Mechanobiology of the Intervertebral Disc and Treatments Working in Conjunction with the Human Anatomy

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Abstract

Degenerative conditions of the spine benefit from a methodical approach for the management of patients with chronic low back pain when offered surgery. Surgical solutions should consider the severity of the disease along with the approach in order to provide the patient with the best potential long-term outcomes. Posterior dynamic stabilization is considered to be an alternative therapy to rigid spinal fusion and is intended to produce equal stability within the affected vertebral space, while promoting additional mobility. Through its use in treating conditions such as spondylolisthesis, disc degeneration, and disc herniation, posterior dynamic stabilization has emerged as a potential solution to unintended consequences of more conventional therapeutic modalities, like rigid spinal fusion. Complications, such as adjacent disc disease, may be

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mitigated through an approach that permits additional mobility, returning the pathological segments to their intact range of movement and functionality. This chapter will review the history and development of posterior dynamic stabilization devices from their early inception to the current state of the art, as well as analyze the current pros and cons (garnered through both biomechanical and clinical testing) of each. Specifically, it will focus on the following device categories: interspinous spacers, pedicle screw and rod-based devices, and total facet replacement systems. Finally, there will be a discussion regarding the shortcomings of current metrics used to test such devices, along with an analysis on the cooperation between industry leaders and surgeons in designing said devices.

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Introduction

The motion of the spine can be studied in the most basic form by investigating a single index level or functional spinal unit (FSU). The FSU is a three-joint complex comprised of two vertebral bodies with three articulations, including the intervertebral, disc as well as the two posterior facet joints. The intervertebral disc forms an integral part of the FSU and has a propensity for degeneration with increasing age. Anatomically, the disc consists of highly oriented unidirectional layers arranged concentrically in alternating lamellar structures in conjunction with a gelatinous inner core, referred to as the nucleus pulposus. The nucleus has the ability to absorb transient forces, of which shock loads may have highest magnitudes, and to subsequently distribute loads to the end plates of the vertebrae. The other important articulations within the FSU are the facet joints which are also susceptible to disease. Facets, in the normal condition, play a role in controlling the motion of the FSU. This three-joint complex within each FSU controls the kinematic response to load. The primary modes of loading taken into consideration when evaluating the kinematic response to physiologic loads include axial compression, flexion extension bending, lateral bending, and axial torsion.

As degeneration occurs the disc may become fibrotic, compromising its ability to dissipate and distribute loads. Consequently, non-physiologic loads are then distributed to the vertebral end plates and the annulus of the disc which may lead to morphologic end plate changes and annular fissuring. With the onset of the degenerative cascade, both the intervertebral disc along with facets becomes compromised. The degeneration within the FSU may lead to the inability to withstand even

physiological loads and eventually, depending on the severity, instability may develop. Both clinically and biomechanically, instability can be defined by the inability of the FSU to control physiological displacement. With instability, the neurological structures are prone to impingement and injury. Instability of the intervertebral disc changes the kinematic loading profile of the spine with increased load transfer through the facet joints and ligamentum flavum. With time, these structures all undergo hypertrophy with narrowing of the central neural canal as well as the lateral recesses and neural foramina.

Mechanobiology

The intervertebral disc is comprised of at least two distinct cellular populations. Within the nucleus pulposus resides a chondrocyte like cellular population, while the cells of the annulus and cartilaginous endplate are primarily fibroblast like with an elongated shape. In a healthy state these cells work to continuously remodel the ECM, maintaining a balance of catabolic and anabolic remodeling. The cellular populations which reside in the soft tissue structures of the intervertebral disc (IVD) respond to applied mechanical stimuli, a phenomenon known as mechanotransduction (Johnson and Roberts 2003). The loads transmitted to the FSU are applied from various vector orientations, with axial compressive forces being converted to a hydrostatic pressure by the nucleus pulposus and then shear stress on the collagen fibers within the annulus (Vergroesen et al. 2015).

The local tissue environment is a key factor in the outcome when treating spinal pathologies. In a diseased state the accumulation of inflammatory cytokines, such as IL-6, IL-1β, and TNF-α, disrupt the balance between anabolic and catabolic remodeling leading to increased matrix degradation. Cytokine accumulation within the IVD may be the product of native cellular activity or the result of immune cells infiltrating the region and disrupting the microenvironment. Recent research has identified the presence of immune cells within degenerated or injured disc tissue. In the case of disc herniation, both neutrophils and macrophage have been identified in pathological tissues removed during microdiscectomy procedures. These cells are biologically active, producing inflammatory factors such as TNF-α. Even if the pathologic disc tissue is removed, pain may persist due to the continued presence of inflammation. Furthermore, inflammation of the disc may accelerate the degenerative process. For example, the presence of TNF-α has been associated with loss in disc height due to matrix destruction (Kang et al. 2015; Wang et al. 2017). Early intervention may be crucial in halting the degenerative cascade, with evidence suggesting the local tissue environment of the disc can be modulated with conservative therapies such as steroid injection or physical therapy (Fig. 1).

Additionally, the classical surgical treatments of degenerative disc disease also alter the kinematic response of an FSU. This abnormal motion may be caused by decompressive-type destabilizing procedures or by increasing the range of motion of the level adjacent to a fusion, also referred to as a "neo hinge." Finite element analysis of the von Misses stresses at the level above a fused level may also exhibit abnormal increases in the loads, and over time, hyper mobility may become evident. The von Misses stresses applied to that segment are altered both in distribution as well as in magnitude (Castellvi et al. 2007). Thus, the need for additional treatments which aim to restore the appropriate kinematic signature has led to serious consideration for the exploration of motion preservation technology as an alternative to fusion in the treatment of lumbar DDD. The goal of these motion preservation systems is to restore the mechanics of the intervertebral disc, thus disrupting the positive feedback loop which results in continued degeneration.

Degenerative Matrix and Utility

With the introduction of motion preservation technology, the matrix shown in Table 1 is proposed as a means to discretize the severity of the pathology by providing three distinct categories: mild, moderate and severe. Similarly, the targeted FSU for treatment can be further broken down into three distinct

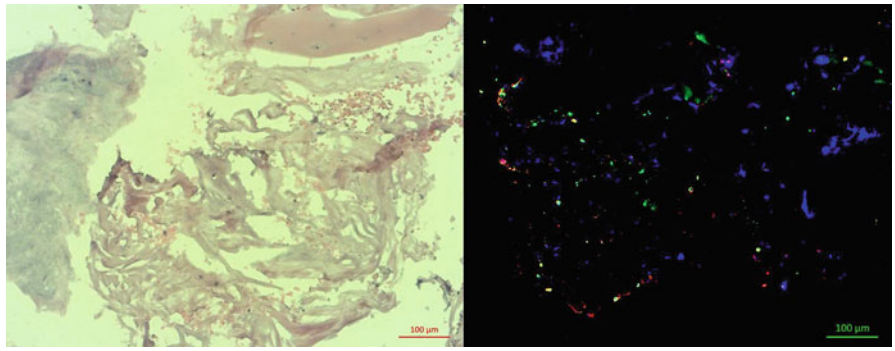

Fig. 1 Inflammatory response of a moderately degenerated human intervertebral disc. (**a**) Tissue sections were stained with hematoyxlin and eosin. Hematoxylin stains cell nuclei blue, while eosin stains extracellular matrix and cytoplasm pink (**b**) Immunofluorescence microscopy techniques were used to identify specific cellular markers of infiltrating immune cells for the same section. Red coloration depicts macrophages identified by the presence of surface marker CD68. Green coloration depicts neutrophils and granulocytes identified by the presence of the surface maker CD66b. Nuclear staining shown is shown in blue

Table 1 Matrix of degenerative condition versus the region of the spine within an FSU

		Region		
		Anterior	Middle	Posterior
Severity	**Mild**	Nucleus replacement Nucleus augmentation Biologics	Annuloplasty	Ligament replacement Interspinous spacers
	Moderate	Nucleus replacement Nucleus augmentation Biologics Total disc replacement	Porsterior pedicle-based systems Facet replacement	Interspinous Interlaminar
	Severe	Fusion	Fusion	Fusion

regions: the anterior, middle and posterior columns. The resulting intersections of these two variables (level of degeneration and region within FSU) provide potential treatment solutions with appropriate implant class descriptions at the junctions shown. This matrix is intended to methodically classify the severity of the pathology, origin or source of pain, and identify a potential implant or procedural solution in a systematic fashion. As technology increases, ideally the design and application of these technologies may be more precise and further refinement of technology classification may result.

Posterior Region

Degenerative conditions that affect the posterior regions may compromise anatomical structures including the facets joints and osteoligamentous tissue. Pathologically, these conditions may occur in combination with a degenerated anterior column. The potential consequences of facet degeneration are clinically well recognized and contribute to conditions such as stenosis. Other consequences include ligamentum flavum infolding into the spinal canal, osteophyte production with subsequent neuroforaminal stenosis, generation of inflammatory proteins with subsequent pain, reduced range of motion from hypertrophic facets and degenerative spondylolisthesis. The posterior degeneration of the lumbar spine is part of the overall degenerative cascade, but interventions through a posterior approach can stabilize or reverse this degenerative cascade, potentially obviating the need for intervention of the middle or posterior columns. The

classification in terms of degeneration has also been aided by the prevalence of imaging modalities and other diagnostic tools, such as diffusion weighted imaging.

A posterior approach provides bone anchoring locations and access to the anterior column via the pedicles. Also, the anatomical layout allows for bone and bone graft substitutes to be placed in the lateral gutters, and between spinous and along transverse processes from the same posterior approach. The posterior column, in combination with the anterior column, absorbs stresses and loads placed onto the spinal column. The articulating cartilaginous surfaces of the two facets within the FSU provide guided motion as a kinematic response to load. Furthermore, facets articulate in combination with the third joint, the intervertebral disc in order to offload, to some degree, a portion of the high loads from the anterior column.

The bony structures of the posterior region, including the lamina and pedicles, present excellent bone anchoring for fixation hardware. The cortical strength and designs that have taken advantage of cortical implants have been well documented. Ease of access is a main benefit of posterior approached. Implants intended to facilitate arthrodesis or preserve motion can be anchored in the posterior column with relatively simple access procedures. In particular, the cortical bone that comprises the pedicle provides a competent bone implant interface for the attachment of fusion constructs and motion preservation devices alike. Both implant designs require osteointegration at the bone implant interface for immediate and long-term stability.

Posterior approaches to the spine are well understood and described, provide direct and extensive access to locations with good bone anchoring and a portal to the vertebral bodies, and allow the surgeon to perform extensive corrective procedures indirectly to the anterior column. Despite the strength of cortical bone fixation in the posterior column, pedicle-based fixation devices often require a strong bone-implant interface access the anterior column via the middle region through a posterior approach. The large surface area of the vertebral endplates allow for the development of a wide variety of mechanical and potentially biological corrective forces to be applied so as to improve FSU mechanics. Direct replacement or removal of degenerative encroaching tissue or material may reduce pain and inflammation, promoting further healing of the diseased FSU while allowing easy access to the lateral gutters and other important structures.

Common Device Categories

Within the PDS space, three major technological approaches have emerged: (1) Interspinous Spacer Devices, (2) Pedicle Screw/Rod-based devices and (3) Total Facet Replacement. Each category has its own counter and normal indication for use in patients. This chapter summarizes all the major modern modalities of treatment for each and will present a detailed list of differing technologies, their claims, and an analysis of them. Notably, this is not all encompassing, as this industry is bristling with new improvements and technologies, some of which are not made public and are in various stages of preliminary research and development (Khoueir et al. 2007).

Interspinous Spacer Devices

Interspinous Spacer Devices are widely recognized as a means to address lumbar spinal stenosis via decompression. In fact, they have a reputation as devices with few significant negative effects. The general premise of this technology involves the placement of a device between the vertebral spinous processes to stabilize the structure and inhibit the compression of the spinal cord. The four major kinds of interspinous devices that are used heavily in the market are as follows: Wallis, XSTOP, DIAM, and Coflex. Each has been assessed in patients and an analysis of their efficacy is as follows.

Wallis implants are comprised of a Polyetheretherketone (PEEK) block, a common material used in both orthopedic and neurosurgical

implants. This implant classifies as a floating system, and it adheres to the spinous process via two Dacron ribbons which warp around them (the spinous processes), creating a tight fit (Sobottke et al. 2009). It has been consistently demonstrated that the Wallis implant can prevent further disc degeneration and pain in patients with spinal stenosis. Floman et al. showed this in their 2007 study where they analyzed whether the Wallis interspinous implant may reduce the number of recurrent lumbar disc herniation in patients with primary disc excision (Floman et al. 2007). The research concluded that while the device did not impact the rate of recurrent herniation, there was a marked decrease in the Visual Analog Scale (VAS) of pain, in both the back and the legs. A study conducted by Senegas et al., performed in 1988, showed a similar point (Senegas et al. 1988). They demonstrated that widening the lumbar vertebral canal served as an effective treatment for patients suffering from spinal stenosis and postoperative spinal stability. The researchers mentioned the method's virtues: it did not need the whole lumbar laminectomy, which usually causes spinal instability. Sobottke et al. further proves the point. After the study analyzed the various interspinous implants, Wallis, X-STOP and DIAM, they found that all devices created significant and long-lasting symptom control (Sobottke et al. 2009). Despite no statistically significant difference in device performance, between the three brands, it should be noted that all produced favorable results in terms of patient satisfaction and treatment of Lumbar Spinal Stenosis (LSS) pain.

In a series of similar technologies within the interspinous Spacer Device market, one example, X-STOP, is an implant crafted out of titanium and coated with a PEEK composite. The spacer is oval in shape and carries two wings on its lateral sides which are intended to prevent lateral migration (Sobottke et al. 2009). Sobottke et al. found that X-STOP displayed a positive ability to combat LSS pain and served as a means to surgically decompress the spine. Puzzilli et al. highlighted this conclusion in their study on the efficacy of X-STOP as a treatment for LSS. This study involved a 3-year patient follow up with 542 patients in total. Of these 542, 422 underwent surgical implantation of X-STOP, while just 120 patients served as the control and were managed conservatively. Results showed a substantial 83.5% of X-STOP treated patients reported positive results in the later follow-up appointments, while 50% of the control group reported these same results. Notably, 38 out of the 120 control cases selected to receive another surgery to decompress the spine, as they found the control (conservative therapy) unsatisfactory. The authors concluded that interspinous process decompression via an interspinous spacer device offered an effective and less invasive alternative to classical microsurgical posterior decompression. This was specifically true in selected patients with spinal stenosis and lumbar degenerative disk diseases (Puzzilli et al. 2014). Furthermore, less than 6% of the patients that did receive the X-STOP intervention had the device removed because of worsening neurological complications.

The Device for Intervertebral Assisted Motion, or (DIAM), is comprised of a sleeve of polyester that surrounds a core of silicon. This device is situated between two adjacent spinous processes. It is bound by three mesh bands which tether it to the spinous process and to the supraspinous ligament for extra support (Sobottke et al. 2009). In a study done by Fabrizi et al., the DIAM device and the Aperius PercLID system were compared in patients, DIAM: 1,315; Aperius PercLID: 260. The patient population was comprised of patients with a spectrum of spinal pathologies including: degenerative disc disease (478), foraminal stenosis (347), disc herniation (283), black disc and facet syndrome (143), and topping-off (64). The study also differentiated between a single level (1,100) and a multilevel (475) intervention and resulted in an overwhelming majority of patients displaying symptom resolution and improvement. They, therefore, declared that both technologies showed clinical benefits, displaying the merits of the system (Fabrizi et al. 2011).

Sharing a similar role to the above devices, Coflex is a titanium-based implant that exists in a characteristically "U" shape. It adheres to the spinous processes by means of wings that are

crimped to the bone. It is believed that the compliant "U" shape of the implant allows for additional load to be transferred through the disc as well (Kettler et al. 2008). Xu et al., in their publication, "Complication in degenerative lumbar disease treated with a dynamic interspinous spacer (Coflex)," resolved that the technology employed in this device was relatively safe, with only 11 patient complications in a sample size of 131. These complications involved three device-related issues (spinal process fracture, Coflex loosening, and fixed wing breakage), two tissue injuries (dura mater tear), and one superficial wound infection. The low complication and reoperation rate of the Coflex technology demonstrates its clinical utility (Xu et al. 2013). The authors of this study mentioned that care should be taken to prevent non-device-related complications emphasizing the importance of surgical proficiency and technique.

Pintauro et al. comprehensively reviewed the different interspinous spacer devices (Pintauro et al. 2017). There, the authors systematically analyzed each of the above technologies and sought to determine if the preliminary generation of implants is preferable to the second generation in terms of outcomes and complications. This review used 37 studies conducted from 2011 to 2016 to gain an up-to-date depiction on the current measures of success. This analysis generated an impressive finding, in that second-generation devices had a significantly lower rate of reoperation as compared to first generation devices (3.7% vs. 11%), which was not influenced by the type of Interspinous process device. This claim argued that older technologies were marginally obsolete, noting that the long-term functionality of first generation is questionable, and that newer devices did not suffer from the same degree of reemergence of symptoms in patients. The authors hypothesized that the differences in outcomes between first and second generation devices was due to two key factors: (1) they do not require additional decompression surgery with their utilization and (2) they are more frequently comprised of PEEK, which may be a more robust and nondegenerative material. The study acknowledged that there was insufficient randomized control trial data to emphatically make the claim that newer generation implants are superior. No statistically significant difference between the symptom relief of patients when their treatment with older versus newer devices was analyzed. The paper also acknowledged the influence of patient selection on the success rate of the surgery, emphasizing the importance of the proposed degeneration matrix and consideration of the stage of degeneration in selecting the appropriate treatment strategy (Pintauro et al. 2017).

In a study conducted by Richter et al., 60 patients were isolated, 30 were treated with decompression surgery for lumbar spinal stenosis and 30 with both decompression surgery and Coflex (a second-generation device). The study found, "... no significant difference between both groups in all parameters, including patient satisfaction and subjective operation decision." (Richter et al. 2009). The implementation of interspinous spacer devices on the whole has shown positive outcomes for patients in a myriad of different ways (pain and re-operation rate); however this study demonstrates that more research into this issue must be conducted to gain better insight into the significance of this treatment modality (implants) compared to spinal decompression surgery.

Pedicle Screw and Rod-Based Devices

One of the more versatile modalities of treatment within the posterior dynamic stabilization device space is that of pedicle screws and rods. These implants differ in terms of materials, design and efficacy in patients. Moreover, this section will be divided into two parts. The first subsection discusses the role of rigid rod-based systems, while the second subsection discusses one of pedicle screw-based systems.

The use of the Isobar TTL (Fig. 2) is considered as a means of mitigating lumbar degenerative disease. This technology is one of the preliminary semirigid rods that was used for dynamic fusion. The physical makeup of this device is a rod comprised of titanium alloy and a dampener which is made out of titanium O-rings that are stacked

Fig. 2 Isobar TTL construct on an anatomical model

upon one another vertically (Gomleksiz et al. 2012). The Isobar TTL device was utilized in a study conducted by Zhang et al., in which 38 cases of lumbar degenerative disease were analyzed in a retrospective study done between June 2007 and May 2011 (Zhang et al. 2012). The cases broke down into the following categories of pathology: 4 cases of grade I spondylolisthesis, 11 cases of lumbar instability and lumbar disc protrusion, 21 cases of lumbar spinal stenosis and lumbar disc protrusion, and 2 cases of postoperative recurrence of lumbar disc protrusion. Of the cases presented in the study, 22 of them displayed adjacent segment disc degeneration. The cases all shared a similar procedure of posterior decompression and the implantation of the Isobar TTL device. The evidence conferred in this study demonstrated near unanimous success in treatment of patients' symptoms. In fact, in the study's 38 cases, 32 were considered "excellent," 3 cases "good," 2 cases "fair," and only 1 case displayed a poor result. The final conclusion showed that the Isobar TTL stabilization system was a more than adequate means of treating lumbar degenerative disease characterized by a lower VAS score.

In a separate study, Gao et al. suggested that using Isobar TTL in a posterior approach provided a fixation system that had shown to "delay degeneration of intervertebral discs" (Gao et al. 2014). They appeared interested in Isobar TTL's unique features that "allowed for mobility of the fixation segments, maintained intervertebral space height, reduced the bearing load in both facet joints and discs and could prevent intervertebral disc degeneration." This study utilized MRI imaging to retrospectively assess 54 patients that had undergone dynamic lumbar fixation using the Isobar TTL. There was a heavy emphasis on both pre- and postoperative imaging to determine how this technology affected spinal health. It was found that after 24 months postoperatively, the associated diffusion coefficient (ADC) values increased significantly. The ADC is an indicator of the health of the nucleus pulposus, the central component of the intervertebral disc. Thus, an increase in the ADC showed an increase in health and hydration (concentration of water) of the disc. It should also be noted that DWI (Diffusion weighted imaging) was used to measure in vivo water molecule diffusion. Thus, this DWI value can demonstrate the structural characteristics of tissue. In effect, the DWI and ADC score are correlated, as a DWI may demonstrate disc health through the ADC value.

Barrey et al. commented on the use of Isobar TTL as a dynamic fusion system without the supposed effects of pseudoarthrosis, bone refraction and mechanical failure that other rigid apparatus suffered from (Barrey et al. 2013). This study is unique because of its long-term patient follow-up, totaling 10.2 years, of 18 patients with degenerative lumbar disc disease. The most important conclusion of this study is that within the 18-patient sample size, there were no adverse

reactions to the treatment, and all patients showed positive signs of a successful treatment. Thus, there were no observed complications or revision surgeries in their sample. Notably this observation did not match those previously reported by other dynamic systems such as Dynesys (27.5% of patients) in a study done by Bothmann et al. (2008). Stoll et al. found that 10% of 73 patients with a Dynesys system displayed complications following the implantation of the device (Stoll et al. 2002). However, it is difficult to compare the efficacy of the two devices (Isobar TTL system vs. the Dynesys system) due to the limited sample size. Therefore, the author indicated that more work needs to be done to assess both systems and measure their respective outcomes.

Cook et al. analyzed the properties of the implant when placed into a cadaveric model. By performing a comprehensive analysis of each FSU's kinematic response to load they found the Isobar TTL rod is uniquely suited as a dynamic fusion system and it provided the same immediate stabilization as that of a rigid fixture, but with a greater potential to handle greater compressive loads, the evidence of which was proven statistically significant. The author, therefore, believed that the Isobar TTL system could mitigate the common problems facing more rigid implantable systems, specifically greater load sharing between the anterior and posterior columns and axial distraction, the latter of which they found could lead to pedicle travel during bending. This data was garnered through the biomechanical analysis of ten human lumbar cadaveric specimens measured upon various indices such as range of motion, anterior column load sharing, facet engagement via vertex distance map (VDM), interpedicular distance excursion, and finite helical screw axis (HSA). Analysis of which showcased the robust mobility of the device and its ability to assist in sharing of loads as previously mentioned (Cook et al. 2015). This evidence may aid in understanding why physicians see clinical benefits in patients, as this potentially sheds light on some of the factors that attribute to the success of an implant under physiological conditions.

Another rod technology to emerge was BalanC, a dynamic rod-based system. The device itself was comprised of two portions marked "dynamic" and "fusion." The dynamic portion of the device contained a complex of PEEK and Silicone, and the more rigid fusion portion was made entirely out of PEEK. Under testing performed by Cheng et al., the device did not display a statistically significant difference in biomechanical performance when compared to titanium and pure PEEK rods (Cheng et al. 2010).

One of the first posterior dynamic stabilization devices to gain wide usage was the Graf Ligamentoplasty system. This technology was notable for its braided polypropylene to connect two titanium pedicle screws (one on the superior and one on the inferior vertebra- on the symptomatic level) to create an apparatus that would provide structural integrity but still maintain a robust mobile characteristic. The intention of the device was to permit load sharing, primarily to the posterior annulus, and to allow micro-tears in the anterior annulus fibrosus to heal (Gomleksiz et al. 2012). Rigby et al. conducted a mid- and long-term follow up study on 51 patients that received the Graf ligament stabilization surgery. There was a very high rate of complication (12 out of the 51 suffered complications), and of those that had complications, four patients required additional follow-up surgeries due to their unresolved condition. A poll conducted during the study showed that 41% of patients indicated that they would choose to not have the operation again. Seven of the patients in the group later went on to have full bony fusion procedures due to unresolved issues. This study's conclusion indicated that the device should be used with caution (Rigby et al. 2001). Hadlow et al. criticized the Graf ligament technology, as they found that this modality of treatment was associated with a worse outcome at 1 year and a significant higher revision rate at 2 years (Hadlow et al. 1998). Sengupta mentions that the Graf ligament has a propensity for producing lateral canal stenosis in patients, particularly in cases where the patient suffers from degeneration of the facet joints or in-folding of the ligamentum flavum, demonstrating early clinical failure (Sengupta 2004). The author further mentions that evidence has elucidated the exact mechanism in which the device

may treat symptoms, as clinical success may be from restriction of movement or from shifting loads to the posterior annulus.

In contrast, Madan et al. showed that the Graf system demonstrated superior results to that of a more conventional rigid fixation and fusion device. The author assessed the outcomes of two groups of 27–28 patients, the first of which was treated with the Graf ligamentoplasty and the second was an anterior lumbar interbody fusion device (ALIF) known as a Hartshill Horseshoe (Madan and Boeree 2003). After a follow-up period of 2.1 years, it was found that the Graf system and ALIF system had successful outcomes in 93% and 77.8%, respectively. The authors attributed this result to the increased lumbar segment mobility and better stabilization results. Likewise, a study performed by Grevitt et al., followed 50 patients postoperatively after Graf stabilization had been performed. A marked decrease was observed in the mean disability score (59% preoperatively compared to 31% postoperatively) and noted that 72% of patients stated the procedure produced good or excellent results (Grevitt et al. 1995). Markwalder and Wenger stated the same, although with the caveat that patient selection was primarily "young patients with painful mechanical disease who are resistant to conservative treatment and yield favorable long-term results" (Markwalder and Wenger 2003). This study demonstrated that while the patient population may be narrow, the device still had potential to combat the demonstrated symptoms. It is evident that more work in this space must be done to gain more knowledge regarding the benefits and potential complications of this technology.

The Dynamic Neutralization System (Dynesys) sought to stabilize the spine without bone grafting (Molinari 2007). The exact specifications of this device apparatus involve a titanium-alloy pedicle screw system connected by an elastic compound. Welch et al. stated that the device showed the ability to mitigate symptoms in patients (back and leg pain) and seemed to avoid any major surgical or device-related complications, some of which are more common in fusion approaches. A group of 101 patients were analyzed using the Oswestry Disability Index (ODI), and postoperative treatment groups displayed a near 30% reduction in disability (55.6% to 26.3%). Additionally, the pain data was conveyed by use of a 12-month follow-up questionnaire in which leg pain and back pain saw substantial reductions in mean values (80.3 to 25.5 and 54 to 29.4, respectively). While they did share a positive outlook on the device's ability to confer strong clinical results, they admitted that more research was needed (Welch et al. 2007). But Schwarzenbach et al. stated "Dynesys technology suggested it had limitations in elderly patients with osteopathic bone or those with severe segmental macro-instability with degenerative olisthesis and advanced disc degeneration," denoting an extra risk of failure. The study highlighted that no complications were found in their analysis and stated that more studies were needed to show that this technology definitively demonstrated a decrease in postsurgical complications (Schwarzenbach et al. 2005) (Fig. 3).

The use of PEEK rods has been a known method of posterior dynamic stabilization for some time. The material properties of such a technology are tremendously advantageous to this type of intervention due to its nonrigid physical nature, its radiolucent quality, and its versatility. Ormond et al., in their retrospective case series, showed that PEEK rods demonstrated similar fusion to Titanium rods. They argued initially that the semirigidity of PEEK rods would provide a reduction in stress-shielding and increased anterior load-sharing properties. This clinical evaluation of the technology showed that these assertions were well founded (Ormond et al. 2016). Additionally, a study in which the PEEK rods were retrieved from 12 patients conducted by Kurtz et al., demonstrated that the rods were comparable to their Titanium counterparts and displayed no cases of PEEK rod or pedicle screw fracture. This study shows that this modality of treatment (PEEK rods) is effective in not producing any major material-specific complications (Kurtz et al. 2013). While the study is limited in its sample size, it seems evident that the semirigid nature of PEEK serves as a comparable material for future device innovation within this space.

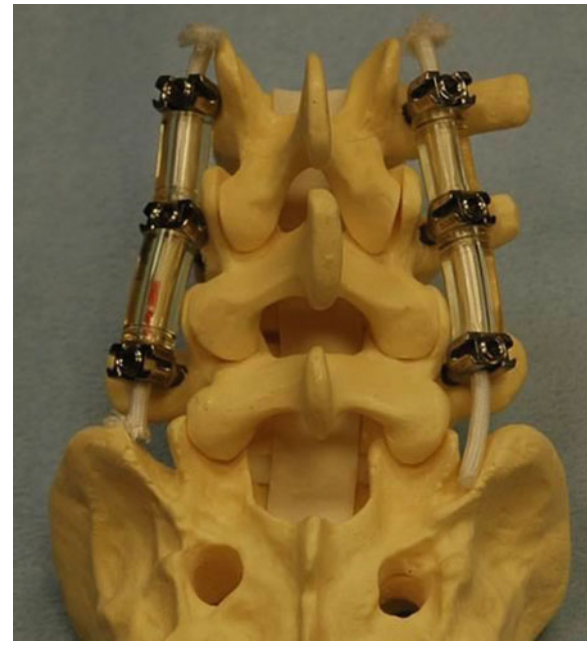

Fig. 3 Dynesys construct on an anatomical model

Notably, however, the same study mentioned that "seven out of eight periprosthetic tissue samples taken from the PEEK rods displayed signs of extensive degeneration, four of which had areas of tissue calcification." Also, PEEK wear shedding and PEEK debris were found in two out of the eight patients and was minimal, producing no significant inflammation.

The Bioflex Spring Rod Pedicle Screw System is comprised of a special Nitinol coil spring made of a small 4 mm diameter wire. The wire is set between the screws for the purpose of generating increased flexibility (Sengupta and Herkowitz 2012). An example of this technology being implemented in patients is shown in a study conducted by Heo et al. The study found that this approach was not significantly beneficial in preventing adjacent level degeneration completely. Based on MRI scans, only 2 of the 13 discs in the implantation segment showed any improvement in their disc degeneration, while 3 of the cranial adjacent discs (out of 25) and 4 of the caudal (out of 25) demonstrated a progression of disc degeneration (Heo et al. 2012). The biomechanics of this system were evaluated by Zhang et al., in which they found that the Bioflex system did not preserve ROM at implantation segments to that of any preoperative values but did preserve functional motion to these same levels (Zhang et al. 2009). This demonstrates that the biomechanical properties are indicative of a stable and effective PDS system; however, more clinical trials are needed to determine if the biomechanical advantages can translate into clinical utility.

Sengupta and Mulholland discussed the Fulcrum Assisted Soft Stabilization (FASS) in their publication assessing whether or not the aforementioned system could be a new means of treatment for degenerative lower back pain. The biomechanical properties of the technology displayed an ability to unload the affected disc and maintain a controlled range of motion. This was achieved by stabilizing the lumbar spine using pedicle screws, ligament, and a fulcrum to permit unloading. The thought process involved the transition of force from the disc to the ligament and fulcrum to achieve this characteristic unloading. Although done in cadaveric models, this study conveyed a new innovation to the PDS field (Sengupta and Mulholland 2005). While little clinical information has been produced as of late, the idea of circumventing any load on the affected disc by means of a mechanical transfer poses an interesting means

of combating the problems that consistently affect PDS systems.

The AccuFlex Rod system was composed of a metal rod with a distinct double helical cut inside of it to permit increased flexibility, primarily in the flexion and extension direction. Because this implant is quite similar to that of conventional metal rod constructs, it may be easily adapted to a surgeon's repertoire of procedures, according to Mandigo et al. (2007). In their study, they compared patients treated with Accuflex rod and with conventional rigid fusion devices. They resolved that the Accuflex technology displayed extremely similar characteristics to rigid fusion devices, demonstrating no significant differences in rate of fusion and highlighting the device's ability to serve as an alternative to other rod-based therapies. Reyes-Sanchez et al. conducted a study with a 2-year follow-up and found that 83% of patients showed a benefit in clinical symptoms after lumbar stabilization with the Accuflex system. They also showcased that the device had a 22% hardware failure rate, which is relatively high compared to other technologies. These competing claims show that the Accuflex system, like others mentioned before, have demonstrated clinical efficacy, in terms of relieving problems associated with lumbar destabilization, but may also show signs of common device complications (Reyes-Sánchez et al. 2010).

Cosmic Posterior Dynamic System is another variant of the pedicle screw and rod system. It employs a 6.25 mm rod which is attached in a non-rigid fashion by pedicle screws with a distinctive hinged screw head, which according to Kim et al., causes load sharing between the anterior vertebral column and the implant. The device is used for conditions such as symptomatic lumbar stenosis, chronically recurring lumbagly in the case of discogenic pain and facet syndrome, recurrent disk herniation, and spondylodesis (Maleci et al. 2011). Moreover, Stoffel et al. analyzed these claims and reviewed 103 patients that were implanted with the Cosmic system and found that 91% of the patients in their study were satisfied with their treatment. Some of the problems displayed in cases involved screw loosening (two patients), disk protrusion in an instrumented segment (three patients), symptomatic degeneration of an adjacent segment (six patients) and osteoporotic fracture of an adjacent vertebra (one patient). Importantly, pain scores were significantly reduced (VAS pre-op 65% +/−1; post op 21% +/−2) and disability scores also decreased showing a marked reduction in ODI by approximately 30% (Stoffel et al. 2010). Safinas, a system similar to the cosmic rod and screw system mentioned above, allows limited motion due to the hinged screw design. Ozer et al. demonstrated that the implementation of this technology resulted in "comparable relief of pain and maintenance of sagittal balance to that of a standard rigid screw-rod fixation" (Ozer et al. 2010). It is evident that the dynamic screw design shows promise in its ability to assist in PDS. There has been wide recognition of the positive outcomes with the use of this technology. While the clinical results are not significantly different than the current rigid fixation techniques, it demonstrates an opportunity for further investigation and research. Additionally, better design clinical studies may highlight the quality-of-life improvements that are currently demonstrated from clinical trials.

An ideological culmination of these technologies presents itself as a dynamic rod and dynamic screw apparatus. This set up entails the utilization of pedicle screws with hinges for increased load sharing and rods that are capable of moving to accommodate for stabilization. Bozkus et al. demonstrated in their biomechanical study that dynamic hinged pedicle screws had a unique ability to increase ROM (flexion extension and lateral bending, and axial rotation). It was noted that this improvement showed a much closer range of motion compared to normal than that of a rigid pedicle screw (30% less than normal ROM, but 160% greater than standard rigid screws) (Bozkus et al. 2010). Kaner et al. reinforces this conclusion. In that study, they assess the use of both dynamic screws and dynamic rods. They observed a significant improvement in the ODI and VAS values of their patients. They also observed "that using dynamic rods with dynamic screws prevented deformity in the rods due to the lower load transfer because of a decrease in the stress shield." This provides an exciting example

of a synergistic effect of current technologies with the potential of providing more mobility for patients (Kaner et al. 2009).

Total Facet Replacement Systems

Total Facet Replacement Systems serve the purpose of fully replacing the facet joints of the spine with a mechanical fixture. This surgery has the potential to be "an alternative treatment to lumbar fusion and instrumentation after laminectomy for spinal stenosis" (Serhan et al. 2011). One of the emerging technologies within this space is known as the Total Facet Arthroplasty System (TFAS). The TFAS is "a sliding ball-in-bowl type joint with a pedicle anchor to treat spinal stenosis," according to Serhan et al. The technology was tested biomechanically using cadaveric spines to assess the loading of this type of implant compared to a more conventional rigid posterior instrumentation system (Sjovold et al. 2012). Sjovold et al. found that TFAS implementation produced near intact anterior column load sharing, which was measured by a disc pressure gauge. It was also found that the rigid system displayed larger implant loads than the TFAS system, potentially demonstrating a successful finding that the TFAS system has loading characteristics preferable to those of more rigid systems. However, the study claimed that more testing was needed to understand the physiological implications of such data (Fig. 4).

The total posterior arthroplasty system (TOPS) is a pedicle screw-based device containing an elastic core. This elastic core serves as a flexible apparatus, permitting additional movement in the treated segment. A study evaluating TOPS was conducted by Anekstein et al., in which they sought to measure the clinical outcomes of patients with the TOPS system implanted to relieve their degenerative spondylolisthesis and spinal stenosis. It was found that there was a substantial decrease in VAS scores (88 to 8.8) in a 7-year follow-up. The results from the long-term follow-up permits the discussion that the device is a solid means of mitigating symptoms associated with Spondylolisthesis and Spinal Stenosis. ODI also dropped dramatically (from 49.1 to 7.8) during the 7-year follow-up (Anekstein et al. 2015).

StabilimaxNZ is built upon the neutral zone hypothesis of back pain, according to Panjabi and Timm (2007). The neutral zone was defined as the region of intervertebral laxity around a neutral position. This assumption is contingent on the relationship between spinal instability, movement, and pain. Thus, they hypothesized that an increase in the neutral zone, due to instability or injury, results in accelerated degeneration of discs and the manifestation of back pain. The device was designed with these biomechanical principles in mind and incorporated a pedicle

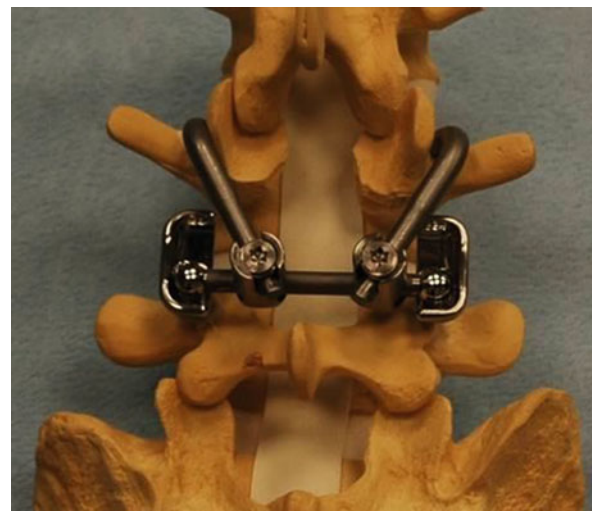

Fig. 4 TFAS construct on an anatomical model

Fig. 5 Stabilimax on an anatomical model

screw-based dynamic stabilization system, dual concentric springs combined with a ball and socket joint at the end. Therefore, according to their hypothesis, the device intends not only to maintain and maximized the range of motion but also add resistance to the passive spinal system to retain a normalized neutral zone, and thus mitigating symptoms. While there has not been any major clinical data published on this device, early biomechanical studies found the device shows promise for single level procedures (Fig. 5).

Posterior stabilization devices that provide immediate postoperative stability and improve chances of arthrodesis in the spinal column have also evolved in parallel with anterior stabilization devices. Cripton et al. investigated the load-sharing properties of lumbar spine segments after being stabilized with a rigid posterior implant (Cripton et al. 2000). Uniaxial strain gauges were used to create six-axis load cells to measure loads and forces through these implants, and pressure transducers measured the IDP. The authors concluded that these implants were not suitable for severe anterior column injuries in the absence of anterior stabilization systems.

These studies showed that PDS devices allow load sharing, but they may not be more efficacious than rigid rod posterior constructs. The rigid systems may also lead to excess load-transfer through the anterior column which can't be handled without anterior plates. Nevertheless, clinical validation through long-term investigations can improve our understanding of these systems.

Spinal Fusion

Posterior Dynamic Stabilization (PDS) and the technology that accompanies it, have remained a vital instrument for surgical implementation. Likewise, there has been tremendous innovation within this space considering the various technologies and approaches to combating common conditions, such as spondylolisthesis, disc degeneration, and other spinal movement disorders. The history of motion preservation requires an examination of the predated rigid body devices. Spinal fusion is a procedure where vertebrae are conjoined thereby creating a greater stabilized structure. While the current gold standard of care remains as rigid spinal fusion, many have argued that the consequences and unintended complications of this system call for a new method of treatment. Thus, the posterior dynamic stabilization (PDS) system emerged as a potential solution. The PDS of vertebrae claimed to yield a beneficial characteristic: it can allow a kinematic signature not found in rigid rod constructs (Gomleksiz et al. 2012; Cheng et al. 2010).

Merits and Downfalls of the PDS System

Understanding the market pressure to adapt to a more dynamic system is contingent upon recognizing the specific pathologies that are resultant of the rigid fusion system. These systems had a

propensity of causing disc degeneration at both the upper and lower margins of the therapeutic window, which often manifested as significant osteoporosis. Rigid systems also had an anterior loading preference, and thus resulted in an imbalance of load sharing between the posterior and anterior elements of the vertebra. PDS was intended to ameliorate these specific concerns and, by virtue, engender a new wave of medical device innovation.

Conclusions

The efficacy of a tool is a function heavily influenced by its effectiveness and ease of use. Technologies that need expansive series of training may dissuade surgeons from adapting such a device. The devices covered within this chapter have showed not only innovation within the posterior dynamic stabilization space, but also a conservation of treatment modality in terms of tools and methods used to treat relevant conditions. A surgeon may have a propensity to retain tools and techniques that have been proven rather than explore new alternative forms of treatment, and so it is evident that the devices mentioned above all display characteristics that are similar to the current state of the art (pedicle screw, rod, drill usage). This observation is reinforced by the findings in the World Health Organization report titled, "Increasing complexity of medical technology and consequences for training and outcome of care," (World Health Organization 2010). In conjunction with its analysis of the use of complicated technology, and the burdens that they may cause, the report emphasizes the importance of training and procedural practice to combat any nondevice-related complications. It is imperative that both surgeons and device innovators work in a synergistic manner to achieve a robust and long-standing educational and co-operational relationship to permit the smooth transition of new technologies into the operating space.

An important observation regarding the value of already existing metrics for rigid fixation technology was found during this review: the merit of applying existing metrics rigid fixation technologies to more motion preserving technologies is debatable. Moreover, there may come a time in which new methods of scoring and characterizing PDS technology compared to rigid instrumentation may be necessary to permit the observation of the novel properties of PDS, which may not be easily elucidated through conventional metrics. An example of this principle is the use of the interpedicular travel characteristic (IPT), which was implemented by Cheng et al. in their biomechanical evaluation of the StabilimaxNZ and ScientX technologies. The author found that most biomechanical testing catered to the specifications and characteristics of rigid systems. Therefore, a new metric was needed to characterize more motion preservation devices. The use of IPT was advantageous because it was a novel property that was more founded in motion preserving technology than its more rigid counterpart. While it remains to be seen if there is a direct correlation between this measurement and positive clinical outcome, it provides an example of researchers recognizing that the novel properties of motion preserving technology may not be best tested through the same procedures as more rigid technology. Moreover, this consideration would need to be a joint effort among both biomechanical and clinical scientists to trace the correlation between these new characteristics and their clinical outcome. It has been shown in the literature throughout this chapter that PDS technology may result in similar, preferable results compared to more conventional rigid implants. Thus, this difference must be studied in more detail if there is generally no statistically significant difference between existing rigid technologies and more dynamic ones with current metrics.

Dedication

Dr. Antonio Castellvi was an early adopter and a pioneer in the field of motion preservation technology. Through his clinical work in motion preservation and design contributions to posterior dynamic stabilization constructs, posterior dynamic stabilization gained special consideration and credibility including the development

of technologies such as the Scient'X Isobar TTL, Archus Total Facet Arthroplasty System (TFAS), while also challenging the status quo in that rigid fixation is preferable to a motion preservation technology. Graduating with honors from the University of Zaragoza Medical School in Spain and training in orthopedic surgery at the University of South Florida with a fellowship in spine at the University of Rochester, Dr. Castellvi's career spanned continents and brought the leading minds in spine surgery together. A surgeon, a prolific researcher, a mentor, and a friend, Dr. Castellvi's curiosity was only second to his compassion for others. He continues to be missed and remembered; this chapter is in his honor.

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