Lumbar Spinal Fusion Alternatives—Review of Emerging Spinal Technologies

a report by
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The traditional answer to a painful, deteriorated joint in orthopaedics has historically been a fusion procedure. Through immobilization and obliteration of the joint, the pain from motion was then eliminated. In doing so, orthopaedists have been trying to mimic the natural history of degenerative joint disease (DJD) in its final stage—an ankylosed painless joint. The price is great however, as the motion of the fused joint is lost and results in overloading of the adjacent joints. For that reason, it became reasonable to apply some of the basic principles of total hip and knee replacements toward the spine. This heralded the new era of spinal arthroplasty and motion preservation, which started in Europe, and has subsequently spread all over the world including to the US.

Indication for Fusion

The main indications for a fusion in the adult lumbar spine include instability, infectious and neoplastic processes; and symptomatic deformity. Discogenic low back pain is also generally considered to be an indication for a fusion in the absence of psychiatric comorbidities and secondary gain issues.

Fusion Alternatives

The motion-preserving devices that are already in investigational and clinical use include total disc replacements, both cervical and lumbar, the X STOP, the Dynesis device and nucleus replacements. These technologies are mostly applicable to adult degenerative disk disease and spinal stenosis with or without spondylolysthesis, which represent a substantial majority of cases encountered in the adult spine surgery practice.

Lumbar Total Disc Replacement

The main rationale for using total disc replacement (TDR) is not so much preservation of motion as avoidance of adjacent level degeneration, which can lead to additional surgery in up to 3% per year of patients undergoing fusion.

Currently there are four main lumbar TDR systems in the clinical use in the US: Charité III (DePuy, US Food and Drug Administration (FDA)-approved), ProDisc II (Synthes, FDA-approved), Maverick (Sofamor Danek, investigational) and Flexicore (Stryker Spine, investigational). With regard to the constraint (limitation of motion), TDRs can be unconstrained (Charité), semi-constrained (ProDisc and Maverick) and constrained (Flexicore). With regard to bearing surfaces, the TDRs can be divided onto polyethylene-on-metal (Charité and ProDisc) and metal-on-metal (Maverick and Flexicore) articulations.

Guyer et al. in the FDA study investigated 144 patients with symptomatic degenerative disc disease treated with Charité artificial disc vs BAK cage.[1] The mean Oswestry Disability Index (ODI) score for the BAK group was 69 pre-operatively and 27 at 24-month follow-up ($p<.001$). The corresponding mean Oswestry score for the Charité disc patients was 71 pre-operatively and 30 at 24-month follow-up ($p<.001$). The authors have concluded that total disc replacement appears to be a viable alternative to fusion for the treatment of single-level symptomatic disc degeneration unresponsive to nonoperative management.

Flexicore has been a part of an on-going FDA investigational device exemption (IDE) trial and the preliminary results have been promising to date. The range of motion (ROM) post-operatively was comparable to the motion pre-operatively. Pre-operative flexion/extension motion decreased from 7° to 5° post-operatively, and lateral bending was maintained at 4° from pre-operative to post-operative. Emerging data also has been accumulating that two-level total disc arthroplasty (TDA) also has a significant place for the treatment of symptomatic disc degeneration at multiple levels and that the results might be at least as good as those of fusion and possibly one-level arthroplasty. Initial data comparing two-level Flexicore to one-level Flexicore and fusion demonstrated similar results to that of fusion with regard to both the ODI and visual analogue scale (VAS) back scores. At two-year follow-up the ODI decreased from 62.0 to 40.5 for two-level, while for one-level ODI decreased from 56.4 to 36.3, for the fusion ODI

decreased from 63.0 to 43.6. VAS scores demonstrated similar trends. The pre-operative score for was 7.7 for two-level; 8.4 for one-level; and 8.4 for the fusion. VAS post-operative was 4.7 for two-level; 3.8 for one-level; and 4.5 for the fusion. The study was limited, however, by the number of patients involved in the study (Sahai, unpublished data).

In another study, two-level Prodisc was compared with one-level Prodisc at two-year follow-up. There was a 37% reduction in VAS compared with 47% for one-level that was not clinically significant. ODI decreased 28% for two-level relative to a 38% decrease for one-level that was also not a clinically significant difference (Hannibal, submitted for publication).

In summary, lumbar TDR is a new and promising surgical technique. More studies are needed to clarify the optimal type of constraint in those devices as well as the best combination of biomaterials to be used.

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Interspinous Process Decompression

Spacers placed between the lumbar spinous processes represent a promising surgical treatment alternative for a variety of spinal pathologies. Intuitively, they provide a flexion-distraction force and have a potential to relieve the symptoms of neurogenic intermittent claudication (NIC), associated with spinal stenosis. The first interspinous process decompression (IPD) device to be used in the US is the X STOP device, which is FDA-approved for the treatment of patients with spinal stenosis. The ideal patient for the X STOP implantation has predominantly lower extremity complaints with limited axial symptoms secondary to mild-to moderate lumbar spinal stenosis at one or two levels. The symptoms should be relieved with flexion.

Zucherman et al. have demonstrated that IPD with the X STOP is superior to non-operative therapy in patients with neurogenic intermittent claudication secondary to spinal stenosis in the multi-center randomized study at one and two years post-operatively.[2-3] At two-year follow-up, 57% of the patients reported a clinically significant improvement in their physical function compared with 15% of the control based on the Zurich Claudication Questionnaire. Seventy-three per cent of the X STOP patients were at least somewhat satisfied compared with 36% of the controls. At all follow-up time points, the X STOP group scored significantly better than the control group in every physical domain. Kondrashov et al. have reported on 18 X STOP patients at the average 4.2-year follow-up.[4] Using a 15-point improvement from baseline ODI score as a success criterion, 14/18 patients (78%) had successful outcomes at follow-up.

Hannibal et al. have compared the hospital costs of IPD with X STOP device to those of laminectomy for the treatment of patients with lumbar spinal stenosis (LSS).[5] Twenty-nine patients with LSS treated surgically were matched for age, length of follow-up and pre-operative Oswestry scores. Eighteen out of 29 had X STOP implantation and 11/29 had laminectomy. The average follow-up was 51 months in both groups. The Oswestry improvement was 29 points in the X STOP group and 10 in the laminectomy group. Average hospital costs for one-level X STOP and laminectomy group were US$17,059 and US$45,302, respectively. Average hospital costs for two-level X STOP and laminectomy groups were US$24,353 and US$45,739, respectively.

Interspinous process decompression with X STOP is an effective treatment for surgical treatment of lumbar spinal stenosis with or without low-grade degenerative spondylolysthesis. The existing level I and III data suggest that it is at least as effective as lumbar decompressive surgery at 2–4 year follow-up and offers significant savings in direct hospital costs over standard laminectomy.

Dynamic Stabilization—The Dynesis System

The Dynesys system is a pedicle screw-based system with a polyethylene cord and a polyurethane spacer connecting the screws instead of the conventional metal rods. The cord and the spacer do permit some motion (hence the term 'dynamic') but with certain restrictions (hence 'stabilization'). With the Dynesys system, no bone grafting is necessary, therefore donor site morbidity can be avoided. The European experience with Dynesys had been marked by initial great

enthusiasm, followed by some skepticism, once the intermediate-term data became available. Schnake et al. reported on the German experience in 26 patients (mean age 71 years) with lumbar spinal stenosis and degenerative spondylolisthesis who underwent lumbar decompression and dynamic stabilization with the Dynesys system at a minimum follow-up of two years.[6] Mean leg pain decreased significantly ($p<0.01$), and mean walking distance improved significantly to more than 1,000m ($p<0.01$). There were five patients (21%) who still had some claudication. A total of 21 patients (87.5%) would undergo the same procedure again.

Dynamic stabilization of the lumbar spine with Dynesys appears to be a promising alternative to a fusion with some reservations about the longevity and loosening of the screws.

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Nucleus Pulposus Replacement

Another alternative for fusion in the face of degenerative disc disease that has arisen in the last several years is nucleus pulposus replacement (NPR). Intradiscal devices are biomechanically more similar to native NP tissue while *in situ* polymers harden after implantation. The most extensively studied NPR to date is the Prosthetic Disc Nucleus (Raymedica, Inc., Bloomington, MN), which is currently undergoing FDA IDE trials. It is a hydrogel pellet encased in a polyethylene jacket, capable of absorbing 80% of its weight in water. Initial biomechanical studies have been favorable to this point, demonstrating that the device is able to maintain disc height, implant form and viscoelasticity up to 50 million cycles. Four-year follow-up data on 350 patients reported improvements in Oswestry pain measurement from 52 to 8.3 and in VAS from 7.0 to 1.9.[7]

NPR is relatively new technology that does hold promise. Only preliminary studies are available and the technology does require more study before any definitive conclusions can be drawn.

Summary

In summary, recently there has been an explosion of motion-preserving techniques and devices in both cervical and lumbar spine surgery. They pose a tempting alternative to spinal fusion. This emphasizes the need to adhere to strict indications for implantation as the success of these devices has been noted in only selected groups of patients. With continued careful interpretation of the biomechanical and clinical data and increased surgical experience, motion preserving technology does seem to usher in a new era of spine surgery. ■

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