MINI-SYMPOSIUM: FRONTIERS IN SPINE SURGERY

(iv) Lumbar stabilisation techniques

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KEYWORDS
Lumbar stabilisation techniques; Lumbar instability; Lumbar spine fusion; Dynamic stabilisation; Lumbar total disc replacement; Nucleus pulposus replacement

Summary
Chronic lower back pain due to degeneration of the lumbar spine, commonly referred to as mechanical back pain, is thought to be due to instability of the lumbar motion segment that is secondary to disc degeneration and facet arthrosis. This article concentrates on the various types of stabilisation techniques used to treat such disorders. Traditionally, fusion has been the mainstay of treatment. Many techniques have been developed to maximise fusion rates but a corresponding improvement in clinical outcomes has not been seen. Motion sparing techniques such as dynamic stabilisation, total disc replacement and nucleus pulposus replacement, are alternative forms of treatment. Such new technologies are predicted to have a big impact on the treatment of lumbar instability but as yet require more development and clinical trials.

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Introduction
Chronic lower back pain due to degeneration of the lumbar spine, commonly referred to as mechanical back pain, is thought to be due to instability of the lumbar motion segment that is secondary to disc degeneration and facet arthrosis. The exact definition of lumbar instability is open to much debate and its relation to back pain is poorly understood.

Panjabi described the concept of the neutral zone as the range of intervertebral movement within which spinal motion occurs with minimal internal resistance. Instability results from the failure to maintain this neutral zone within normal physiological limits, resulting in pain and disability.  

Most attempts to define radiological instability appear to accept vertebral translation of at least 3.0–3.5 mm or intervertebral angulation greater than 10° on dynamic radiographs with resultant pain or neurological symptoms.  

The hypotheses put forward to link instability to pain include excessive translation leading to disc degeneration and reduced shear–flexion ratio at the degenerate disc.

The term “instability” has been used to describe a non-specific mechanical failure of the spine causing abnormal movement at the joint surface and altered load transmission, resulting in pain. This article will concentrate on the various types of common stabilisation techniques used to treat lower back disorders secondary to degenerative disc disease. Where appropriate a brief history relating to early techniques will be reviewed and this is followed by a description of the current modern fusion techniques used. A brief review of the more novel and controversial motion preserving techniques such as disc arthroplasty, dynamic stabilisation, and nucleus replacement will be discussed.

Lumbar stabilisation has traditionally been achieved by fusion, with the aim to prevent abnormal movement in the painful motion segment such that direct load transmission...
can occur from ‘bone to bone’ across the fused segment. Spinal fusion was first described in the treatment of Pott’s disease.\(^6\) Its use was extended for the treatment of other spinal conditions including lower back pain.\(^8\) Since then, many techniques have evolved, including posterior, posterolateral, posterior interbody, anterior interbody and circumferential fusion. Fusion aims to eliminate segmental instability, maintain sagittal balance and prevent further degeneration at the level in question. Therefore, pain relief is achieved by eradicating motion across an unstable or degenerate segment.

**Fusion techniques**

Lumbar fusion surgery has improved dramatically over the last two decades. Newer fusion surgery techniques allow for improved fusion rates, shorter hospital stays, and a more active and rapid recovery period. Additionally, better diagnostic tools and improved understanding of indications for a spine fusion are improving outcomes. Lumbar spinal fusion techniques can be divided into posterior, anterior or circumferential fusions.

**Posterior fusion techniques**

**Uninstrumented posterior fusion**

There are three specific techniques for uninstrumented fusion via the posterior approach: (i) posterior fusion, (ii) facet joint fusion and (iii) intertransverse process fusion (ITF). Posterior fusion involves placing bone graft onto the decorticated laminae and spinous processes. As the facets joints need not be exposed, there is less soft tissue disruption than for other techniques, and thus posterior fusion has the theoretical advantage of lower infection rates. This technique is not possible if spinal decompression is required. Facet joint fusion requires thorough curettage of the facet joint surfaces followed by insertion of bone graft. Less bone graft is required for this procedure as it bridges the shortest distance between the segments to be fused. Because of the poor early results with uninstrumented posterior onlay and facet joint fusions, ITF became the standard fusion technique prior to the advent of spinal instrumentation (Fig. 1). ITF requires exposure of the tips of the transverse processes and places bone graft across the decorticated transverse processes.\(^9\) Exposure can be via a midline approach, which involves extensive muscle stripping as far laterally as the tips of the transverse processes or the muscle splitting Wiltse approach, between the longissimus and multifidus muscles, which has the advantage of less muscle trauma.\(^10\)

There is still much debate as to the superiority of uninstrumented versus instrumented fusion. Several studies exist, citing no significant differences in clinical or radiological outcomes between instrumented and non-instrumented posterior fusions for the treatment of degenerative disc disease causing lower back pain.\(^11\)-\(^14\) Yet in contrast, other studies have suggested that instrumented fusion had a higher fusion rate and improved clinical outcome when compared to uninstrumented techniques.\(^15\),\(^16\) Uninstrumented fusion is suitable for patients with sufficient intrinsic stability to allow fusion to occur, those with isthmic spondylolisthesis, degenerative spondylolisthesis associated with disc space narrowing and patients who will comply with external bracing should they require it.\(^14\),\(^17\),\(^18\) Instrumentation is indicated for other scenarios such as spinal trauma as it provides the initial stability required for fusion to occur.

**Instrumented posterior fusion**

Pedicle screw fixation was first used in the treatment of spondylolisthesis\(^19\) and its use soon extended to the treatment of various degenerative diseases of the lumbar spine. Pedicle screw fixation with adjoining rods provides initial immobilisation, thus allowing a superior environment for fusion to occur, permits correction of the deformity and aids rehabilitation because immediate post-operative mobilisation is possible. However, disadvantages include a higher rate of vascular and neurological complications, increased soft tissue trauma that is related to screw insertion leading to increased infection rates, and the presence of stainless-steel metalwork which may adversely affect subsequent investigations such as MRI scanning.\(^14\)

Good surgical experience, a thorough knowledge of spinal anatomy and improved imaging and navigational techniques should help reduce such complications.

Instrumented facet joint fusion is an alternative technique, which has been shown to provide similar biomechanical properties to pedicle screw fixation.\(^20\) Two techniques exist. The transfacet technique, first described by Boucher in 1959,\(^21\) involves inserting a traversing screw across the facet joint from medial to lateral (Fig. 2). The translaminar facet technique was first described by Magerl in 1984.\(^22\) This method requires insertion of a screw from a starting point at the base of the spinous process contralateral to the facet to be fused (Figs. 3 and 11). The screw crosses the entire length of the lamina and the facet joint. This latter technique, although technically more challenging and associated with a greater risk of complications,\(^23\) allows increased screw purchase and is biomechanically superior to the Boucher technique because the screws cross the facet joint perpendicularly.

Compared to pedicle screw fixation, facet screws require less soft tissue dissection, allow more space for bone graft,
have a lower neurological complication rate and cost a great deal less. Several studies have reported excellent clinical results and fusion rates from 91–95%. 23-25 Facet joint screws are indicated for one to two level lumbar degenerative disc disease, where the facet joints are intact, closely apposed, and there is an associated collapsed disc segment which results in reduced biomechanical loading anteriorly. It has been demonstrated that both pedicle and facet screws have similar biomechanical properties.26 Many studies have shown that posterior arthrodesis benefits patients with degenerative or isthmic spondylolisthesis, or those patients with instability due to extensive decompressions.11,13,14,17,18 It is thought to relieve pain due to degenerative disc disease by limiting movement at the painful motion segment. While clinical outcomes have been shown to be comparable to that of interbody procedures for the treatment of degenerative disc disease,27 there is great debate as to whether an isolated posterior arthrodesis is as effective as an interbody or circumferential fusion. An isolated posterior fusion may not totally eliminate motion through the painful segment, nor does it remove the disc, which may be a source of inflammatory pain.28 One study, investigating instrumented posterolateral fusion in the treatment of discography-proven discogenic pain, showed a 39% good outcome versus 48% poor results.29 Several studies demonstrate superior outcomes with circumferential fusion for the treatment of degenerative disc disease.30,31 Although there is mounting evidence showing the superiority of interbody fusion techniques for the treatment of degenerative disc disease, posterior instrumented fusion is still widely used as it is easier technically, takes less operating time, has lower complication rates and does not destabilise the anterior spinal column.32

Figure 2 Antero-posterior and lateral plain film X-rays showing Boucher screws inserted at L5/S1.

Figure 3 Antero-posterior plain film X-rays showing L5/S1 translaminar facet screws fusion.

Posterior lumbar interbody fusion (PLIF)

PLIF, referring to the placement of implants into the disc space via a posterior approach, was described and popularised by Cloward in 1953 with the aim of obtaining simultaneous nerve decompression and fusion.33 However, it did not gain interest until the introduction of spinal instrumentation and interbody devices. The steps involve laminectomy, discectomy, restoration of disc height space, decortication of the vertebral endplates and insertion of an intervertebral graft. This can be the patient’s own bone (autograft) or an interbody spacer packed with bone (metal or polyetheretherketone (PEEK)), inserted into either side of the cleared disc space. Instrumentation in the form of pedicle screws is then used to provide posterior stability (Fig. 4).

The advantages of PLIF include restoration of disc height space, improved maintenance of sagittal balance, allow decompression of the nerve roots and the provision of a superior environment for fusion to occur.34 The risks associated with nerve root retraction make other interbody fusion techniques more appealing. Transforaminal lumbar interbody fusion (TLIF) places the interbody device through a unilateral posterior approach without violating the spinal canal. The unilateral removal of the pars interarticularis and facet complex allows posterolateral access to the disc space. This method reduces the amount of neural retraction and preserves the contralateral facet complex. As with PLIF, posterior instrumentation is used to stabilise the spine.
segment immediately following the insertion of an oblique interbody device. Indications for PLIF and TLIF are outlined in Table 1.

### Anterior lumbar interbody fusion (ALIF)

Although posterior techniques are more popular, fusion can also be achieved by anterior methods, of which the most frequently used is the ALIF. This was first described by Capener\(^3\) in 1932 for the treatment of spondylolisthesis. Interbody fusion combats the disadvantages of uninstrumented posterior fusion, which primarily include the significant rate of fusion failure, possible canal stenosis from the posterior fusion mass and persistent movement across the disc at the fused level\(^3\) as well as continued pain emanating from the disc.\(^2\) The anterior lumbar spine may be approached through an open transperitoneal or retroperitoneal approach, and via a mini-open or laparoscopic technique. A mini-open exposure minimises the size of the wound and with the aid of a 360° self-retaining frame-based retractors, e.g. SynFrame\(^\text{TM}\) (Synthes-Stratec, Switzerland), allows a complete discectomy to be performed with direct placement of interbody devices via a direct anterior approach (Fig. 5). The senior author advocates the use of intra-operative fluoroscopy to ensure safe positioning of the interbody device.

Various interbody devices exist for performing an ALIF. Interbody implants may be (autograft or allograft), non-bone materials such as acrylic, or a combination of both. Bone, in the form of tricortical iliac crest or fibula autograft can be harvested and inserted between the endplates. This has the disadvantage of patient donor site morbidity and unreliable bone quality. Allograft is a popular alternative as it eliminates morbidity associated with donor site complications. Pre-contoured, pre-sized femoral ring allograft (FRA) implants and PLIF or TLIF bone spacers are available for use as interbody fusion devices. The FRA implants that are packed with autograft or demineralised bone matrix (DBM) are ideally placed via the anterior approach with...
instrumentation in the form of a plate or a screw and washer to prevent dislodgement (Figs. 6–8). The pros and cons of different graft types are summarised in Table 2.

Metal or PEEK interbody cages packed with harvested bone autograft are also widely used but have the disadvantage of subsidence and difficulty to radiographically assess bone incorporation. Titanium cages are MRI-compatible and are closer to the modulus of bone than stainless steel. Carbon fibre cages have elastic properties closer to those of cortico-cancellous bone compared to metallic cages, and also have the advantage of being radiolucent. However, carbon cages still present concerns associated with foreign bodies. Previous use of carbon fibre in the body, such as cruciate ligament reconstructions, has caused chronic destructive inflammatory reactions and long term follow up of such devices is necessary.

Stand-alone threaded cages (Fig. 8), such as the BAK cage (Zimmer), are now no longer favoured in Europe, since the advent of biomechanical papers revealing that stand-alone cages are unstable in extension. This instability resulted in pseudarthrosis with poor clinical outcome, and therefore required posterior stabilisation. First generation stand-alone titanium-threaded interbody devices have now been replaced with PEEK or metal cages with locking screws (e.g. Hartshill Horseshoe and SynFix™ [Synthes-Stratec, Switzerland]). More recently newer generation anterior locking screw/plate devices, e.g. ATB™ (Synthes-Stratec, Switzerland) or Pyramid plate (Medtronic Inc., Minneapolis, MN) have gained increased popularity with surgeons trained in the anterior approach, since these devices can be easily

![Figure 6](image-url) Top: Plain film radiographs of ALIF performed with femoral ring allograft packed with BMP/collagen sponge and supplemented anteriorly using a locking plate or anterior tension band plate (ATB™ Synthes-Stratec, Switzerland). Bottom: CT scan taken at 3 months confirming solid interbody fusion.
inserted via a minimal access anterior retroperitoneal route thus obviating posterior surgery and the need to damage the posterior structures (Fig. 6). The locking plates help neutralise the segment following insertion of a load sharing interbody device, thus optimising the occurrence of an interbody fusion. Stand-alone anterior devices are generally indicated for use in end-stage degenerative disc disease, where the facet joints are very rigid, and thus allows the segment to be locked into extension following the insertion of the devices. These devices have been shown to be biomechanically comparable to circumferential fusion with pedicle screws.

**Circumferential fusion**

Circumferential fusion, referring to combined interbody and posterior fusion, has resulted in high fusion rates, with some series reporting 100%. The traditional method of anterior–posterior fusion involves a separate anterior approach for interbody device placement followed by posterior instrumentation (Fig. 9), such as pedicle screws or translaminar screws. The two procedures can be performed under the same anaesthetic or staged over a planned period of time. To that end, the single approach PLIF and TLIF procedures, which are considered by some authors to be 270° fusions, have gained popularity against a circumferential fusion. Technically, 360° fusions allow larger single body grafts or cages to be inserted compared to posterior techniques. In addition, device insertion does not require neural retraction and avoids the excessive bone resection that PLIF and TLIF procedures require. However, as 360° fusions consist of two procedures instead of one, operating times are longer with higher blood loss, cost and hospital stay. Interestingly, fusion rates have been shown to be comparable between the different procedures, which questions the justification of circumferential 360° fusions. New minimal access techniques for ALIF combined with percutaneous pedicle screws, resulting in less invasive surgery, further fuel this debate.
<table>
<thead>
<tr>
<th>Graft type</th>
<th>Advantage</th>
<th>Disadvantage</th>
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</table>
| Autograft—bone taken from one anatomical site and transferred to another site in the same individual (no immune reaction) 1. Autograft—cortical | • Allows immediate load sharing  
• Provides structural support | • Increased donor site morbidity  
• Lower surface area for bone to form  
• Non-viable bone remains, increasing risk of infection |
| 2. Autograft—vascularised cortical | • Faster bony incorporation  
• Graft hypertrophies with compressive load  
• Less necrotic bone | • Technically demanding with increased operating time  
• Increased donor site morbidity |
| 3. Autograft—cancellous | • Lower donor site morbidity  
• Good osteoconductivity | • Low compressive strength |
| Allograft—bone transferred from one member of a species to another member (e.g. FRA) (Fig. 7) | • no donor site morbidity  
• Available in multiple forms  
• Osteoconductive, weakly osteoinductive | • Risk of infection (<1/10^6 risk HIV infection)  
• Immune response (degree related to treatment and storage)  
• Cost |
| Demineralized bone matrix—processed allograft bone (decalcified cortical bone) (Fig. 7) | • Low immunogenicity (due to extensive processing)  
• Available in multiple forms | • Lacks structural support  
• Cost |
| Synthetic implants—ceramics (sintered [porous hydroxyapatite or tricalcium phosphate]/replamiform [sea coral]) | • Not immunogenic  
• No risk of transmitting infectious disease  
• No donor site morbidity | • Lower fusion rates compared to autograft/allograft when used alone  
• Difficult to assess healing with X-ray  
• Potential non-immune inflammatory response (e.g. seroma)  
• Poor load sharing properties |

Figure 9  Plain film radiographs taken 12 months post-circumferential fusion using femoral ring allograft, anterior tension band plate and pedicle screws.
Minimally invasive/access spinal techniques

Minimal access spinal procedures have been developed with the aim of reducing approach-related morbidity while obtaining the same clinical outcomes of traditional open procedures. Essential equipment includes an image guidance device, an access portal and modified instruments. The two main methods of guidance are fluoroscopy and frameless spinal stereotaxy. The advantages of fluoroscopy are that it is widely available, simple to use and provides immediate imaging feedback, which may be in multiple planes, while its main disadvantage is radiation exposure. Frameless spinal stereotaxy limits radiation exposure but requires a separate incision for placement of a dynamic reference array.

The two main techniques for percutaneous spinal fixation are pedicle screws and facet screws. Both have been developed to complement ALIF procedures in order to perform circumferential fusions with minimal morbidity to the patient. Currently, the most widely used percutaneous pedicle screw system is the Sextant system (Medtronic Inc., Minneapolis, MN). Cannulated, polyaxial screws are placed over guide wires and inserted under fluoroscopic guidance. Screw extenders and rod inserters are attached. A separate incision is made for rod insertion which, after measuring for the right length, is swung into position to engage with the screw heads (Fig. 10). The feasibility of percutaneous facet screw insertion (Fig. 11) was first mentioned by Grob and Humke in 1998, but their report contained insufficient details to reproduce the technique. Shim et al. described a technique for inserting translaminar facet screws under fluoroscopic guidance, without the use of any device. Cannuluted lag screws were inserted over carefully placed K-wires. This required careful planning and the surgeon to have good three-dimensional spatial awareness.

Minimally invasive techniques are also being practised for ITF, PLIF and TLIF. Tubular retractors (e.g. METRx System, Medtronic Inc., Minneapolis, MN) are used for access with visualisation via microscope, endoscope or loupes. The blunting of sharp instruments allows the surgeon to slip past the nerve root while minimising soft tissue retraction. Such surgery is still evolving; at present there are few outcome studies, and none comparing the outcomes of open versus minimal access techniques, particular in the long term.

Biologics

In 1965, Dr. Marshall Urist discovered that bone extracellular matrix is able to induce new bone formation. This osteoinductive agent was later termed bone morphogenic protein (BMP). Over the last 40 years, there have been many advances towards using osteoinductive agents to promote
spinal fusion. Currently, recombinant human bone morphogenic protein-2 (rhBMP-2 or Inductos™ [Medtronic Inc., Minneapolis, MN]) carried on a Type 1 collagen sponge (Fig. 6) is FDA-approved for use in conjunction with a tapered intervertebral cage (LT-cage, Medtronic Inc., Minneapolis, MN) for the treatment of degenerative disc disease. Recombinant human osteogenic protein-1 (rhOP-1), commercially available from Stryker Biotech, has been approved for revision posterolateral lumbar fusions. The superior efficacy of osteoinductive agents, as compared to autologous bone graft, has recently been shown in a few randomised controlled studies. There is no doubt that these osteoinductive agents will have a significant role to play in the future of lumbar fusion surgery. However, the exact role and long-term efficacy are yet to be defined by further case series and randomised clinical trials. Furthermore, the high costs and uncertainty of reimbursement by insurance companies for these biologic agents will affect their use.44

Motion sparing techniques

Despite all the advances in fusion techniques over the years, with fusion rates approaching 100%, there has not been a corresponding improvement in clinical outcomes.45,46 Suggested explanations include unrecognised pseudarthrosis, abnormal load transmission through the metal–bone interface with cage fusions and abnormal restoration of sagittal balance. There is also evidence that fusion may increase the biomechanical stresses on adjacent segments leading to premature degeneration. This line of thought has led to the development of alternative forms of treatment for lumbar instability where motion is preserved.

Dynamic stabilisation

Dynamic stabilisation (also known as soft stabilisation) devices attempt to address the matters outlined above by placing the posterior structures under tension, thus increasing lordosis in that area. This aims to shift load transmission favourably and alter movement so as to avoid painful positions with the aim of alleviating both back and leg pain. Many systems have been developed and can be classified into four categories (Table 3). A few of the more popular devices are described, but of note, there is yet to be a prospective randomised controlled trial for any dynamic stabilising device.

The Graf ligament is a non-elastic braided polyester ligament loop, which is placed around pedicle screws under tension (Fig. 12a). This transfers the load from the anterior to the posterior part of the disc. Several studies have shown clinical outcome comparable to that of fusion; however, there have been documented complications of narrowing of the lateral recess causing undesirable post-operative radiculopathy and late failure due to accelerated posterior disc degeneration.

The Dynesys system consists of polycarbonurethane spacers, placed between titanium alloy pedicle screws, which resist compressive forces. Polyester cords, which are connected to the screws, run within the spacer and resist tensile forces. Results have been reported for 83 patients, with the system being concluded by the authors as a safe

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Outlining the main categories of dynamic stabilisation devices.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Device name</td>
</tr>
<tr>
<td>Free-floating interspinous distraction device</td>
<td>Wallis implant (Abbott) X-stop (St. Francis Medical Technologies Inc.)</td>
</tr>
<tr>
<td>Interspinous ligaments looped around spinous processes</td>
<td>DIAM—Dynamic Intervertebral Assisted Motion (Medtronic Inc., Minneapolis, MN) (Fig. 12b)</td>
</tr>
<tr>
<td>Ligaments placed around pedicle screws</td>
<td>Graf ligament (SurgiCraft) (Fig. 12a) Dynesys (Zimmer)</td>
</tr>
<tr>
<td>Semi-rigid metallic devices placed across pedicle screws</td>
<td>TOPS-on-Fusion System™ (Impliant Inc.)</td>
</tr>
</tbody>
</table>

Figure 12  (a) (left)—Image of the global (graf ligament) placed on a spine model; (b) (right)—image of the dynamic intervertebral-assisted motion (DIAM) placed on a spine model.
and effective alternative in the treatment of unstable lumbar conditions. However, of the 83 patients, 7 suffered from screw loosening and 12 required revision surgery for same or adjacent segment disease.

The Wallis implant is a hybrid of an interspinous distraction device and an interspinous ligament which is made of PEEK. It is the second generation of a titanium implant that was held between the spinous processes by Dacron tape, originally described by Senegas et al. in 1988. In clinical trials, the original implant was shown to be effective against low-back pain due to degenerative instability and free of serious complications. A randomised clinical trial of the Wallis implant is currently underway.

The X-stop device (St. Francis Medical Technologies Inc) (Fig. 13) is a titanium interspinous distraction device, which has completed FDA clinical trials and recently received FDA approval. Results of the multi-center trial conducted in the US indicated that among patients with pain arising from neurogenic claudication secondary to spinal stenosis, the X-STOP provided significantly greater pain relief than the epidural steroid injections. A newer PEEK version has been launched recently.

Spinal arthroplasty

The aim of any spinal arthroplasty device is to maintain disc height space, allow motion at the affected segment and provide stability. It avoids the problems that fusion procedures encounter with bone graft harvest sites and pseudarthrosis. The posterior structures are left intact as the disc replacements are inserted via an anterior approach, and by maintaining motion at the involved segment, it is thought to reduce accelerated adjacent disc degeneration. Two broad groups exist: total disc replacements (TDRs) and partial nucleus pulposus replacements (NPRs).

Artificial disc replacement

One of the first reports of attempted disc arthroplasty was by Fernstrom who implanted stainless steel balls into the disc space. Results were published in 1966 for 191 implants in 125 patients. During the 4–7-year follow-up period, there was an 88% subsidence rate. Many years of research into spinal degeneration, biomechanics and biomaterials followed before the development of intervertebral disc prostheses.

TDR devices are implanted via an anterior retroperitoneal approach, with 360° retractors allowing mini incisions and simple access to the L5/S1 disc. Gaining access to the discs above this level requires mobilisation of the major retroperitoneal blood vessels, and even in the hands of experienced surgeons, there is a reported 2.8% vascular complication rate.

The clinical outcome of TDR is highly dependent on patient selection. The inclusion and exclusion criteria used for the FDA controlled, randomised trials for TDR are shown in Table 4. One prospective study reported better outcomes in patients with degenerative disc disease in association with disc herniation and patients under the age of 40. Bisegmental disc replacements had a significantly higher rate of complications and inferior outcomes.

Diagnostic tools used to ascertain suitability for TDR include plain film radiographs, MRI and discography. Facet joint blocks, sacroiliac joint injection and nerve root blocks may also help exclude non-discogenic sources of pain.

At present, there are five implants used in the lumbar spine, of which only two, the SB Charite III (Depuy, Johnson and Johnson) and the ProDisc-II (Synthes-Stratec, Switzerland) have been approved in the US by the FDA. The SB Charite III (Fig. 14) consists of two metal endplates made of cobalt–chromium–molybdenum with the bone interface aspect covered with porous plasma-sprayed titanium, coated with calcium phosphate to promote bone on-growth. A free-floating biconvex sliding core made from ultra-high molecular weight polyethylene is inserted and held between the two concave endplates. Over 10,000 implants have been inserted worldwide and a randomised controlled trial for patients with single level L4/5 or L5/S1 degenerative disc disease showed significant improvement in visual pain analogue scores (VPAS) and Oswestry Disability Index (ODI).
scores. Overall success rates at 2 years were 63% for TDR compared to 53% for fusion. The ProDisc-L (Figs. 15 and 16) and the ProDisc-II, its second-generation counterpart, are also three component devices made from the same materials as the SB Charite III. The main difference is that the UHMWP insert is locked to the lower endplate. Both endplates also have a central keel for immediate stability upon insertion. Success rates between 80% and 98% have been reported in uncontrolled trials. The FDA-controlled randomised study comparing ProDisc-II with circumferential fusion reported a statistically significant shorter hospital stay, superior ODI success and higher satisfaction rates in favour of the disc replacement.

Major, but uncommon, complications of total disc arthroplasty include vertebral body fracture, subsidence, malpositioning and radicular pain. Other available devices include the metal-on-metal Maverick device (Medtronic, Minneapolis, MN), the Flexicore disc (Stryker Corp, Kalamazoo, Michigan), and the Mobidisc (LDR Medical, Troyes, France) (see Table 4).

There is no doubt that TDR is a new and developing frontier in spinal surgery. Its precise role in the treatment of lumbar instability has yet to be fully defined. More long-term evidence-based data are required to determine its safety, superiority, longevity and ability to prevent adjacent level degeneration as compared to conventional spinal fusion.

### Nucleus pulposus replacement

Another motion preserving technique is that of NPR, which aims to reconstruct the nucleus pulposus while preserving the biomechanics of the annulus fibrosus and cartilaginous endplates. NPR devices are designed for use in cases in which there is significant nucleus pulposus degeneration but where the annulus is still healthy. Indications presently include lumbar discogenic back pain unresponsive to active conservative treatment for a minimum of 6 months, spondylolisthesis of less than grade 1 at the symptomatic segment, disc height loss of less than 50% (disc height of >5 mm on MRI) and only early stage degenerative changes with absent Schmorl’s nodes.

Presently, there are two categories of NPR devices: Intradiscal implants, which are biomechanically similar to native nucleus pulposus tissue, and in situ curable polymers, which consist of liquid-based compounds that harden after implantation. The curable polymers have the advantage of

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**Table 4** Showing details of the five main total disc replacement devices.

<table>
<thead>
<tr>
<th>Device</th>
<th>Materials</th>
<th>No. of components</th>
<th>Articulation</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>SB Charite-III</td>
<td>CoCrMo on UHMWPE</td>
<td>3</td>
<td>Mobile bearing (unconstrained)</td>
<td>Commercially available</td>
</tr>
<tr>
<td>Prodisc-II</td>
<td>CoCrMo on UHMWPE</td>
<td>3</td>
<td>Ball and socket (semi-constrained)</td>
<td>Commercially available</td>
</tr>
<tr>
<td>Maverick</td>
<td>CoCrMo metal-on-metal</td>
<td>2</td>
<td>Ball and socket (semi-constrained)</td>
<td>Under trial</td>
</tr>
<tr>
<td>Flexi-core</td>
<td>CoCrMo metal-on-metal</td>
<td>2</td>
<td>Ball and socket (semi-constrained)</td>
<td>Under trial</td>
</tr>
<tr>
<td>Mobidisc</td>
<td>CoCrMo on UHMWPE</td>
<td>3</td>
<td>Mobile bearing (semi-constrained)</td>
<td>Under trial</td>
</tr>
</tbody>
</table>
allowing minimally invasive implantation techniques via a small annulotomy and hence a lower risk of extrusion.

Clinical results are available only for a few intradiscal implants. By far, the most studied device is the prosthetic disc nucleus (Raymedica Inc., Bloomington, MN) (Figs. 17 and 18), with over 400 patients treated between 1996 and 2002. The device consists of a hydrogel pellet encased in a polyethylene jacket. The hydrogel can absorb up to 80% of its weight in water and swells in size to restore and maintain disc height. The inelastic jacket limits height gain so as to prevent damage to the vertebral end plates. Two small pellets are commonly inserted, via a posterior approach, although a single larger device has also been used more recently to lower the risk of extrusion. Initial success rates for the PDN were reported at 83%, but fell to 62%, with an increased migration rate, after modification. Re-modification improved the clinical outcome to 79%. This increased to 91% (in 51 patients) after changes in protocol and surgical
instrumentation. The main complications are those of device migration, a factor which led to the changes in design and protocol, and end plate fracture with subsidence and extrusion. Other devices are at different preclinical and clinical stages. Some are outlined in Table 5.

Most curable polymers are toxic when absorbed in high doses secondary to leaching of the chemical before it sets. Leaching is dependent upon the polymerisation time and the degree of annulus disruption. Two curable polymers are being developed: the DASCOR disc arthroplasty device (Disc Dynamics Inc., Eden Prairie, MN) and the BioDisc (Cryolife, Kennesaw, GA). The DASCOR disc arthroplasty device is an injectable polyurethane, which is injected into a polyurethane expandable balloon and polymerises within minutes. The BioDisc is a protein hydrogel that is injected directly into the disc space.

The minimally invasive insertion prospects and motion sparing nature of NPR has caused widespread interest in this developing field. Issues that will affect success include which materials are used and implant design to help minimise migration. Table 5 shows details of selected nucleus pulposus replacement devices.

<table>
<thead>
<tr>
<th>Device</th>
<th>Implant type</th>
<th>Biomaterial</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prosthetic disc nucleus (Raymedica)</td>
<td>Intradiscal</td>
<td>Hydrogel pellet with polyethylene jacket</td>
<td>Commercially available outside US and Canada</td>
</tr>
<tr>
<td>Neudisc (Replication Medical Inc.)</td>
<td>Intradiscal</td>
<td>Hydrolyzed polycrylonitrile polymer reinforced by Dacron mesh</td>
<td>Clinical trials planned autumn 2006</td>
</tr>
<tr>
<td>Newculeus (Zimmer, Spine) (Fig. 17)</td>
<td>Intradiscal</td>
<td>Polycarbonate urethane coiled into spiral</td>
<td>Implanted into 10 patients</td>
</tr>
<tr>
<td>DASCOR disc arthroplasty device</td>
<td>In situ curing polymer</td>
<td>Injectable polyurethane into expandable balloon</td>
<td>Clinical study in Europe and US</td>
</tr>
<tr>
<td>BioDisc</td>
<td>In situ curing polymer</td>
<td>Protein hydrogel</td>
<td>Clinical trial in UK, 10 patients</td>
</tr>
</tbody>
</table>

Conclusion

For many years, spinal fusion has been the mainstay of treatment for back pain caused by lumbar instability. A variety of techniques exist, with ever-increasing fusion rates. However, the increase in fusion rates has not been paralleled with an improvement in clinical outcomes. Motion sparing techniques, such as dynamic spacers and spine arthroplasty, have gained widespread popularity as they hold several advantages over spinal fusion, thus increasing the number of techniques available to stabilise the abnormal motion segment. Spinal implants represent the fastest growing sector of the orthopaedic market, with a projected market value of over $7 billion by 2010. Spinal surgeons will face enormous pressure from industry and the public to embrace new technology. Due to the lack of evidence-based data available, it is the author's opinion that the application of such technology must be approached with caution. Efforts need to be directed towards research, development and clinical trials before motion sparing devices can seriously challenge spinal fusion as the gold standard treatment for lumbar instability. Nonetheless, a new chapter has been opened and the coming years look set to be a period of exciting change in lumbar stabilisation techniques.

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References


