Spinal arthroplasty: Indications and early results. What will the future hold?

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Total joint replacement for end-stage arthritis of the hip and knee has revolutionized the field of orthopaedic surgery. Both primary total hip and knee replacement have resulted in high rates of patient satisfaction and surgeons and patients have become accustomed to excellent long-term results.

Spine surgeons and industry are now attempting to achieve similar results with spinal arthroplasty, i.e. total intervertebral disc replacement, for the treatment of degenerative disc disease (DDD). Lumbar and Cervical disc replacement have been proposed for one or two levels of DDD.

Arthrodesis (fusion) has been the preferred treatment for DDD in the lumbar spine for over 100 years. Degeneration of the intervertebral disc is felt to be the main component of the pain seen in DDD. Because every year, substantial numbers of patients fail to benefit from nonoperative therapies, the numbers of lumbar fusions has risen rapidly over the last 2 decades(1, 2). However spine surgeons have long recognized that lumbar fusion for DDD is not as successful as for other diagnoses such as spinal stenosis with instability and spondylolisthesis(2). Specifically, adjacent segment degeneration is now a well recognized long term complication of spine fusion surgery (3). It has been shown that as one segment stiffens after fusion, adjacent segment hypermobility above and below the fusion site leads to accelerated degeneration in those segments (4,5). Despite this problem, lumbar spine fusion still remains the major surgical procedure for those patients who have exhausted conservative measures with unremitting axial back pain from DDD. Now spinal arthroplasty with an artificial disc replacement has been proposed as an alternative to fusion for patients with symptomatic DDD thus avoiding adjacent segment degeneration.

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Surgeons must have professional expectations that are increasingly being demanded by the public for any new procedure that they have not performed and whose long-term outcomes are unknown. In the past, surgeons often performed new procedures without oversight and surgical privileges were unlimited in their specialty. Outcomes were not scrutinized as they are today and there was less concern for cost. In today's medical environment shared decision making between surgeons and patients is expected. Any new procedure demands an institutional review board (IRB) oversight. Surgical privileges are being defined by subspecialties where unique skills are required. Costs are increasingly important and outcome studies are increasingly expected. If these challenges for our profession are not enough, the practice environment is becoming even more complicated with the increase of direct marketing to the consumer, i.e. patients. Tom Russell, MD, the Executive Director of the American College of Surgeons recently stated: "It is sad to see the principles of market economics overtake the profession's long-held emphasis on the precepts of quality, self-regulation, education, training and patient care."

Disc arthroplasty was first considered in the early 1950's in an attempt to achieve the major goals of maintaining mobility of the intervertebral motion segment and restoring natural disc function (6). Fernstrom first implanted a stainless steel ball bearing into the disc space after discectomy in 1966. These and other implants developed in the 1960s and 1970s were not successful because of poor durability, toxicity, and migration. Since the beginning of implant development, more than 70 different materials and devices have evolved but few have entered into clinical trials (7).

What are the goals of cervical and lumbar total disc replacement? Like fusion, they are to remove the painful and degenerated disc, restore disc height therefore re-establishing the height of the intervertebral foramen, increase the volume of the spinal canal, and restore sagittal alignment. But unlike fusion, arthroplasty aims to maintain intervertebral motion at the disc space. By preserving motion at the involved segment of the spine, theoretically the forces across adjacent segments will not increase and thus minimize the problem of adjacent segment degeneration (2).

A summary of the current indications for lumbar disc replacement with the current FDA investigational devices is as follows (8). Both male and female patients should be optimally below age 50. Patients should have DDD at one or two levels and have a positive discogram, demonstrating concordant pain

reproduction with at least one control disc level that does not reproduce the patient's symptoms. Radiographically, patients should have a contained herniated nucleus pulposus, a paucity of posterior facet joint degeneration changes, a decrease in the intervertebral disc height of at least 4 mm, and scarring of the annulus fibrosis with osteophytes indicating osteoarthritis. The patient should have nonradicular leg pain or back pain in the absence of nerve root compression or stenosis. All candidates should have exhausted conservative therapy.

The indications for cervical disc replacement are the same as for lumbar disc degeneration but in contrast also include nerve pain: radiculopathy or myelopathy caused by either one, two or three levels of anterior cervical compression (9-10). As with lumbar disc replacement, the goal is to prevent adjacent segment degeneration following a fusion which has proven to be a major problem affecting the long term success of anterior cervical spine fusions (11). Importantly, in contrast to the indications for cervical disc replacement, leg pain radiculopathy in the lumbar spine would disqualify a patient from receiving lumbar disc replacement. On the other hand, while pure axial back pain from DDD qualifies a patient for lumbar disc replacement, axial neck pain without neurological abnormality actually disqualifies the patient from cervical disc replacement. The following diagnoses at one to three levels from C3-T1 can qualify a patient for cervical disc replacement: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy or spondyotic myelopathy. Exclusion criteria include diagnoses like ankylosing spondylitis, rheumatoid arthritis, ossification of posterior longitudinal ligament, or diffuse idiopathic skeletal hyperostosis. As in the lumbar spine, exclusion criteria include insulin-requiring diabetes mellitus, prior cervical spinal infection, chronic steroid use, morbid obesity, and pregnancy (8).

Several studies have recently shown that lumbar disc replacement can provide similar or better outcomes than fusion at least in the short term, namely 1 to 2 years. In 1999, an FDA sponsored IDE (Investigational Device Exemption) study comparing artificial disc replacement with spine fusions was initiated. 15 hospital centers participated in a 2:1 randomization study. Guyer et al. (12) have recently shown that the Charite (DePuy Spine, Raynham, MA) artificial disc provides similar patient satisfaction outcomes at 24 months when compared to the BAK (Spine Tech Inc, Minneapolis, MN) anterior interbody fusion. These authors also reported that the complications of total disc replacement were similar to those encountered with BAK anterior interbody fusion. More importantly, there were no device related failures or complications and almost 90 percent of patients returned to work within 3 months.

Zigler (13) has reported 6 month and 1 year followup on ProDisc II (Synthes, Paoli, PA), a similar device that is completing its IDE, in comparison with a 360 degree anterior and posterior fusion. He has reported improved patient satisfaction and improved recreational activity at both 6 months and 1 year. Zigler however reported some significant complications in the artificial disc group. These included a dislodgement of the polyethylene spacer that was improperly inserted and an iliac vein laceration that required repair. Similar outcomes and complications are reported in short-term follow up from several European centers and South Africa (14-15). These include osteolysis and surrounding tissue inflammatory reactions from polyethylene wear debris, problems often seen in the early years of joint replacement surgery.

Others have also cited some complications with artificial disc replacement. Van Ooij et al have reported on 27 patients who had failed Charite disc replacements (16). Early complications included an anterior displacement of the prosthesis 1 week after surgery. Another patient that had undergone replacement at both the L4-L5 and L5-S1 levels needed removal of the L5-S1 prosthesis 12 months after surgery also for anterior dislocation. Four patients in this study experienced an abdominal wall hematoma. 2 patients developed neurologic complications including retrograde ejaculation and difficulty obtaining an erection.

Potential long-term complications associated with disc replacement also remain. Polyethylene wear and the resulting inflammatory cascade could lead to scar formation and nerve damage while periprosthetic loosening and fibrosis could pose a very difficult challenge for the revision surgeon. Loss of bone stock in the vertebral body above and below a loose prosthesis would indeed lessen the chance of successful fusion after a revision operation. Periprosthetic loosening resulting from infection may prove difficult to differentiate from loosening resulting from other causes (17).

Most short-term complications seem to be related to the surgical procedure itself suggesting that a learning curve exists among spine surgeons. Disc arthroplasty is a technically demanding procedure, requiring very precise preparation of the intervertebral space and careful positioning of the components. Any malposition of the components might lead to new symptoms from facet arthropathy as well as adjacent level disc pathology. Surgeons are going to be expected to participate in extensive cadaveric practice before installing these devices in their patients.

It must be stressed that short term follow up does not address the main theoretical advantage of the lumbar or cervical disc replacement: the avoidance of adjacent segment degeneration. We will need approximately five to ten years of followup to document this. While many centers are clinically studying disc arthroplasty in the cervical spine, prospective randomized trials comparing cervical disc replacement with fusion are still lacking at this time.

It is important that stringent indications be followed in addition to the recognition that a significant learning curve exists with disc replacement surgery. The critical issues for success will be patient selection, sizing and positioning of the components and the experience that surgeons have in the anterior approach to the lumbar and cervical spine. All decisions regarding disc replacement surgery should take these factors into account. Patients should be aware, finally, that although the early results seem promising, any long term improvement

over that of fusion remains theoretical, and a very cautious approach should be taken by both surgeon and patient.

As of this writing, only the SB Charite disc (DePuy Spine, Raynham , MA) has completed its IDE and is approved for use by the FDA. Surgeons, however, must attend a minimum of three training sessions before being granted access. The ProDisc II (Synthes, Paoli, PA) is soon to conclude its IDE and will be marketed soon. In keeping with Dr. Russell's comment we suggest that, in addition to surgeons obtaining the required training before inserting an artificial disc, they practice the surgical technique in cadavers and most importantly use the IRB process to ensure that patients are properly informed and that long-term outcomes of this new technology are measured and reported. We urge spine surgeons to organize a national spinal artificial disc registry to record all data. By doing so they will continue to ensure high-quality, patient-centered care, self-regulation and education.

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