Classification of posterior dynamic stabilization devices

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✓Numerous new posterior dynamic stabilization (PDS) devices have been developed for the treatment of disorders of the lumbar spine. In this report the authors provide a classification scheme for these devices and describe several clinical situations in which the instrumentation may be expected to play a role. By using this classification, the PDSs that are now available and those developed in the future can be uniformly categorized.

KEY WORDS • facet disease • facet replacement • posterior dynamic stabilization • interspinous device classification

IT IS ESTIMATED that up to 50 million individuals in the US suffer from symptoms related to spinal degeneration, and that in 2004 more than 1 million spinal procedures were performed to alleviate or mitigate this condition.^{8,25} For the neurosurgeon treating this population, open surgical intervention has traditionally been directed at decompressive procedures to relieve neural element compression and/or fusion techniques to stabilize the spinal column.

Advancements in technology have added to the surgeon's armamentarium and necessitate new classification schemes. For example, widely adopted new surgical procedures, such as percutaneous vertebral augmentation (vertebroplasty and kyphoplasty) and total disc replacement, do not fit easily within the rubric of decompressive or fusion techniques.

One of the most rapidly evolving fields in spinal surgery is PDS. This new category of thoracolumbar spinal surgery focuses on the concept of maintaining or restoring intervertebral motion in a controlled fashion, whether by restricting the extremes of spinal movement or by dampening the kinetic energy involved in motion. The goal of these implantable devices is to mimic the behavior of the healthy spinal column (Fig. 1).

Indications for PDS

Although the indications for PDS are still being identified, there are several disorders in which the devices are expected to play a role. These are detailed in the sections that follow.

Controlled Motion in the Iatrogenically Destabilized Spine

Spinal surgery for neural entrapment syndromes typical-

ly involves a partial or complete laminectomy with some element of facet joint removal. Although minimal access procedures such as microdiscectomy require very little bone removal, the treatment of lumbar spinal stenosis accompanied by lateral recess stenosis and superior facet encroachment can result in significant facet joint resection. In some instances this results in iatrogenic destabilization,¹ requiring the surgeon to decide whether to fuse the patient's spine primarily or watch expectantly for the finite possibility of sagittal plane imbalance or deformity. One possible role of PDS devices would be to limit and control motion after a potentially destabilizing laminectomy, avoiding the need for arthrodesis and reducing the likelihood of iatrogenic destabilization.

Increased Anterior Load Sharing to Augment Interbody Fusion

Interbody fusion techniques have become highly popular over the last two decades. Although pedicle screw/rod stabilization is typically used as an adjunct in these operations, concerns have arisen surrounding the highly rigid nature of these constructs. Stress shielding of the interbody graft is believed to be implicated in a certain percentage of pseudarthroses.¹⁵ Thus, PDS devices may play a role in limiting the extremes of motion, which could result in graft displacement, while allowing for maximal anterior load sharing and fusion.

Protection and Restoration of Degenerated Facet Joints and Intervertebral Discs

This is perhaps the most controversial and least understood indication for PDS. Contemporary surgical treatments for spinal pain generators, such as the intervertebral disc or facet joints, involve extirpation or complete destruction of the poorly functioning unit. In the case of what is believed to be discogenic pain, the disc is completely removed and replaced with an interbody fusion or arthroplasty device. Alternatively, a posterior fusion can be used to treat facet or disc disease, with the goal of pre-

Abbreviations used in this paper: FDA = Food and Drug Administration; PDS = posterior dynamic stabilization; PEEK = polyetheretherketone; TFAS = Total Facet Arthroplasty System; TOPS = Total Posterior Motion Preservation System.

FIG. 1. Graph showing the load displacement curve of the intact spine compared with the degenerated spine, and the ideal concept of "restoring" normal motion of the degenerated spine with posterior dynamic devices.

venting any motion in the diseased unit. The PDS devices may be able to shield the disc and facet joint structures from motion that is destructive, potentially allowing for a reduction in local inflammatory processes or permitting self-repair mechanisms.

In Combination With Anterior Motion Preservation for 360° Circumferential Motion Segment Reconstruction

One of the major drawbacks of total disc arthroplasty is that facet disease remains a contraindication. In fact, it is believed that disc arthroplasty may accelerate facet degeneration.⁴⁵ Using PDS technology, circumferential reconstruction of all the mobile units in a spinal segment (the intervertebral disc and two facet joints) becomes possible.

Adaptation of Stabilization Techniques to the Aging Spine

Current spinal stabilization devices (pedicle screws and rods or transfacet screws) provide a high degree of rigidity. Although this can be desirable, the use of these devices in the treatment of patients with osteopenia or osteoporosis can result in catastrophic destruction of host bone at metallic interfaces.¹⁴ The application of "softer stabilization" techniques may be more desirable in these settings, reducing the likelihood of construct failure.

Prevention of Fusion-Related Sequelae

Perhaps the most widely appreciated application of PDS lies in its theoretical advantages over rigid arthrodesis. Loss of spinal motion due to fusion can result in a number of sequelae, including accelerated adjacent-level degeneration, fusion into states of malalignment, and pseudarthrosis. With respect to adjacent-level disease, it is believed that the elimination of mobility can overload adjacent segments and lead to accelerated degeneration and arthrosis. This can result in axial pain, deformity and kyphosis, and neurological compression.^{21,22,33,37,39}

Furthermore, loss of lumbar lordosis as a result of poorly contoured or excessive distraction of instrumentation can lead to flatback deformity or fixed sagittal imbalance. This syndrome can result in postoperative pain, hardware failure, fatigue, and gait disturbance characterized by an inability to stand erect without flexing the knees and ex-

FIG. 2. Photographs and a radiographic study showing a Wallis (Abbott Spine) interspinous process stabilization device before and after implantation. This device is inserted between the spinous processes after removal of the interspinous ligament (see intraoperative view). The arrow on the radiographic study indicates the radiodense lines of the Wallis device after insertion between the spinous processes.

tending the hips to compensate for loss of segmental lumbar lordosis.¹⁰

Finally, pseudarthrosis is a significant complication of fusion surgery, with a reported incidence that can reach 30% in certain circumstances.^{5,6,46} Frequently, it requires repeated operation, adding to patient morbidity and costs.

Classification of Devices

Since the mid-1980s, a number of PDS devices have been introduced in the market. To simplify the discussion of these devices, we have classified them into three main categories: 1) posterior interspinous devices; 2) pedicle-based dynamic rod devices; and 3) total facet replacement systems (Table 1).

TABLE 1
Classification system for PDS devices

Classification	Indication	Device
interspinous spacer devices	neurogenic claudication	Wallis, X STOP, DIAM Coflex, ExtendSure CoRoent
pedicle screw/rod-based devices	to unload discs & facets to promote fusion to prevent adjacent-segment disease	Graf ligament, Dynesys AccuFlex rod Medtronic PEEK rod Scient'X Isobar
total facet replacement systems	to control motion in the iatrogenically destabilized spine replacement device for facet disease as part of a functional spine unit reconstruction to prevent adjacent-segment disease to control motion in the iatrogenically destabilized spine	TFAS TOPS Stabilimax NZ

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Interspinous Spacer Devices

The posterior interspinous devices were designed as an alternative treatment for neurogenic claudication and the pain attributed to facet joint disease. By keeping the spine in a rather flexed position, the interspinous devices increase the total canal and foraminal size, decompressing the cauda equina responsible for neurogenic claudication.^{23,34,43} This type of device allows neural decompression with only a minimal amount of tissue resection, making the procedure less invasive. The devices are intended to be implanted without a laminectomy and function through indirect decompression, thus avoiding the risk of epidural scarring and cerebrospinal fluid leakage. Furthermore, these devices limit extension of the spine, unload the facet joint, and relieve the pain attributed to facet disease.

The Wallis System. In 1986 the first interspinous device (Fig. 2), the Wallis System (Abbott Spine), was introduced in Europe. It was developed by Sngas⁴¹ and has the longest history. The device's original design was a titanium block that was inserted between adjacent processes and held in place with a flat Dacron cord or ribbon wrapped around the spinous process above and below the block. After this first-generation device showed positive results, a second generation of Wallis implants was developed. The primary change was in the material used to build the interspinous block; it was changed from titanium to PEEK, a strong, plasticlike polymer that has more elasticity and is therefore less rigid than the previously used material. An important aspect of the Wallis implant is in its design and material, which minimizes the need for bone resection and avoids constraint on bone. It has notches that fit the physiological shape of the spine.⁹

In a prospective controlled study conducted between 1988 and 1993, more than 300 patients were treated for degenerative lesions, with positive results. This trial of the first-generation implant provided evidence that the interspinous system of nonrigid stabilization is efficacious against low-back pain caused by degenerative instability.³ These results are being confirmed with a new clinical trial of the Wallis Stabilization System, which is being regulated by the FDA. The trial is designed to compare one-or two-level surgery for lumbar degenerative disc disease with conservative treatment.

The X STOP Device. This device (St. Francis Medical Technologies, Inc.) is an oval titanium metal spacer (Fig. 3) that received FDA approval in November 2005. This implant is designed to fit between two adjacent lumbar spinous processes.

The implant procedure for this device can be done after induction of either local or general anesthesia. After a small midline incision, the paraspinal muscles are lifted subperiosteally from the spinous processes while all midline structures are left intact. The X STOP device is then placed between the spinous processes while the patient is in a slight flexion position. The supraspinous ligament is carefully protected. Starting just posterior to the lamina, a dilator is placed between the spinous processes. A sizing instrument is then inserted between the spinous processes and expanded until the supraspinous ligament is taut. Using a gauge on the sizing instrument, the X STOP device is sized (range 6–14 mm) and then inserted.⁵⁰ Al-

FIG. 3. Intraoperative lateral x-ray showing the X STOP device (St. Francis Medical Technologies, Inc.) after its insertion between the spinous processes. Inset: Photograph of the X STOP rigid interspinous process stabilization device.

though the implant is not rigidly attached to the osseous anatomy, it is restricted from migrating posteriorly by the supraspinous ligament, anteriorly by the lamina, cranially and caudally by the spinous processes, and laterally by the device's wings on each side.⁴⁹

Several clinical studies have been performed and have shown the efficacy of the X STOP device in treating neurogenic claudication secondary to lumbar stenosis. In randomized controlled prospective multicenter trials and retrospective studies, investigators reported a better outcome with X STOP compared with conservative management.^{3,49,50}

The DIAM System. The DIAM Spinal Stabilization System (Medtronic Sofamor Danek) is a soft interspinous spacer (Fig. 4). The core is made of silicone, which is covered by a polyethylene coating. The surgical technique consists of identifying the interspinous space, removing the remnants of the interspinous ligament down to the ligamentum flavum, and using a distracter of the spinous processes to facilitate the insertion of the device. It is secured in place with two laces, one around the spinous process above, and another around the one below.

Biomechanical tests have demonstrated that a posterior soft shock-absorbing implant in the lumbar spine is able to reduce intradiscal pressure, retighten posterior elements of the vertebral bodies, and reduce rotatory dislocation.²⁸ This represents an attractive alternative for stabilizing the painful segment and yet allowing some spinal mobility.²⁷

Few articles on the efficacy of this product have appeared in the literature.^{9,27} In those studies a good satisfaction rate among patients receiving this device is reported, but the studies are all retrospective and lack controls. Today, this device is being tested in a clinical trial for FDA approval.

The Coflex, ExtendSure, and CoRoent Devices. Another

FIG. 4. Photographs showing the DIAM (Medtronic Sofamor Danek) interspinous process soft-stabilization system. This device is inserted between the spinous processes, with preservation of the interspinous ligament (see intraoperative views).

device that is used in Europe but is not currently FDA approved is the Coflex (Paradigm Spine) (Fig. 5). It is a U-shaped metallic device that is inserted between the spinous processes. As with other interspinous devices, these are designed to increase the cross-sectional diameter of the stenotic canal in patients suffering from neurogenic claudication. However, very little information is available in the literature on the biomechanics and efficacy of this product. Furthermore, ExtendSure and CoRoent (both from NuVasive) are other interspinous dynamic stabilization devices that were recently launched, in 2005 and 2006, respectively.

Pedicle Screw/Rod-Based Stabilization Devices

Pedicle-based dynamic devices were first designed to stabilize the abnormal segment and to unload degenerated discs and facet joints, while maintaining the same level of normal motion.⁴² By unloading the pressure on the degen-

FIG. 5. Photograph showing the U-shaped Coflex device (Paradigm Spine).

FIG. 6. Drawing from the US patent of an early ligamentoplasty model.

erated disc and facets, pedicle-based dynamic devices have the potential to reduce pain associated with these anatomical structures.

Furthermore, these devices can be used to prevent adjacent-segment disease, either by replacing the whole construct with dynamic rods or by “topping off” the rigid instrumented segment with pedicle-based dynamic devices, avoiding an abrupt change from a rigid construct to the more mobile adjacent segment. It has also been argued that using pedicle-based dynamic devices can promote better fusion because of micromovements across endplates, and can protect from implant failure because of better load sharing through the implant. Finally, these devices can be used to stabilize posterior iatrogenic destabilizing surgery, such as wide laminectomy and facetectomy.

The Graf System. The pedicle screw-based devices were first designed and launched in Europe, with Graf ligament (Surgigraft) being their first prototype (Fig. 6). The Graf system is the only pedicle-based device with polyester bands instead of rods. It is composed of 5- to 7-mm titanium pedicle screws and looped 8-mm braided polyester bands. After the spine is exposed and pedicle screws inserted, the bands are connected under applied compressive force between the pedicle screws as a ligamentoplasty. The tension and compression force used is determined by the length of the bands.^{16,18}

The product was conceived to immobilize the lumbar spine in lordosis; alter the load bearing on the anulus and endplate; compress the posterior anulus, resulting in fewer anular tears; splint the motion segment, allowing healing of damaged tissue to occur; and relax over time, allowing some return to movement.¹⁷ However, variable outcome results are reported in the literature. Some authors showed a good outcome score in the mid-term and even long-term follow-up evaluation.^{12,16–18,24,30} Others were less enthusiastic with their outcome scores, and reported high revision rates.^{4,35}

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FIG. 7. A: Intraoperative photograph showing transpedicular insertion of a semirigid rod system (Dynesys; Zimmer Spine). B and C: Anteroposterior and lateral radiographic views of the instrumentation in place.

The Dynesys System. The Dynesys Spine System (Zimmer Spine), like standard frame devices, is fixed in place by using standard pedicle screws made of a titanium alloy (Fig. 7). The whole system is stabilized by polyester cords that connect the screw heads through a hollow spacer and hold the screws in place.³⁸

In 1991, Zimmer Spine launched the Dynesys project development, and the product was introduced in the market and first implanted in 1994. The manufacturer stated that stabilization was possible with this implant without bone grafting. In 1999, the product gained popularity in Europe. Since then 13,000 implantations have been performed worldwide, and several clinical and biomechanical studies of this product have been published.

The Dynesys devices restabilize and realign the segments in physiological position and neutralize the excessive forces. Once the devices are attached bilaterally to the affected segments, the dynamic “push-pull” relationship between the spacer and the polyester cord stabilizes the joints, keeping the vertebra in normal position. This theoretically reduces segmental motion to a physiological level, neutralizing bending, torsional, and shear forces. The stabilizing cords resist flexion movements, and the spacers resist compressive forces. The overall effect of this stabilization is designed to limit the loading of the disc.^{13,32,38,40}

Several clinical studies have reported on the efficacy of the Dynesys system as a posterior stabilizing device. Prospective and retrospective studies have shown better outcome with Dynesys than with conservative treatment alone. However, those results were comparable to conventional rigid fixation,^{32,38,44} and a 17 to 19% rate of failure was reported in the literature.^{13,38} Today the Dynesys is the only FDA-approved pedicle-based dynamic device that is used not as a motion-preserving implant but as an adjunct to fusion procedures.

The AccuFlex, PEEK, and Isobar Rods. Other semirigid rods being used in the US include the AccuFlex (Globus Medical, Inc.), Medtronic's PEEK rod, and Scient'X's

FIG. 8. Photograph showing the Isobar (Scient'X) semirigid rod system. The arrow indicates the Isobar without the screws. (Reprinted with permission.)

Isobar (Fig. 8). To date, only limited clinical and biomechanical data are available on these devices.

Total Facet Replacement Systems

Total facet replacement is an emerging new technology designed to completely restore facet joints functionally. Until recently, the focus on the intervertebral disc has resulted in an underestimation of the facet joints as a potential pain generator, and little is known about the pathogenesis of facet disease.¹⁹ Nevertheless, the concept of facet arthropathy is not new and was first described by Goldthwait in 1911. The contemporary literature focuses on anterior column failure as leading to posterior element degeneration, with subsequent stenosis and segmental instability.^{2,7,11,19,20,29,31,48} However, facetogenic pain can occur in the absence of or combined with significant disc degeneration.^{19,26,36,47,48} For this reason, total facet replacement and arthroplasty may be a potential treatment analogous to total disc arthroplasty for discogenic pain.

The second indication for total facet arthroplasty could be for reconstruction of the iatrogenically destabilized spine. In some instances, wide laminectomy with facetectomy is required to treat lumbar and lateral recess stenosis. Total facet arthroplasty would become an interesting adjunct to these surgeries, reducing the likelihood of iatrogenic destabilization while preserving a potentially functioning facet and averting the need for arthrodesis.

The third potential role of total facet arthroplasty would

FIG. 9. A: Intraoperative photograph showing the TFAS (Archus Orthopedics) in place. B: Photograph of a model spine with the TFAS implant affixed. C: Lateral radiographic view showing the instrumentation in place.

be to augment total disc arthroplasty for complete functional spine unit reconstruction. Because facet disease remains a contraindication to disc arthroplasty, combining both technologies in a 360° circumferential motion segment reconstruction would allow a broader application of these motion-preserving devices.

The TFAS Implant. The TFAS (Archus Orthopedics) is anchored with its stems fixated to the vertebral body (Fig. 9). Motion is achieved by a sphere sliding along a curved plate. An FDA-regulated multicenter prospective randomized trial for this device is currently underway to study the safety and effectiveness of TFAS compared with posterior instrumented fusion in treating moderate-to-severe lumbar stenosis that requires neural decompression and facetectomy of L3/4 and L4/5 levels.

The TOPS Implant. The TOPS (Impliant) is anchored by devices much like pedicle screws by using a standard posterior approach (Fig. 10). The posterior elements are removed and the device is implanted, occupying the same position as the posterior elements. It is a unitary device composed of a top and bottom titanium construct with an interlocking flexible polyurethane core connecting the bottom and top components. Within the polyurethane cover are “bumpers” that allow but at the same time limit the extent of motion in axial, lateral bending, and extension. Further investigations with this device are being planned, and recently it received FDA approval to begin a pivotal clinical trial.

The Stabilimax NZ Implant. Another device, the Stabilimax NZ (Applied Spine Technologies, Inc.), has recently been introduced to the market. As with the two previous devices, it is anchored in place through pedicle fixation (Fig. 11). Motion is achieved by two independent concentric springs on each side, which are incorporated into the system through connecting rods.

Conclusions

The future of PDS devices is promising. Although the

Fig. 10. Photograph showing a spine model with the TOPS instrumentation (Impliant) affixed. (Reprinted with permission.)

biomechanics, long-term clinical efficacy, and indications for these devices are not yet clear, this classification scheme will serve as a useful construct with which to view this emerging technology.

Disclaimer

The authors have no financial interest in any of the products discussed in this paper.

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Fig. 11. Three-dimensional reconstruction of a spine showing the Stabilimax NZ device (Applied Spine Technologies, Inc.) in place. (Reprinted with permission.)

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