

## Authors and Disclosures

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Disclosure: Dr. Scott-Young is a shareholder in Impliant, Inc., which owns the TOPS device.

## From Neurosurgical Focus

# Posterior Dynamic Stabilization Devices in the Coming Age of Lumbar Disc Replacement

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## Abstract and Introduction

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### Abstract

Posterior dynamic stabilization (PDS) devices promise to relieve pain by altering the transmission of any abnormal loads across degenerative discs. These devices can function as an adjunct in the presence of anterior and posterior total disc replacement (TDR). Clinical reports on currently available PDS devices are reviewed and their applicability to TDR is discussed. Products being developed that incorporate posterior TDR prostheses with PDS devices are also reviewed. The PDS devices described can be used in conjunction with anterior TDR at the time of the initial surgery or at a later date. Posterior TDR prostheses used in conjunction with PDS devices will have a role in the marketplace in the future.

### Introduction

Posterolateral spinal fusion used to be regarded as the gold standard for the surgical management of lumbar spinal instability. With time, however, the question arose as to whether spinal arthrodesis increased the mechanical stresses at other segments and, indeed, whether it might even accelerate the degeneration, resulting in adjacent-segment disease.<sup>[8]</sup> This issue, together with the unpredictability of outcomes in fusions and the problems associated with bone grafting, has led surgeons to explore nonfusion technologies, including artificial nucleus pulposus replacement, TDR, PDS, or a combination thereof.

Posterior dynamic stabilization of the lumbar spine has gained considerable attention in recent years.<sup>[5,10]</sup> The surgeon's intention in using the implants is to maintain or restore the inner segmental motions to magnitudes that match those of the intact spine. The second potential benefit of this procedure is that it may have no negative effects on the adjacent motion segment.<sup>[14]</sup>

The concepts for nonfusion systems have ranged from TDR with complete excision of the disc, replacing the nucleus while maintaining the anulus, to maintaining the disc with a controlled motion of the segment. A more recent theory is that these concepts can be combined and are not mutually exclusive.

There are two possible clinical areas in which TDR and PDS may complement each other. First, a PDS device may be of use when a TDR is revised; during the revision procedure, a PDS device may be used to stabilize the mechanics or reduce the pain emanating from the motion segment already treated with a TDR. Second, there may be cases in which TDR and PDS devices may be used together appropriately. The potential for this procedure arises when a TDR prosthesis is inserted anteriorly followed by a PDS construct posteriorly and, in addition, when a TDR device is inserted via a posterior approach and supplemented with PDS during the same procedure.

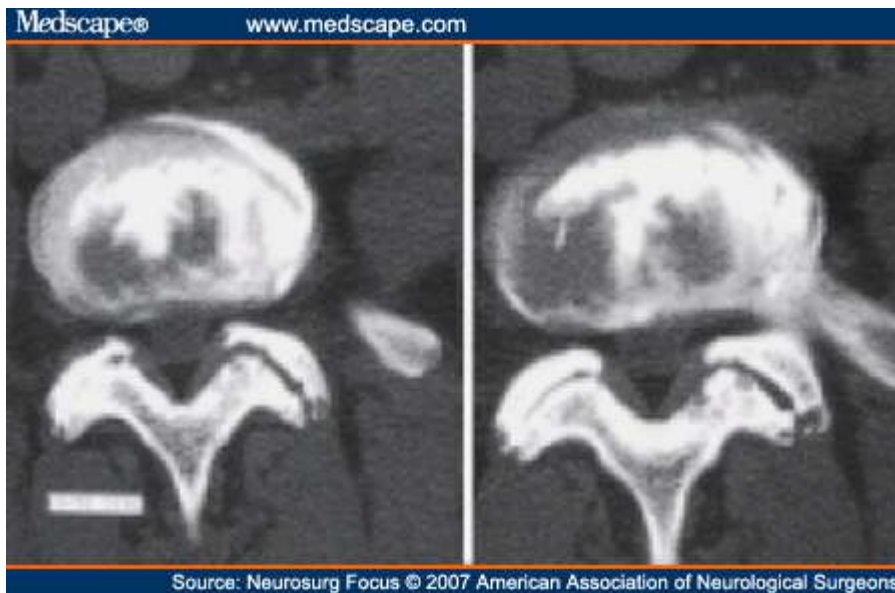
## Classifications of Potential Use

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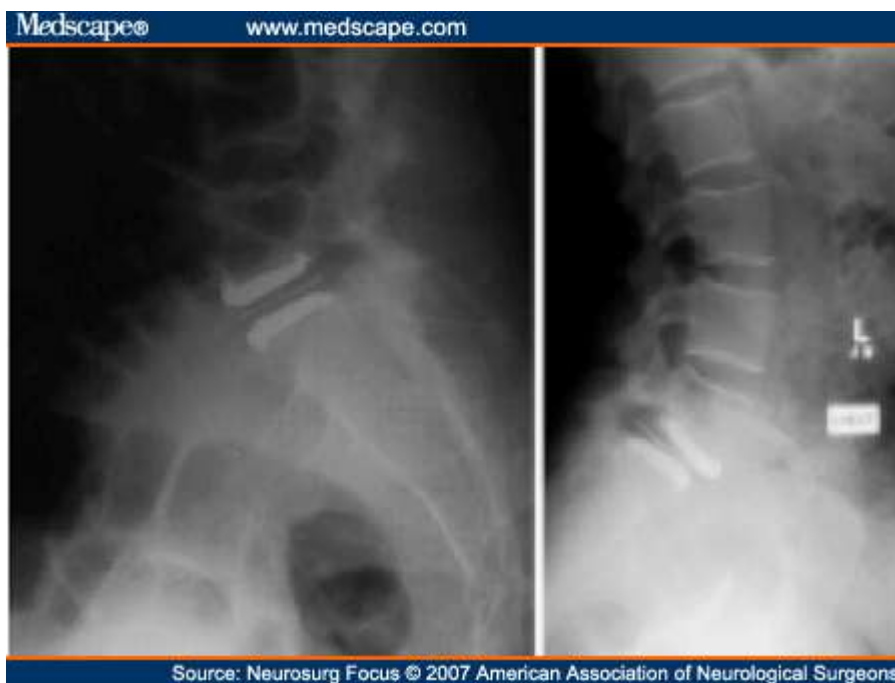
A PDS device can be used in either of two ways: 1) in a revision of a TDR; or 2) in conjunction with TDR, either for anterior TDR and PDS or posterior TDR and PDS.

## Role of PDS in Revision of TDR

In my experience during a decade of performing TDRs, postoperative instabilities occur for several reasons, and there are four possible scenarios. The first occurs as a result of facet arthropathy. This is a failure of indication, in which the facet arthropathy is overlooked by the surgeon. Performing a TDR in the presence of incompetent posterior structures can worsen the biomechanical situation (see Figs. 1 and 2). The surgeon has several possibilities when considering TDR revision options. One is to choose to augment the arthroplasty with a PDS device.



**Figure 1.** Preoperative concordant discograms displaying L5–S1 Grade 3 facet arthropathy.



**Figure 2.** Postoperative x-ray films. Left: Lateral view of L5–S1 obtained immediately postoperatively, displaying optimum positioning and placement of the prosthesis. Right: Lateral view demonstrating asymptomatic instability of L5–S1 with subluxation at 12 months postoperatively.

The second scenario occurs when, after a number of years, facet arthropathy develops and symptoms arise. There may or may not be appositional, biomechanical, or clinical instability. If the patient has little pain, with evidence of minor radiographic instability, then once again a PDS may be indicated.

A third situation arises when a TDR device has been placed eccentrically and/or is undersized. This scenario creates a functional spinal unit imbalance. The mechanics of the discs are suboptimal and, as a result, wear may increase. In this situation, the surgeon may elect to revise with a pedicle screw fusion or apply PDS.

A fourth situation occurs in multilevel TDR (that is, replacement of two or more discs). Multilevel TDR requires great skill in determining the midline of the disc, so that the prostheses are in the coronal midline and in the correct sagittal position at each level. In my opinion, the critical issue is that of equal lateral annular resection. Too much annulus being resected on one side will lead to coronal plane instability; thus, the prosthesis would have a tilt (see Figs. 3 and 4). Often patients who undergo this procedure are relatively asymptomatic. The concern in the long term, however, is whether the altered mechanics in the facet will result in facet arthropathy, possibly combined with pain and instability. As a result, the surgeon may elect to augment the multilevel TDR with a PDS.



**Figure 3.** Postoperative x-ray films. Left: Anteroposterior view of segmental scoliosis secondary to asymmetrical annular resection. Right: Lateral view of segmental scoliosis secondary to asymmetrical annular resection.



**Figure 4.** Postoperative x-ray films. A: Coronal plane correction using the Dynesys system. B: Sagittal view of lumbar spine in extension with Dynesys system in situ. C: Sagittal view of lumbar spine in flexion with Dynesys system in situ.

When performing anterior TDR, resection of the anterior longitudinal ligament and the anterior portion of the annulus fibrosus is always performed. Indeed, sometimes the posterior annulus fibrosus and posterior longitudinal ligament need to be stretched, ruptured, or resected to allow insertion of a TDR device. These procedures destabilize the lumbar spinal segment to some extent and create the potential for segmental scoliosis. Studies by Cunningham et al.<sup>[3]</sup> and McAfee et al.<sup>[9]</sup> have shown that when an unconstrained lumbar TDR prosthesis is inserted, the ROM in flexion, extension, and lateral flexion is very similar to the physiological level, although rotational movement is increased up to 40%. Obviously, multilevel TDR has an additive destabilizing effect when two annuli are resected. This effect can be up to 240% of normal (100%).<sup>[9]</sup>

The studies reported by Cunningham and McAfee were benchtop biomechanical findings. These studies therefore had limitations because they did not take into account the in vivo contribution of muscle forces, progressive biological healing, heterotopic ossification, fibrosis, adhesions, and other issues that may limit the rotational instability that follows dissection of these structures.

Lemaire et al.<sup>[7]</sup> performed an in vivo comparative study of axial rotation in patients in whom one and two TDR prostheses had been inserted. They found that 65% of patients who had undergone one-level TDR showed normal mobility and torsion, whereas 35% showed a slightly increased mobility. In relation to two-level TDR, 50% of the patients experienced increased mobility. These findings need to be considered with caution in view of the small numbers included in the study. Furthermore, it was not clear what, if any, postoperative rehabilitation program was followed. I believe that a rehabilitation regimen focused on core stability is essential to optimize the outcome.<sup>[13]</sup>

Several technical issues are important when performing multilevel TDR. First, meticulous positioning of the prosthesis in the midline of the disc is mandatory, and great care should be taken to place the device in the correct sagittal and coronal plane. The second technique is to decrease the size of the TDR device in cephalad compared with caudal levels. This leaves more annular tissue intact laterally for stability. The third issue is the need to produce symmetrical lateral annular resections. The vast majority of postoperative segmental scolioses are due to asymmetrical resection of the annulus and imperfect sagittal placement, resulting in a segmental scoliosis in addition to a possible rotational instability.

In cases of segmental scoliosis, PDS can be used to salvage the mechanical function of the spine. The PDS device selected should suit the patient's stage of facet degeneration and take into account the amount of additional iatrogenic instability that will result from resection of the facets and decompression of the neural elements.

Several PDS devices are now on the market. Dorsal interspinous blocking devices are placed between the spinous processes; they are placed under distraction, and may be kyphogenic.<sup>[2]</sup> These devices generally provide a block to extension, and they may provide very minimal resistance to rotation through interspinous blocking, but overall they provide very little stabilization. These devices may be appropriate for Stages I, II, and III disc degeneration classified according to the Thompson system, but would be unsuitable for supplementation when using an anterior or posterior TDR. Devices currently available that were developed according to this principle include the X STOP, DIAM, and Wallis devices.

Other types of PDS devices are the posterior dynamic semistabilizing systems. These provide moderate stabilization, they allow for some varying degrees in the ROM, and are primarily stabilizing in flexion and extension.<sup>[16]</sup> They have minimal rotation or lateral bending stability and may be appropriate for treating more advanced stages of the primary disorder. Examples of these devices include the Graf ligament or the Dynesys system. These devices have enough strength and flexibility to be combined with anterior (see Fig. 4) or posterior TDR.

The next group includes posterior semirigid stabilization devices. These are based on standard pedicle screws that are essentially the same as screws used with fusion devices. They allow a very limited ROM and some concerns exist about the bone/screw interface. These types of implants have been designed for use in very stiff Stages III and IV disc degeneration. This type of device currently includes the Isobar and Cosmic.<sup>[17]</sup>

Other PDS devices that may be appropriate for one-level TDR augmentation include posterior dynamic full stabilizing devices, such as the TOPS system. This device provides tangible stabilization in all modes, including flexion, extension, rotation, and lateral bending. It also provides a shock-absorber effect in axial compression. In my opinion, it represents the only truly dynamic device on the market, in that it provides a near-normal physiological ROM. There is very minimal

bone/screw interface loading because of the unique design, and the prosthesis may be suitable for actual physiological replacement of the facets, thus allowing full decompression of these facets in the lateral recesses. This device would be suitable for all stages of disc degeneration, from Stages II to V, in conjunction with TDR. It is probably unsuitable if a significant spondylolisthesis is present.

The choice of the application of a particular PDS device for augmentation of an anterior TDR depends on the severity of the patient's symptoms and disease as well as the surgeon's experience with and preference of PDS devices.<sup>[16]</sup>

Figures 3 and 4 demonstrate a case in which a PDS device was successfully used in a revision of a TDR procedure. This case involved a 41-year-old woman who had a 10-year history of chronic persistent low-back pain that affected her social, recreational, and employment opportunities. The condition was resistant to conservative management. Clinical investigations included a magnetic resonance image that revealed three-level degenerative disc disease and provocative discography that confirmed reproduction of the patient's pain at three levels.

A three-level TDR was performed using CharitE9 prostheses. Immediate postoperative x-ray films showed anatomical alignment of the prostheses. A subsequent follow-up evaluation showed significant reduction in pain scores and improvement in functional scores. Nevertheless, the postoperative x-ray films showed the development of a segmental scoliosis (Fig. 3). This disorder was believed to be due to asymmetrical annular resections and loss of the anterior longitudinal ligament over three levels. Despite the significant reduction in pain and functional levels, it was thought that long-term mechanical instability and asymmetrical wear of the prosthesis could be deleterious to the patient.

After discussions with the patient, a PDS procedure was performed in which the Dynesys system was used to correct the segmental scoliosis (Fig. 4A). The patient had a good result and returned to full-time work (Fig. 4B and C).

## **The PDS and TDR Techniques Applied Together at the Index Procedure**

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### **Anterior Disc Replacement Followed by PDS**

There is no evidence reported in the literature that the technique of an anterior TDR followed by a PDS has been used as the index procedure. The potential benefit of such a technique is that of motion preservation of one or more segments. Potential disadvantages are those usually connected with a circumferential procedure, including approach- and device-related complications. However, in my opinion this technique has appeal and potential.

### **Posterior TDR in Conjunction With PDS**

There is a perception that the prostheses used for posterior TDR performed in conjunction with PDS will be the next generation of spinal arthroplasty devices. The rationale is that the technique provides a posterior TDR and a matching facet replacement device, thereby becoming a multipurpose dynamic stabilization system. This view is based on the premise that the current TDR prostheses on the market do not address the facet joint as part of the motion segment. The indications for posterior TDR are significantly different from those of anterior TDR. For example, conditions such as Grades 2 and 3 facet arthropathy with stenosis are contraindications for anterior TDR, but these conditions may be included in the indications for posterior TDR in conjunction with PDS. The use of this style of prosthesis could ultimately shift the age of the population eligible for TDR to allow treatment of patients older than 60 years. The other proposed benefit of posterior TDR and PDS is that it may address neural compression.

The anterior approach remains unfamiliar territory to many spine surgeons and is perceived to be hazardous. In the US, general or vascular access surgeons are used for anterior approaches.<sup>[12]</sup> Ideally, the spine surgeon should perform his or her own approach and exposure. This practice leads to economical use of time and eventually a volume performance threshold such that approach-related complications are negligible. A posterior approach for TDR is more attractive to the majority of spine surgeons, mainly because of their familiarity with it.

The proponents of the posterior TDR argue that access to the main pain generators of the motion segment (that is, the disc, the facet, and the neural structures) can be provided using this approach, and they consider that it deals with 90% of disorders, whereas only 5 to 10% of disorders can be dealt with anteriorly.<sup>[6]</sup>

Several systems are in the early stages of development. To avoid damage to the cauda equina, the design is essentially for a lumbar paired-disc prosthesis. With respect to this style of device, lessons can be learned from the destabilizing effects of stand-alone PLIF cages. Brodke et al.<sup>[1]</sup> performed a study in which they used a calf spine model for biomechanical testing. This model has been validated as an appropriate alternative to human cadavers. These investigators compared PLIF in which bone graft was used against PLIF with a posterior spinal fixation and found that the addition of posterior spinal instrumentation increased the stiffness significantly. This result suggests that if one is to insert a paired TDR posteriorly, the addition of posterior instrumentation, in conjunction with an intact posterior longitudinal ligament and posterior annulus, leads to stability in flexion and extension. The challenges that arise with using two dual-radius anterior discs revolve around getting enough of a footprint to prevent subsidence and making sure that there is movement with nonparallel (unconstrained) placement.

Posterior TDR may require a variety of surgical techniques for insertion. These techniques may have different distractive capabilities, and this can affect the initial stability of the device. A comparison may be drawn from experience with the destabilizing effects of PLIF procedures. For example, the Ray Threaded Fusion Cage required complete medial and partial lateral facetectomies. This is a large-diameter cylinder with a transverse dimension that when inserted as a pear may exceed the interfacetal interval. To obtain the necessary height restoration (implant height diameter plus 6 mm) is often impossible, and would result in destabilization of the motion segment.<sup>[11]</sup> Other implants include contact fusion cages that were implanted and rotated 90°. The risk here is with endplate fracture.<sup>[4]</sup> In terms of posterior TDR, this would be inserted into the interbody space in an upright orientation. An attempt should be made to preserve as much facet joint and capsule as possible. From a biomechanical point of view, any extensive or partial facetectomy can indeed destabilize the motion unit in axial rotation. One would also expect increases in the neutral zone due to injuries to the annular tissue. Studies have shown an increase in the ROM of stand-alone PLIF devices.<sup>[11]</sup> Differences in stability were observed in stand-alone implants compared with those that had a pedicle screw supplementation posteriorly, which showed a substantial increase in stability. Applying these principles to posterior TDR, posterior paired dynamic implants based on a pedicle screw system can be inserted. Several systems are already available on the market, including the Graf ligament, Dynesys system, and TOPS system, to name a few.

Several specific challenges need to be faced to attain long-term viability of posterior TDR in association with PDS procedures. These include screw/bone interface and fatigability of the implants. As a result, biomechanical, biocompatible, and preclinical testing in animals and cadavers is mandatory. A multicenter prospective trial is needed in which the true benefits in treated patients are compared with a control or other population group.

## Conclusions

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It is clear that dynamic stabilizing systems have several theoretical advantages.<sup>[14]</sup> They allow movement, they load-share, and they avoid adjacent motion segment degeneration and bone grafting. We have already seen improved patient outcomes after treatment with these prostheses compared with fusions, and the safety and efficacy of the devices are similar.<sup>[2,15,16]</sup> In the context of the advent of lumbar TDR, there appear to be two main roles for these devices, one of which is their use in the revision of a TDR, and the other their use in conjunction with a posterior TDR.

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**Abbreviation Notes**

PDS = posterior dynamic stabilization; PLIF = posterior lumbar interbody fusion; ROM = range of motion; TDR = total disc replacement. *Neurosurg Focus*. 2007;22(1) © 2007 American Association of Neurological Surgeons