is diminished as a result of advancing age in most patients undergoing anterior cervical decompression; therefore, whether these devices can restore native motion at the operated level or preserve the motion that existed before the anterior cervical decompressive procedure is unclear.

Biomechanics of Cervical Disc Arthroplasty

The biomechanics and biomaterial considerations associated with cervical disc arthroplasty are complex. Biomechanical factors include the number and shape of the articulating surfaces, their centers of rotation, any constraints on motion caused by the design and the subsequent effect these factors may have on other parts of the motion segment, including the facet joints. Material considerations include the composition of the endplates of the prosthesis, method of implant fixation to the native bone stock and the materials used to form the articulating surfaces.

Perhaps one of the most important aspects of cervical disc arthroplasty design is an understanding of the bony anatomy where the prosthesis will reside. A series of studies were performed to evaluate this anatomy, including evaluation of endplate mineralization, trabecular structure of the cervical vertebrae and the bone density of cervical vertebrae. The results of these studies demonstrated that the most dense bone mineralization in the cervical vertebrae was located in the lateral portions of the endplate. This density in bone mineralization is in part caused by the higher bending loads and increased lateral mobility seen in the cervical spine. Bone density was found to be higher in the cervical spine than in the lumbar spine. As a result of these findings, certain design properties were recommended: (1) the implant should have a large surface area to maximize contact area with the vertebral body, especially in the areas of highest mineralization; (2) the implant should have a profile that would obviate the need for removal of the highly mineralized bone in the uncovertebral areas; and (3) any porous coating on the implant should account for the dense bone structure of the cervical spine. These principles were suggested as a way to avoid subsidence of a cervical disc prosthesis, a devastating complication that may lead to focal deformity and loss of local bone stock. These complications could hamper any attempts at salvage and revision.

Implant materials currently being used in cervical disc replacement include titanium alloys, cobalt-chromium alloys and stainless steel. In addition to metal-on-metal, bearing surfaces also include ultra-high molecular weight polyethylene (UHMWPE) and polyurethane. All of these biomaterials have been used and tested extensively in adult reconstruction. The data regarding strength, biocompatibility, resistance to wear and generation of debris particles have significantly influenced decisions about the components used in cervical disc prostheses. The physiologic loads placed across the cervical disc space are far less than in the knee or hip, and thus any of these metals/alloys would provide a solid platform. One benefit of using a titanium alloy rather than stainless steel in the cervical spine is that it would result in less artifact on CT and MRI studies.

The choice of bearing surfaces has been a source of controversy in the field of adult reconstruction, and these concerns have affected the development of cervical disc replacements. Hard bearing surfaces such as ceramic-on-ceramic or metal-on-metal have been used to minimize the generation of wear debris that might result in periprosthetic osteolysis. Currently, both hard-on-hard bearing surfaces and hard-on-soft bearing surfaces are being used in cervical disc prosthesis. The intervertebral space is devoid of synovial tissue, which is considered a primary source of macrophages believed to be responsible for the development of osteolysis. In addition, the production of wear debris in the cervical spine will most likely not be as significant as in total knee or total hip arthroplasty because much smaller loads are encountered. The other factor that may cause particulate wear is the sliding distance, which is relatively small in the cervical spine.

Three primary modes of fixation are used in cervical disc replacement. The first method is via a press-fit approach similar to that performed with cementless total hip and total knee arthroplasty. Short-term fixation is achieved through the press-fit with bony ingrowth along the prosthesis providing long-term fixation. A minimal amount of bone resection is typically required, and cutting jigs are not used in this process. The second method of fixation involves the use of screws in the adjacent vertebral bodies in a process similar to that used in anterior cervical plating. A third mode of fixation involves the use of porous ingrowth combined with a prosthetic "fin" to provide immediate stability in all planes.

Current Cervical Disc Replacements

Bryan Disk

The Bryan cervical disc replacement is a one-piece prosthesis made of titanium alloy and polyurethane. The titanium endplates articulate with a polyurethane nucleus creating two articulating surfaces. The device is unconstrained in nature and allows for a variable center of rotation. The endplates are porous-coated titanium and the device is implanted in a press-fit fashion, requiring no supplemental fixation. The articulating surfaces are contained within a polyurethane sheath that attaches to the titanium endplate, forming a barrier that can contain any potential wear debris. The prosthesis is configured to five different diameters and one height.

Prestige

The Prestige cervical disc replacement is a two-piece prosthesis made of stainless steel. The prosthesis has one articulating surface that is titanium (metal-on-metal). The inferior endplate portion contains a ball configuration that articulates with the superior endplate, which has a trough configuration. The device is a semi-constrained device with a mobile center of rotation. The prosthesis is fixed to the adjacent vertebra via a constrained locking screw mechanism. The prosthesis is available in 6- to 9-mm heights, a constant width of 17.8mm and depths of 12 and 14mm. See more information on Prestige.

Prodisc-C

The Prodisc-C is a three-piece prosthesis. The endplates are made of cobalt-chromium alloy. The device contains one articulation that is made of UHMWPE. The polymer insert is fixed on the caudal endplate and articulates via a concavity formed in the superior endplate. The prosthesis is semi-constrained and

has a fixed center of rotation. The endplates contain sagittal keels that are plasma sprayed. The implantation of this device requires use of a chisel to make slots in the vertebral bodies for the keels. The prosthesis is fixed using a press-fit technique. See more information on Prodisc-C.

Annotated Bibliography

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