Abstract
Spinal fusion remains the gold standard for surgical management of instability and mechanical low back or neck pain. However, even in carefully selected patients, successful clinical results can be difficult to achieve. Reasons for failure include pseudarthrosis and adjacent spine segment disease. The theoretic advantages of removing the painful disk while preserving motion have led to increasing interest in total disk arthroplasty. Although disk replacements have been implanted in Europe for decades, the procedure is relatively new in the United States. Recently, two artificial disks for symptomatic lumbar degenerative disk disease have been approved by the US Food and Drug Administration; several others are undergoing clinical trials. Short-term studies demonstrate similar clinical improvements for both disk replacements and fusion procedures at up to 2-year follow-up. Issues requiring further research include optimal design specifications, potential complications, and appropriate patient selection. Consequently, the long-term benefit of total disk arthroplasty over fusion for the treatment of axial low back or neck pain remains to be determined.

Axial spine pain is among the more difficult treatment problems faced by spine surgeons. Several different modalities have been developed in an attempt to help patients manage symptoms of mechanical back pain. Arthrodesis of the spine is the gold standard for surgical treatment of low back pain. However, the etiology of the specific pain generators involved can be difficult to determine, and surgical outcomes to date leave substantial room for improvement.

The use of biologic growth factors combined with bone grafting and more rigid instrumentation has led to an increase in spine fusion rates. However, total disk arthroplasty (TDA) has recently received significant attention in the United States as an alternative to spine fusion.

Etiology of Axial Symptoms in the Spine
The etiology of mechanical back and neck pain is not well understood. Causes of the pain can be multifactorial, ranging from specific anatomic abnormalities to reasons that include psychiatric and social issues. Anatomically, the functional spinal unit consists of two vertebral bodies and the intervertebral disk. Areas with potential pain generators include the disk and facet joints. Arthritis of these articulations can lead to spinal instability, abnormal or restricted motion, and progressive de-
terioration, all of which can result in significant pain. Moreover, research in biology of the intervertebral disk has shown that degenerative disk disease itself can result in irritation of pain fibers within the annulus fibrosus.

Radiographs and magnetic resonance imaging (MRI) aid the clinician in diagnosing degenerative disk disease. Plain radiographs can demonstrate loss of disk space height, development of osteophytes, and end plate sclerosis. Changes on MRI include loss of disk water content (diminished intensity on the T2-weighted images), high-intensity zone signal, and end plate irregularities. Clinically, provocative diskograms and facet joint injections can be used to pinpoint the painful area more accurately. However, because these procedures are operator- and patient-dependent, the consistency of the results is highly variable.

History of Spine Fusion

Spinal arthrodesis for degenerative disk disease is a controversial treatment modality for low back and neck pain. Although fusion of an arthritic joint may reliably reduce pain in the appendicular skeleton for many patients, multiple factors can adversely affect outcomes and lead to suboptimal results in the spine. Nevertheless, eliminating motion at an arthritic functional spinal unit has been the surgical answer for many years to painful degeneration of the spine, both to decrease symptoms and to prevent further instability. Successful patient outcomes from lumbar spinal fusion range from 60% to 85%. These studies demonstrate the complexity of the surgical approach to low back pain. For example, pain relief can be incomplete even in patients with radiographic evidence of solid spine fusion. This suggests that fusion of the arthritic functional spinal unit may not be the answer and that the pain could be from another source.

Adjacent spinal disk segment disease is also a well-described entity that can develop after cervical and lumbar spine fusion. It is unclear whether adjacent segment disease is related to altered biomechanics, natural history of disk degeneration, a genetic predisposition, or, more likely, a combination of several of these factors. As well, harvesting autologous iliac crest bone graft for spinal fusion can be associated with considerable donor site morbidity. However, in a landmark study, Fritzell et al prospectively demonstrated that, compared to nonsurgical modalities, lumbar spine fusion significantly ($P = 0.0002$) improved outcomes in patients with chronic low back pain. Furthermore, better patient selection, improved spinal instrumentation, and biologics to improve bone healing have accounted collectively for increased rates of solid fusion. As a result, all current US Food and Drug Administration (FDA) investigational device exemption (IDE) studies involving TDAs use spine fusion as the control treatment.

Theory of Disk Arthroplasty

The intervertebral disk consists of an outer annulus fibrosus and inner nucleus pulposus. When healthy, the intervertebral disk cushions the axial load of the spine during weight bearing while acting as a joint during spinal motion for translation and rotation. Over time and with continued stress, the spinal disks may degenerate and lose their inherent mechanical properties, occasionally resulting in abnormal motion and pain.

TDAs were developed to replace the diseased disk and to alleviate pain and restore functional motion at the level of the disk replacement. The prostheses have been designed using principles derived from total hip and knee arthroplasties. The primary goal of TDAs is to remove the pain generator while maintaining disk height, ensuring spinal stability, and preserving motion. In comparison with fusion, this approach would potentially have two distinct advantages. First, no fusion must occur; therefore, pseudarthrosis is removed as a potential complication, allowing for earlier patient mobility. Second, by preserving motion, the TDA may decrease the incidence of adjacent spine segment degeneration by reducing stress at adjacent spine levels.

In vitro biomechanical research has shown normalization of adjacent segment alterations after TDA implantation in cadaveric specimens. In addition, several short-term clinical studies have confirmed that, not only do patients experience symptom relief, but recovery time also is comparable. Furthermore, radiographic motion is maintained with TDA compared with fusion. How this will affect intermediate and long-term outcome, however, is unknown.

History and Current Design Concepts

In the late 1950s, Fernstrom implanted the first disk prosthesis into the cervical and lumbar spines of humans. The prosthesis consisted solely of a steel ball placed within the annulus fibrosus after the nucleus pulposus had been removed. The theory was to maintain height and motion. Predictably, after a short period of symptom relief, the prosthesis ultimately failed secondary to subsidence of the implant within the spine vetebra. Since the introduction of that prototype, more complex designed prostheses have been developed to replicate the mechanical functions of a healthy spinal disk.

Disk arthroplasty can be classified as either nuclear replacement and TDA; TDA is discussed below. Current designs of both lumbar and cervical disks are a “ball and socket” or trough. Essentially, the functional characteristics of a prosthesis...
should include long-term endurance (to last the lifetime of a patient), composition of biologically compatible materials, and avoidance of premature disintegration.\textsuperscript{17}

**Indications**

As with spinal fusion, the success of TDA is highly dependent on patient selection. This well-recognized fact is reflected by the current inclusion and exclusion criteria for enrollment in the FDA IDE trials for a possible TDA\textsuperscript{18,19} (Table 1). Of particular importance is that the primary indication for lumbar TDA is isolated discogenic low back pain without instability. This differs from the cervical spine, where TDAs replace fusion (when no instability is present) after decompression for radiculopathy/myelopathy. It is hoped that, as experience is gained with TDAs, the list of inclusion criteria will be modified to ensure safe and effective implantation of these prostheses.

With more widespread application of TDAs in the near future, spine surgeons will continue to push the currently accepted indications. What will happen to the complication rate when strict guidelines are not followed is unknown. Already, however, reports of implanting TDAs at degenerated juxtafusional levels\textsuperscript{20} and revising failed TDAs with another TDA\textsuperscript{21} have been published.

**Surgical Technique**

The surgical technique for both cervical and lumbar TDAs uses an anterior approach. In the cervical spine, a standard Smith-Robinson approach is used to gain access to the desired disk space. Frequently in the lumbar spine, a general or vascular surgeon assists in accessing the diseased level through an anterior retroperitoneal dissection.

Once adequate exposure is achieved, the intervertebral disk is removed and the end plates of the vertebral bodies are prepared. An important step is adequately releasing the posterior anulus fibrosus to allow correct positioning and function of the prosthesis. At this point, each implant system varies in specific technique; essentially, however, before implanting the final prosthesis, the proper size and lordotic angle is determined with anteroposterior/lateral fluoroscopy to ensure proper spinal implant placement.

### Lumbar Disk Arthroplasty

To date, the most experience and interest in lumbar TDA has been for treatment of discogenic low back pain. In Europe, thousands of prostheses have been implanted since the mid-1980s. However, reports of efficacy have been criticized for their retrospective nature and lack of randomization with controls.

The first TDA in the lumbar spine to be implanted in the United States was the SB Charité III (DePuy Spine, Raynham, MA) in March 2000, as part of a controlled randomized study. Other prostheses currently under investigation include the ProDisc-L (Spine Solutions/Synthes, Paoli, PA), Maverick (Medtronic Sofamor Danek, Memphis, TN), and FlexiCore (Stryker Spine, Allendale, NJ). Each design has specific differences with respect to material, bearing surface, number of articulations, constraint, mobility of the center of rotation, and fixation to bone\textsuperscript{22} (Table 2).

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Current Indications for Total Disk Arthroplasty\textsuperscript{18,19}</th>
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<tbody>
<tr>
<td><strong>Criteria</strong></td>
<td><strong>Cervical</strong></td>
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<tr>
<td><strong>Inclusion</strong></td>
<td>Young age (18-65 yr)</td>
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<td>Subjective and objective evidence of radiculopathy/myelopathy with 1- to 3-level disk disease ± axial neck pain; concordant with CT/MRI</td>
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<tr>
<td>Failure of &gt;6 wk of conservative treatment</td>
<td>Central/lateral recess stenosis</td>
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<tr>
<td><strong>Exclusion</strong></td>
<td>AS, RA, OPLL, DISH</td>
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<tr>
<td>Insulin-dependent diabetes mellitus</td>
<td>Facet arthropathy</td>
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<tr>
<td>Cervical instability</td>
<td>Spondylolysis/ spondylolisthesis</td>
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<tr>
<td>Previous cervical fusion/ infection/fracture</td>
<td>Radiculopathy secondary to HNP</td>
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<tr>
<td>Osteoporosis</td>
<td>Scoliosis</td>
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<td>Chronic corticosteroid use</td>
<td>Osteoporosis</td>
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<tr>
<td>Obesity</td>
<td>Chronic corticosteroid use</td>
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<tr>
<td>Pregnancy</td>
<td>Previous lumbar fusion/infection/fracture</td>
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<tr>
<td>Isolated axial neck pain</td>
<td>Obesity (&gt;1 SD over ideal body weight)</td>
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<td></td>
<td>Pregnancy</td>
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The initial design of the SB Charité III, developed by Buttner-Janz and Schellnack, consisted of small bottlecap-like end plates with a polyethylene core. Because of the increased stress concentration over a small contact surface area, subsidence into the vertebral bodies became a concern. The next generation used thin lateral extensions to augment the surface area, but these succumbed to fatigue fracture.

The SB Charité III has end plates manufactured from cobalt-chromium-molybdenum (CoCrMo) alloy with small fins projecting into the vertebral bodies (Figure 1). To assist bony ingrowth, the outer layer is porous-coated with plasma-sprayed titanium and calcium phosphate (TiCaP), which is available only outside the United States. An important feature of the SB Charité III is the sliding, unconstrained biconvex polyethylene core, which is designed to allow for an instantaneous axis of rotation during flexion and extension, more closely paralleling the natural motion of the native disk (Figure 2).
However, there are potential disadvantages to the SB Charité III disk. Because it has two articulations, over time it is theoretically more prone to polyethylene wear and debris than are single-articulation designs. In addition, as an unconstrained device, the risk of polyethylene extrusion is greater and potentially catastrophic. Although the extent of complications is currently unknown, early clinical reports suggest a low incidence. At 2-year follow-up, Guyer et al\textsuperscript{23} reported similar significant ($P < 0.001$) improvements in Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores for both 100 patients with the SB Charité III and 44 patients with an anterior fusion (BAK Interbody Fusion System, Zimmer Spine, Warsaw, IN). Three patients in the Charité group required additional posterior spinal fusion for persistent pain, but no cases of dislodgement, significant subsidence, loosening, or infections were reported.

The ProDisc I (Spine Solutions/Synthes), developed by Marnay in the 1980s, was designed in France and implanted first in 1990. With an average 8.7-year follow-up, Troppiano et al\textsuperscript{24} reported 75% good to excellent results in their series. Most recently, the ProDisc-L has achieved FDA approval after undergoing modifications, including changing the end plate metal from titanium to CoCrMo and adding the polyethylene core bearing as a separate modular piece [Figure 3]. In contrast with the SB Charité III, end plate fixation is accomplished with a single, large, porous-coated, midline sagittal keel. The polyethylene core is snap-fit and fixed to the inferior end plate, resulting in a semiconstrained design, which hypothetically decreases the risk of extrusion. On the other hand, the fixed axis of rotation does not allow for coupled vertebral translation with flexion and extension. Proponents claim that a degenerated disk segment has an increased range of motion; thus, the semiconstrained design permits stability during a more controlled arc of motion and protects the facet joints from shear. Opponents of this model argue that abnormal forces generated could shift to the bone–end plate interface, causing loosening\textsuperscript{25}

Nevertheless, early results with the ProDisc-L have been encouraging. Delamarter et al\textsuperscript{26} reported significant ($P < 0.05$) reduction in pain (VAS) and disability (ODI) with ProDisc-L at 6- and 12-week follow-ups. By 6 months, however, the relative improvements were similar for patients with the ProDisc-L and those with anterior/posterior lumbar spine fusion. In a separate study, Troppiano et al\textsuperscript{27} showed similar improvements in functional scores but an associated 9% complication rate and 6% revision rate in 53 patients treated with ProDisc-L (average follow-up, 1.4-years).

The Maverick Artificial Disk [Medtronic Sofamor Danek] was first implanted in Europe in early 2002.
The characteristic feature of this prosthesis is its CoCrMo metal-on-metal bearing surface (Figure 4). Recent biomechanical and biomaterial research on articulating surfaces has shown that metal-on-metal bearings generate significantly fewer wear particles and stimulate less of an immune response than do metal-on-polyethylene bearings. The bottom end plate includes a superiorly projecting dome that articulates with a matching concavity from the superior end plate.

Like the ProDisc-L, the Maverick uses large, porous-coated keels for fixation and a semiconstrained design. However, with the intention of more accurately reproducing normal spinal motion, the fixed axis of rotation is slightly more posterior compared with that of the ProDisc-L. Even so, the same theoretic advantages or disadvantages of a semiconstrained system apply to the Maverick. Recently, Mathews et al reported an average 36-point improvement in ODI scores in seven patients with the Maverick Artificial Disk at 18 months postsurgery.

The FlexiCore Intervertebral Disc (Stryker Spine) is the latest prosthesis to begin an FDA IDE clinical trial. This disk also has a metal-on-metal (CoCrMo) articulating surface with titanium porous coating for bony ingrowth (Figure 5). The unique feature of the FlexiCore disk, however, is the fully constrained design. To date, no published data are available on the FlexiCore prosthesis.

Cervical Disk Arthroplasty

Treatment of isolated discogenic neck pain with cervical fusion is controversial. However, in patients who have radiculopathy/myelopathy and/or instability secondary to degenerated disks, anterior disectomy and fusion has been shown to have a high rate of success. However, notable percentages of adjacent spinal segment disease after cervical fusion have been reported. Swallowing difficulty secondary to anterior plate fixation also has been described. In an effort to avoid these complications, cervical spine TDAs have been manufactured and implanted in humans internationally. In the United States, FDA-sponsored IDE trials have begun in the last year.

The Bryan Cervical Disk (Medtronic Sofamor Danek) is an unconstrained, biarticulating, metal-on-polyurethane prosthesis (Figure 6). The metal is titanium alloy with porous-coated end plates. The Bryan disk contains a polyurethane sheath surrounding the nucleus; the sheath is filled with saline, which acts as synovial fluid. Hypothetically, this would aid in keeping any potential wear debris within the cavity while preventing soft-tissue ingrowth. In vivo testing has confirmed satisfactory wear characteristics without producing a significant inflammatory response. At 2-year clinical follow-up, Goffin et al reported excellent, good, or fair outcomes in 44 of 49 patients (90%) implanted with a single-level Bryan disk. Radiographically, a high percentage (93%) demonstrated >2° of flexion-extension (signifying motion) at the implanted level (Figure 7). At the same time, problems in maintaining focal cervical lordosis have been described.

The Prestige ST (Medtronic Sofamor Danek) is a modification of the Prestige II (Figure 8), Prestige I, and original Bristol-Cummins disk. Its articulation is also metal-on-metal (stainless steel) but, in contrast with other designs, the fixation is through a screw-locking mechanism into the vertebral body, similar to anterior cervical plates. Following the relative success of its precursors, Porchet and Metcalf prospectively re-
ported similar improvements in patient outcome measures with the Prestige II device compared with fusion. Traynelis reported that the Prestige disk successfully preserves normal spinal range of motion (follow-up, 2 years).

The Porous Coated Motion artificial cervical disk (Cervitech, Rockaway, NJ) is a minimally constrained prosthesis with cobalt-chromium alloy end plates, TiCaP porous-coated serrated surfaces, and a polyethylene core affixed to the inferior end plate. Short-term clinical results are encouraging. At 1-year follow-up of 53 patients, Pimenta et al showed significant improvements in VAS and Neck Disability Index scores, with 97% of patients reporting excellent or good results.

The ProDisc-C (Spine Solutions/Synthes) is very similar in design to its lumbar counterpart. Although in vitro biomechanical analyses show favorable results, no clinical outcomes are available to date.

**Complications**

van Ooij et al reported on 27 cases of failed SB Charité prostheses. At an average of 53 months after surgery, adjacent level spinal disease, subsidence, and facet joint arthrosis were the most common causes of failure.

Two patients experienced anterior dislocation of the implant; overall, 11 patients required additional salvage surgery.

Low incidences of infection, vertebral body fracture, implant malposition, subsidence, mechanical failure, and paravertebral heterotopic ossification also have been reported by authors of the ongoing clinical trials. Because follow-up is relatively short-term, it is likely that most morbidities have been related to technique and/or to surgical approach and not to the implant itself. However, it is too early to fully determine all of the potential complications that may be associated with TDAs.

**Questions for the Future**

Many questions remain unanswered regarding the safety and efficacy of TDAs over the long term. For example, will TDAs be superior to spinal fusion or simply be an option in a subset of cases? Who will be the ideal patient? How many patients will fit the current or future inclusion and exclusion criteria? Can we reliably and accurately predict who will have improved symptoms while maintaining spinal stability and motion? How long can we expect these prostheses to last before failing? What will be the optimal design? Will the property of shock absorption of a healthy disk, not addressed by current TDAs, be an issue?

With variations in the current prostheses (and with more designs emerging), the clinical outcomes of each will, in time, provide answers to these questions. However, biologic treatment, including intradiscal
administration of growth factors such as osteogenic protein-1\textsuperscript{38} and/or gene therapy, also may become readily available to help regenerate diseased disks.

Several biomechanical and short-term clinical studies have demonstrated that TDAs preserve motion. Huang et al\textsuperscript{39} retrospectively reported on 58 ProDisc implants at a mean follow-up of 8.7 years; 66\% of prostheses retained $>2^\circ$ of motion at the implanted level. Although the incidence of adjacent segment disk degeneration in their series was 24\%, no patients required further surgery. Furthermore, there seemed to be an association between implant range of motion and development of junctional degeneration.\textsuperscript{39} Will this hold true in longer follow-ups? If so, will it decrease the incidence of adjacent spinal segment disease?

**How reliably will surgeons be able to accurately implant the prostheses and replicate physiologic motion?** McAfee et al\textsuperscript{40} concluded that, at a minimum 2-year follow-up of 205 patients, accurate surgical placement of the SB Charité III significantly correlated with clinical outcomes including ODI, VAS, and range of motion ($P < 0.001$ for all). As surgeons who are at the “top of the learning curve” in terms of experience, these authors were able to implant the Charité in an “ideal” position (defined as within 3 mm of ideal in both planes) only 83\% of the time. It can be expected that, with more general use by spine surgeons who are less familiar with the procedure, and who have performed fewer procedures, this percentage will be noticeably lower.

Will there be any adverse effects from wear particles in the spine? Aseptic loosening secondary to osteolysis and peri-implant immune responses are of particular concern. In addition, the systemic effect of metal ions from metal-on-metal articulations, including carcinogenicity, is currently unknown. Loads sustained by a single intervertebral disk during normal activity, although not insignificant, are considerably less than those of a hip or knee. As a result, simulated wear cycling of TDAs predicts that prosthesis wear is relatively low in vivo and that the likelihood is minute of these small amounts of debris causing a significant inflammatory response within the epidural tissues.\textsuperscript{41}

How will we deal with the complications and manage revision surgeries? One opinion is that a TDA will not “burn any bridges,” that failure is salvageable with fusion. Is this the case? Notwithstanding the potential devastation from implant dislocation, difficulties with repeat anterior surgical exposure of the spine, subsidence, osteolysis, and subsequent bone loss may be extremely challenging to repair.

Finally, if current and future research proves that TDA is superior to fusion in a select group of patients, will TDA be more cost-effective in the long run? Recently, Singh et al\textsuperscript{42} reported that, by 2010, an estimated $2.18$ billion will be spent on spinal arthroplasty procedures in the United States.

**Summary**

TDA is a novel and exciting technology for spine surgeons to consider as a possible alternative to fusion. Potential advantages include motion preservation, thereby preventing (or at least postponing) adjacent segment disease; shorter recovery time; and avoidance of fusion-related complications. Two lumbar designs have been recently approved by the FDA for commercial use; others will follow. Short-term clinical results appear to be promising, with acceptable complication rates, but should continue to be critically analyzed in peer-reviewed literature. Whether hypothetic advantages will outweigh potential pitfalls has yet to be determined. Only as reliable, prospective, long-term outcomes data and cost-analysis research become available will we understand the true place of TDA in spine surgery.

**References**

Citation numbers printed in bold type indicate references published within the past 5 years.

**Evidence-based Medicine:** Level I studies include references 11, 23, 24, 26, 27, and 40. Level II studies include references 1 through 10, 12 through 16, 28, 29, 31 through 36, 39, 41, and 42. Level III studies include references 18, 20, and 37.


41. Anderson PA, Rouleau JP, Toth JM,