Pedicle screw-based dynamic stabilization of the lumbar spine

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Abstract: Although spinal fusion has been the definitive surgical management of symptomatic lumbar degenerative conditions, continued reports of adjacent level degeneration and suboptimal patient outcomes have prompted the advancement of motion-preserving technology. Posterior dynamic stabilization (PDS) devices are designed to maintain native motion while providing indirect foraminal decompression and off-loading of the facets and posterior anulus. Posterior dynamic stabilization systems relying on pedicle screws as vertebral anchors have the advantage of surgeon familiarity with screw placement technique and instrumentation. Interconnections between the screws serve as a tension band to resist posterior distractive forces during flexion and maintain foraminal height in extension. Short-term results of pedicle screw-based PDS systems show comparable pain relief to traditional fusion with the added advantage of retained motion and potential reduction of fusion-related morbidity and of the incidence of adjacent segment degeneration. As with most new technology, pedicle screw based PDS systems require further evaluation to determine their long-term clinical benefit. *(p1-8)*

Introduction

Spinal fusion has been accepted as the definitive surgical treatment of symptomatic lumbar degenerative disk disease and/or instability. The rationale for spinal arthrodesis as a treatment modality for low back pain centers on the assumption that abnormal intervertebral motion causes pain and that immobilization of adjacent vertebral bodies will lead to a reduction in mechanical back pain. Unfortunately, the potential benefits and the results of arthrodesis can often be compromised by symptomatic adjacent segment degeneration and/or pseudarthrosis.[4,5,12,18,35,43] Biomechanical studies have shown that fusion results in increased stress on neighboring vertebral segments, with increased intradiscal pressures and supraphysiologic vertebral motion. Furthermore, long-term clinical studies have documented radiographic degeneration of the adjacent vertebral segments.[19,36,42,44]

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Spinal arthroplasty has been introduced as an alternative to allow stable pain-free motion without the required healing for fusion. Posterior motion sparing systems have been designed to off-load the posterior facets and anulus and control motion in defined planes. Through stabilization of the vertebral motion, pain may be minimized and the controlled motion may decrease the secondary effects of fusion.

Posterior dynamic stabilization systems can be categorized into three types of devices: 1) posterior interspinous spacers; 2) pedicle-based constructs; and 3) total facet replacement systems.[33] In this review article, we will focus on the pedicle screw-based PDS devices which can be further subdivided into tension band-based systems (soft) and rod systems (semi-rigid).

Soft posterior dynamic stabilization

Graf Ligament

The Graf ligament was introduced in 1992 as an alternative treatment for spinal fusion.[8,22,26,40] Henri Graf theorized that abnormal rotary motion might be the primary source of mechanical low back pain. To address this problem, Graf used a braided polyester tension band to link titanium pedicle screws (Fig. 1), stabilize rotary motion, and realign the segment in physiological lordosis.[29,43] The "ligament" was also intended to compress the posterior anulus and allow healing of anular tears. Strauss et al, found that the Graf construct mainly reduced motion in flexion and extension and not translation. They recommended this device for problems related to flexion instability.[55]

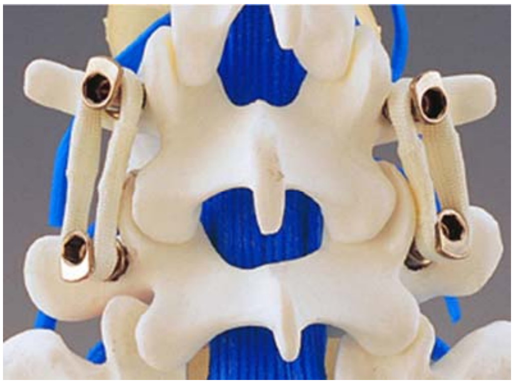


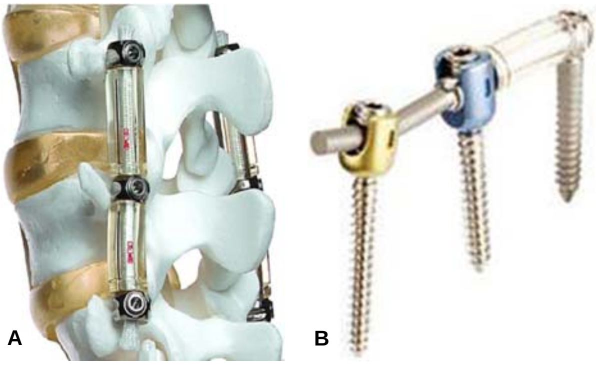
Figure 1 - Graf ligament device on a spine model. (Reprinted with permission).

Initial outcomes following Graf ligament placement showed only modest improvement in functional ability and a high re-operation rate. Grevitt et al, reviewed 50 chronic lower back pain patients that were treated with the Graf ligament construct and reported improvement in Oswestry Disability Index (ODI) scores from 59 preoperatively to 31. However, postoperative radiculopathy was reported in 12 of 50 patients leading to the recommendation of prophylactic foraminal decompression prior to device placement.[23] Other published retrospective case-control studies showed significantly better outcomes in patients following a traditional spinal fusion compared to those treated with the Graf ligament due to a higher revision rate in the Graf treatment group after two years (73% for Graf ligament group versus 43% for the traditional fusion group).[25] Rigby et al, cautioned against the use of the Graf ligament device based on a retrospective review of 51 patients after four years follow up in whom the Graf device had only a six point improvement in their ODI scores and 41% of patients reported that they would not undergo a similar procedure again.[49]

More recent prospective randomized evaluations reported better clinical outcomes in patients undergoing the Graf ligament placement compared to fusion. Good to excellent results were reported in 93% of the Graf ligament group compared to 78% with traditional spinal fusion patients.[21] Moreover, a recent ten year follow-up study of 56 patients who were treated with the Graf system showed that the construct maintained segmental lordosis and disability improved in patients with spondylolisthesis or flexion instability. Patient with scoliosis or lateral listhesis, however, had poor clinical improvement requiring re-operation. The authors reiterated careful patient selection to optimize good clinical outcomes[(22,23)] due to the potential for exacerbating facet disease and lateral recess/foraminal stenosis.[41]

Dynamic neutralization system for the spine (Dynesys)

The Dynesys system (Zimmer Spine, Warsaw, IN) is composed of two titanium pedicle screws connected by a cylindrical polycarbonate urethane (PCU) spacer with a tensioned polyethylene terephthalate (PET) cord tunneled through the PCU spacer. The PET cord resists tensile forces and provides resistance to spine flexion (Fig. 2a) similar in concept to the Graf system. However, the Dynesys PCU spacer resists compression during extension and thereby maintains foraminal height and decreases load to the posterior annulus.[3,13,15,50,51,57] The Dynesys system is FDA approved as an adjunct device for spinal fusion, however, through controlled motion and indirect decompression, the Dynesys system attempts to decrease discogenic low back pain while minimizing the risk for adjacent segment degeneration.



A B

Figure 2a - Dynesys device on a spine model, **b**) Dynesys DTO device. (Reprinted with permission).

Clinical studies on the Dynesys system have shown mixed results. Although a recent biomechanical study by Cheng et al, demonstrated no significant difference in stress at the adjacent level between Dynesys or traditional titanium rod constructs,[(11)] the literature reports equivocal to superior clinical outcomes using the Dynesys system as a non-fusion device compared to traditional rigid fusion.[6,7,9,16,32,46-48,54] In 2005, Grob et al, published a retrospective study on 50 patients (31 patients of which most of the results focused on) who were treated with the Dynesys system for symptomatic degenerative disk disease or stenosis with associated instability (listhesis). Back and leg pain improved in 67% of patients, however, functional capacity only improved in 40% of the patients with a high rate of re-operation (19%).[24]

Recently, Davis et al, (2007) reported the results of a multi-center, randomized study examining the non-fusion application of the Dynesys system in 305 patients with degenerative spondylolisthesis, retrolisthesis, or lateral or central stenosis. Two-hundred-and-nine patients were treated with the Dynesys system and 96 patients were treated with traditional rigid spinal fusion. At short-term follow-up (12 months), patients treated with Dynesys were better or clinically comparable to patients who underwent a traditional fusion procedure.[13]

The Dynesys system has recently become available in a hybrid configuration, the Dynesys DTO device (Fig. 2b). This device is intended to combine the features of dynamic stabilization at one spinal segment with rigid rod stabilization at an adjacent level. Further long-term evaluation is necessary to truly understand the efficacy of Dynesys in terms of junctional disease, local facet degeneration, implant loosening, and fatigue survival.

Semi-rigid rod dynamic stabilization systems

AccuFlex

The AccuFlex rod (Globus Medical, Inc., Audubon, PA) is designed with helical cuts within its substance to minimize rigidity (Fig. 3). This more flexible rod is currently FDA approved as an adjunct for single-level fusions. In a one year prospective, randomized study of 170 patients treated with the Accuflex rod system, comparable fusion rates and clinical outcomes were reported between interbody fusion using the traditional rigid instrumentation versus the flexible rods.[39]

Figure 3 - AccuFlex rod device on a spine model. (Reprinted with permission).

Isobar TTL

One of the first introduced semi-rigid rods is the Isobar TTL system (Scient'x USA, Maitland, FL). This implant has been used in Europe for over ten years and was granted FDA clearance for use as an adjunct to spinal fusion in 1999 (www.accessdata.fda.gov). Composed of a titanium alloy rod with a dampener element made of stacked titanium alloy o-rings, the Isobar TTL allows a small amount of both axial and angular motion to the rigid rod (Figs. 4a and b). Perrin and Cristini reported a retrospective study with a mean follow-up of 8.27 years using the Isobar TTL system in 22 patients with lumbar spondylolisthesis. The slipped levels were treated with a PEEK cage followed by a two level posterior fixation with the Isobar TTL system. All patients went on to fusion at the rigidly fixed level, with no device failure or revision surgery required. Long-term clinical outcomes were excellent with 68.2% of patients reporting mild leg pain, 72% no or mild back pain with 91% of patients very satisfied with the procedure. The adjacent level also appeared to be protected using this type of rod.[44]

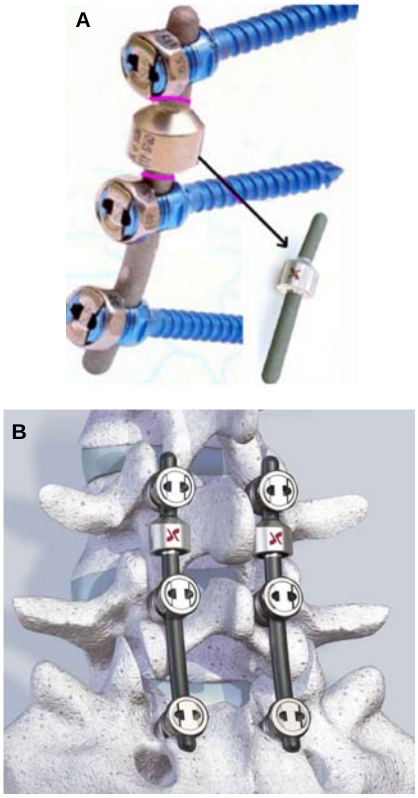


Figure 4a - Isobar TLL device. **b**) the Isobar device on spine model. (Reprinted with permission).

Awasthi et al, confirmed these findings in a prospective study on 13 patients treated with the Isobar TTL system. At 18 month follow-up, all patients were fused over the levels of rigid fixation, while the semi-rigid rod levels remained unfused. Follow-up MRI scans demonstrated no evidence of degeneration over the levels spanned by the semi-rigid rod. Oswestry Disability Index functional scores improved from 51 to 22% and the Prolo functional scale improved from 1.7 to 3.1. No implant related complications were noted. The authors concluded that the Isobar TTL effectively stabilizes the motion segment above a fusion and retards the progression of adjacent level degeneration.[2]

CD-Horizon Legacy PEEK rod

A semicrystalline thermoplastic polymer, polyetheretherketone (PEEK), has gained acceptance for use in spinal interbody fusion (Fig. 5). Recently, PEEK rods have been introduced as an alternative to titanium rods in pedicle screw-based instrumentation. Although PEEK rods (Medtronic Sofamor Danek, Inc., Memphis, TN) are inherently more flexible than titanium rods, biomechanical testing shows comparable flexion/extension rigidity when combined with an interbody spacer.[10,27] The PEEK rod is currently FDA approved for adjunct fixation for one-level interbody fusions.

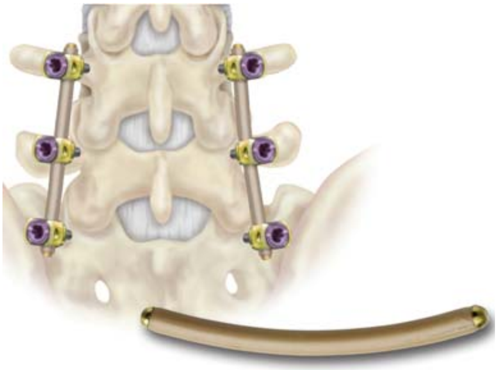


Figure 5 - CD-Horizon Legacy PEEK rods™ device and an illustration of the device on a spine. (Reprinted with permission).

Truedyne PDS

The Truedyne PDS (Disc Motion Technologies, Boca Raton, Florida), is a pedicle screw based adjustable posterior dynamic stabilizer, in which 5mm of flexion, 3mm of extension and rotation can be set separately (Fig. 6). It is designed to move in an arc that elongates in flexion ensuring normal angular segmental motion, and due to a closed design, it is also stable to shear forces. This system is designed to allow synchronous motion resulting in less strain on the disc above. The dynamic pedicle screw still allows motion between the head and shaft of the screw after being locked down. This minimises screw loosening and also allows the screw to be used for multi-level non-fusion constructs in degenerative scoliosis. This system is currently in pre-clinical testing.[21]

Stabilimax NZ

During normal spine motion, the ranges at which there is minimal resistance to motion by the disc is referred to the Neutral Zone (NZ). The NZ is believed to increase with disc degeneration or injury, resulting in more “instability” and pain. The Stabilimax NZ (Applied Spine Technologies (AST) Inc., New Haven, CT) device was created to reduce the impact of the NZ on mechanical back pain. The Stabilimax NZ system uses a rod with dual concentric springs, to maintain the spinal segment in a neutral position during spinal motion (Fig. 7) serving as a sort of internal splint.[58] The Stabilimax NZ is currently undergoing randomized clinical trials for dynamic fusion applications in the United States.

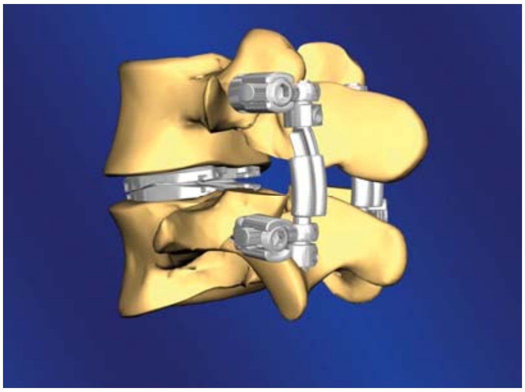


Figure 6 - Truedyne PDS construct with a posteriorly inserted disc arthroplasty device. (Reprinted with permission).

Figure 7 - NZ device on a spine model. (Reprinted with permission).

Cosmic Posterior Dynamic System

The Cosmic posterior dynamic system (Ulrich GmbH & Co. KG, Ulm, Germany) uses hinged pedicle heads to allow for segmental motion. Van Strempel et al, published a two-year follow-up study on the Cosmic system in patients treated surgically for lumbar degenerative disorders. Overall, patients treated with the Cosmic system had comparable clinical outcomes to the fusion group. This study showed that the Cosmic device may be an alternative to traditional fusion therapy, however long-term follow-up studies are needed to assess its impact on adjacent level degeneration.[56]

Bioflex Spring Rod Pedicle Screw System

The Bioflex System (Bio-Spine, Inc.) is a pedicle screw-based system which uses a Nitinol rod shaped with one or two loops intended to confer stability in flexion, extension and lateral bending (Figs. 8a and b). Nitinol is an alloy of nickel and titanium, commonly referred to as "memory metal" for its ability to return back to its original shape after deformation. Kim et al, reported outcomes on 103 patients that were divided into two groups, each being treated with the Bioflex system with or without a PLIF. The authors noted favorable fusion success on the levels treated with the Bioflex implant and PLIF (90%). Additionally, there was no significant difference between the preoperative ROM and ROM at the 1-year follow-up in those levels not fused but instrumented with the Bioflex system.[34]

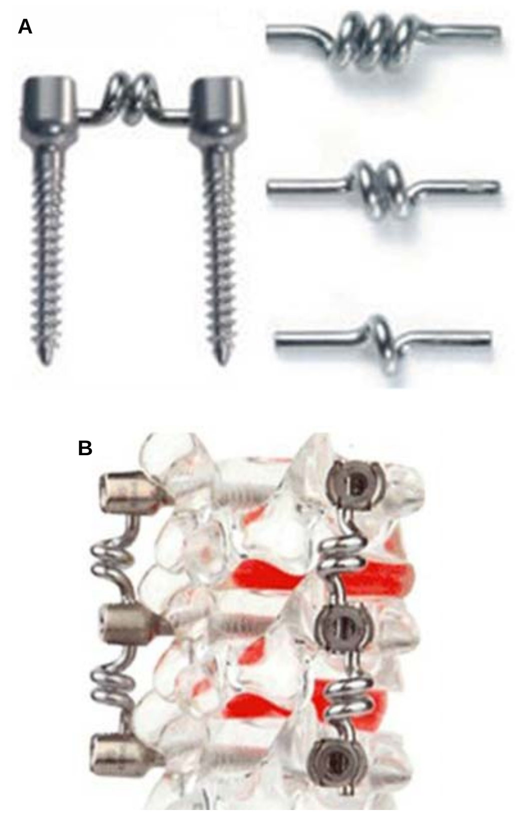


Figure 8a - Bioflex deivce, **b**) An illustration of the device on a model spine. (Reprinted with permission).

CD-Horizon Agile

The CD Horizon® Agile™ (Medtronic Sofamor Danek, Inc. Memphis, TN) dynamic stabilization device was intended to provide posterior dynamic stabilization through a floating cable design that allows for an axial compressive load while retaining constant stiffness. Agile was first used in late 2006 following FDA clearance for use as an adjunct to fusion. The device consisted of pre-curved, lordotic titanium rods with a titanium cable and PCU bumper. Originally promoted as offering greater motion than the Dynesys device in combined flexion and extension, the device was later recalled by Medtronic Sofamor Danek, due to implant failures that were occurring in both on-label and off-label use.[17] The implants were noted to break due to shear-related failure of the cable component and were noted as being more likely to occur with advanced instability.

Fulcrum Assisted Soft Stabilization System (FASS)

The FASS system, as described by Sengupta and Mulholland, is another dynamic pedicle screw system that uses a fulcrum placed between the pedicle screws and more proximally or posteriorly placed tension band to keep the spinal segment in lordosis. This is intended to impart anterior annulus distraction forces in addition to off-loading the posterior elements. The fulcrum maintains foraminal height and minimizes overloading of the posterior annulus. Biomechanical testing has supported this assertion, however at this time, no clinical data is available on the FASS system.[52]

Dynamic Stabilization System (DSS)

The DSS system was designed as an improvement of the FASS system. Biomedical studies have suggested that the FASS system experiences too much load during flexion which may lead to early device failure. The DSS system uses a flexible titanium spring that connects two adjacent pedicle screws. The DSS system to date has gone through two developmental cycles. The latest model, called the DSS-II (Fig. 9), uses a coil shaped titanium spring as its longitudinal component. In 2005, Sengupta et al, presented the results of a one-year pilot study using the DSS-II system in 16 patients treated for single or two-level disease. Mean VAS scores improved from 7.3 to 3.5 and ODI improved from 65 to 27 at follow-up. No radiographic loosening or implant failure was observed.[53]

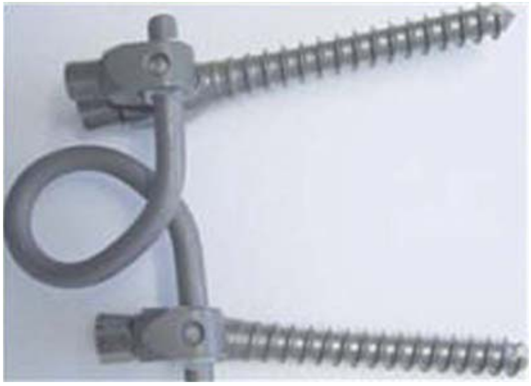


Figure 9 - DSS-II device. (Reprinted with permission).

N-Flex

The N-Flex device (Synthes Spine Inc., West Chester, PA) was designed to accommodate this physiologic motion via a bumper element that permits elongation and angulation during flexion and allows compression during extension. In the unaltered lumbar spine, flexion is necessarily coupled with elongation of the posterior segments; therefore, any device hoping to provide support through physiologic flexion would be required to elongate as well. Though several of the aforementioned devices adequately restrict lumbar extension, reproduction of normal spinal flexion has proved more difficult to emulate. The N-Flex system is semi-rigid and composed of a titanium rod with one end containing a composite titanium-polycarbonate urethane sleeve (Figs. 10a and b) positioned over the titanium core.

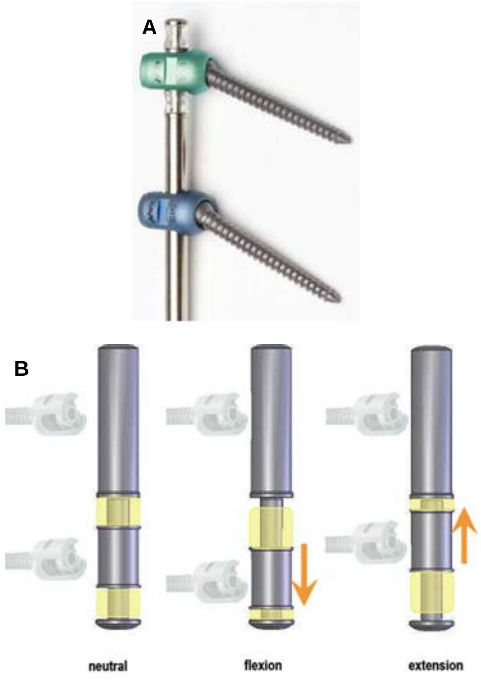


Figure 10a - N-flex device. **b**) An illustration depicting the motion of the N-Flex device. (Reprinted with permission).

The rod may be attached to pedicle screws in the standard fashion, with one pedicle screw attached to the titanium ring of the sleeve and one or more pedicle screws attached to the solid titanium rod. The composite sleeve is not bonded to the solid titanium rod, allowing compressive loads to be borne primarily by this dynamic structure as opposed to the titanium core. Biomechanical study of this device demonstrated that in all loading modes, the N-Flex device provided a decompressed lumbar segment with sufficient stability (i.e., greater than the intact case) but significantly less rigidity than a similar segment stabilized with a solid rod, suggesting the applicability of this implant as a dynamic fixation device in clinical practice.[37]

Early radiographic and clinical outcomes of 40 consecutive patients with spinal stenosis, degenerative spondylolisthesis, adjacent segment disease, recurrent disk herniation, or symptomatic degenerative disk disease treated with this device at one level with or without a rigid fusion at a contiguous level appears promising. The average follow-up was 6.3 months (range 4-12). The mean VAS scores improved from 7.8 preoperatively to 3.8 postoperatively ($p<0.001$), and ODI scores improved from 46.5 to 25.0 at follow-up ($p<0.001$). ROM measurements in 4 selected patients at 6 month follow-up demonstrated an average of 53% of retained preoperative segmental motion at the dynamically-stabilized level. No rod related complications or loosening of screws was observed. The authors concluded that dynamic stabilization with the N-Flex System is a viable method of retaining stable motion at the implanted levels and appears comparable to other presently available methods used to preserve segmental motion.[1]

The N-Flex device bears the CE mark for non-fusion indications and is not sold in the United States at the present time.

Conclusion

In recent years, more attention has been given to the problem of adjacent segment degeneration following traditional spinal fusion. Long-term results (10 year follow-up) show the incidence of radiographic adjacent segment degeneration has been reported to range from 20% to as high as 70% with symptomatic disease as high as 36% of cases.[20,28] This phenomenon has also been shown in biomechanical studies which have shown that stabilizing a motion segment transfers stresses to the adjacent level.[36,42,44] Posterior dynamic stabilization devices are designed to minimize the incidence of adjacent segment degeneration by restoring some native motion, while providing stability to the affected vertebral segment.

Pedicle screw-based PDS systems are attractive due to surgeon familiarity with pedicle screw placement. The aim of these implants is to decrease abnormal segmental motion as well as to unload the symptomatic degenerated disk and facet joints while preserving motion. Currently, PDS devices are presently only approved by the FDA as an adjunct for spinal fusion, a few devices are in clinical trials for approval in non-fusion applications (www.clinicaltrials.gov).

Short-term results of pedicle screw-based PDS systems appear to be promising. The issues at hand will be the longevity of these implants to resist physiologic stresses over time. Unlike traditional fusion, there is no biologically active fusion mass to resist physiological loads and therefore there is a higher risk for loosening fatigue and catastrophic failure. The success of pedicle screw-based systems will be affected by bone quality, and appears not to be a viable option in osteoporotic patients. It should be noted that pedicle screw-based PDS systems are in their infancy and further long-term clinical studies are needed to assess their efficacy in relationship to traditional fusion procedures.

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