Lumbar Spinal Fusion Alternatives—Review of Emerging Spinal Technologies

a report by
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The traditional STanswer for a painful deteriorated joint in orthopaedics has historically been a fusion procedure. By immobilizing a joint and obliterating it, the pain from abnormal motion is eliminated. Sometimes, nature accomplishes this at the end stage of degenerative joint disease (DJD), which ends up in the ankylosed painless joint. The rationale of doing a fusion has been to speed up the natural process of ankylosis. The price is great, however, as the motion of the fused joint is lost, which overloads the adjacent joints, as well as diminishing mobility. Hip and knee fusions are rarely seen now as other ways have been discovered to stabilize joints and reduce the amount of inflammatory tissue. In the hip and knee, the answer to end-stage arthritis has been total and partial joint replacements for the last several decades. These entail much quicker healing time than fusions, restoration of approximate joint function, and removal of deteriorated joint tissues, which are a source of pain and inflammation. Both total hip replacement (THR) and total knee replacement (TKR) are remarkably common and represent some of the most successful procedures in orthopaedics. It has been appropriate to apply some of the principles of THR and TKR, including the biomaterials, concepts of constraint, and modes of fixation to the spine. This heralded the new era of spinal arthroplasty and motion preservation. In US spine surgery in recent years, new vistas of technology have been entered that will hopefully be superior to fusions in patient morbidity, safety, and efficacy. The motion-preserving devices that are already in clinical use include total disc replacement (TDR), both cervical and lumbar, the X STOP device, and the Dynesis device, among others.

Lumbar Spine Fusion Alternatives

The main indications for a fusion in the adult lumbar spine include degenerative instability (degenerative spondylolysthesis or multiple (two or more) recurrences of herniated nucleus pulposus at the same level); acute traumatic instability (two- or three-column injury); instability from chronic trauma (isthmic spondylolysthesis); developmental (dysplastic spondylolysthesis), infectious and neoplastic processes; and symptomatic coronal (scoliosis) and saggittal (kyphosis) plane deformity. Severely symptomatic one- or two-level disc degeneration (discogenic low back pain) is also generally considered to be an indication for a fusion in the absence of psychiatric co-morbidities and secondary gain issues, but still remains a controversial issue mostly due to the lack of accurate diagnostic testing. The technologies discussed here are mostly applicable to adult degenerative disc disease and spinal stenosis with or without spondylolysthesis, which represent a substantial majority of cases encountered in the adult spine surgery practice.

TDR

The natural extrapolation of the total hip and knee replacement to the spine has been the development of TDR. The main rationale for using 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 TDR systems in clinical use in the US: Charite III (DePuy, US Food and Drug Administration (FDA)-approved), ProDisc II (Synthe, FDA approval expected this year), Maverick (Sofamor Danek, investigational), and Flexicore (Stryker Spine, investigational). The four TDR systems have dramatic design differences, which is likely to have clinical consequences. With regard to constraint (limitation of motion), TDR systems can be unconstrained (Charite), semi-constrained (ProDisc and Maverick), and constrained (Flexicore). The early concerns with unconstrained TDR include device dislodgement, which has already been reported. Concerns with semi-constrained devices include overloading the posterior elements, causing fractures and accelerated facet arthrosis. With regard to bearing surfaces, the TDR systems can be divided into polyethylene-on-metal (Charite and ProDisc) and metal-on-metal (Maverick and Flexicore) articulations. The concerns with the former include polyethylene-wear debris and aseptic loosening, while concerns with the latter include some rare cases of metal allergy.

Lumbar TDR has been performed in Europe for more than 20 years for a variety of indications. In general, there is a lack of level I and II data summarizing that experience. Recently, however, there has been a

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requirement for FDA-mandated rigorous US studies regarding those prostheses.

In the most favorable of the several clinical series on the Charite device, Lemaire et al. have reported clinical and radiological outcomes for the artificial disc in 107 patients at minimum follow-up of 10 years. A total of 147 prostheses were implanted with 54 one-level and 45 two-level procedures, and one three-level procedure. The prostheses were placed through a standard anterior retroperitoneal approach. Clinically, 62% had an excellent outcome, 28% had a good outcome, and 10% had a poor outcome. Of the 95 eligible to return to work, 88 (91.5%) either returned to the same job as prior to surgery or a different job. Mean flexion/extension motion was 10° for all levels. Five patients required a secondary posterior fusion.

Guyer et al. in the FDA study investigated whether the patients with symptomatic degenerative disc disease treated with the Charite artificial disc (DePuy Spine) arthroplasty would show significant improvement in functional outcome measures, and to compare these results to Bagby and Kuslich (BAK) cage fusions (Zimmer Spine). They reported on a consecutive series of 144 patients randomized using a 2:1 ratio of Charite versus BAK. All patients were being treated for single-level discogenic pain confirmed by plain radiography, magnetic resonance imaging (MRI), and provocative discography. The mean Oswestry Disability Index score for the BAK group was 69 pre-operatively and 27 at 24-month follow-up ($p < 0.001$). The corresponding mean Oswestry score for the Charite disc patients was 71 pre-operatively and 30 at 24-month follow-up ($p < 0.001$). The authors have concluded that TDR appears to be a viable alternative to fusion for the treatment of single-level symptomatic disc degeneration unresponsive to non-operative management. Results from other FDA pivotal trials on newer artificial discs will be forthcoming.

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 biomaterials to be used.

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 the 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 was FDA-approved for the treatment of patients with spinal stenosis in November 2005. The X STOP, St. Francis Medical Technologies Inc.) was developed to treat NIC from spinal stenosis with minimal morbidity and intervention.

The ideal patient for X STOP implantation has predominantly lower extremity complaints, with or without back symptoms secondary to lumbar spinal stenosis (LSS) at one or two levels. The clinical diagnosis of LSS should be confirmed with either MRI or computed tomography (CT) myelogram. The symptoms should be relieved with flexion or sitting.

The X STOP fills the large void of treatment options between the safer yet less effective conservative care and the riskier but more effective surgical decompression, with or without fusion. The X STOP limits terminal extension movement at only the individual level(s) that provoke symptoms, while allowing unrestricted movement of the remaining motion axes of the treated level(s) and the untreated levels. Biomechanical studies have shown that the X STOP significantly increases the spinal canal, subarticular recess, and neuroforaminal size, limits terminal extension, and reduces intradiscal pressure and facet loading.

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. It was the first study to provide level I data for surgical and non-surgical treatment of LSS. At two-year follow-up, 57% of the patients reported a clinically significant improvement in their physical function compared to 15% of the control, based on the Zurich Claudication Questionnaire, a validated outcome tool for neurogenic claudication. Seventy-three per cent of the X STOP patients were at least somewhat satisfied, compared with 36% of the non-surgically treated patients. 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 four-year follow-up. Using a 15-point improvement from baseline oxygen desaturation index (ODI) score as a success criterion, 14 out of 18 patients (78%) had successful outcomes at follow-up, demonstrating that intermediate-term clinical outcomes of X STOP surgery are stable over time.

Hannibal et al. have compared the hospital costs of IPD with the X STOP device to those of laminectomy for the treatment of LSS. 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 out of 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. The main savings in the X STOP group were in operating room (OR) costs (shorter operative time), hospital charges (X STOP is an outpatient procedure), and anesthesia charges (X STOP patients are placed under local anesthesia).

In summary, IPD with the X STOP device is a new effective treatment option for surgical treatment of LSS with or without degenerative spondylolysthesis. The existing level I data suggest that it is at least as effective as lumbar decompressive surgery at two- and four-year follow-up and offers significant savings in direct hospital costs over standard laminectomy. Its main advantages include avoiding general anesthesia in elderly patients; avoiding iatrogenic nerve root injury, dural tears, and epidural scarring; and other risks associated with laminectomy. It also obviates the need for a fusion in a subset of patients with degenerative instability. The current research is focusing on using X STOP for discogenic low back pain, as well as modifying it for the cervical spine.

Dynamic Stabilization—The Dynesis System

Whenever pathological motion from either trauma (fracture) or arthritis (degenerative instability) has to be obliterated, either external stabilization or internal fixation can be used. Historically, whenever internal stabilization/fixation has been utilized, the orthopaedists have also usually performed fusions, since any metallic hardware has a limited number of cycles before fatigue failure or hardware loosening in the bone ensues. Therefore, any fusion has always been a race between a solid bony union and a failure of the metallic fixation. A new concept was introduced into spine surgery about a decade ago: stabilization without fusion, or 'dynamic stabilization,' best exemplified by the Dynesys system (Zimmer Spine). 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 procedure can be revised to a fusion by changing the cords to rods and adding some bone graft, as long as the screw to bone fixation holds.

The European experience with Dynesys was initially marked with great enthusiasm, followed by some skepticism, once the intermediate-term data became available. Schnake et al. have reported on the German experience in 26 patients (mean age 71 years) with LSS and degenerative spondylolisthesis, who underwent lumbar decompression and dynamic stabilization with the Dynesys system at a minimum follow-up of two years. 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. The implant failure rate was 17%, and none of them was clinically symptomatic. The authors have concluded that in elderly patients with LSS and degenerative spondylolisthesis, dynamic stabilization with the Dynesys system, in addition to decompression, leads to similar clinical results as seen in established protocols using decompression and fusion with pedicle screws.

Schwarzenbach et al. have cautioned, however, that a dynamic stabilization device has to provide stability throughout its lifetime, unless it activates or allows reparative processes with a reversal of degenerative changes. They emphasized that anchorage to the bone is crucial, at least for pedicular systems. This is a great demand on spinal implants and assumes rest and motion going together. Their Swiss experience has shown that Dynesys has limitations in elderly patients with osteoporotic bone, or in patients with a severe segmental macro-instability combined with degenerative olisthesis and advanced disc degeneration. Such cases have an increased risk of failure. The authors have called for controlled prospective randomized studies to prove the safety, efficacy, appropriateness, and economic viability of dynamic stabilization.

In summary, the dynamic stabilization of the lumbar spine with Dynesys and similar concepts may be a promising alternative to a fusion, with some reservations about the longevity and loosening of the screws. Level I data is still lacking for this device to support the indications for its use, which currently include degenerative spondylolysthesis and as an adjunct to a discectomy.

Summary

Recently, there has been an explosion of new motion-preserving techniques and devices available in lumbar spine surgery that pose a tempting alternative to spinal fusion. However, care has to be taken when interpreting the clinical data and study design, and particular attention should be paid to the definition of success. ■

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