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Chapter 1 : Publications Authored by Brian Hughes | PubFacts

Dilip K. Sengupta, MD, Harry N. Herkowitz, MD William Beaumont Hospital, West Thirteen Mile Road/Suite , Royal Oak, MI , USA Spinal stenosis is defined as a narrowing of the.*

Received Aug 16; Accepted Oct This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. This article has been cited by other articles in PMC. Abstract Posterior dynamic stabilization PDS indicates motion preservation devices that are aimed for surgical treatment of activity related mechanical low back pain. A large number of such devices have been introduced during the last 2 decades, without biomechanical design rationale, or clinical evidence of efficacy to address back pain. Implant failure is the commonest complication, which has resulted in withdrawal of some of the PDS devices from the market. In this paper the authors presented the current understanding of clinical instability of lumbar motions segment, proposed a classification, and described the clinical experience of the pedicle screw-based posterior dynamic stabilization devices. Introduction The mechanism and surgical treatment of axial mechanical back pain remain controversial. The concept of instability as a cause of activity related, mechanical back pain is not well defined, and poorly understood. Spinal fusion had been the cornerstone of surgical treatment for back pain during the last three decades [2]. While fusion works in the majority of the patients, in many cases persistent back pain despite a solid fusion continues to haunt the surgeons and patients [3]. Besides, accelerated degeneration of the adjacent segment after initial clinical success with fusion surgery is fairly common. The concept of dynamic stabilization was developed out of failure of fusion to deliver the desirable clinical result. Spinal Instability in Degenerative Disorder as a Cause of Back Pain Instability is commonly understood as loss of stiffness or an increased motion to a given load, as originally defined by Pope and Panjabi in [4]. In presence of an abnormal motion like horizontal translation on flexion-extension radiographs, especially in the setting of spondylolisthesis, a clinical instability is considered to be present [5]. By this standard, however, relatively few patients with low back pain have overt subjective or objective evidence of instability. Radiological studies using open MRI in flexion and extension have shown that segmental motion either does not change significantly with the disc degeneration [6 â€” 8] or may in fact decrease, except during early stages of disc degeneration [9]. More recently, Panjabi redefined spinal instability as an abnormal motion often accompanied by an increased neutral zone NZ motion caused by ligament laxity, even when the ROM is diminished [10]. Panjabi uses the analogy of a marble rolling on a soup bowl [1]. In normal hydrated disc, homogeneous gel of collagen and proteoglycan act like a fluid-filled bag, that allows uniform load distribution across the vertebral endplates [11]. In a degenerated collapsed disc, the hydration of the nucleus is lost, and load transmission across the vertebral endplate becomes irregular. Most of the load is transmitted directly from bone to bone towards the periphery of the endplate [13]. This hypothesis of abnormal loading as the primary cause of mechanical back pain was supported by a close association of abnormal disc pressure profiles to positive discography with pain provocation [14 , 15]. The Modic changes associated with disc degeneration, as seen in the MRI scan, change over time form oedema followed by sclerosis and may represent the effect of reaction of the cancellous bone to abnormal stress or load-bearing. This may be an indirect evidence in support of abnormal load bearing theory proposed by Mulholland. Abnormal motion and abnormal load distribution may be interrelated and there may be no real conflict between the motion Panjabi and load distribution Mulholland theories of spinal instability. An abnormal motion may lead to an abnormal load distribution leading to pain. Conversely, if an abnormal motion does not cause abnormal load distribution, it may not be associated with pain production. The abnormal load concept may also help explain the lack of correlation between degrees of disc degeneration and back pain. The magnitude of abnormal load transmission may vary highly between individuals with similar degree of disc degeneration, and even in the same individual from time to time, causing acute painful episodes

in the setting of chronic low back pain. With advanced degeneration, complete collapse of the disc may once again distribute loads more evenly, resulting in a degree of spontaneous relief of pain with advancing age [16]. Total disc replacement TDR , nucleus replacement devices e. In contrast, dynamic stabilization devices work in conjunction with the motion segment, without replacing any anatomical part of it. The other major group of dynamic stabilization devices comprises Interspinous Process Distraction devices IPD , which are essentially floating devices that do not require any bony anchorage like pedicle screw insertion. Semirigid fixation is the term used to describe the devices, intended for achieving solid fusion without the stress shielding effect of conventional rigid fixation. These are often flexible metallic devices of various designs, as opposed to conventional fusion rods, which offer no mobility at the instrumented segment. The true pedicle screw-based posterior dynamic stabilization devices like Dynesys and Transition, are introduced in the US market as a fusion device under k approval from FDA. This has lead to frequent use of these devices as fusion devices. The argument in favor of using dynamic stabilization devices for semirigid fixation over rigid fixation to achieve fusion is that, the fusion mass may be more robust, being free from stress shielding. There has been no clinical study to establish this concept. The current paper however focuses the discussion on the regular use of these devices as true posterior dynamic stabilization without fusion and without the use of bone graft at the index level. Design Rationale for the Posterior Dynamic Stabilization Devices During the last decade, a large number of PDS devices were introduced, with very little understanding of their mechanism of action. Thus, in the short term, any device may be effective to reduce back pain to some extent. For long-term survival, the load sharing and motion control by the device should be complementary to the kinematics of the motion segment, through the range of motion. The device may end up in fatigue failure, if there is a conflict in kinematics between the device and the motion segment. For example, if the device becomes total-load bearing structure at certain phase of motion, which is not uncommon towards the end of extension in case of posterior dynamic stabilization devices, the device may fail eventually. This has been explained further in the following sections. Biomechanical goals for posterior dynamic stabilization are as follows: The goal is to preserve as much of normal motion as possible, but to limit any abnormal motion. Some degree of loss of motion is inevitable with application of any PDS device. Normally, it is unlikely that a dynamic stabilization device will increase the ROM of a degenerated segment. On rare occasions, however, it may be expected that the device may restore the disc height from collapsed state by distraction and eventually may increase the ROM to some degree. When the ROM is abnormal qualitatively or quantitatively, for example, following laminectomy or discectomy, the goal of posterior dynamic stabilization should be to restore a normal range and quality of motion. Regardless of the magnitude of motion preservation, the device must ensure normal load distribution across the endplate, throughout the range of motion, in order to achieve painless motion. The challenges of the PDS devices are as follows: Unlike fusion devices, the PDS device has to survive fatigue failure for an indefinite period. Since the PDS devices need to work in conjunction with the normal anatomical structures of the motion segment, it is essential that there is no conflict in kinematic and kinetic properties of the motion segment and the PDS device. For controlling ROM, the device should allow pedicle-to-pedicle excursion in both opposing directions in three planes of motion. The clue to the device failure screw loosening or breakage , as has been discussed in the following sections, may be hidden in the fact that device may act as an extension stop, denying pedicle excursion, and behaves like a total load-bearing device in extension [1]. The other design related factors are as follows: Dynamic Stabilization Devices The classification of dynamic stabilization devices is a moving target; new devices are being introduced, and some devices are being constantly withdrawn. As defined earlier, only the PDS devices are included in the classification presented in Table 1. The IPD devices, semirigid fixation devices, and prosthetic devices, including facet replacement devices, were excluded. Table 1 Classification of the pedicle screw-based posterior dynamic stabilization devices. The indications are summarized in Table 2. Table 2 Indications for posterior dynamic stabilization. Open in a separate window Unfortunately, many PDS devices have been introduced to address secondary indications, without establishing their efficacy to address any of the primary indications. Once that is

established, application in conjunction with decompression procedures could be justified. Dynamic stabilization to supplement total disc replacement is still at an experimental stage and may be considered as a future indication [1]. This may be considered as the first generation PDS device. This is a very simple device, consisting of braided polypropylene circular bands, which is looped around the pedicle screw heads under tension. Essentially, the device locks the facet joints under compression, presumably preventing any abnormal and pain movement, the so-called instability. Henry Graf never presented any peer reviewed article on the design rationale, or mechanism of action of Graf ligament. The exact mechanism of action of the Graf ligaments therefore remains a matter of educated guess rather than established on a sound biomechanical basis. The apparent clinical success may project Graf ligament as an attractive surgical option, particularly in young subjects with intractable back pain secondary to multilevel disc degeneration, where fusion is a difficult choice. Unfortunately, as a result of the compression applied to the screws, there is a high incidence of radicular symptoms secondary to either disc herniation or foraminal narrowing [18 , 19]. The compressive force may also have a deleterious effect on the facet joint and may lead to back pain. Short-term clinical outcome up to 2 years with Graf ligament is reported to be comparable to conventional fusion [19]. Long-term outcome has conflicting reports. Gardner and Pande [20] and Markwalder and Wenger [21] reported reasonably good result with Graf ligament even at 5â€”year followup. On the other hand, Hadlow et al. The Graf ligament is still being used in a few centers in both Europe and Asia, but its use has declined [20 , 22]. The design rationale is based on improvement over Graf ligament, preventing compression between the screws by introduction of a polythene spacer. This device may therefore be called a second generation PDS device. The plastic cylinder sulene-polycarbonate urethane PCU is placed around the cord to apply a distraction force between the pedicle screws, and thereby unloading the facet joints, which addresses a disadvantage of Graf ligament. The biomechanical effect of Dynesys on the range of motion as seen in cadaver experiments in vitro is diametrically opposite to its in vivo effect after implantation in patients. In cadaver spine, Dynesys holds the motion segment in near full flexion and permits minimal further flexion [25]. It can still allow significant extension by an abnormal distraction of the disc space, with the plastic cylinder acting like a fulcrum. This is evidenced by an abnormal negative disc pressure during extension [26]. Conversely, in vivo Dynesys limits extension more than flexion [27], The device acts like an extension stop and becomes a totally load-bearing structure in extension. In the initial clinical report, presented by the inventors Stoll et al. Dynesys was introduced in the United States in with FDA approval under k as a fusion device [30]. Its sporadic use as a nonfusion device represents an off-label use. An FDA controlled investigations device exemption IDE clinical trial was completed in , comparing Dynesys, as a stand-alone dynamic stabilization device against instrumented fusion. The preliminary report showed promising outcome [30]. Unfortunately, FDA executive panel did not approves use of Dynesys as a stand-alone device for nonfusion stabilization on the basis of the noninferiority study for various shortcomings of the study. They reviewed outcome studies that included a total of patients from 4 nonrandomized comparative studies and 3 case series, published between and This review concluded that the use of Dynesys is both safe and efficacious as a dynamic stabilization technique for some patients with intractable lumbar pain [32]. It may therefore be considered as a third generation PDS device.

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Chapter 2 : Dynamic spinal stabilization system - Spine Wave, Inc.

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Chapter 3 : Pedicle Screw-Based Posterior Dynamic Stabilization: Literature Review

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What is claimed is: A method for dynamic stabilization of motion segments of the spine comprising the steps of: The method for dynamic stabilization according to claim 1, wherein the step of repairing or replacing includes replacing all or part of the nucleus pulposus with a polymeric prosthesis having physical properties substantially similar to the physical properties of a natural nucleus pulposus. A method for dynamic stabilization of a motion segment of the spine comprising the steps of: The method for dynamic stabilization according to claim 3, wherein the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc. The method for dynamic stabilization according to claim 4, wherein the step of introducing a device includes introducing a polymeric prosthesis to replace or augment the nucleus pulposus in which the polymeric prosthesis exhibits physical properties similar to the natural nucleus pulposus. The method for dynamic stabilization according to claim 5, wherein the polymeric prosthesis is formed from a hydrogel. The method for dynamic stabilization according to claim 4, wherein the device for replacing or augmenting the nucleus pulposus is a mechanical device. The method for dynamic stabilization according to claim 8, wherein the step of introducing a device includes introducing a device for replacing or augmenting the nucleus pulposus of the intervertebral disc. The method for dynamic stabilization according to claim 9, wherein the step of introducing a device includes introducing a polymeric prosthesis which exhibits physical properties similar to the natural nucleus pulposus. The method for dynamic stabilization according to claim 10, wherein the polymeric prosthesis is formed of a hydrogel. The method for dynamic stabilization according to claim 8, wherein the center of rotation of the motion segment is located substantially at the posterior surface of the pedicle of the vertebrae of such segment. The present invention relates to spinal implant systems, and particularly systems for stabilization of the spine. The invention provides a dynamic stabilization system that permits limited relative movement between the instrumented vertebrae and the stabilization system. In the past, the principal protocol for the treatment of the spine has been rigid fixation combined with fusion of the affected vertebral body or intervertebral disc. Arthrodesis, as this approach is known, has been achieved with a variety of rigid fixation elements, such as spinal rods or plates that are rigidly fixed to a vertebra using bone screws, bone bolts and spinal hooks. However, spinal fusion has been recognized to have limitations in the treatment of disc degeneration, especially in the earlier stages of the degeneration where it may be unnecessary to eliminate motion of the spinal motion segments. Clinical studies suggest that cells of the intervertebral disc respond favorably to reduced but not eliminated mechanical loading through deposition of extracellular matrix proteins collagen, proteoglycan, fibronectin, etc. In some cases, a degenerated disc may simply involve a mechanically overloaded and hypermobile segment that can be repaired by reversing the mechanically damaging load environment. For instance, clinical experiences with dynamic stabilization systems suggest that the disc becomes increasingly hydrated over time, as judged by MRI scanning. Spinal instability is a recognized effect of degenerative disc disease. In contrast to arthrodesis, arthroplasty is a protocol that contemplates restoring segmental spinal motion while treating the degenerative condition. Arthroplasty has been successfully used in the treatment of degenerative conditions of the hip and knee. In recent years, efforts have been made to implement arthroplasty in the spine, and most particularly in the intervertebral space. Intradiscal arthroplasty is now clinically available in the form of articulating prosthetic discs and polymeric disc nucleus replacements. With the availability of viable intradiscal arthroplasty devices, interest has grown in providing some means for dynamic spinal stabilizationâ€”i. Drawing from the approaches developed for intradiscal arthroplasty, efforts have made to develop an extradiscal arthroplasty. Current theories suggest that preventing movement of the spinal segments may not be a significant factor in clinical success of spinal

stabilization systems. Instead, these theories focus on creating a normal loading pattern for the spine as a primary vehicle for successful spinal instrumentation. Thus, the goals for dynamic stabilization has been to restrict movement of the spine to a zone or range where normal or near normal loading of the spinal segments can occur. At the same time, dynamic stabilization techniques have sought to prevent the spine from adopting a position or orientation where abnormal loading of the spine can occur. One approach to achieve these goals for dynamic stabilization utilizes the spinous process. In yet another approach, a polymeric spacer is held in place between the adjacent spinous processes. One system utilizes a coil spring that spans several vertebrae and that is anchored to the lamina of the end vertebrae. In one version, a rod extends through part of the coil spring to control rotation. Some dynamic stabilization systems have relied upon fixation to the pedicle of the vertebrae. In these types of systems, a pedicle screw is threaded into the pedicle of adjacent vertebrae. A member spans between the heads of the pedicle screws to limit the movement of the spinal segments. In one device, known as the Graf Ligament, a non-elastic band is wrapped around pedicle screw anchors. The non-elastic bands lock the spinal segment into lordosis, while permitting minimal rotation movements of the spine. Another system utilizing pedicle screws, known as the Dynesys System, incorporates a polymeric cylinder between the bone anchors. The Dynesys System permits, but limits, relative motion between adjacent vertebrae. The DSS System employs still another approach by including a spring element connected to pedicle screws. The spring element is contained within a polyurethane tube to prevent tissue ingrowth. Finally, some systems utilize a rigid member, such as a spinal plate, spanning between vertebrae. The flexible stabilization feature is incorporated into the interface between the pedicle screw and the rigid member, such as through a flexible washer or a spherical screw-plate interface. These prior extradiscal arthroplasty approaches all involve the introduction of flexible elements between spinal motion segments. Consequently, many of these systems are susceptible to over-loading the disc annulus or are, by necessity, unduly restrictive with respect to motion of the spinal segment. Moreover, these prior systems are not capable of altering the stiffness of a segment in various loading modes e. Furthermore, these early approaches to arthrodesis do not allow selection of where, or at which motion segment, dynamic movement is permitted. Finally, no system exists that can readily convert to and from a soft stabilization to a more rigid or completely rigid system. In a preferred embodiment, the bone anchor comprises an engagement portion configured for engagement within a spinal motion segment and a head portion configured for engagement to a stabilization element outside the vertebral body. The engagement portion can be of many known forms, such as bone screw, bone bolt or spinal hook. The head portion can also assume a variety of known configurations depending upon the type of stabilization element being utilized for the construct. For instance, the stabilization element can be a spinal rod or an elongated plate. The head portion can be configured to engage either type of stabilization element. In an important feature of this embodiment of the invention, the bone anchor further comprises a flexible portion between the shank and the head portion. The flexible portion permits movement of the head portion relative to the engagement portion when both portions are fixed to the stabilization element and the vertebral body, respectively. In certain embodiments, the flexible portion is arranged to reside substantially extra-pedicular when the bone anchor is engaged within the pedicle of a vertebra. The flexible portion is configured to limit the relative movement between the head portion and the engagement portion to a single plane, most typically a plane parallel to the sagittal plane through the spine. In one embodiment, the flexible portion includes an elongated body spanning between the engagement portion and the head portion. The elongated body defines at least one hinge element, and preferably several such hinge elements. The hinge element includes a slot defined in the elongated body having an axis substantially transverse to the longitudinal axis of the body. Several hinge elements can be arranged in alternating opposing relation along the length of the body. To reduce stress risers, each slot terminates within the elongated body with a bore substantially perpendicular to the axis of the slot. In an alternative embodiment, the flexible portion includes a helical spring disposed between the engagement portion and the head portion. The spring can be constrained to deflect in a predetermined plane or planes. In a further embodiment, the flexible portion includes an elongated flexible element disposed between

the engagement portion and the head portion. The flexible element is a flexible sleeve or a similar tube-like structure spanning between the head and engagement portions. In one configuration, the engagement portion includes an elongated shank, and the elongated shank and the flexible sleeve have substantially equal outer diameters. Moreover, the elongated shank and the flexible sleeve can be configured for interlocking engagement. The flexible sleeve may be affixed to the head and engagement portions. Alternatively, a tension element may be provided that is anchored at one end to the engagement portion and at an opposite end to the head portion. The tension element extends through the flexible sleeve to clamp the sleeve between the head portion and the engagement portion. In one embodiment, the tension element is a cable. With this embodiment, the engagement portion includes an elongated shank that defines a longitudinal bore, opening at a proximal and an opposite distal end of the shank. The flexible element and the head portion also define a respective bore therethrough aligned with the longitudinal bore. The cable is then anchored to the shank at the distal end and extends through the longitudinal bore and the bores in the flexible element and the head portion. The cable anchor can be accomplished by the cable including an enlarged head relative to the diameter of the longitudinal bore at the distal end of the shank. In yet another embodiment of the invention, the bone anchor includes an engagement portion having an elongated shank, in which at least the shank and the flexible portion are integral. The flexible portion defines a cross-sectional area along the longitudinal axis of the shank that is substantially less than the cross-sectional area of the shank along the longitudinal axis. Thus, the flexible portion will exhibit bending tendencies in the region of the reduced cross section. This bone anchor comprises means surrounding the flexible portion for preventing bone overgrowth at the flexible portion. To achieve the reduced cross sectional area, the flexible portion has a first dimension in a first plane passing through the bone anchor that is less than a dimension of the engagement portion in the first plane. In certain embodiments, the flexible portion has a second dimension in a second plane substantially transverse to the first plane that is greater than the first dimension. With this configuration, the bone anchor exhibits greater flexibility in the first plane than in the second plane. In still other embodiments, the second dimension of the flexible portion is also greater than a dimension of the engagement portion in the second plane. An alternative embodiment of the inventive bone anchor utilizes a flexible portion that includes an elongated body spanning between the engagement portion and the head portion, in which the elongated body defines an elongated slot therethrough. Preferably, the elongated slot originates in the head portion and extends toward the engagement portion. The present invention further contemplates a dynamic spinal stabilization system comprising a stabilization element configured to span a length of the spine adjacent the vertebrae and at least one bone anchor having a flexible intermediate portion and at least one other anchor selected from the group including a bone anchor having a flexible intermediate portion, a spinal hook having a hook portion configured to engage a portion of a vertebra and a head portion configured to engage the stabilization element, and a substantially rigid bone screw having a threaded portion configured to engage a portion of a vertebra and a head portion configured to engage the stabilization element. The stabilization element can be an elongated plate defining at least two openings therethrough for receiving a corresponding one of the bone anchors. In this case, the head portion of the bone anchors can include a substantially spherical surface, while the elongated plate can define a substantially spherical recess at each of the openings. The present invention further contemplates a method for dynamic stabilization of motion segments of the spine comprising the steps of: This method may be performed in conjunction with repairing or replacing all or part of the intervertebral disc between at least two motion segments. Another inventive method dynamic stabilization of motion segments of the spine comprises the steps of: The present invention contemplates improvements to a method for correction of scoliosis in which a contoured rod is engaged to at least a portion of the deformed spine and is rotated to de-rotate the spine in the transverse plane. In particular, the improvement comprises engaging at least one vertebrae at either or both the superior and inferior ends of the rod to the rod to provide a center of rotation for the at least one vertebra that is between the rod and the normal anatomic center of rotation for the vertebra. The invention also provides improvements to a method for correction of spondylolisthesis in which a slipped vertebra is pulled posteriorly

to a stabilization element engaged to spinal elements adjacent the slipped vertebra. This improvement comprises engaging a bone anchor to the slipped vertebra that is configured to be pulled toward the stabilization element and that is configured to provide a center of rotation for the slipped vertebra that is between the stabilization element and the normal anatomic center of rotation for the vertebra.

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Chapter 4 : - NLM Catalog Result

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Sengupta and Harry N. This is an open access article distributed under the Creative Commons Attribution License , which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. Abstract Posterior dynamic stabilization PDS indicates motion preservation devices that are aimed for surgical treatment of activity related mechanical low back pain. A large number of such devices have been introduced during the last 2 decades, without biomechanical design rationale, or clinical evidence of efficacy to address back pain. Implant failure is the commonest complication, which has resulted in withdrawal of some of the PDS devices from the market. In this paper the authors presented the current understanding of clinical instability of lumbar motions segment, proposed a classification, and described the clinical experience of the pedicle screw-based posterior dynamic stabilization devices. Introduction The mechanism and surgical treatment of axial mechanical back pain remain controversial. The concept of instability as a cause of activity related, mechanical back pain is not well defined, and poorly understood. Spinal fusion had been the cornerstone of surgical treatment for back pain during the last three decades [2]. While fusion works in the majority of the patients, in many cases persistent back pain despite a solid fusion continues to haunt the surgeons and patients [3]. Besides, accelerated degeneration of the adjacent segment after initial clinical success with fusion surgery is fairly common. The concept of dynamic stabilization was developed out of failure of fusion to deliver the desirable clinical result. Spinal Instability in Degenerative Disorder as a Cause of Back Pain Instability is commonly understood as loss of stiffness or an increased motion to a given load, as originally defined by Pope and Panjabi in [4]. In presence of an abnormal motion like horizontal translation on flexion-extension radiographs, especially in the setting of spondylolisthesis, a clinical instability is considered to be present [5]. By this standard, however, relatively few patients with low back pain have overt subjective or objective evidence of instability. Radiological studies using open MRI in flexion and extension have shown that segmental motion either does not change significantly with the disc degeneration [6 â€” 8] or may in fact decrease, except during early stages of disc degeneration [9]. More recently, Panjabi redefined spinal instability as an abnormal motion often accompanied by an increased neutral zone NZ motion caused by ligament laxity, even when the ROM is diminished [10]. Panjabi uses the analogy of a marble rolling on a soup bowl [1]. In normal hydrated disc, homogeneous gel of collagen and proteoglycan act like a fluid-filled bag, that allows uniform load distribution across the vertebral endplates [11]. In a degenerated collapsed disc, the hydration of the nucleus is lost, and load transmission across the vertebral endplate becomes irregular. Most of the load is transmitted directly from bone to bone towards the periphery of the endplate [13]. This hypothesis of abnormal loading as the primary cause of mechanical back pain was supported by a close association of abnormal disc pressure profiles to positive discography with pain provocation [14 , 15]. The Modic changes associated with disc degeneration, as seen in the MRI scan, change over time form oedema followed by sclerosis and may represent the effect of reaction of the cancellous bone to abnormal stress or load-bearing. This may be an indirect evidence in support of abnormal load bearing theory proposed by Mulholland. Abnormal motion and abnormal load distribution may be interrelated and there may be no real conflict between the motion Panjabi and load distribution Mulholland theories of spinal instability. An abnormal motion may lead to an abnormal load distribution leading to pain. Conversely, if an abnormal motion does not cause abnormal load distribution, it may not be associated with pain production. The abnormal load concept may also help explain the lack of correlation between degrees of disc degeneration and back pain. The magnitude of abnormal load transmission may vary highly between individuals with similar degree of disc degeneration, and even in the same individual from time to time, causing acute painful

episodes in the setting of chronic low back pain. With advanced degeneration, complete collapse of the disc may once again distribute loads more evenly, resulting in a degree of spontaneous relief of pain with advancing age [16]. Total disc replacement TDR , nucleus replacement devices e. In contrast, dynamic stabilization devices work in conjunction with the motion segment, without replacing any anatomical part of it. The other major group of dynamic stabilization devices comprises Interspinous Process Distraction devices IPD , which are essentially floating devices that do not require any bony anchorage like pedicle screw insertion. Semirigid fixation is the term used to describe the devices, intended for achieving solid fusion without the stress shielding effect of conventional rigid fixation. These are often flexible metallic devices of various designs, as opposed to conventional fusion rods, which offer no mobility at the instrumented segment. The true pedicle screw-based posterior dynamic stabilization devices like Dynesys and Transition, are introduced in the US market as a fusion device under k approval from FDA. This has lead to frequent use of these devices as fusion devices. The argument in favor of using dynamic stabilization devices for semirigid fixation over rigid fixation to achieve fusion is that, the fusion mass may be more robust, being free from stress shielding. There has been no clinical study to establish this concept. The current paper however focuses the discussion on the regular use of these devices as true posterior dynamic stabilization without fusion and without the use of bone graft at the index level. Design Rationale for the Posterior Dynamic Stabilization Devices During the last decade, a large number of PDS devices were introduced, with very little understanding of their mechanism of action. Thus, in the short term, any device may be effective to reduce back pain to some extent. For long-term survival, the load sharing and motion control by the device should be complementary to the kinematics of the motion segment, through the range of motion. The device may end up in fatigue failure, if there is a conflict in kinematics between the device and the motion segment. For example, if the device becomes total-load bearing structure at certain phase of motion, which is not uncommon towards the end of extension in case of posterior dynamic stabilization devices, the device may fail eventually. This has been explained further in the following sections. Biomechanical goals for posterior dynamic stabilization are as follows: The goal is to preserve as much of normal motion as possible, but to limit any abnormal motion. Some degree of loss of motion is inevitable with application of any PDS device. Normally, it is unlikely that a dynamic stabilization device will increase the ROM of a degenerated segment. On rare occasions, however, it may be expected that the device may restore the disc height from collapsed state by distraction and eventually may increase the ROM to some degree. When the ROM is abnormal qualitatively or quantitatively, for example, following laminectomy or discectomy, the goal of posterior dynamic stabilization should be to restore a normal range and quality of motion. Regardless of the magnitude of motion preservation, the device must ensure normal load distribution across the endplate, throughout the range of motion, in order to achieve painless motion. The challenges of the PDS devices are as follows: Unlike fusion devices, the PDS device has to survive fatigue failure for an indefinite period. Since the PDS devices need to work in conjunction with the normal anatomical structures of the motion segment, it is essential that there is no conflict in kinematic and kinetic properties of the motion segment and the PDS device. For controlling ROM, the device should allow pedicle-to-pedicle excursion in both opposing directions in three planes of motion. The clue to the device failure screw loosening or breakage , as has been discussed in the following sections, may be hidden in the fact that device may act as an extension stop, denying pedicle excursion, and behaves like a total load-bearing device in extension [1]. The other design related factors are as follows: Dynamic Stabilization Devices The classification of dynamic stabilization devices is a moving target; new devices are being introduced, and some devices are being constantly withdrawn. As defined earlier, only the PDS devices are included in the classification presented in Table 1. The IPD devices, semirigid fixation devices, and prosthetic devices, including facet replacement devices, were excluded. Classification of the pedicle screw-based posterior dynamic stabilization devices. The primary indication for posterior dynamic stabilization is to address activity related mechanical axial back pain. The indications are summarized in Table 2. Indications for posterior dynamic stabilization. Unfortunately, many PDS devices have been introduced to address secondary

indications, without establishing their efficacy to address any of the primary indications. Once that is established, application in conjunction with decompression procedures could be justified. Dynamic stabilization to supplement total disc replacement is still at an experimental stage and may be considered as a future indication [1]. This may be considered as the first generation PDS device. This is a very simple device, consisting of braided polypropylene circular bands, which is looped around the pedicle screw heads under tension. Essentially, the device locks the facet joints under compression, presumably preventing any abnormal and pain movement, the so-called instability. Henry Graf never presented any peer reviewed article on the design rationale, or mechanism of action of Graf ligament. The exact mechanism of action of the Graf ligaments therefore remains a matter of educated guess rather than established on a sound biomechanical basis. The apparent clinical success may project Graf ligament as an attractive surgical option, particularly in young subjects with intractable back pain secondary to multilevel disc degeneration, where fusion is a difficult choice. Unfortunately, as a result of the compression applied to the screws, there is a high incidence of radicular symptoms secondary to either disc herniation or foraminal narrowing [18 , 19]. The compressive force may also have a deleterious effect on the facet joint and may lead to back pain. Short-term clinical outcome up to 2 years with Graf ligament is reported to be comparable to conventional fusion [19]. Long-term outcome has conflicting reports. Gardner and Pande [20] and Markwalder and Wenger [21] reported reasonably good result with Graf ligament even at 5â€”year followup. On the other hand, Hadlow et al. The Graf ligament is still being used in a few centers in both Europe and Asia, but its use has declined [20 , 22]. The design rationale is based on improvement over Graf ligament, preventing compression between the screws by introduction of a polythene spacer. This device may therefore be called a second generation PDS device. The plastic cylinder sulene-polycarbonate urethane PCU is placed around the cord to apply a distraction force between the pedicle screws, and thereby unloading the facet joints, which addresses a disadvantage of Graf ligament. The biomechanical effect of Dynesys on the range of motion as seen in cadaver experiments in vitro is diametrically opposite to its in vivo effect after implantation in patients. In cadaver spine, Dynesys holds the motion segment in near full flexion and permits minimal further flexion [25]. It can still allow significant extension by an abnormal distraction of the disc space, with the plastic cylinder acting like a fulcrum. This is evidenced by an abnormal negative disc pressure during extension [26]. Conversely, in vivo Dynesys limits extension more than flexion [27], The device acts like an extension stop and becomes a totally load-bearing structure in extension. In the initial clinical report, presented by the inventors Stoll et al. Dynesys was introduced in the United States in with FDA approval under k as a fusion device [30]. Its sporadic use as a nonfusion device represents an off-label use. An FDA controlled investigations device exemption IDE clinical trial was completed in , comparing Dynesys, as a stand-alone dynamic stabilization device against instrumented fusion. The preliminary report showed promising outcome [30]. Unfortunately, FDA executive panel did not approves use of Dynesys as a stand-alone device for nonfusion stabilization on the basis of the noninferiority study for various shortcomings of the study. They reviewed outcome studies that included a total of patients from 4 nonrandomized comparative studies and 3 case series, published between and This review concluded that the use of Dynesys is both safe and efficacious as a dynamic stabilization technique for some patients with intractable lumbar pain [32]. It may therefore be considered as a third generation PDS device.

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Dilip K. Sengupta Operative reports were reviewed for patients who underwent laparoscopic fusion at the L4-L5 level and information regarding the mobilization of the vessels was recorded.

In normal hydrated disc, homogeneous gel of collagen and proteoglycan act like a fluid-filled bag, that allows uniform load distribution across the vertebral endplates [11]. In a degenerated collapsed disc, the hydration of the nucleus is lost, and load transmission across the vertebral endplate becomes irregular. Most of the load is transmitted directly from bone to bone towards the periphery of the endplate [13]. This hypothesis of abnormal loading as the primary cause of mechanical back pain was supported by a close association of abnormal disc pressure profiles to positive discography with pain provocation [14 , 15]. The Modic changes associated with disc degeneration, as seen in the MRI scan, change over time form oedema followed by sclerosis and may represent the effect of reaction of the cancellous bone to abnormal stress or load-bearing. This may be an indirect evidence in support of abnormal load bearing theory proposed by Mulholland. Abnormal motion and abnormal load distribution may be interrelated and there may be no real conflict between the motion Panjabi and load distribution Mulholland theories of spinal instability. An abnormal motion may lead to an abnormal load distribution leading to pain. Conversely, if an abnormal motion does not cause abnormal load distribution, it may not be associated with pain production. The abnormal load concept may also help explain the lack of correlation between degrees of disc degeneration and back pain. The magnitude of abnormal load transmission may vary highly between individuals with similar degree of disc degeneration, and even in the same individual from time to time, causing acute painful episodes in the setting of chronic low back pain. With advanced degeneration, complete collapse of the disc may once again distribute loads more evenly, resulting in a degree of spontaneous relief of pain with advancing age [16]. Total disc replacement TDR , nucleus replacement devices e. In contrast, dynamic stabilization devices work in conjunction with the motion segment, without replacing any anatomical part of it. The other major group of dynamic stabilization devices comprises Interspinous Process Distraction devices IPD , which are essentially floating devices that do not require any bony anchorage like pedicle screw insertion. Semirigid fixation is the term used to describe the devices, intended for achieving solid fusion without the stress shielding effect of conventional rigid fixation. These are often flexible metallic devices of various designs, as opposed to conventional fusion rods, which offer no mobility at the instrumented segment. The true pedicle screw-based posterior dynamic stabilization devices like Dynesys and Transition, are introduced in the US market as a fusion device under k approval from FDA. This has lead to frequent use of these devices as fusion devices. The argument in favor of using dynamic stabilization devices for semirigid fixation over rigid fixation to achieve fusion is that, the fusion mass may be more robust, being free from stress shielding. There has been no clinical study to establish this concept. The current paper however focuses the discussion on the regular use of these devices as true posterior dynamic stabilization without fusion and without the use of bone graft at the index level. Design Rationale for the Posterior Dynamic Stabilization Devices During the last decade, a large number of PDS devices were introduced, with very little understanding of their mechanism of action. Thus, in the short term, any device may be effective to reduce back pain to some extent. For long-term survival, the load sharing and motion control by the device should be complementary to the kinematics of the motion segment, through the range of motion. The device may end up in fatigue failure, if there is a conflict in kinematics between the device and the motion segment. For example, if the device becomes total-load bearing structure at certain phase of motion, which is not uncommon towards the end of extension in case of posterior dynamic stabilization devices, the device may fail eventually. This has been explained further in the following sections. Biomechanical goals for posterior dynamic stabilization are as follows: The goal is to preserve as much of normal motion as possible, but to limit any abnormal motion. Some degree of loss of motion is inevitable with application of any PDS device. Normally, it is unlikely that a dynamic stabilization device will

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A. Tsouknidas / The effect of pedicle screw implantation parameters on a spinal fusion assembly [25] E.C. T eo and K.K. Lee, An accurately represented ï¬•nite element model of lumbar motion.

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